QUALITY

Sonora Quest Laboratories provides laboratory services in various settings to both adult and pediatric patients. Sonora Quest Laboratories provides comprehensive health services throughout Arizona.

Striving for continuous improvement of our processes and outcomes for the betterment of our patients, our physicians, our community, and ourselves is Sonora Quest Laboratories' commitment to quality.

The Sonora Quest Laboratories' Quality Plan defines the quality structure and goals for our organization and is an integral part of quality. How we achieve our quality goals is defined in the policies, process charts, and procedures contained in Sonora Quest Laboratories' Quality System.

Guiding Principles

- Comply with all applicable regulatory and accrediting requirements
- Customer focus
- Safely perform error-free work
- Lean error proofed processes
- Decisions based on facts and data
- Compassion for our patients
- Personal accountability
- Communicate effectively
- Quality at the best value
- Foster teamwork

Quality Assurance Program

Sonora Quest Laboratories has established and follows written policies and procedures for a comprehensive quality assurance program. The program is designed to monitor and evaluate the ongoing and overall quality of the total process (pre-analytic, analytic, and post-analytic). The program evaluates the effectiveness of its policies and procedures, identifies and corrects problems, assures accurate, reliable and prompt reporting of test results, and assures adequacy and competency of staff.

Quality Improvement

For Sonora Quest Laboratories, Quality is one of our core Values. Our decision is to proactively take the challenge to reduce laboratory errors by endeavoring to attain Six Sigma: 99.9997% accuracy or 3.4 ppm (parts per million) errors. The pursuit and attainment of Six Sigma Quality is not a quick fix. It is a major challenge, particularly since no medical institution or laboratory has ever attained this level of quality. This is a unique opportunity to improve the quality of healthcare we provide to our patients and clients, reduce the cost of poor quality, and distinguish Sonora Quest Laboratories as the preeminent leader for laboratory medicine in Arizona. Our goal at Sonora Quest Laboratories is to become the quality benchmark for laboratories in Arizona. Our dedicated employees are committed to providing the level of outstanding quality and service to our patients and clients that will make this goal a reality. Our proven focus on quality is recognized by numerous awards representing our hard work and commitment to patient care. Sonora Quest Laboratories is the only healthcare company ever to receive our state's highest quality award, the **Arizona Governor's Award for Quality**. No organization has attained this award since. Other recent awards include **#1 Bioscience Company in Arizona** for eleven consecutive years, most recently in 2022 by *Ranking Arizona / Az Big Media*; one of the top 100 Best Arizona Companies; by BestCompaniesAZ, most recently in 2022, **Top 40 Most Admired Companies in Arizona** from 2010 - 2019, most recently in 2021, by *az magazine/BestCompaniesAZ*; **Industry Leaders of Arizona Award (Healthcare Category)**, most recently in 2019, awarded by AZ Business Magazine, and a **2011 Business Ethics Award** by the *Better Business Bureau of Greater Arizona*.

Sonora Quest Has Combined Two Proven Methodologies to Drive Improvement

a. Lean
b. Six Sigma

Lean utilizes tools to reduce waste and includes high employee engagement and input.

What is Six Sigma Quality?

From the beginning, Quality has been our core focus at Sonora Quest Laboratories. Six Sigma is a breakthrough process improvement strategy, which when combined with Lean, allows us to decrease variation and improve processes. Combining these methods we strive to achieve a new quality standard for the healthcare industry. Lean/Six Sigma is focused on preventing problems by building mistake-proofing into the processes – preventing errors and problems in the first place. Lean/Six Sigma methods utilize full-time, dedicated Master Black Belts working with Black Belts (project managers) and Green Belts throughout all key areas of the organization. The Black Belts receive a formal blended training program that includes 130 hours of online training and 70 hours of classroom training in process analysis and statistical methods as well as mentoring by Lean/Six Sigma experts.

How Lean/Six Sigma Works

At Sonora Quest Laboratories, we are driven by a customer focus. The Lean/Six Sigma method starts by asking the fundamental question "What is critical to our customers?" Rigorous analysis is then applied to processes in our organization to assess whether we are delivering what customers require. Each time processes don't deliver, that is a defect. Six Sigma is passionate about using data to uncover the root causes of those defects and eliminating them from our processes. The ultimate objective is to deliver to customers what is critical to them each and every time – to produce "virtual perfection" from the customer's perspective.

The Moral Imperative – Why We Are Doing It

According to the Institute of Medicine's study, medical mistakes kill between 44,000-98,000 hospitalized Americans a year. That is more people than are killed in automobile accidents per year. While other industries (primarily manufacturing industries) have adopted Six Sigma processes to improve performance, healthcare has lagged behind . . . until now!

SG Cowen Securities, a leading market analyst with a focus on healthcare, has determined that 70% of health care spending is impacted by clinical test results. Sonora Quest Laboratories provides critical input to healthcare decisions for more than 20,000 patients each day. Quite simply, we have a clear and real responsibility to our customers and patients to deliver unparalleled quality and excellence in clinical testing.

The Business Imperative

Lean/Six Sigma is good business. We believe it is providing the foundation and fuel to attract and retain the best employees and help us to exceed our customers' expectations. Experience has shown Lean/Six Sigma delivers business results that can accelerate growth and reduce costs.

Our Progress

Our Master Black Belts and Black Belts are recruited from varied backgrounds and industries. They lead high-impact project teams focused on improving performance in areas of our organization that are critical to customers. Each member of our Lean/Six Sigma team has received a minimum 200 hours of intensive training to learn the Six Sigma approach and how to lead teams through the process. The training is dedicated to a disciplined, rigorous, and data based process improvement strategy. It is proven to achieve dramatic results. We have also trained over 70 Green Belts, part-time Six Sigma project leaders, and over 50 Lean Practitioners to help drive Lean Six Sigma quality throughout the organization.

The senior leadership team of Sonora Quest Laboratories is driving the major investment and commitment to continuously improve our quality. They have overseen the recruitment of Master Black Belts, Black Belts and Green Belts, the selection of project focus areas, and a rigorous review process of each of the projects currently underway. Projects have been initiated in a variety of process areas, such as Patient Service Centers, Specimen Management, Billing Services and the analytical laboratory. These projects are achieving dramatic defect rate reductions of 50-90% in a variety of areas and proven solutions are being deployed throughout our organization.

Our expectation is that customers will feel the difference in their daily experience with Sonora Quest Laboratories.

ACCREDITATION

	Address	Interstate (CLIA)	College of American Pathologists (CAP)	NPI
Main Laboratory	424 S. 56th St., Suite 100 Phoenix, AZ 85034	03D0528878	2220001	1538105366
Regional Laboratories	1515 E. Cedar Ave. Suite F Flagstaff, AZ 86004-1640	03D1056168	7197614	1134216567
	980 Willow Creek Rd., Suite 202A Prescott, AZ 86301	03D1094808	7220871	1043547870
	630 N. Alvernon Way, Suite 120 Tucson, AZ 85711-1895	03D0669882	2668603	1205923612
	2270 S. Ridgeview Dr., Suite 306 Yuma, AZ 85364	03D1104679	7230355	1174857841
Limited Service Laboratories (RRLs)				
	13640 North Plaza Dl Rio BlvdPeoria, AZ 85381	03D0531185	2224701	1700207750
	603 N. Wilmot Rd., Suite 141 Tucson, AZ 85711	03D1050496	71948989	1922188747
	2070 W. Rudasil, Suite 130 Tucson, AZ 85704	03D2096833	9285219	1104207778
	1620W St Mary's Rd Tucson, AZ85745	03D2122622	809365401	1801331269
PSC Locations Waived Testing	5605 W. Eugie Ave., Suite 104 Glendale, AZ 85304-1273	03D0965633		1700973260
	1151 S. La Canada Dr., Suite 206 Green Valley, AZ 85614	03D2070708		1194148726
	1432 S. Dobson Rd., Suite 201 Mesa, AZ 85202-4724	03D0694827		1558458034

The College of American Pathologists requires that all samples include 2 FORMS of patient identification on EVERY container at time of collection. The information provided in this General Information section is for informational purposes only and is subject to change. Please contact our Client Services Department at 602.685.5050 to confirm any of the information presented within.

ACCREDITATION (continued)

	Address	Interstate (CLIA)	College of American Pathologists (CAP)	NPI
PSC Locations Waived Testing	130 S. 63rd St., Bldg 2 Suite 107 Mesa, AZ 85206	03D2061035		1255763504
	13760 N. 93rd Ave., Suite 107 Peoria, AZ 85381	03D0641963		1861589376
	9445 E Ironwood Square Dr Suite 110 Scottsdale, AZ 85258	03D2066301		1598196438
	3161 N. Windsong Suite B, Prescott Valley, AZ 86314	03D2003652		1578804282

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REFERRAL OF SPECIMENS

Our courier service provides daily specimen pickup and report delivery in many geographical areas. Contact the laboratory to arrange for this service.

Patients may be referred to one of our Patient Services Centers for specimen collection. Our Patient Service Center listing is available on our website at www.SonoraQuest.com. A charge for venipuncture service will be added to the laboratory services bill when a venipuncture is performed.

Regional STAT testing is available based upon laboratory locations and testing menu. Testing requested as STAT is picked up at the location of collection within two hours of notification and is performed immediately upon arrival at the STAT facility. Most results can be expected within four hours of notification. An additional fee is charged for all STAT pick-ups and testing. Please contact your regional laboratory for STAT testing availability.

Sonora Quest Laboratories encompasses a network of affiliated laboratories. Testing that is requested but not performed within our network of laboratories may be forwarded as a courtesy in some cases; however, reporting and billing will be solely between the testing laboratory, patient and requesting physician.

Sonora Quest Laboratories is a clinical laboratory. In cases of suspected criminal activity where a laboratory specimen and test result may be used as evidence, the physician should report the matter to the appropriate authorities to assure appropriate collection is obtained and the specimen is sent to the appropriate forensic testing laboratory.

VERBAL REQUESTS

Federal and State regulations require that oral requests for laboratory testing **must be** followed up with a written request for verification.

SPECIMEN REQUIREMENTS

Generally, the specimen requirements are written in a format that specifies the requested volume, specimen type, minimum volume, storage temperature, and any special handling notes. The requested volume is an amount sufficient to allow multiple runs of the assay. The minimum volume allows one testing run. Storage temperature is specified as room temperature (18-22°C), refrigerated (2-8°C) or frozen (-20°C or colder). When temperature is not indicated, store specimens refrigerated (2-8°C) until and during transport to the laboratory.

SUBMISSION OF LABORATORY ORDERS

All tests submitted under a single order number are required to be collected on the same day, which is considered the date of service by government payors. Please use the following guide to assist in the ordering process used by your office:

IF	THEN
All samples are to be collected in your office on the same day	Submit all testing requested under a single order number
Only some of the samples will be collected in your office on the same day, and the patient will have the remainder collected by a Patient Service Center or other facility	Submit using 2 order numbers – 1 for the samples being collected in your office and 1 for the samples to be collected at a later time
None of the samples will be collected in your office – patient is being sent to a Patient Service Center	Submit the testing requested under a single order number; if any samples are unable to be collected (urine, fasting, etc.), they will be assigned a separate order number by the Patient Service Center staff

Please note that orders received by the laboratory that do not include all necessary samples for the testing requested will be managed using the following process:

IF	THEN
A single order is received and only some of the samples are submitted to the laboratory	The order will be held open until all samples for the day are processed; if all samples are not received, the tests with no samples will be cancelled with the notation of "no sample received"
Samples from the example above are sent to the laboratory after the initial order has reported and the testing was cancelled	A new order will be created using the provided collection date; testing will be performed and reported

LABORATORY REPORTS

Approximately 90% of routine testing is reported to our clients by 8:00 A.M. the following morning.

Gynecologic Cytology reports are routinely reported within 4 working days and Non-gynecologic Cytology reports within 2 working days. Histology reports are routinely reported within 2 working days. Genetics/Genomics: FISH test results are generally reported in 3-5 days; Chromosome studies are generally reported in 7-10 days. Cytology, Histology, and our Genetics/Genomics Division are staffed Monday through Friday, excluding holidays.

Laboratory reports list age and sex specific reference ranges for commonly performed tests, when age and sex are provided on the test requisition. If age and sex are not provided, reference ranges for an adult male are listed.

As part of our services, the laboratory's department heads, directors and consultants are available for assistance with explanation of laboratory data.

CRITICAL VALUES

Pursuant to federal regulation, Sonora Quest Laboratories must "immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition or panic or alert values, (42CFR493.1291(g))". A policy implementing this regulation is required by the College of American Pathologists (CAP).

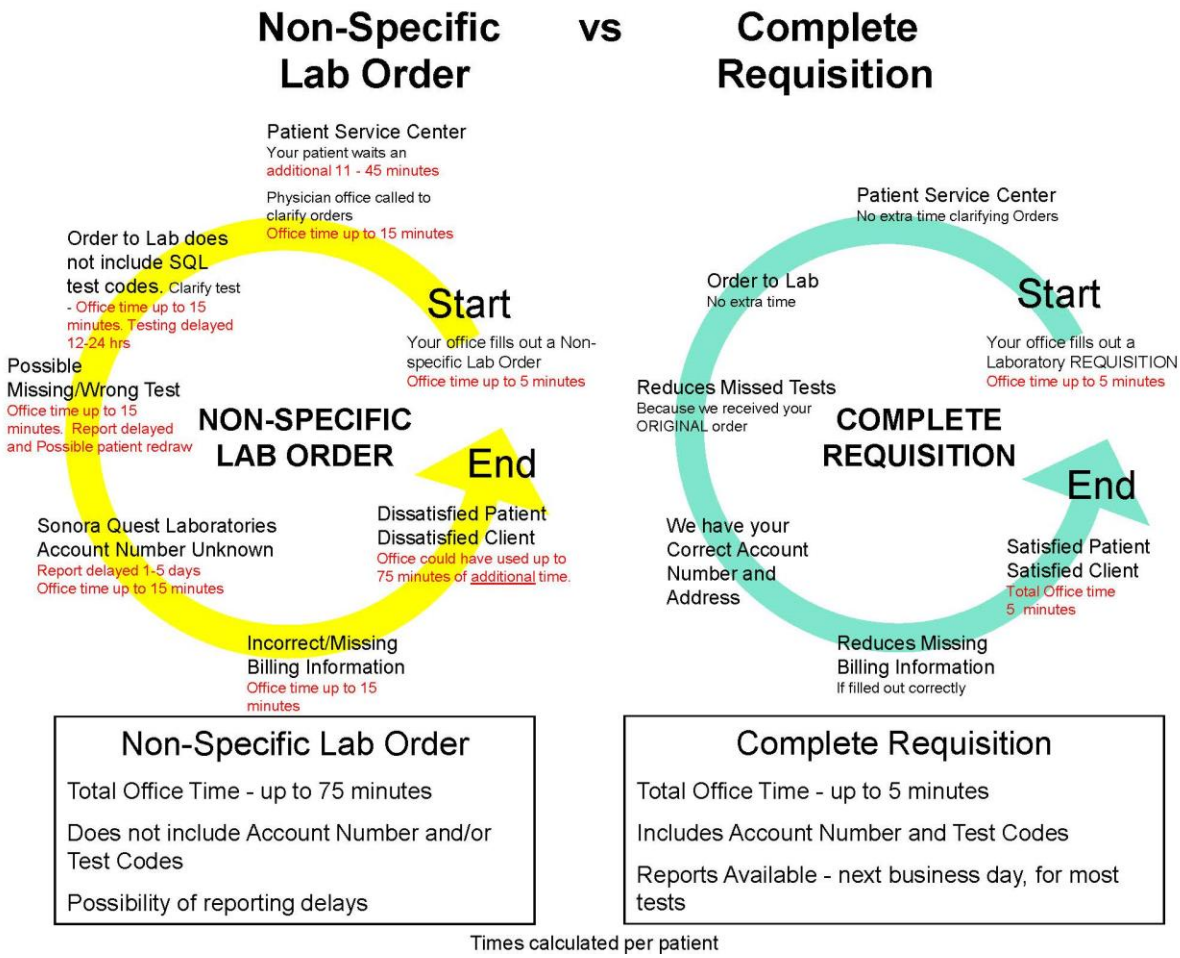
Certain test results have been identified as potentially life threatening when their values fall outside established reference ranges. These results will be flagged a *critical values* and handled differently than abnormal or STAT test results.

Sonora Quest Laboratories is responsible for effectively communicating critical value test results to the appropriate clinical individual immediately when such results are generated, 24 hours a day and 7 days a week. The laboratory is required to document the appropriate clinical individual receiving notice of critical value test results. When results are communicated verbally, laboratory personnel are also required to ask for a verification "read back" of the critical value test results to ensure clear communication.

Alternate Process for Reporting Critical Values:
Certain clients treat patient whose test results routinely have panic or alert values and choose to only receive notification by telephone during certain hours. CAP has determined that communication of critical value results by facsimile or electronic transmission is acceptable as long as verbal confirmation of the receipt of said results is made at the end of the exception period. Clients may request exceptions to Sonora Quest Laboratories Critical Value Reporting Policy if:

- The request are reasonable and within regulatory guidelines
- The client completes a Critical Call Exception Form
- The client acknowledges that occasionally, due to uncontrollable circumstances (system down, etc.), Sonora Quest Laboratories may be unaware of exceptions to the Critical Value Reporting Policy and will default to the standard procedure

TEST REQUEST FORMS (REQUISITIONS)



Top Reasons for Using a Sonora Quest Laboratories Requisition or Electronic Order when Ordering Tests

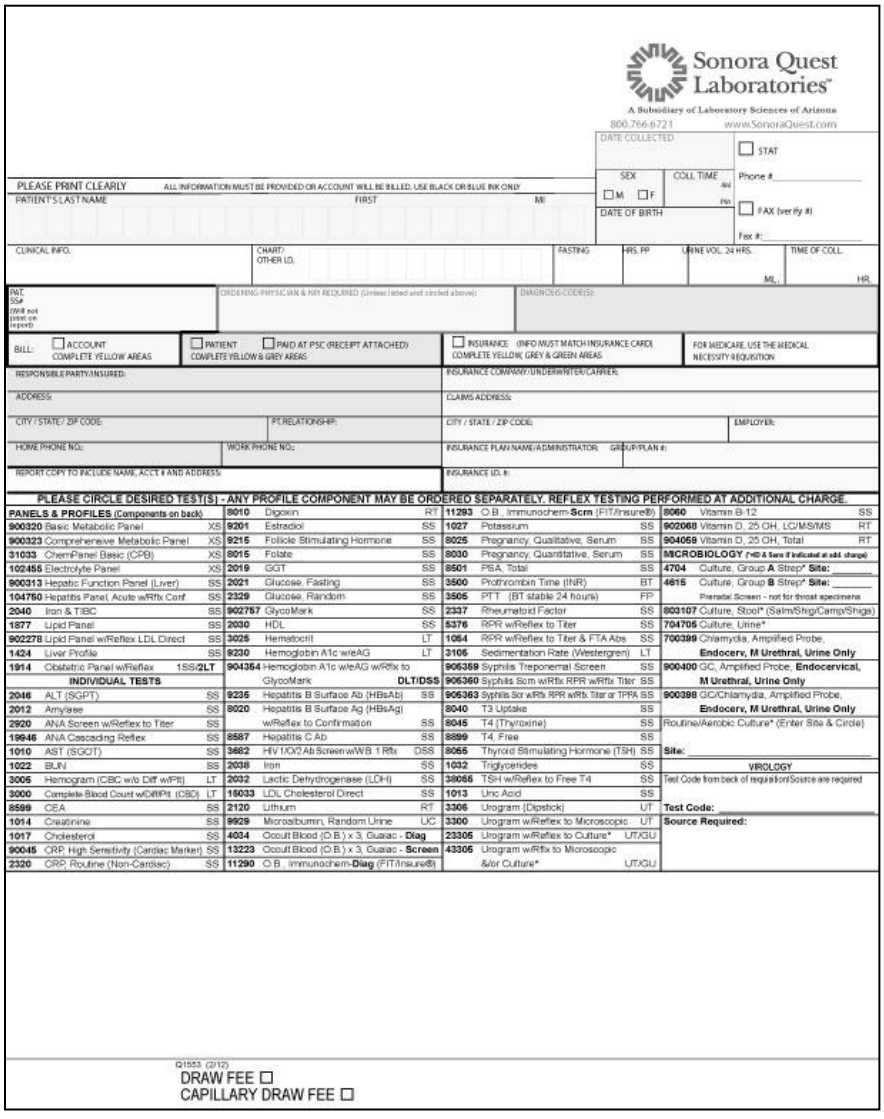
1. Your patient will be promptly served at our Patient Service Centers. Prescription pad or Non-Specific orders cause delays.
2. The Medical Necessity Requisition or logic in electronic systems conveniently highlights “limited coverage tests”, which require diagnosis codes and possibly the beneficiary’s signature.
3. Laboratory processing errors are reduced when samples are accompanied by a requisition or electronic order containing the Account Number and test codes.
4. When the requisition is properly completed, the likelihood of billing errors diminishes.
5. There will be no ambiguity of tests ordered. Many profiles/panels vary in test composition.
6. Your office won’t be interrupted by calls from Patient Service Centers seeking clarification of orders and diagnosis codes.
7. Reporting of results will be timelier. Non-Specific lab orders do not include your important account information.
8. Your staff will spend less time on the phone seeking lab results and providing billing information.
9. Your staff will have more office time to continue providing quality patient care.

TEST REQUEST FORMS (REQUISITIONS)

Our laboratory has a single test request form for non-Medicare Clinical Chemistry, Hematology, and Microbiology (illustrated below) in order to simplify processing at the physician's office. Separate test request forms are available for BRCAvantage™, Cytology, Mobile Diagnostic Services (formally Long Term Care), Medicare, Prescription Drug Monitoring, and Surgical Pathology. Your Account Manager can also provide a customized test requisition listing any combination of tests that meet your needs.

Please note that we also offer Quanum™ eLabs (formerly Care360® Labs & Meds), our on-line physician portal, which provides 24/7 access to the resources physicians need: patient laboratory test orders and results, electronic drug prescriptions and medication history, and access to information across a secure network. Quanum™ eLabs helps provide efficient management of your patients' lab results for additional clinical insights while letting you securely store, access, and share patient information with all-around ease. Learn more at https://www.sonoraquest.com/provider/provider-resources/care360-electronic-solutions/ or contact your Account Manager.

- Each test request form is preprinted with the Client's name, address, phone, and account number to ensure that both the medical report and billing are properly directed.
- Any information provided in the Clinical Information field will print on the laboratory report.
- Complete the Billing Information Section. The patient's address, as well as ICD-10 code(s) need to be provided for both patient and insurance billing.
- Ordering physician's first and last names must be provided.
- Your customized profiles, tests, and standard profiles may be preprinted on the test request form and can be ordered by circling the test number.
- Additional tests may be ordered by writing the test name and number as they appear in the Test Directory.
- For any patient of any payor, including Medicare, you should order only those tests that are medically necessary for the diagnosis and treatment of the patient.
- Provide the patient's name as an exact match to the insurance card, DOB, sex, and date collected in the appropriate areas at the top of the form.
- Check the "FAX (verify #)" box if you require notification of results by fax.



Sonora Quest Laboratories®

A Subsidiary of Laboratory Sciences of Arizona

800.766.6721 www.SonoraQuest.com

DATE COLLECTED | STAT | SEX ☐M ☐F | COLL. TIME | Phone # | DATE OF BIRTH | FAX (verify #) | Fax #:

PLEASE PRINT CLEARLY — ALL INFORMATION MUST BE PROVIDED OR ACCOUNT WILL BE BILLED. USE BLACK OR BLUE INK ONLY

PATIENT'S LAST NAME | FIRST | MI

CLINICAL INFO. | CHART/OTHER I.D. | FASTING | HRS. PP | URINE VOL. 24 HRS. | TIME OF COLL.

DAT. SS# (Will not print on report) | ORDERING PHYSICIAN & NPI REQUIRED (Unless listed and circled above) | DIAGNOSIS CODE(S):

BILL: ☐ ACCOUNT COMPLETE YELLOW AREAS | ☐ PATIENT ☐ PAID AT PSC (RECEIPT ATTACHED) COMPLETE YELLOW & GREY AREAS | ☐ INSURANCE (INFO MUST MATCH INSURANCE CARD) COMPLETE YELLOW, GREY & GREEN AREAS | FOR MEDICARE, USE THE MEDICAL NECESSITY REQUISITION

RESPONSIBLE PARTY/INSURED: | INSURANCE COMPANY/UNDERWRITER/CARRIER:

ADDRESS: | CLAIMS ADDRESS:

CITY / STATE / ZIP CODE: | PT. RELATIONSHIP: | CITY / STATE / ZIP CODE: | EMPLOYER:

HOME PHONE NO.: | WORK PHONE NO.: | INSURANCE PLAN NAME/ADMINISTRATOR: | GROUP/PLAN #:

REPORT COPY TO (INCLUDE NAME, ACCT # AND ADDRESS): | INSURANCE I.D. #:

PLEASE CIRCLE DESIRED TEST(S) - ANY PROFILE COMPONENT MAY BE ORDERED SEPARATELY. REFLEX TESTING PERFORMED AT ADDITIONAL CHARGE.

PANELS & PROFILES (Components on back)			INDIVIDUAL TESTS								
900320	Basic Metabolic Panel	XS	2046	ALT (SGPT)	SS	8010	Digoxin	RT	11293	O.B., Immunochem-**Scrn** (FIT/Insure®)	SS
900323	Comprehensive Metabolic Panel	XS	2012	Amylase	SS	9201	Estradiol	SS	1027	Potassium	SS
31033	Chem Panel Basic (CPB)	XS	2920	ANA Screen w/Reflex to Titer	SS	9215	Follicle Stimulating Hormone	SS	8025	Pregnancy, Qualitative, Serum	SS
102455	Electrolyte Panel	XS	19946	ANA Cascading Reflex	SS	8015	Folate	SS	8030	Pregnancy, Quantitative, Serum	SS
900313	Hepatic Function Panel (Liver)	SS	1010	AST (SGOT)	SS	2019	GGT	SS	8501	PSA, Total	SS
104750	Hepatitis Panel, Acute w/Rflx Conf.	SS	1022	BUN	SS	2021	Glucose, Fasting	SS	3500	Prothrombin Time (INR)	BT
2040	Iron & TIBC	SS	3005	Hemogram (CBC w/o Diff w/Plt)	LT	2329	Glucose, Random	SS	3505	PTT (BT stable 24 hours)	FP
1877	Lipid Panel	SS	3000	Complete Blood Count w/Diff/Plt (CBC)	LT	902757	GlycoMark	SS	2337	Rheumatoid Factor	SS
902278	Lipid Panel w/Reflex LDL Direct	SS	8599	CEA	SS	2030	HDL	SS	5376	RPR w/Reflex to Titer	SS
1424	Liver Profile	SS	1014	Creatinine	SS	3025	Hematocrit	LT	1064	RPR w/Reflex to Titer & FTA Abs	SS
1914	Obstetric Panel w/Reflex	1SS/2LT	1017	Cholesterol	SS	9230	Hemoglobin A1c w/eAG	LT	3105	Sedimentation Rate (Westergren)	LT
			90045	CRP, High Sensitivity (Cardiac Marker)	SS	904354	Hemoglobin A1c w/eAG w/Rflx to GlycoMark	DLT/DSS	906359	Syphilis Treponemal Screen	SS
			2320	CRP, Routine (Non-Cardiac)	SS	9235	Hepatitis B Surface Ab (HBsAb)	SS	906360	Syphilis Scrn w/Rflx RPR w/Rflx Titer	SS
						8020	Hepatitis B Surface Ag (HBsAg) w/Reflex to Confirmation	SS	906363	Syphilis Scr w/Rflx RPR w/Rflx Titer or TPPA	SS
						8587	Hepatitis C Ab	SS	8040	T3 Uptake	SS
						3682	HIV1/O/2 Ab Screen w/WB 1 Rflx	DSS	8045	T4 (Thyroxine)	SS
						2038	Iron	SS	8899	T4, Free	SS
						2032	Lactic Dehydrogenase (LDH)	SS	8055	Thyroid Stimulating Hormone (TSH)	SS
						15033	LDL Cholesterol Direct	SS	1032	Triglycerides	SS
						2120	Lithium	RT	38055	TSH w/Reflex to Free T4	SS
						9929	Microalbumin, Random Urine	UC	1013	Uric Acid	SS
						4034	Occult Blood (O.B.) x 3, Guaiac - **Diag**		3306	Urogram (Dipstick)	UT
						13223	Occult Blood (O.B.) x 3, Guaiac - **Screen**		3300	Urogram w/Reflex to Microscopic	UT
						11290	O.B., Immunochem-**Diag** (FIT/Insure®)		23305	Urogram w/Reflex to Culture*	UT/GU
									43305	Urogram w/Rflx to Microscopic &/or Culture*	UT/GU

MICROBIOLOGY (*HSV & Sens if indicated at add. charge)	
4704	Culture, Group **A** Strep* **Site:**
4615	Culture, Group **B** Strep* **Site:** Prenatal Screen - not for throat specimens
803107	Culture, Stool* (Salm/Shig/Camp/Shiga)
704705	Culture, Urine*
700399	Chlamydia, Amplified Probe, **Endocervical, M Urethral, Urine Only**
900400	GC, Amplified Probe, **Endocervical, M Urethral, Urine Only**
900398	GC/Chlamydia, Amplified Probe, **Endocerv, M Urethral, Urine Only**
	Routine/Aerobic Culture* (Enter Site & Circle)
Site:	
	VIROLOGY
	Test Code from back of requisition/Source are required
Test Code:	
Source Required:	

Q1553 (2/12)

DRAW FEE ☐

CAPILLARY DRAW FEE ☐

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SPECIMEN COLLECTION, PREPARATION & HANDLING

TWO PATIENTS IDENTIFIERS REQUIRED ON ALL SPECIMEN TUBES AND CONTAINERS

Per College of American Pathologist (CAP) regulations ANP.11460, CYP.03300 and GEN. 40491, all primary specimen containers (the innermost container submitted to Sonora Quest Laboratories that contains the specimen to be tested) MUST be labeled with two patient identifiers. Submitted slides must also contain two patient identifiers. If two patient identifiers are not provided, testing may be delayed until such information is obtained by Sonora Quest Laboratories. These patient identifiers include (in order of preference) but are not limited to:

- FULL PATIENT NAME (FIRST AND LAST)
- REQUISITION NUMBER OR BAR CODE LABEL
- PATIENT DATE OF BIRTH
- UNIQUE PATIENT IDENTIFIER

Patient identifiers on the specimen container and the laboratory order form must match in order for the specimen to be processed. Patient identifiers on specimen bags or container lids do not satisfy CAP requirements and cannot be used by Sonora Quest Laboratories.

1. Our online Test Directory presents instructions for proper submission of specimens to maintain specimen stability. It is essential that these instructions be followed exactly to assure delivery of a specimen that is adequate for testing. This enables the laboratory to report reliable results back to you. Please be sure to submit the quantity of sample designated in this manual. The laboratory depends upon your care, skill, and knowledge when preparing the patient and the specimen for testing.

2. The laboratory has established standards for specimen integrity to provide optimal reliability of patient test results. Prior to specimen collection, review the specimen requirements in our online Test Directory. Note the proper specimen to be collected, the collection procedures, and handling required. If there are any questions, please contact the laboratory prior to specimen collection.

3. a. Collection of a blood sample is obtained by using the usual venipuncture technique. New gloves must be worn for each and every venipuncture procedure.
   b. Apply a tourniquet to the patient's extended arm and select the best vein. Cleanse the site with an alcohol prep pad (sterile alcohol 70%) (there are a few exceptions to the use of alcohol prep pads, such as alcohol testing. Please see the specimen requirements of the test if you have any questions). Allow the site to air dry after cleaning – do not wipe clean or blow to dry, as this contaminates the draw site.
   c. Anchor the vein in position using one finger below the draw site and with the needle at an acute angle, quickly penetrate the skin and vein. Puncture the tube stopper by pushing the tube forward. This initiates the vacuum suction.
   d. The tourniquet should be released as soon as possible. Never leave the tourniquet on for more than 60 seconds. Otherwise, hemoconcentration will occur. Tests such as cholesterol, proteins, and hematology values increase significantly from 3-5 minutes of tourniquet application.
   e. Allow the tube to fill until the vacuum is exhausted before withdrawing the tube from the holder.
   f. If only a single collection tube is required, allow the tube to exhaust it's vacuum, remove tube then the entire assembly from the arm. Place a dry gauze pad over the venipuncture site and withdraw the needle carefully. Immediately activate the safety device to prevent injury from an exposed needle.
   g. When multiple specimens are required, follow the proper order of draw:
      1) Sterile blood culture specimens
      2) Coagulation studies (blue-top tubes)
      3) Specimens that require no preservatives (serum separator tubes (SSTs))
      4) Specimens with additives, (for example, green, lavender, gray, yellow-top tubes); mix all tubes containing additives as soon as each is filled. Refer to the inside back cover of this manual for more information.
      5) Specimens for QuantiFERON® TB Gold testing
   h. All specimens submitted to the laboratory must be properly identified by indicating the patient's name or identification code on every specimen tube, slide, or container submitted, along with a second patient identifier as referenced above.
   i. Ensure bleeding has completely stopped before applying the bandage and remind patients to limit exercise or bending of the arm to avoid bruising at the venipuncture site.
4. When serum is the required specimen, use of the barrier tube will provide the most accurate results, except for drug levels where barrier tubes cannot be used. Gentle inversion of the tube 8-10 times after venipuncture is essential. Allow blood to clot

for at least 30 minutes in a vertical position. Centrifuge at full speed (1000-1300 RCF-Relative Centrifugal Field) for 15 minutes. **Centrifuge specimens when fully clotted between 45 minutes and 2 hours after collection.** Please refer to the Supplies Section of this manual for detailed instructions. Also see the Serum Separator Tube (SST) Troubleshooting Guide below. Serum from non-barrier tubes must be separated from the cells within 30 minutes by transferring to another tube.

5. Complete the test request form according to the instructions on the previous page.

6. Place the test request form and specimen tubes, from a single patient, in an individual plastic specimen bag. To facilitate handling and to eliminate possible confusion between specimens, please do not combine different patient's samples in the same specimen bag. Fold the test request form in half and place in the back pocket of the specimen bag with the patient information showing. Place the specimens in the sealable pocket. Be sure to secure the zip lock seal.

Serum Separator Tube (SST) Troubleshooting Guide

Symptoms Affecting Test Quality (If correct technique is not used)

Poorly-Sealed Barrier Containing Red Cells	No Gel Flow	Partial Gel Flow	Tube Breakage in Centrifuge	Red Cells on Top of Barrier	Fibrin in Serum	
✓	✓			✓	✓	After collecting sample, invert tube gently 8-10 times. This allows the clot activator to mix properly. Vigorous inversion may damage red cells and promote leakage of cell contents into the serum.
✓	✓			✓	✓	Allow tube to clot for at least 30 minutes in a vertical position. This ensures complete clot formation for specimens. An incomplete clot will allow latent fibrin to contaminate the serum and inhibit flow of gel, at which point a redraw will be necessary.
✓	✓	✓				Centrifuge for 15 minutes (after 30 minute clotting time). This is needed to provide complete barrier formation.
			✓			Check centrifuge sleeves for debris and remove if detected. This may cause the tube to break.
✓	✓	✓				Centrifuge sleeves should be balanced to assure proper performance. Place an equivalent size tube filled to the same level in the sleeve opposite the patient's specimen.

Specimen Interference

The degrees of potential interference (Serum Indexes) caused by bilirubin (icterus), hemoglobin, and lipemia (intralipid) is measured automatically and objectively on each sample that has a Chemistry panel of eight tests or more ordered. A comment will be generated in the event a specimen is slightly, moderately or grossly icteric, hemolyzed or lipemic. The following is a description of how to interpret each comment.

Icteric: Creatinine, Triglycerides, GGT, HDL, Total Protein, Uric Acid and Aldolase may be artificially decreased. Fructosamine and Ammonia may be increased.

Slightly Lipemic: Direct Bilirubin and TIBC may be artificially increased.

Moderately Lipemic: Direct Bilirubin, Ammonia, TIBC, and Prealbumin may be artificially increased. Carbon Dioxide and Aldolase may show a decrease. Magnesium and Alcohol may show variable results.

Grossly Lipemic: Digoxin, Direct Bilirubin, Ammonia, TIBC, Total Protein, and Prealbumin may be artificially increased. Carbon Dioxide and Aldolase may show a decrease. Magnesium and Alcohol may show variable results.

Slightly Hemolyzed: Aldolase, Ammonia, Creatine Kinase (CK), Direct Bilirubin, Haptoglobin, Iron, Lactic Dehydrogenase (LD), Potassium (K), Magnesium, ALT, Total Protein, CSF Protein, and AST may be artificially increased due to erythrocyte contamination.

Moderately Hemolyzed:	Aldolase, Lactic Dehydrogenase (LD), Potassium (K), Phosphorus (PO4), Creatine Kinase (CK), ALT, AST, Ammonia, Iron, Magnesium, Lipase, Alkaline Phosphatase, Direct Bilirubin, GGT, CSF Protein, Triglycerides, Alcohol, Prealbumin, Amylase, Microalbumin, Fructosamime, LDL, Direct and Total Protein may be artificially increased. T4, UIBC, and Carbon Dioxide may be artificially decreased.
Grossly Hemolyzed:	Aldolase, Lactic Dehydrogenase (LD), Potassium (K), Phosphorus (PO4), Creatine Kinase (CK), ALT, AST, Ammonia, Iron, Magnesium, Cholesterol, Alkaline Phosphatase, Direct Bilirubin, Fructosamine, Amylase, GGT, CSF Protein, Triglycerides, Alcohol, Prealbumin, and Total Protein may be artificially increased. T4, and Carbon Dioxide may be artificially decreased.

How to Submit Frozen Specimens

- **DO NOT FREEZE GLASS TUBES.**
- Never leave frozen samples in your lock box unless they are stored in Sonora Quest Laboratories ConstanTemp Frozen Specimen Totes. These totes can be requested by contacting our Logistics Department at 602.685.5052 or 520.886.8101. However, to ensure specimen stability, it is recommended that frozen samples be stored frozen in your office for pick up on the following business day rather than being left in a lock box.
- Make sure frozen samples are labeled with the patient name and a second identifier, date drawn, sample type (serum, plasma, etc.), and, if timed testing, label each sample with collection times (fasting, 30 minutes, etc.).
- Check specimen requirements to see if serum or plasma needs to be aliquotted into a plastic vial prior to freezing.
- Attach a "Frozen" label (supply #8152) on the specimen bag. Do not submit frozen specimens in a bag with non-frozen specimens.

Lock Box Reminder

To ensure specimen stability in the summer months, please place an adequate amount of ICE PACKS in your lockbox with your specimens. Using paper to separate refrigerated samples from the ice packs will keep the specimens from freezing. Place specimens in T-shirt bags separate from ice pack and then place ice packs on top of specimens to maintain specimen integrity. Please request additional ice packs through your courier. If specimens are found without ice packs, specimens may be cancelled due to stability.

Additionally, please remember to never leave frozen samples in your lock box unless they are stored in Sonora Quest Laboratories' ConstanTemp Frozen Specimen Totes. These totes can be requested by contacting our Logistics Department at 602.685.5052 or 520.886.8101. However, to ensure specimen stability, it is recommended that frozen samples be stored frozen in your office for pick up on the following business day rather than being left in a lock box.

Finger Stick Collection Procedure

NOTE: The depth of any finger stick device must not exceed 2.0mm. Puncturing the finger of an infant less than 1 year of age is not recommended. Puncturing of the heel is more suitable for these children. See below.

1. Prior to blood collection process, put on disposable examination gloves. Have the patient wash his/her hands with soap and warm water and dry with a paper towel.
2. Cleanse the site with alcohol and allow to air dry.
3. Use the middle or ring finger and puncture slightly to the left or right of center with a sterile lancet. Immediately turn the patient's hand over so that the blood drop forms towards the floor (gently massaging the finger will promote better blood flow).
4. Wipe away the first drop of blood to prevent the contamination of tissue fluid in the blood specimen.
5. Apply moderate pressure while collecting sample (do not squeeze or milk the site). Touch the collection device to the drop of blood formed on the surface of the skin. Avoid scraping the surface of the skin with the tube. Blood will flow freely through the FloTop collector and down the tube wall. To help the blood flow to the bottom, gently tap the tube.
6. After blood specimen has been collected, apply cap to top of tube. Gently invert tubes containing additives 8-10 times to thoroughly mix and prevent clotting. Be sure to hold cap in place during mixing.
7. Label tube with patient's name/identification and a second patient identifier.
8. Apply pressure to site until bleeding stops.

Heel Puncture Collection Procedure

NOTE: The depth of any device used for a heel stick must not exceed 1.00 mm.

1. If necessary, warming of the heel for three minutes prior to puncture may be performed ensuring all materials used do not exceed 42°C. Warming increases the blood flow to the area by seven-fold.
2. Prior to the blood collection process, put on disposable examination gloves. Cleanse the site with alcohol and allow to air dry.
3. Hold the heel with a moderately firm grip. Using an approved heel stick device, perform the puncture on the most medial (inner edge) or lateral (outer edge) portion of the plantar surface of the heel. *Do not puncture the arch or the curvature of the heel.*
4. Wipe away the first drop of blood to prevent the contamination of tissue fluid in the blood specimen. Maintain the foot in a downward position.
5. Gently apply continuous pressure to the heel while collecting sample (do not squeeze or milk the site). Touch the collection device to the drop of blood formed on the surface of the heel. Avoid scraping the surface of the skin with the tube. Blood will flow freely through the FloTop collector and down the tube wall. To help the blood flow to the bottom, gently tap the tube.
6. After blood specimen has been collected, apply cap to top of tube. Gently invert tubes containing additives 8-10 times to thoroughly mix and prevent clotting. Be sure to hold cap in place during mixing.
7. Label tube with patient's name/identification and a second patient identifier.
8. Apply pressure to site until bleeding stops.

How to Prepare and Submit a 24-Hour Urine Collection

Some urine tests, including most urine chemistry tests, require a 24-hour collection. Please note that 24-hour urine collection is NOT an acceptable specimen for testing by the Cytology Department. ALWAYS verify specimen requirements prior to submitting for testing.

1. The first morning urine (on the day of collection) MUST BE DISCARDED. Write the time of this void on the specimen container.
2. Collect all urine voided for the next 24 hours.
3. The final collection should be the first morning void of the second morning. Write the time of collection on the specimen container and the test request form.
4. Depending upon the test, the container may also contain a preservative. It is required that the container be refrigerated during the collection period. Instruct the patient to keep containers out of the reach of children.
5. Submit the 24-hour collection container to the laboratory.

How to Prepare and Submit a 24-Hour Urine Collection for Pediatric Patients

For very small children, when the 24-hour urine output is less than 1 liter, 4 grams of boric acid can be used when boric acid is the specified preservative or 10 mL 6N HCl can be used when HCl is specified.

1. The first morning urine (on the day of collection) MUST BE DISCARDED. Write the time of this void on the specimen container.
2. Collect all urine voided for the next 24 hours. It is required that the container be refrigerated during the collection period.
3. The final collection should be the first morning void of the second morning. Write the time of collection on the specimen container.
4. Submit the 24-hour collection container to the laboratory.

Semen Analysis

Semen Analysis Complete, Test No. 703640 and Semen Analysis Post-Vasectomy w/reflex to Count/Motility, Test No. 901289
Appointments are required. Please instruct patients to visit www.SonoraQuest.com or call 1.855.367.2778 and schedule an appointment at one of the following Patient Service Centers:

Phoenix: 1275 W. Washington St., #109, Tempe
Tucson: 630 N. Alvernon Way #200, Tucson

The semen specimen should be collected after 2-7 days of sexual abstinence unless otherwise instructed by the physician.

Required Information for Semen Analysis Complete, Test No. 703640
Patient questionnaire form (supply #25804) must be submitted with the sample.
The information below is needed to properly evaluate the results of this test.

1. Number of days of abstinence (days since last ejaculation)
2. Method of Collection: Masturbation (Required)

Semen Analysis, Post-Vasectomy, Test No. 3645 and Semen Analysis, Post-Vasectomy w/reflex to Count, Test No. 900865

1. Appointments are NOT necessary.
2. The semen specimen should be collected after 2-7 days of sexual abstinence unless otherwise instructed by the physician.
3. Collect the specimen at home and deliver to any Sonora Quest Laboratories Patient Service Center within 24 hours of collection (Monday – Friday only). (Keep the sample near body temperature (25°-40° C or 77°-104° F).)
4. Collect the specimen by masturbation into a sterile container (containers are provided by the laboratory). **Collecting semen in a condom or by coitus interruptus is not acceptable.** Since the volume of semen produced may be significant to diagnosis, it is important to submit the entire specimen. Be sure the container lid is closed tightly.
5. Label the container with patient name, a second identifier, date of collection, and exact time of collection.

Timed Specimens (Dynamic Testing)
How to Submit Multiple Specimens for the Same Test on a Single Patient

Special computer programming is in place to accommodate serial timed specimens from a single patient. See our online Test Directory for timed specimen tests. If a test is not listed, call the laboratory for special instructions.

ALLERGY TESTING

Specific IgE Determinations

Allergen specific IgE assays measure circulating IgE. Currently, the ImmunoCAP System® is used for testing allergy antibody reactivity to pollens, environmental allergens, foods, and insects. This *in vitro* quantitative assay measures allergen-specific IgE in human serum or plasma. It is intended for *in vitro* use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical symptoms.

ImmunoCAP® has been accepted by the FDA as a quantitative measurement of specific IgE that can accurately determine if patients are allergic and to what they are allergic. ImmunoCAP® reagent source materials are calibrated to WHO reference standards.

A class system has been devised to facilitate interpretation. Class values increase from 0/1 to 6, with 0/1 indicating small amounts of specific IgE present. Class values of 1 to 6 are associated with increasing IgE antibody, as well as increasing clinical relevance. As with any laboratory test, the patient's clinical symptoms must be considered in the assessment of test results. Non-allergic individuals have been shown to be non-reactive in the CAP system.

Pediatric and Adult Profiles

Detection of IgE antibodies and determination of specific allergens allow for better outcomes and quality of life for allergy patients. IgE antibodies against foods, molds, dust, animal allergens, and mites can be observed during the first four years of a child's life. By five years, the child can react to pollens and other allergens. Pediatric profiles are provided for young children. Adult profiles of grasses, weeds, tree pollens, occupational allergens, foods, animal dander, molds, and dusts are also provided. For specific panels, refer to the Test Directory under Allergen.

Specimen Requirements

Minimum specimen requirement is 0.3 mL refrigerated serum per each allergen ordered.

INTERPRETIVE GUIDELINES FOR IgE SPECIFIC IN-VITRO TESTING

Specific IgE Class	KU/L	Level of Allergen Specific IgE Antibody
0	<0.10	Absent/Undetectable
0/1	0.10-0.34	Very Low Level
1	0.35-0.70	Low Level
2	0.71-3.50	Moderate Level
3	3.51-17.5	High Level
4	17.6-50	Very High Level
5	51-100	Very High Level
6	>100	Very High Level

ALLERGENS BY CATEGORY

Contactants/Epidermal/Dust	
38410	Bumble Bee Venom (I205), IgE
6000	Cat Epithelium and Dander (E1), IgE
6441	Chicken Feathers (E85), IgE
6599	Cockroach (I6), IgE
6597	Cow Dander (E4), IgE
6190	*Dermatophagoides farinae* (D2), IgE
6193	*Dermatophagoides pteronyssinus* (D1), IgE
6012	Dog Dander (E5), IgE
6632	Duck Feathers (E86), IgE
6419	Goose Feathers (E70), IgE
6017	Horse Dander (E3), IgE
6226	House Dust (Greer) (H1), IgE
6229	House Dust (Hollister-Stier) (H2), IgE
7717	Latex (K82), IgE
906693	Mouse Urine Protein (E72), IgE

Food – Cocoa/Egg/Grain/Milk/Yeast

904539	Alpha Lactalbumin (F76), IgE
6034	Barley (F6), IgE
904538	Beta Lactoglobulin (F77), IgE
91051	Black Pepper (F280), IgE
6086	Buckwheat (F11), IgE
902669	Caraway (F265), IgE
903042	Casein (F78), IgE
6073	Cheddar Cheese (F81), IgE
900872	Chick Pea (RF309), IgE
2559	Chocolate/Cocoa (F93), IgE
5726	Cinnamon (F220), IgE
101738	Coffee (F221), IgE
900509	Dill (F277), IgE
5691	Egg (Whole) (F245), IgE
6061	Egg White (F1), IgE
6058	Egg Yolk (F75), IgE
900508	Ginger (FRF270), IgE
6094	Gluten (F79), IgE
15838	Malt (F90), IgE
6009	Milk (Cow) (F2), IgE
902115	Mint (F332), IgE
5964	Mustard (F89), IgE
905348	Nutmeg (RF282), IgE
6067	Oats (F7), IgE
902287	Ovalbumin (F232), IgE
905210	Ovomucoid (F233), IgE
705349	Poppy Seed (RF224), IgE
6046	Potato (F35), IgE
6115	Rice (F9), IgE
6121	Rye (F5), IgE
6127	Sesame Seed (F10) IgE
6133	Soybean (F14), IgE
904385	Sunflower Seed (K84), IgE
6052	Wheat (F4), IgE
901399	Whey (F236), IgE
6321	Yeast Baker's (F45), IgE

Food – Fish/Meat

708508	Beef (F27), IgE
6609	Blue Mussel (F37), IgE
706064	Chicken Meat (F83), IgE
903036	Clam (F207), IgE
6082	Codfish (F3), IgE
6088	Crab (F23), IgE
6089	Lamb (F88), IgE
6100	Lobster (F80), IgE
903040	Oyster (F290), IgE
6118	Pork (F26), IgE
6124	Salmon (F41), IgE
903037	Scallops (F338), IgE
706130	Shrimp (F24), IgE
6139	Tuna (F40), IgE
903038	Turkey Meat (F284), IgE

Food – Fruit/Vegetable

706403	Apples (F49), IgE
91112	Apricot (F237), IgE
7764	Avocado (F96), IgE
5707	Blueberry (RF288), IgE
6407	Banana (F92), IgE
6040	Carrot (F31), IgE
101233	Celery (F85), IgE
6079	Coconut (F36), IgE
6085	Corn (F8), IgE
3796	Cucumber (F244), IgE
902440	Fig (F328), IgE
6091	Garlic (FF47), IgE
905529	Grape (F259), IgE
107974	Grapefruit (F209), IgE
705280	Kiwi (F84), IgE
7743	Lemon (F208), IgE
7475	Lime (RF306), IgE
5479	Mango (F91), IgE
5476	Melon (F87), IgE
6103	Onion (F48), IgE
6055	Orange (F33), IgE
71181	Papaya (RF293), IgE
6109	Pea (F12), IgE
7472	Peach (F95), IgE
7469	Pear (F94), IgE
5274	Pineapple (F210), IgE
905350	Plum (F255), IgE
6046	Potato (F35), IgE
6136	Strawberry (F44), IgE
706049	Tomato (F25), IgE

Grasses

703047	Alfalfa (RW45), IgE
6164	Bahia Grass (G17), IgE
6145	Bermuda Grass (G2), IgE
6430	Johnson Grass (G10), IgE
6422	June Grass (Kentucky Blue) (G8), IgE
6160	Orchard Grass (G3), IgE
706163	Perennial Rye Grass (G5), IgE
900457	Redtop Grass (G9), IgE
6172	Timothy Grass (G6), IgE

Mixes (Reported As Positive/Negative)

5310	Common Food Mix [FX5–Egg White (F1), Milk (Cow) (F2), Codfish (F3), Wheat (F4), Peanut (F13), Soybean (F14)]
903044	Feather Mix [EX71-Goose Feathers (E70), Chicken Feathers (E85), Duck Feathers (E86), Turkey Feathers (E89)]
1702	House Dust Mix [HX2–House Dust (Hollister-Stier) (H2), *Dermatophagoides pteronyssinsus* (D1), *Dermatophagoides farinae* (D2), German Cockroach (I6)]
5749	Nut Mix [FX1–Peanut (F13), Hazelnut (F17), Brazil Nut (F18), Almond (F20), Coconut (F36)]
16001	Seafood Mix [FX2–Codfish (F3), Shrimp (F24), Blue Mussel (F37), Tuna (F40), Salmon (F41)]

Molds

6259	*Alternaria alternata* (M6), IgE
706262	*Aspergillus fumigatus* (M3), IgE
905530	*Aspergillus niger* (M207), IgE
6678	*Aureobasidium pullulans* (M12), IgE
6264	*Botrytis cinerea* (M7), IgE
6265	*Candida albicans* (M5), IgE
6268	*Cladosporium herbarum* (M2), IgE
903048	*Curvularia spicifera* (RM46), IgE
90020	*Fusarium monoliforme* (M9), IgE
6440	*Helminthosporium halodes* (M8), IgE
706320	*Mucor racemosus* (M4), IgE
6546	*Penicillium notatum* (M1), IgE
6504	*Phoma betae* (M13), IgE
7493	*Rhizopus nigricans* (M11), IgE
6656	*Stemphylium botryosum* (M10), IgE
900755	*Trichophyton rubrum* (M205), IgE

Nuts

6028	Almond (F20), IgE
6037	Brazil Nut (F18), IgE
5673	Cashew (F202), IgE
91180	Chestnut (F299), IgE
6079	Coconut (F36), IgE
903043	Hazelnut (F17), IgE
90094	Macadamia Nut (F345), IgE
6112	Peanut (F13), IgE
6105	Pecan (F201), IgE
900602	Pine Nut (RF253), IgE
703039	Pistachio (F203), IgE
900620	Walnut (F256), IgE
91681	Peanut Components, IgE: rAra h 1 (f422), rAra h 2 (f423), rAra h 3 (f424), rAra h 8 (f352), rAra h 9 (f427)

Trees	
7522	Arizona Cypress (T222), IgE
6210	Acacia Tree (T19), IgE
6238	Cottonwood Tree (T14), IgE
6241	Elm Tree (T8), IgE
6209	Eucalyptus Tree (T18), IgE
6232	Grey Alder Tree (T2), IgE
6253	Juniper Tree (T6), IgE
6250	Maple Tree (Box Elder) (T1), IgE
6491	Mesquite Tree (T20), IgE
6487	Mulberry Tree (T70), IgE
6244	Oak Tree (T7), IgE
706247	Olive Tree (T9), IgE
6664	Pecan Tree (T22), IgE
905501	Red Cedar Tree (T57), IgE
6235	Silver Birch Tree (T3), IgE
6508	Sycamore Tree (T11), IgE
6567	Walnut Tree (T10), IgE
706593	White Ash Tree (T15), IgE
6459	White Pine Tree (T16), IgE
6256	Willow Tree (T12), IgE

Weeds	
903041	Carelessweed (RW82), IgE
900414	Cocklebur (W13), IgE
6217	Common Pigweed (W14), IgE
6175	Common (Short) Ragweed (W1), IgE
6196	English Plantain, Ribwort (W9), IgE
6181	False Ragweed (W4), IgE
6199	Firebush (W17), IgE
706205	Lamb's Quarters (Goosefoot) (W10), IgE
706208	Mugwort (W6), IgE
6211	Nettle (W20), IgE
7528	Rough Marshelder (W16), IgE
6220	Russian Thistle (W11), IgE
6223	Scale (W15), IgE
7525	Sheep Sorrel (W18), IgE
903046	Sugar Beet Pollen (RW210), IgE
6185	Western Ragweed (W2), IgE
903045	Yellow Dock Weed (RW23), IgE

The College of American Pathologists requires that all samples include 2 FORMS of patient identification on EVERY container at time of collection. The information provided in this General Information section is for informational purposes only and is subject to change. Please contact our Client Services Department at 602.685.5050 to confirm any of the information presented within.

COAGULATION

Specimen Collection and Processing

Tests for the hemostatic mechanism are extremely sensitive to methods of sample collection and processing. The test results are dependent entirely on specimen integrity. It is imperative that specimen collection and preparation for transport be followed strictly to ensure the quality of the samples and subsequently the test results. Special Coagulation Laboratory hours: Monday through Saturday 7:00 a.m. to 4:00 p.m.

Call the Sonora Quest Laboratories' Courier Department for prompt pick-up of all special coagulation studies at 602-685-5052.

If you have any questions about the status of your testing or need test results, please call the Special Coagulation Laboratory at 602-685-4107.

Plasma samples that are received thawed (unless cold and collected within 4 hours), contain clots, or are grossly hemolyzed cannot be utilized for coagulation testing. The laboratory will notify you if a sample is unacceptable.

Specimens for Platelet Aggregation should be scheduled in advance with the Banner University Medical Center - Phoenix. Call 602-839-3471 to schedule the test Monday through Friday, 6:00 a.m. to 5:00 p.m. The specimen should be transported at room temperature via STAT Courier within one hour of collection. Call 602-685-5052 for STAT Courier Services. We recommend that the courier be called just prior to drawing the specimen to allow time for pick-up.

Anticoagulated specimens may be collected by evacuated tube system in siliconized glass or plastic tubes using only 3.2% sodium citrate. Collection tubes must be filled completely by vacuum to preserve the 9:1 ratio of blood to anticoagulant. Carefully invert the sample 8-10 times to ensure proper mixing of anticoagulant.

Samples collected from patients with in-dwelling catheters should have a discard of 20 mL of blood prior to collecting for the coagulation testing. The discard blood may be used for other testing if appropriate.

Correct patient identification (two patient identifiers required) and appropriate labeling of the specimen is essential. **Please provide the following information on each sample submitted: Patient Name, Date and Time Collected, Phlebotomist Initials, Specimen Type, i.e., Serum, Citrated Plasma, Whole Blood.**

Package the samples and complete the requisition per usual Sonora Quest Laboratories procedures. Follow the guidelines for frozen samples when appropriate. Be sure to check the sample requirements for each test ordered to ensure all requirements are met.

When collecting specimens for coagulation testing, the blood to anticoagulant ratio is imperative. If the patient's hematocrit is above 55%, the amount of anticoagulant used should be adjusted according to the following formula:

$C = (100 - H) \div (595 - H) \times V$ where:

C = volume of 3.2% sodium citrate in milliliters
H = hematocrit in percent
V = volume of whole blood in milliliters

Processing Citrated Plasma

1. Draw blood into a buffered sodium citrate tube and fill by vacuum. The tube must be completely filled by vacuum to preserve the 9:1 ratio of blood to anticoagulant. The sodium citrate used should only be 0.109 molar (3.2%) sodium citrate. Use of other anticoagulants may cause discrepant or invalid results.
2. Carefully invert tubes 8-10 times to mix. Failure to mix completely may lead to clotted specimens.
3. The specimens should be centrifuged at 2000 rpm for 15 minutes. This step will provide platelet-free plasma (<10,000 platelets/mm3) for testing.
4. Using a plastic pipette, remove only the top 2/3 of the plasma so as not to disturb the platelets or buffy-coat layer on top of the red cells.
   Note: This step should be strictly adhered to and is extremely important. Should you accidentally withdraw any of the buffy-coat or red cells, **the specimen must be re-centrifuged and the supernate plasma removed to ensure the validity of testing.**
5. Dispense the plasma into plastic aliquot tubes following the specimen requirements for the tests being ordered.
6. Cap with plastic caps and label the tubes with patient's name, a second patient identifier, date of draw, your initials, and specimen type.
7. For Lupus Anticoagulant testing and the Lupus portion of the APS Panel, it is strongly recommended that the sample be "double spun" to ensure that the plasma is platelet free.

A. Perform steps #3, 4, 5, and 6 (above).
B. Centrifuge the aliquot tubes a second time for 10 minutes at 2000 rpm.
C. Once again remove the plasma into properly labeled plastic aliquot tubes, being careful not to pull up any platelets that may have pelleted at the bottom of the tube. Cap the tubes with plastic caps.

8. Freeze the tubes immediately. Package in Sonora Quest Laboratories' specimen bag according to standard protocol. Include the completed test request form in the second pocket of the specimen bag and store frozen for transport.
   Note: Never, under any circumstances, place frozen samples in an outside lockbox. The ambient temperature is much too high and will thaw the sample regardless of packaging.
9. Place only one patient's draw per specimen bag.

Processing Whole Blood Specimens

Sodium Citrate Samples
Draw blood into a buffered sodium citrate tube and fill by vacuum. The tube must be completely filled by vacuum to preserve the 9:1 ratio of blood to anticoagulant. The sodium citrate used should be 0.109 molar (3.2%) sodium citrate.

EDTA Samples
EDTA anticoagulant may be needed when ordering DNA tests such as the Prothrombin Gene Mutation or the Factor V Leiden. DNA tests should be as fresh as possible. Call for courier pick-up ASAP (same day) to preserve the integrity of the sample.

1. Fill tubes completely by vacuum.
2. Carefully invert the tubes 8-10 times to mix. Failure to mix completely may lead to clotted specimens.
3. Label the tubes with patient's name, a second patient identifier, date of draw, phlebotomist's initials, and specimen type.
4. Package samples in a Sonora Quest Laboratories' specimen bag according to standard protocol. Place only one patient's draw in each bag and include the test request form in the second pocket of the bag.

Whole blood samples should be kept UN-CENTRIFUGED at REFRIGERATED TEMPERATURE (2-8° C).

Processing Serum Specimens

1. Draw plain red-top tube. Do not use serum separator tubes (SST's).
2. Allow to clot for 20-30 minutes.
3. Centrifuge for 10 minutes.
4. Using a plastic pipette, dispense serum into plastic aliquot tubes following the specimen requirements for the test being ordered.
5. Label the tubes with patient's name, a second patient identifier, date of draw, phlebotomist's initials, and specimen type.
6. Cap with plastic caps and freeze samples immediately.
7. Samples should be packaged in a Sonora Quest Laboratories' specimen bag according to standard protocol. Place only one patient's draw in each specimen bag and include the properly completed test request form. Store frozen for pick-up.

CYTOGENETICS (GENETICS & GENOMICS DIVISION)

Tel: 602-685-5700 / Fax: 602-685-5750

Our Tempe laboratory has a full service Genetics & Genomics Division employing classical chromosome analysis, fluorescence in-situ hybridization (FISH), microarray, polymerase chain reaction (PCR) and Next Generation Sequencing (NGS) technologies to investigate genetic abnormalities. We are a COG and CALGB approved laboratory. The laboratory directors are certified by the American Board of Medical Genetics and are available for consultation. For questions or rush orders – please call the lab at **602-685-5700.**

[Tests with an interpretive result are restricted for client/physician billing per Arizona statute ARS §32-3210]

CHROMOSOME ANALYSIS (Methodology: tissue culture, microscopy, karyotype)

General Specimen Requirements:
Include a completed requisition, or Quanum™ eReq, with: Clinical information/patient history; physician's name and contact numbers; and insurance/payment information. The absence of relevant clinical information may compromise the report interpretation.
DO NOT ADD FIXATIVE (e.g.: formalin, alcohol) or send in any container containing cytotoxic material.
DO NOT refrigerate or freeze.
DO include an ice pack in shipping, April through October.
Store and transport at room (ambient) temperature (65-85°F/17-29°C). Ship to lab as soon as possible (within 48 hours) to preserve cell viability. For questions: please call the lab at 602-685-5700.
EXCEPTION: for Products of Conception (POC) – please store and transport refrigerated (38-46°F/4-8 °C)

Specimen Type	Test Code	Additional Specimen Requirements / Notes
Amniotic Fluid	**88851**	15-25 mL in sterile tube(s). Discard first 1-2 mL of draw.
Chorionic Villus Sample (CVS)	**88852**	25-40 mg with sterile tissue culture medium (or saline) in sterile tube.
Peripheral Blood, Routine Hi-resolution Mosaic	 **88853** **88912** **88855**	2-5 mL blood (2-3 mL for infants) - Sodium heparin (green top tube). Invert tube to mix.
Products of Conception (POC)	**788856**	At least ~4x4mm tissue from fetus, if possible, and ~4x4mm of chorionic villi from placenta. Sterile container with sterile culture medium (or saline). ** Store and transport refrigerated (38-46°F/4-8 °C) ** Recommended fetal tissue types include: skin and muscle. **NOTE**: If histopathologic studies are required, please submit the entire fresh specimen to cytogenetics to ensure receipt of viable tissue (testing cannot be performed on fixed tissue). Specimen will be promptly forwarded to pathology to complete their testing.
Skin / Tissue	**88857**	Punch biopsy (3x5 mm). Do not use alcohol or iodine to cleanse site (use antibiotic soap). Sterile container with sterile culture medium (or saline).
Bone Marrow	**88858**	2-3 mL aspirate in sodium heparin tube (green top). Invert to mix.
Leukemic Blood	**88859**	5 mL blood (>10% blasts), sodium heparin tube (green top). Invert to mix.
Lymph Node	**88847**	At least ~3x3 mm sample. Sterile container with sterile tissue culture medium (or saline).
Solid Tumor	**88862**	At least ~3x3 mm sample from *tumor tissue.* Sterile container with sterile tissue culture medium (or saline).

FLUORESCENCE IN-SITU HYBRIDIZATION (FISH) (Methodology: FISH, microscopy)

General Specimen Requirements:
Include a completed requisition, or Quanum™ eReq, with: Clinical information/patient history; physician's name and contact numbers; and insurance/payment information. The absence of relevant clinical information may compromise the report interpretation.
DO NOT ADD FIXATIVE (e.g.: formalin, alcohol) or send in any container containing cytotoxic material.
DO NOT refrigerate or freeze. Include an ice pack in shipping, April through October.
Store and transport at room (ambient) temperature (65-85°F/17-29°C). Ship to lab as soon as possible (within 48 hours) to preserve cell viability. For questions: please call the lab at **602-685-5700.**

Specimen Type / Tests Available:	TEST CODE	Additional Specimen Requirements / Notes
FISH: Constitutional Blood		2-3 mL peripheral blood (1-2 mL for infants) Sodium heparin (green-top tube). Invert tube to mix.
FISH: Angelman syndrome (15q11.2-13)	**88816**	
FISH: Cri-du-chat syndrome (5p15.2)	**88833**	
FISH: DiGeorge/VCFS syndrome (22q11.2)	**88834**	
FISH: Kallmann syndrome (Xp22.3)	**88835**	
FISH: Miller-Dieker Lissencephaly syndrome (17p13.3)	**88836**	
FISH: Postnatal Aneuploidy Screen (panel)	**88911**	For trisomy 13, 18, 21; sex chromosome aneuploidy.
FISH: Prader-Willi syndrome (15q11.2-13)	**88841**	
FISH: Smith-Magenis syndrome (17p11.2)	**88843**	
FISH: SRY/ male detection (Yp11.3)	**88923**	
FISH: Steroid sulfatase deficiency (STS) (Xp22.3)	**88844**	
FISH: Sub-Telomere Panel	**88917**	
FISH: Williams (elastin) syndrome (7q11.23)	**88845**	
FISH: Wolf-Hirschhorn syndrome (4p16.3)	**88846**	
FISH: X/Y sex determination	**88818**	
FISH: Prenatal Aneuploidy Screen (panel)	**88820**	2-3 mL amniotic fluid (in addition to the ~15-20 mL for chromosome analysis). Sterile tube. For trisomy 13, 18, 21; sex chromosome aneuploidy

FISH ONCOLOGY PROBES:

General Specimen Requirements:
Include a completed requisition, or Quanum™ eReq, with: Clinical information/patient history; physician's name and contact numbers; and insurance/payment information. The absence of relevant clinical information may compromise the report interpretation.
DO NOT ADD FIXATIVE (e.g.: formalin, alcohol) or send in any container containing cytotoxic material.
DO NOT refrigerate or freeze. Include an ice pack in shipping, April through October.
Store and transport at room (ambient) temperature (65-85°F/17-29°C). Ship to lab as soon as possible (within 48 hours) to preserve cell viability. For questions: please call the lab at **602-685-5700.**

Specimen Type / Tests Available:	Test Code	Additional Specimen Requirements / Notes
Bone Marrow (or Leukemic blood) (Tests may also be possible for other specimen types – **CALL LAB**)		2-4 mL bone marrow or peripheral blood. Sodium heparin (green top) tube. Invert to mix.
FISH: ALK rearrangement (2p23)	**88893**	Anaplastic T-cell lymphoma, non-small cell lung cancer
FISH: ATM (11q22.3) deletion	**906791**	CLL
FISH: BCL2 (18q21) rearrangement	**88896**	

FISH ONCOLOGY PROBES continued:

Specimen Type / Tests Available:	Test Code	Additional Specimen Requirements / Notes
Bone Marrow (or Leukemic blood) (Tests may also be possible for other specimen types – **CALL LAB**)		2-4 mL bone marrow or peripheral blood. Sodium heparin (green top) tube. Invert to mix.
FISH: BCL6 (3q27) rearrangement	**88894**	
FISH: BCR/ABL1 t(9;22)	**88840**	
FISH: BIRC3/MALT1 (API2/MALT1) t(11;18)	**88892**	
FISH: CBFB (16q22) rearrangement	**88810**	
FISH: CDKN2A (9p21.3) rearrangement	**88916**	
FISH: CKS1B (1q21) gain /CDKN2C (1p32) deletion	**906095**	
FISH: Deletion / Monosomy 13 (13q14, 13q34)	**788922***	FISH: Misc. Lymphoid/Hematopoietic. *Must specify test on requisition.
FISH: Deletion / Monosomy 20 (D20S108) (20q12)	**88931**	
FISH: Deletion / Monosomy 5 (EGR1) (5q31.2)	**88925**	
FISH: Deletion / Monosomy 7 (D7S486)	**88927**	
FISH: EGFR (7p11) rearrangement	**788922***	FISH: Misc. Lymphoid/Hematopoietic. *Must specify test on requisition.
FISH: ETV6 (12p13) rearrangement	**88819**	
FISH: ETV6 / RUNX1 t(12;21)	**88811**	
FISH: EWSR1 (22q12) rearrangement	**88897**	
FISH: FGFR1 (8p12) rearrangement	**88996**	
FISH: FIP1L1-PDGFRA del(4)(q12q12)	**88817**	
FISH: FOXO1 (FKHR) (13q14) rearrangement	**88814**	
FISH: IGH (14q32) rearrangement	**88886**	
FISH: IGH / BCL2 t(14;18)	**88890**	
FISH: IGH / CCND1 t(11;14)	**88887**	
FISH: IGH / FGFR3 t(4;14)	**88888**	
FISH: IGH / MAF t(14;16)	**88889**	
FISH: IGH / MAFB t(14;20)	**906097**	
FISH: IGH / MALT1 t(14;18)	**88891**	
FISH: IGH / MYC t(8;14)	**88933**	
FISH: KMT2A (MLL) (11q23) rearrangement	**88837**	
FISH: MALT1 (18q21) rearrangement	**88910**	
FISH: MECOM (EVI1) (3q26.2) rearrangement	**88998**	
FISH: MYB (Deletion 6q23)	**88895**	
FISH: MYC (C-MYC) (8q24) rearrangement	**88830**	
FISH: MYCN (N-MYC) (2p24) rearrangement	**88838**	
FISH: PDGFRβ (5q33) rearrangement	**88995**	
FISH: PML / RARA t(15;17)	**788831**	Lab will run as STAT for new diagnoses.
FISH: RARA (17q21) rearrangement	**788922***	FISH: Misc. Lymphoid/Hematopoietic. *Must specify test on requisition.
FISH: RUNX1 / RUNX1T1 (ETO/AML1) t(8;21)	**88809**	
FISH: SS18 (SYT) (18q11) rearrangement	**88901**	
FISH: TCF3 / PBX1 t(1;19)	**88900**	
FISH: TP53 (p53) (17p13.1) deletion	**788898**	
FISH: TRA/D (TCR) (14q11) rearrangement	**788815**	
FISH: Trisomy 12	**88937**	
FISH: Trisomy 17	**788898**	(ordered as TP53 deletion)

FISH ONCOLOGY PROBES continued:

Specimen Type / Tests Available:	Test Code	Additional Specimen Requirements / Notes
Bone Marrow (or Leukemic blood) (Tests may also be possible for other specimen types – **CALL LAB**)		2-4 mL bone marrow or peripheral blood. Sodium heparin (green top) tube. Invert to mix.
FISH: Trisomy 8	**88929**	
FISH: X/Y sex determination	**88818**	

FISH ONCOLOGY PANELS:

Specimen Type / Tests Available:	Test Code	Additional Specimen Requirements / Notes
Bone Marrow (or Leukemic blood), (Tests may also be possible for other specimen types – **CALL LAB**)		2-4 mL bone marrow or peripheral blood. Sodium heparin (green top) tube. Invert to mix.
FISH: ALL Hyperdiploidy Panel	**88812**	Includes chromosomes 4, 10, and 17.
FISH: ALL Panel	**88879**	Includes BCR/ABL1 t(9;22), ETV6/RUNX1 t(12;21), KMT2A (MLL)(11q23) rearrangements, and chromosomes 4, 10, and 17.
FISH: AML Panel	**788807**	Includes BCR/ABL1, PML/RARA t(15;17), KMT2A (MLL) (11q23), RUNX1/RUNX1T1 t(8;21), CBFB (16q22) rearrangements, trisomy 8, and deletion/monosomy 5 (EGR1), 7 (D7S486), 20 (D20S108).
FISH: CLL Panel	**88915**	Includes trisomy 12 and 13q14.3, 13q34, ATM (11q22.3), and TP53 (17p) rearrangements. (Does not include t(11;14) which can be ordered separately)
FISH: Lymphoma Panel, High Grade	**906763**	Includes BCL2(18q21), BCL6(3q27), MYC(8q24) gene rearrangements
FISH: Lymphoma Panel, Low Grade	**906762**	Includes IGH(14q32), BCL2(18q21), BCL6(3q27), MALT1(18q21), IGH/CCND1 t(11;14) gene rearrangements.
FISH: MDS Panel	**88919**	Includes deletion / monosomy 5 (EGR1), 7 (D7S486), 20 (D20S108); and trisomy 8.
FISH: Multiple Myeloma Panel	**88808**	Includes 1p deletion / 1q trisomy, deletion / monosomy 13, TP53 (17p), and IGH (14q32) rearrangements. (Does not include specific IGH translocations; some may be ordered separately)
FISH: Myeloproliferative Neoplasm (MPN) Panel	**906543**	Includes BCR/ABL1 t(9;22), trisomy 8, deletion 13 (13q14, 13q34), & deletion / monosomy 20. These tests may also be ordered individually.

FISH: BLADDER CANCER **3462**
Urine or barbotage (bladder wash)

General Specimen Requirements:
Include a completed requisition, or Quanum™ eReq, with: Clinical information/patient history; physician's name and contact numbers; and insurance/payment information. The absence of relevant clinical information may compromise the report interpretation.
DO NOT freeze.
Store and transport at low temperature (35-39°F/2-4°C).
Include an ice pack in shipping.
For questions: please call the lab at **602-685-5700.**

Samples should be preserved and refrigerated immediately: mix ≥33 mL of specimen with 2:1 (v:v) with PreservCyt® or Carbowax (2% polyethylene glycol in 50% ethanol). Ship to lab with an ice pack within 72 hours.

Criteria for **REJECTION** of specimen:
Samples with <33 mL will be processed, but may be cancelled if insufficient cells or contamination are present.
Samples with any other preservative than those stated will be rejected.
Transportation kits, with handling instructions, are available upon request by calling **602-685-5264**.

FISH, Formalin fixed, Paraffin Embedded Tissue (FFPET)

3-4 silanized slides, prepared from 4-6µm sections of tissue cut sequentially with an H&E stained adjacent slide marked **with tumor area of interest by a pathologist. Sections must be within 10 cuts from H&E.**
Specimens must be fixed in 10% neutral buffered formalin (NBF) within 1 hr from removal. Cut slides are stable for 6 weeks at 2-8°C. Blocks are stable indefinitely at 2-27°C/35-80°F**.**

Criteria for **REJECTION** of specimen:

- Slide is received frozen.
- Slide not paraffin embedded.
- Slide not formalin fixed.
- Tissue microwave processed.
- Other pre-analytic variables as stated by a pathologist.

General Specimen Requirements:
Include a completed requisition, or Quanum™ eReq, with: Clinical information/patient history; physician's name and contact numbers; case#; block#; pathology report; and insurance/payment information. The absence of relevant clinical information may compromise the report interpretation. For questions: please call the lab at **602-685-5700.**

Specimen Type:	Test Code	Additional Specimen Requirements / Notes
FISH, Paraffin Embedded Tissue		
FISH: ALK rearrangement	**88893**	
FISH: BCL2 rearrangement	**88896**	
FISH: BCL6 rearrangement	**88894**	
FISH: EWSR1 rearrangement	**88897**	
FISH: FGFR1 rearrangement	**88996**	
FISH: FOXO1(FKHR) rearrangement	**88814**	
FISH, HER2 (ERBB2)	**905837**	Breast tissue (or metastatic tissue from breast primary). Only invasive tumors will be processed. Ductal carcinoma in-situ will not be scored in invasive tumors. **FFPE only**
FISH: IGH (14q32) rearrangement	**88886**	
FISH: IGH/CCND1(BCL1) t(11;14)	**88887**	
FISH: MALT1 rearrangement (18q21)	**88910**	
FISH: MDM2 rearrangement	**88921**	**FFPE only**
FISH: MECOM (EVI1) rearrangement	**88998**	
FISH: MYC (C-MYC) rearrangement	**88830**	
FISH: Lymphoma Panel, High Grade	**906763**	Includes BCL2(18q21), BCL6(3q27), MYC(8q24) gene rearrangements
FISH: Lymphoma Panel, Low Grade	**906762**	Includes IGH(14q32), BCL2(18q21), BCL6(3q27), MALT1(18q21), IGH/CCND1 t(11;14) gene rearrangements.
FISH: PDGFRβ rearrangement	**88995**	
FISH: ROS1 rearrangement	**88995**	**FFPE only**
FISH: SS18 (SYT) rearrangement	**88901**	

MOLECULAR TESTS:
1-3 mL refrigerated whole blood in lavender-top EDTA tube. Invert to mix.

Include a completed requisition, or Quanum™ eReq, with: Clinical information/patient history; physician's name and contact numbers; and insurance/payment information. The absence of relevant clinical information may compromise the report interpretation.
DO NOT ADD FIXATIVE (e.g.: formalin, alcohol) or send in any container containing cytotoxic material
DO NOT freeze.
Store and transport at low temperature (35-39°F/2-4°C).
Include an ice pack in shipping, April through October.
For questions: please call the lab at **602-685-5700.**

Polymerase Chain Reaction (PCR)	Test Code	Additional Specimen Requirements / Notes
Factor II (Prothrombin) 20210G>A mutation	**11887**	(Method: linear signal amplification)
Factor V (Leiden mutation)	**21315**	(Method: linear signal amplification)
JAK2 V617F Mutation	**906423**	(Method: PCR, sequencing)
MTHFR	**906664**	(Method: linear signal amplification)
BCR/ABL1 Quantitative	**905842**	(Method: PCR, sequencing)

CYTOLOGY

Per Arizona Statute ARS §32-3210, testing performed by a Pathologist may not be billed directly to a physician office, and may only be billed to the patient; the responsible insurer or other third party payor; the health care institution; government agency; or a referring laboratory, excluding the laboratory of the health professional who ordered the test.

Requisitions and Labels for all Specimens Submitted
The following information is required on all requisitions and EMR forms in order to render a pathologic diagnosis:

1. Patient demographic information: name, sex, date of birth, age
2. Full name of physician(s) to receive copies of report
3. Brief statements of clinical history / diagnosis, disease process(es) to rule out, and previous results
4. Type and body location of specimen
5. Appropriate diagnostic code(s)
6. Each specimen container MUST be labeled with the patient name plus a second identifier (date of birth, social security number, requisition number or a unique random number which correlates directly to the accompanying requisition).

TWO PATIENT IDENTIFIERS REQUIRED ON ALL SPECIMEN CONTAINERS
Per the College of American Pathologist (CAP) regulations GEN. 40491 and COM.06100, all primary specimen containers (the innermost container submitted to Sonora Quest Laboratories that contains the specimen to be tested) MUST be labeled with two patient identifiers. Submitted slides must also contain two patient identifiers. If two patient identifiers are not provided, testing may be delayed until such information is obtained by Sonora Quest Laboratories. These patient identifiers include (in order of preference) but are not limited to:

- FULL PATIENT NAME (FIRST AND LAST)
- REQUISITION NUMBER OR BAR CODE LABEL
- PATIENT DATE OF BIRTH
- UNIQUE PATIENT IDENTIFIER

Patient identifiers on the specimen container and the laboratory order form must match in order for the specimen to be processed. Patient identifiers on specimen bags or lids do not satisfy CAP requirements and cannot be used by Sonora Quest Laboratories.

Discrepancies and/or missing information will cause a delay in turnaround time. Cases will not be processed until the necessary identification, information, and/or correction of discrepancies are obtained.

GYNECOLOGIC
Pap Test, Female Genital, Quality Statement
The Female Genital Pap test technique for the detection of cervical cancer is one of the most successful screening tests and has saved thousands of lives. However, it is not widely recognized or understood that this test is subject to the same general types of error as most other laboratory tests, which can be classified as “false negatives” and “false positives”. Several recently published articles conclude that there is a significant, very likely irreducible “false negative” rate even in the best of hands. False negatives can be the result of a clinical component such as poor sampling, or a laboratory component, such as inaccuracy in slide evaluation and in some cases a combination of both. The laboratory error component, i.e., a falsely negative designation among the 6-7% of slides containing abnormal epithelial cells, is called the “false negative fraction”, and is between 5% and 10%, even in the best hands. Another way of saying this is “the chance that a slide with positive findings will be called negative is between one in ten and one in twenty”. This is one of the reasons most experts feel Pap tests should be repeated periodically.
Considering that the Pap test is part of an overall detection system, other reasons for “false negatives” include:

- The sample collection device did not contact the site of the lesion.
- Abnormal cells failed to be transferred from the collecting device to the slide or ThinPrep® vial.
- Improper fixation or other interfering factors such as excessive thickness, blood, lubricant or inflammatory cells render abnormal cells impossible to see or interpret.

Our keen awareness of the sources of Pap test errors goes hand-in-hand with our insistence on using the finest procedures and systems for cytology quality assurance and quality control. Intensive measurement, training, and rescreening efforts are integral parts of the work environment at the laboratory. These ensure the highest overall quality of Pap testing available anywhere.

Education Statement:

This is a screening test with an inherent, but low, probability of error. For further information on appropriate follow-up, please refer to The American Society for Colposcopy and Cervical Pathology guidelines for the management of women with abnormal Pap test diagnoses (www.ASCCP.org).

Collection of Pap Test

This specimen is obtained under direct visualization after the speculum is introduced utilizing saline or water.
It is preferred that lubricant **not be used**. If lubricant must be used due to patient discomfort or other circumstances, a **carbormer-free** lubricant should be used sparingly and applied only to the exterior sides of the speculum blades, avoiding contact with the tip of the speculum. A piece of gauze should be used to clear away the mucus plug, if present. Any of the following devices may be used to collect the sample: endocervical brush, plastic scraper/spatula, and/or cervical broom (pipette).

A. Liquid Based Collection:

1. Write patient's name and second identifier on the collection vial (ThinPrep®).
2. Using a plastic cervical scraper, lightly scrape the entire ectocervix, especially the borders of erosion, with a 360° rotation. Immediately and vigorously agitate the scraper in the ThinPrep® vial to dislodge all cells. Remove and discard the scraper as biohazardous waste. Insert a cervical brush into the endocervix and rotate ¼ to ½ turn. DO NOT OVER-ROTATE. Immediately and vigorously agitate the brush in the ThinPrep® vial, including pressing the brush against the walls of the ThinPrep® vial. Remove the brush at once and discard the brush as biohazardous waste. OR
3. If a cervical broom (pipette) is preferred, rotate the device clockwise a full 5 turns. Immediately and vigorously agitate in the ThinPrep® vial, including pressing the broom against the walls of the ThinPrep® vial. Remove the broom at once and discard the broom as biohazardous waste. Tighten the cap so that the torque line on the cap aligns with the torque line on the ThinPrep® vial. Do not over tighten.
4. May include HPV or HPV reflex request. Additional charges will apply if performed.

Optimal specimens contain cervical squamous cells and endocervical cells. ThinPrep® samples must contain 5,000 squamous cells.

Test Name	Specimen Requirements	Set-Up	Turnaround Time	CPT Code
GYN ThinPrep® , Bethesda Interpretation	ThinPrep® vial, labeled	Monday – Friday	5 Days, Monday - Friday	88142
GYN ThinPrep®, with imaging Bethesda Interpretation	ThinPrep® vial, labeled	Monday – Friday	5 Day, Monday - Friday	88175
HPV mRNA	ThinPrep® vial, labeled	Monday – Friday	5 Days, Monday - Friday	87624
HPV mRNA w/Rflx Genotype 16, 18/45	ThinPrep® vial, labeled	Monday – Friday	5 Days, Monday - Friday	87624

NON-GYNECOLOGIC

Test Name	Specimen Requirements	Set-Up	Turnaround Time	CPT Code
Cyto Fluids, Interpretation	Fresh sample or sample in CytoLyt for ThinPrep Procedure	Monday – Friday	24 hours, Monday - Thursday	88112
Cyto Smears, Interpretation	Prepared slides, 5 or less, labeled with #2 pencil	Monday – Friday	24 hours, Monday - Thursday	88161
Cyto Smears, Extended Study	Prepared slides, more than 5, labeled with #2 pencil	Monday – Friday	24 hours, Monday - Thursday	88162
Cell Block	Fluid must contain tissue fragments or clot	Monday – Friday	24 hours, Monday - Thursday	88305

Anal-Rectal Cytology Specimens

Place the patient in a lateral knee-chest or dorsal lithotomy position. Gently insert a Cytobrush or moistened Dacron swab approximately 5-6 cm into the anal canal past the anal verge, ensuring sampling of the ano-rectal junction. This is done without direct visualization. Rotate the brush or swab 360 degrees while gently pulling back and forth, and brushing the mucosal lining all the while. Remove the brush or swab from the anus. A sample of the peri-anal skin is not sufficient for diagnosis and may result in an unsatisfactory sample.

Liquid-based collection:

1. Write patient's name and second identifier on the collection ThinPrep® Vial (PreservCyt solution) or container of CytoLyt solution.
2. Immediately and vigorously agitate the Cytobrush in a labeled ThinPrep® Vial (PreservCyt solution) or in a labeled container of CytoLyt solution.
3. Remove and discard the brush as biohazardous waste.
4. Securely tighten the container cap.
5. May include HPV or HPV reflex request. Additional charges will apply if performed.

The slides or vial should be submitted to the laboratory with a properly completed Cytology requisition including source, date of birth, sex and any pertinent clinical history.

Body Fluids (Pleural, Pericardial, Peritoneal, and CSF)

Effusions should be sent to the laboratory immediately after collection (50-500 mL volumes preferred; for CSF a minimum of 1.5 cc is needed but more is desirable). Send the leak proof container, labeled with the patient's name, second identifier, date of birth and the body site (including laterality as applicable), with a properly completed Cytology requisition, including patient's sex and pertinent history, to the laboratory. Do not add any fixative, formalin, or anticoagulant to the specimen. Refrigerate until transported. If multiple studies are desired (e.g., cell counts, cultures, etc.), clearly indicate tests on requisition. Make certain an adequate amount of specimen is submitted for each test.

Joint fluids and ganglion cyst fluids rarely have any cytologic clinical value. Cell counts, cultures, and crystal ID may provide more value.

Cytology sample exclusions: samples taken for therapeutic drainage need NOT be sent to Cytology for analysis unless there is a specific clinical question to be addressed.

Breast Samples

1. Nipple Secretions: Label frosted-end glass slide with patient's name and second identifier and R (Right) or L (Left), using #2 lead pencil. Gently express nipple and subareolar area only until pea-size drop appears. Immobilize breast and with fixative bottle below breast, draw labeled slide across nipple and drop into fixative in one motion. Send to laboratory with properly completed Cytology requisition, including patient's sex, date of birth and pertinent history. (For supplies fax request to Supply Department at 602-685-5402).
2. Fine Needle Aspiration of solid mass: Follow FNA procedure.
3. Cyst Aspirates: If lump is cystic (i.e., disappears following aspiration), flush syringe contents into container of CytoLyt or into clean container with no additives. Submit all labeled slides or containers with a properly completed Cytology requisition. Include patient's sex, date of birth and pertinent history, and specific location (i.e., 2 o'clock solid mass right breast).

Bronchial Washings

With the bronchus in question, fill the bronchus to its carina with normal saline and, after allowing the saline to stand in contact as long as possible, aspirate the washing. Label the container with the patient's name, second identifier, specimen site, and immediately send to the laboratory with the properly completed Cytology requisition, including patient's sex, date of birth and pertinent history. Do not add any fixative to the specimen and a minimum of 10 mL is required for evaluation. Refrigerate (or place in wet ice) until transport. If multiple studies are desired (e.g. cultures, etc.), clearly indicate test requests on requisition, making certain an adequate amount of specimen is submitted for each test.

Brushings (Bronchial, Esophageal, Gastric, Etc.)

Brushing specimens should be submitted by cutting brush into 30 mL CytoLyt (fax request to Supply Department at 602-685-5402). Prepared, labeled frosted-end slides may be submitted after immediate fixation, but the CytoLyt method is preferred. Send labeled CytoLyt container or labeled slides with patient's name and second identifier, properly completed Cytology requisition, including patient's sex, date of birth and pertinent history, to the laboratory.

Fine Needle Aspirates (FNA)

When given prior notification, the laboratory will provide CytoLyt or formalin to physicians (fax request to Supply Department at 602-685-5402) performing fine needle aspirations in their office. Techniques vary; a general guide follows:

Label frosted end of slide(s) with patient's name, using a #2 lead pencil. Use 22-25 gauge needle attached to syringe. Introduce needle into mass. Apply vacuum pressure to syringe and move needle back and forth within the mass and in different directions. If blood or any other material appears in hub of needle, stop aspirating. Release plunger and withdraw needle (it is not necessary to see aspirated material in hub of the needle). Detach needle from syringe. Introduce air into syringe. Reattach needle. Touching needle to slide, place 1 or 2 drops onto each slide and prepare smear. Fix one slide immediately before any drying occurs by dropping slide into jar of 95% alcohol. After Spray fixative may be used. Insert: Label fixed slide with an "F" to denote fixed slide. The other slide should be allowed to air dry and labeled with an "A" to denote air-dried slide. Repeat for additional material. An adequate aspirate consists of 3 to 6 smears.

If adequate material is not obtained on the first aspiration, the mass should be re-aspirated. After preparation of the smears, the needles and syringe barrels may be rinsed with CytoLyt (for Thyroid, Salivary and those cases in which no smears are made), or Formalin/Saline (for all other sources) expelling the material into a clean, leak-proof tube or vial labeled with the patient's name and second identifier. Send the labeled slides, labeled container and a properly completed Cytology requisition, including patient's sex, date of birth and pertinent history, to the laboratory. **Please do <u>not</u> send needles to laboratory!**

At the physician's request, Fine Needle Aspirations can be performed in Radiology at any of the Banner Facilities listed below with immediate interpretation by a pathologist. This requires scheduling. Please fax patient's order to Central Scheduling at 480-684-7501for all Phoenix area Banner Facilities. Patients will follow-up by calling Central Scheduling at 480-684-7500 to set appointment at the logistically convenient site listed below. Please fax patient's order to Central Scheduling at 520-694-0216 for all Tucson area Banner Facilities. Patients will follow-up by calling Central Scheduling at 520-694-4034 to set appointment. Please fax patient's order to Central Scheduling at 480-684-7501 for Banner Payson. Patients will follow-up by calling Central Scheduling at 844-848-5373 to set appointment.

Site
Banner Baywood Medical Center
Banner Boswell Medical Center
Banner Casa Grande Medical Center
Banner Del E. Webb Medical Center
Banner Desert Medical Center
Banner Estrella Medical Center
Banner Gateway Medical Center
Banner Ironwood Medical Center
Banner Ocotillo Medical Center
Banner Payson Medical Center
Banner Thunderbird Medical Center
Banner University Medical Center - Phoenix
Banner University Medical Center - Tucson

Test Name	Specimen Requirements	Set-Up	Turnaround Time	CPT Code
FNA, Interpretation and Report		Monday – Friday	24 hours, Monday – Thursday. Friday specimens will be reported on Monday	88173
FNA; immediate study to determine adequacy for diagnosis, first evaluation episode, each site	Requires scheduling. Fax patient's order to Central Scheduling with patient follow-up call for appointment.	Monday – Friday	24 hours, Monday – Thursday. Friday specimens will be reported on Monday	88172
FNA; immediate study to determine adequacy for diagnosis, each separate additional evaluation episode, same site	Requires scheduling. Fax patient's order to Central Scheduling with patient follow-up call for appointment.	Monday – Friday	24 hours, Monday – Thursday. Friday specimens will be reported on Monday	88177

*Electromagnetic Navigational Bronchoscopy samples (ENB), Endoscopic Ultrasound Guided (EUS), Endobronchial Ultrasound Guided (EBUS), Transbronchial (TBNA) and WANG Needle Aspirations will be evaluated as Fine Needle Aspiration (FNA) specimens.

Gastric Washing

After passing tube, draw off and discard resting contents. While patient sits, lies down, and rotates from side to side, aspirate and re-pass 300-500 mL normal saline several times to flush cells from stomach lining. Place aspirated specimen in tubes that are sitting IN ICE. When wash is completed, immediately take tubes labeled with patient's name and second identifier ON ICE to laboratory with properly completed Cytology requisition, including patient's sex, date of birth and pertinent history. Do not add anything to the specimen.

Post Bronchoscopy Sputum

Have the patient expectorate into a clean sputum cup immediately after the bronchoscope is withdrawn. Label container with patient's name and second identifier and send to the laboratory immediately with properly completed Cytology requisition, including patient's sex, date of birth and pertinent history. Do not add any fixative to the specimen. Refrigerate until transported.

Sputum

The patient should be given a sputum cup prior to the collection/testing day, and instructed how to obtain the specimen upon awakening and before eating. Explain that this is to be a '**deep'** cough sputum, not saliva. Send the cup labeled with patient's name and second identifier, plus the properly completed Cytology requisition, including patient's sex, date of birth and pertinent history, to the laboratory immediately or refrigerate until transported. Do not add any fixative to the specimen. This procedure should be repeated for a total of three mornings.

Tzanck Smear (for Herpes Simplex Virus)

Preferred Collection Method:
Label CytoLyt vial with patient label and specimen location. Moisten the area to be scraped with saline solution. The lesion should be scraped vigorously at the base of the vesicles. Skin cells are needed, not the fluid inside the vesicle. Place spatula in CytoLyt vial and swirl to dislodge cellular material into fixative solution. Discard spatula. Submit vial to the laboratory with properly completed Cytology requisition that includes source, patient's sex, date of birth and pertinent history.

Alternate Collection Method:
Scrape lesion and spread material on frosted-end glass slide labeled with patient's name and second identifier using a #2 lead pencil. Fix in 95% alcohol solution or with spray fixative before any drying occurs. Submit with properly completed Cytology requisition that includes source, patient's sex, date of birth and pertinent history.

Test Name	Specimen Requirements	Set-Up	Turnaround Time	CPT Code
Tzanck Smear	Source required; If alternate method: slide labeled with #2 lead pencil	Monday – Friday	24 hours, Monday - Thursday	88161

Note: Tzanck Smear is not the recommended technique. Culture or DFA is more sensitive.

Urine

Send clean-catch voided or catheterized fresh urine or bladder wash specimen to the laboratory (25 mL volume minimum requirement) in a clean, labeled, leak-proof, sterile container labeled with patient's name and second identifier and properly completed Cytology requisition, including patient's sex, date of birth and pertinent history. Do not send a 24-hour sample. Denote whether specimen is voided, catheterized, or bladder washing. Document history of chemotherapy. Do not add any fixative to specimen and refrigerate until transported.

Rejection Criteria for Non-Gynecologic Specimens

1. Integrity of specimen not maintained
2. Quantity Not Sufficient (QNS): Insufficient material submitted, including broken container or leaked in transit
3. Inappropriate specimen submitted
4. Slide(s) received broken beyond repair

Special Stains

Special stains (i.e., GMS for Pneumocystis on respiratory samples) may be ordered in conjunction with the cytology (separate CPT Code). If, in the opinion of the pathologist, special stains or studies are essential, those procedures or tests will be performed at an additional charge.

*Non-gynecologic and Fine Needle Aspirate specimens coming into the laboratory on Friday will be reported Monday. Those coming in on Saturday or Sunday will be reported on Monday or Tuesday. The Cytology Department days of operation are Monday through Friday, closed weekends and holidays.

FLOW CYTOMETRY

The Flow Cytometry Lab is staffed Monday and Saturday from 7:00 AM to 3:30 PM and Tuesday through Friday from 7:00 AM to 5:30 PM. On Sundays we provide on-call service for STAT cases only. All specimens received after 12:00 Noon on Saturday will be processed on Monday.

For any questions concerning Flow Cytometry, please call 602-685-5233.

Flow Cytometry can be used as a powerful and versatile adjunctive tool to diagnose disease and monitor therapy. The major clinical applications of Flow Cytometry in our laboratory are:

- Leukemia/Lymphoma immunophenotyping
- T-B-NK cell quantitation for determining immune status

Immunophenotyping by Flow Cytometry assists in the identification and characterization of subpopulations of cells based on their expression of specific antigens. This characterization is accomplished through the use of antibodies conjugated to fluorescent dyes, which can be detected through a Flow Cytometer. All leukemia/lymphoma samples submitted for immunophenotyping will include morphologic slide review and morphologic correlation with immunophenotypic results. A board-certified pathologist reports each interpretation and may add additional markers, FISH or molecular studies as necessary (additional charges apply).

Current available markers include: CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11b, CD11c, CD13, CD14, CD16, CD19, CD20, CD22, CD23, CD25, CD26, CD33, CD34, CD38, CD41, CD45, CD49d, CD52, CD56, CD57, CD58, CD61, CD64, CD103, CD117, CD138, CD235a, HLA-DR, FMC-7, KAPPA and LAMBDA, TCR Pan α/β, TCR Pan δ/γ, Cytoplasmic CD3, MPO, TDT, and Cytoplasmic Kappa and Lambda. For interpretation, all markers should be ordered within a panel. See the Test Directory under Flow Cytometry for available panels.

All samples should be received within 24 hours of collection for optimal viable testing. Please provide date and time of collection, sample source, clinical information, and/or diagnosis. Use “Room Temperature” labels when appropriate.

Bone Marrow and Peripheral Blood

Acceptable specimen types are bone marrow aspirates and peripheral blood collected in lavender-top (EDTA), completely full yellow-top (ACD solution A), or green-top (sodium heparin) tubes. Sample volume is dependent on cellular yield of the sample. The sample should be stored and shipped at room temperature. **Do not freeze or expose to extreme heat.**

Tissues for Flow Cytometric Phenotyping

Surgically removed lymphatic tissue, bone marrow biopsy, or other tissue should be placed in a sterile, leak-proof transport container that contains enough sterile nutritive media (RPMI-1640 or McCoy’s) to cover the tissue. If possible, slice the tissue several times to allow penetration of the nutrient media. The nutritive media should be pink or magenta. If it turns yellow or cloudy, it should be discarded. Do not freeze the tissue, fix the tissue, or allow the tissue to dry out. The size of the tissue sample required is dependent on the cellular yield in the sample. In some cases, an adequate cell yield can be obtained from very small samples or even needle aspirates. The sample should be stored and shipped at room temperature or 4°C (summer months). **Do not freeze or expose to extreme heat.**

CSF, Pleural Fluids or other Body Fluids

Body fluids should be collected and shipped in a sterile, screw-cap container. The volume of fluid required is dependent on the cell count. Generally 20 mL of pleural or peritoneal fluid is sufficient. Cerebrospinal fluids usually yield too few cells for analysis and are not recommended unless there is clear evidence of a high WBC count (>1000 cells /mm3). **Vitreous fluid, which rarely yields sufficient cellular recovery for testing, is not recommended.** Add equal parts of RPMI to sample. The sample should be stored and shipped at room temperature or 4°C (summer months). Do not freeze or expose to extreme heat.

HISTOLOGY

Per Arizona Statute ARS §32-3210, testing performed by a Pathologist may not be billed directly to a physician office, and may only be billed to: the patient; the responsible insurer or other third party payor; the health care institution; government agency; or a referring laboratory, excluding the laboratory of the health professional who ordered the test.

Safety Notice

Most tissue specimens will be submitted in chemical fixatives. The most routinely used - 10% formalin and Bouin's solutions - need to be appropriately handled to minimize exposure.

1. Open containers only to transfer specimens into them. Re-cap as soon as possible to minimize exposure to fumes and odors.
2. Avoid direct skin contact. Immediately rinse with soap and water if contact does occur.

If in the opinion of the Pathologist special stains or studies are essential, those procedures or tests will be performed at an additional charge.

Requisitions and Labels for all Specimens Submitted

The following information is required on all requisitions and EMR forms in order to render a pathologic diagnosis:

1. Patient demographic information: name, sex, date of birth, age
2. Full name of physician(s) to receive copies of report
3. Brief statements of clinical history / diagnosis, disease process(es) to rule out, and previous results
4. Type and body location of specimen
5. Appropriate diagnostic code(s)
6. Each specimen container MUST be labeled with the patient name plus a second identifier (date of birth, social security number, requisition number or a unique random number which correlates directly to the accompanying requisition) and each container must ALSO identify the biopsy and its location. It is critical to identify laterality (left, right) in all instances.
7. Specimen(s) should also be listed on the requisition. The listing on the requisition MUST match the information on each specimen container.

TWO PATIENTS IDENTIFIERS REQUIRED ON ALL SPECIMEN TUBES AND CONTAINERS

Per the College of American Pathologist (CAP) regulations GEN. 40491 and COM.06100, all primary specimen containers (the innermost container submitted to Sonora Quest Laboratories that contains the specimen to be tested) MUST be labeled with two patient identifiers. Submitted slides must also contain two patient identifiers. If two patient identifiers are not provided, testing may be delayed until such information is obtained by Sonora Quest Laboratories. These patient identifiers include (in order of preference) but are not limited to:

- FULL PATIENT NAME (FIRST AND LAST)
- REQUISITION NUMBER OR BAR CODE LABEL
- PATIENT DATE OF BIRTH
- UNIQUE PATIENT IDENTIFIER

Patient identifiers on the specimen container and the laboratory order form must match in order for the specimen to be processed. Patient identifiers on specimen bags or lids do not satisfy CAP requirements and cannot be used by Sonora Quest Laboratories.

Discrepancies and/or missing information as noted on the lists above will cause a delay in turnaround time. Cases will not be processed the necessary identification, information, and/or correction of discrepancies are obtained.

Rapid Reporting

In select cases the need for a rapid pathology interpretation and diagnosis may be important. For next day turnaround:

1. Indicate "STAT" on the requisition and provide a contact person's name for results.
2. Specimen needs to be in the lab no later than 5:00 PM, Monday through Friday. You may need to call a STAT courier if your normal pickup time does not accommodate this schedule. Additional STAT charges will apply.
3. Advance notice not required.
4. Submit in 10% formalin.
5. Large specimens must be placed in generous containers that have adequate volumes of fixative (10 parts formalin to 1 part specimen).

Bone Marrow Specimens

Advance notice and scheduling are required if Pathologist is expected to obtain the bone marrow specimen

1. Submit bone marrow clot and biopsy in 10% formalin.
2. Submit six to ten air-dried marrow smears; kept separated from fixatives.
3. Submit two peripheral blood smears; kept separated from fixatives.
4. Please include CBC results and other pertinent clinical data.
5. For cell surface marker studies, please refer to the Flow Cytometry Section. For DNA studies, please refer to the specific test listing or Cytogenetics (Genetics & Genomics) Section. A separately submitted specimen is required for each section receiving a sample.

Frozen Section (Performed only at Banner Hospital Surgical Pathology Lab locations)

1. Advance notice required. 24-hour advance notice with date and approximate time of arrival in laboratory.
2. Submitted fresh, no fixative. Submit wrapped in saline moistened gauze and packed in wet ice.
3. Additional documentation: Note on the requisition that frozen section has been requested and the phone number for the person to receive the diagnosis.
4. Additional notes: Couriers delivering these specimens must be told to transport in a cooler and deliver directly to personnel in the Banner Surgical Lab.
5. Frozen section cannot be performed on specimens that have been placed in fixatives.

Immunofluorescence Studies (IF)

Skin IF:

1. 24-hour advance notice required to obtain Michel's transport medium.
2. Submitted as two biopsies from same site. One submitted for routine exam in 10% formalin; the other in Michel's transport medium for immunofluorescence studies. Label containers appropriately.
3. Additional notes: Indicate the IF studies request on requisition.

Other tissue types IF:

1. 24-hour advance notice required to obtain Michel's transport medium.
2. Submitted in Michel's transport medium.
3. Additional notes: Indicate the IF studies request on requisition.

Lymph Nodes

1. Advance notice recommended if the possibility of a lymphoma is considered.
2. Submitted in fresh saline-moistened gauze and packed in wet ice.
3. Additional documentation: Note on the requisition the specimen is submitted fresh and clearly indicate all required testing.
4. Additional notes: Couriers delivering these specimens must be told to transport in a cooler and deliver directly to personnel in the Histology laboratory.

Kidney Biopsy

1. 24-hour advance notice required so appropriate fixatives can be provided. Please call 602-839-2343.
2. Submitted in the fixatives provided for the following studies (Place at least one biopsy core into each container).
   - Light microscopy (routine exam) - to 10% formalin)
   - Immunofluorescence - Michel's transport medium
   - Electron microscopy – 3% gluteraldehyde
3. Contact SQL Logistics at 602-685-5052 for specimen pick-up.
4. These specimens are directly routed to the SQL Histology Department.
5. For next day routine exam reporting, the specimens need to be delivered no later than 4:00 PM.
6. If preliminary results by phone are requested, a contact physician and phone number must be listed on the requisition.

Miscellaneous

Calculi/Stone (Urinary Tract –bladder, Kidney, or ureter)	Identify source and required test on requisition (i.e. Stone Analysis), gross exam only Submitted in dry container; no additives required
Flow Cytometry	Refer to the Flow Cytometry Section.
Bone Marrow Aspirate or Biopsy	For Flow Cytometry marker(s), refer to the Flow Cytometry Section. For DNA studies, refer to the specific test listing.
Lymph Nodes and Other Tissue	For Flow Cytometry marker(s), refer to the Flow Cytometry Section. For DNA studies, refer to the specific test listing.
Genetic Studies (Tissue, Products of Conception - Chromosome Analysis, Karyotyping)	Submitted in sterile container containing tissue culture media or sterile saline. DO NOT use any fixatives. Refrigerate until pickup. Courier delivering these specimens must be told to transport in a cooler and deliver directly to laboratory. Identify required tests.
Gout Crystals	Submit dry, or in 100% alcohol, identify source and required test (i.e. Gout Crystal Identification)
Hormone Receptor/Her2neu	Available on any routinely handled tissue biopsy case.

MICROBIOLOGY

The success of any laboratory method used to isolate an organism and therefore assist in the diagnosis of an infectious disease is contingent on the timely acquisition of the proper specimen and transporting such in the correct transport medium at the right temperature. To accomplish this, please adhere closely to the instructions for specimen collection and transport.

All specimens are processed for the recovery of the most frequent pathogen(s) from the body site. It is therefore necessary to indicate the suspected diagnosis and the body site in the comments field of the test request form (this will also appear on the laboratory report) and to order the most applicable test, based on suspected organism and body site, as outlined in our online Test Directory.

General Consideration for Collection and Transport

1. Please use the specified transport container as indicated for each test.
2. Specimens should be transported to the laboratory as soon as possible (next scheduled pickup). Use "**Room Temperature"** labels when appropriate.
3. Collection containers should be closed securely and precautions taken to prevent leaking of samples during transport. These specimens may be a biohazard.
4. Specimens should be obtained prior to the administration of antibiotics. Specimens must be selected from appropriate, non-contaminated sites.
5. **Do not use expired container or medium to transport specimens. Specimens submitted in outdated (expired) transport media may not be accepted for culture or testing.**
6. Please print specimen source, patient's name and identification (two patient identifiers required) on each specimen container. Indicate source of specimen on the test request form.

Note: Do not place Microbiology specimens that must be kept at room temperature in the same bag with specimens that have to be refrigerated. In these instances a separate requisition form has to be completed and submitted in an appropriately labeled specimen bag.

Antimicrobial Susceptibility Testing of Microbiology Specimens

The laboratory follows the guidelines and standards set by the Clinical and Laboratory Standards Institute (CLSI). These standards are based on the most recent pharmacologic, pharmacokinetic and outcome studies available and endorsed by all Medical, State and Federal agencies. Susceptibilities will be reported only on those antibiotics and microorganisms recommended by CLSI. The susceptibility reports will include interpretive criteria and minimal inhibitory concentrations (MICs expressed in micrograms per milliliter - mcg/mL) where appropriate. Susceptibilities may not be available on some drug/bug combinations because of lack of appropriate techniques or because of poor correlation between susceptibility data and actual clinical response. Please call Microbiology with more specific questions.

Anaerobic Culture, Test No. 4008

Only submit appropriate, non-contaminated specimens for anaerobic cultures and transport in an anaerobic environment. To achieve this "oxygen free" atmosphere, the anaerobic transport system must be used. Collection of material is similar to that of the aerobic wound culture. Specimens collected on sterile swabs (use of swabs is discouraged and in some situations inappropriate) should be placed into the appropriate transport and tightly capped. **Fluid aspirates, body fluids and deep tissue biopsy are the most appropriate specimens** and should be submitted in an anaerobic transport system.

Deep wounds and body fluids are appropriate specimens for anaerobic culture. Specimens should be stored at room temperature (20-25°C) until and during transport to the laboratory.

Blood Culture, Aerobic and Anaerobic Bacteria, Test No. 4040

Venipuncture -- Due to the presence of skin microflora, special precautions must be followed when collecting a blood culture. Wipe the venipuncture area with 70% alcohol, 2% iodine or 2% chlorhexidine to the site. For infants <2 months, do not use chlorhexidine for skin preparation. For maximal effectiveness allow the site to dry for 1 to 2 minutes. The intended venipuncture site should not be touched unless the finger used for palpation is similarly disinfected. After collection, iodine should be removed with the use of alcohol, because many patients are sensitive to iodine.

Caution: For patients who are sensitive to iodine, wipe site twice with 2 separate alcohol swabs. **Do not** palpate the prepared area after cleaning with ungloved fingers.

Prepare two yellow-top (sodium polyanethol-sulfonate, "SPS") vacutainer tubes or two blood culture bottles for each culture ordered by wiping the top with isopropyl alcohol. Apply a tourniquet and, with a single venipuncture, draw blood into **two** yellow-top (sodium polyanethol-sulfonate, "SPS") vacutainer tubes or two blood culture bottles that have been wiped with alcohol on the top. A syringe may also be used to draw the blood which must then be transferred immediately into **two** yellow-top (SPS) vacutainer tubes which have been wiped with iodine on the top or directly into iodine prepared blood culture bottles. **Two** SPS tubes must be drawn for each culture ordered (one for the aerobic culture and one for the anaerobic culture).

Transport the blood culture tubes at room temperature to the laboratory as soon as possible.

Blood Culture Guidelines

Purpose of the Guideline: 1) To maximize recovery rate of pathogens causing bacteremia, while minimizing recovery of organisms colonizing the skin (false positives); 2) to help in the interpretation of significance of results of blood cultures.

Timing and Number of Cultures: At least 2 blood cultures (2 sets of 2 bottles each) and no more than 3 blood cultures (3 sets of 2 bottles each) should be collected simultaneously one after the other, each from a separate, appropriately disinfected skin site. Single blood cultures do not sample adequate volumes of blood for optimal recovery of pathogens and may be difficult to interpret; 2 blood cultures are optimal for any event within 48 hours; 3 blood cultures are not normally necessary; 4 or more blood cultures require a telephone consult with the appropriate laboratory personnel.

All attempts should be made to collect blood cultures prior to initiation of therapy if at all possible. Spacing of cultures is unnecessary except to document continuous bacteremia on rare occasions (in which case cultures may be spaced at least an hour apart).

Additional cultures within 48-72 hours of initial culture sets are not recommended unless a new episode of clinical sepsis or bacteremia is suspected.

Volume of Blood

Adult: 16-20 mL per culture (8-10 mL per bottle of a 2 bottle set; one aerobic and one anaerobic); 2 cultures minimal per episode. Every effort should be made to collect maximum blood volumes on adult patients. Percentage of organisms in low volume collections from adults is considerably less than in volume collections from children. See Blood Inoculation Chart for how blood will be divided.

Adolescent: 10-20 mL per culture as available (divided into 2 bottles per culture; 2 cultures minimum). See Blood Inoculation Chart for how blood will be divided.

BLOOD INOCULATION CHART

<0.5cc	Recollect	
0.5-3cc	Place in PEDS bottle if unable to redraw	
3-5cc	Aerobic bottle only	
6cc	3 aerobic	3 anaerobic
7cc	3 aerobic	4 anaerobic
8cc	3 aerobic	5 anaerobic
9cc	4 aerobic	5 anaerobic
10cc	4 aerobic	6 anaerobic
11cc	5 aerobic	6 anaerobic
12cc	5 aerobic	7 anaerobic
13cc	6 aerobic	7 anaerobic
14cc	6 aerobic	8 anaerobic
15cc	7 aerobic	8 anaerobic
16cc	7 aerobic	9 anaerobic
17cc	8 aerobic	9 anaerobic
18cc	8 aerobic	10 anaerobic
19cc	9 aerobic	10 anaerobic
20cc	10 aerobic	10 anaerobic

Pediatric: 3-10 mL per culture as available, from patients weighing 80 pounds or less. If >4 mL is collected, split specimen into [PEDS or AEROBIC] and [ANAEROBIC] bottles inoculating the PEDS or AEROBIC bottle with 3 mL first and inoculating the ANAEROBIC bottle with the remainder. If less than 4 mL of blood is drawn, only a Pediatric bottle (PEDS) should be inoculated. NOTE: Two (2) separate venipuncture blood draws are recommended for a total of 2 blood cultures.
**For patients ≥7 years old and >80 pounds, drawing guidelines for adult patients may be used.

Neonates and infants: 0.5-2.0 mL as available (2 cultures minimum). Placed in Pediatric (low volume) Blood culture bottle.

Turnaround Time/Test Availability: Available 24 hours/day, 7 days/week. Approximately 85% of truly positive bacterial cultures are recovered within 24 hours and overall 90-95% of all positives are recovered by 48 hours. Yeasts in the Candida family may require 4 to 5 days for recovery. Cultures are not called negative until after 5 full days of incubation. Positive results are called as soon as they are available to the unit nurse in hospitalized patients and to the requesting (or covering) physician in outpatients.

Body Fluid Culture, Test No. 4003

Pleural, pericardial, peritoneal and synovial fluids must be aspirated aseptically from the patient and promptly injected into a sterile container. The body site should be cleaned with an iodophor or chlorhexidine prior to aspiration. Specimens should be stored at room temperature until and during transport to the laboratory.

For Peritoneal dialysis effluent, refer to Culture, Dialysate Fluid, CAPD, w/Gram Stain.

Spinal Fluid Culture (Culture, CSF w/Gram Stain), Test No. 4405

The prompt delivery of specimens to the laboratory is critical for the recovery of fastidious organisms such as Haemophilus influenzae or Neisseria meningitidis. Specimens should be stored at room temperature until and during transport to the laboratory. Do not refrigerate spinal fluid prior to transport.

Bordetella, DFA, Test No. 15053

If the DFA is also requested, use one of the nasopharyngeal swabs and inoculate 2 slides (air-dry). DFA cannot be performed from swabs submitted in Regan-Lowe transport media.

Bordetella Culture (Pediatric), Test No. 4274

Use a mini-tipped Dacron or Calcium – alginate swab to collect 2 nasopharyngeal swabs. Do not use eSwab. The swab is gently inserted through the nose to the posterior nasopharynx where it is gently rotated. It should remain in this position for several seconds. The withdrawal should be slow to minimize irritation. Place in Regan-Lowe Transport Media. Specimens should be stored refrigerated until and during transport to the laboratory. Cultures are not useful in adults and serologies or molecular testing (Dacron swab only) should be considered.
NOTE: Rayon or cotton swabs are not acceptable for culture.

Genital Culture, Test No. 704713/GC Culture, Test No. 4785

Lower Genital Tract

From a clinical and laboratory standpoint, genital tract specimens can be divided into two major groups:

Specimens originating from the upper uterine tract in association with pelvic inflammatory disease (PID), surgical procedures or wound infections and may include tissue, aspirates, or pus from uterine, tubo-ovarian, abdominal, culdocentesis fluid, abscess material (IUD, Bartholin's abscess), postsurgical infection material (vaginal cuff), pre/peri/post-partum material (amniotic, endometrial, placental, uterine), and prostatic secretions. These specimens are usually collected during surgical procedures or with more invasive methods such as aspiration and never with a swab. NOTE: Such upper tract specimens should be considered and submitted to the laboratory as "WOUND SPECIMENS" (including endocervical aspirates - cervical aspirates - but not specimens collected by swab).

Specimens originating from the lower tract (vulval, vaginal, cervical/endocervical) haveetiologies that are frequently organisms not routinely found as normal flora of the area and are acquired by sexual or otherwise direct contact - thus they are often called SEXUALLY TRANSMITTED DISEASES (STDs) or Sexually transmitted infections (STIs). They can, however, be caused by organisms that

are normally found in very small numbers, but which for one reason or another are able to multiply to great enough numbers to cause disease.

Normal flora of the lower genital tract in the healthy female is made up of high concentrations (10^{8-9} organisms/gram of discharge) of both aerobic/facultative and anaerobic bacteria. Predominant flora includes lactobacilli (aerobic and anaerobic), coagulase negative Staphylococci, diphtheroids, as well as anaerobes. Variation of normal flora may occur between vaginal and cervical locales in the same female, between the same locales in different females, and between the same locales in a female at different time periods. The flora may also change during menstrual cycles, during pregnancy, during hospitalization or postoperatively, with age, and during immunosuppression. Additionally, normal flora may consist of smaller or transient numbers of Group B Streptococcus, *Gardnerella vaginalis*, as well as enterics.
Evaluations of lower tract genital specimens normally include searches for specific organisms correlated to specific infectious processes or syndromes and their differentiation from normal or transient flora. The following are most commonly encountered as pathogens or suspected etiologic agents. Testing for the following must be specifically requested when suspected, (use of specialized media and techniques is required).

Trichomoniasis, Test No. 5575

Trichomonas vaginalis is not considered to be normal flora of the urogenital tract and its presence during symptomatic vaginitis implicates it as an etiology. Thus the most sensitive methods for its diagnosis include molecular methods or culture (Test #5575). Wet mounts may also be used but have a lower sensitivity. Collection in the Trichosel broth container is recommended for the Wet mount. (Test #704002).

Candida Vaginitis (Wet Prep Exam Test No. 704002, Gram stain Test No. 4000, Culture, Yeast Test No. 708177)

Smaller concentrations of Candida may be found in the female urogenital tract in asymptomatic patients. Candida vaginitis is due to the presence of higher numbers of yeast, which can be diagnosed either by culture or direct preparations (wet mounts or Gram stains) in conjunction with appropriate clinical symptoms. If Gram stain / Wet Prep Exam is negative and the patient is symptomatic or refractory to treatment, yeast culture is recommended. Alternative methods, such as nucleic acid amplification must be able to provide lower limit cut-offs to minimize falsely positive results.

Vaginosis

Clinical diagnosis of vaginosis requires the positivity of 3 of 4 characteristic features of the vaginal secretions (called the Amsel criteria and includes grayish-white vaginal discharge, the presence of clue cells, positive whiff-amine test, and pH >4.5). The evaluation of Gram-stained smears using the standardized Nugent criteria (which weighs the presence or absence of a number of cells and bacterial morphotypes) has been shown to be clinically valuable. It remains the primary accepted as well as most efficient method in the diagnosis of bacterial vaginosis. Culture for *Gardnerella* is no longer acceptable as it has too high of a false-positive rate. As with *Candida*, molecular diagnostic methods for *Gardnerella* must have lower limit cut off values, to minimize false-positives.

Bacterial Vaginosis/Vaginitis Panel, Test No. 902043

Two common vaginal conditions of medical importance in women include vaginitis caused by the yeast *Candida* and vaginitis caused by the parasite *Trichomonas vaginalis*. These are characterized by vaginal inflammation with pain and purulent discharge. A third condition, termed bacterial vaginosis, is characterized by vaginal inflammation and perivaginal irritation considerably milder than that in vaginitis. However, bacterial vaginosis (BV) may have serious consequences during pregnancy, including miscarriage and premature labor and delivery. Recently, BV has also been implicated in endometritis and pelvic inflammatory disease. Bacterial vaginosis is attributed to multiple etiologies, but primarily characterized by abnormal changes in vaginal flora. *Lactobacilli*, which normally make up 95% of the vaginal bacteria, are considerably reduced in number, resulting in a concomitant increase of a number of other bacterial species normally present in much smaller quantities. The species contributing to the overgrowth of normal flora in this condition include: *Gardnerella, Mobiluncus*, genital *Mycoplasma*, and *Ureaplasma*, and over 20 other bacterial species.
The Bacterial Vaginosis/Vaginitis Panel (DNA Hybridization Probe) using molecular technology has FDA approval and lower cut-off limits for both *Candida* and *Gardnerella,* thus minimizing false-positives for these two organisms. It also has a probe for *Trichomonas* thus three etiologies of Vaginosis/Vaginitis are detectable in one specimen. According to the manufacturer (Becton Dickinson, Affirm™ VPIII Package Insert, 2005) initial studies of the panel showed sensitivities and specificities of greater than 90% for the detection of vaginosis or vaginitis.

To collect, open the seal on outer plastic pouch of AFFIRM™ VPIII Ambient Temperature Transport System (ATTS) and remove all components. Each plastic pouch contains enough material for the collection and transport of one vaginal specimen. Tear open the

foil pouch and remove the ATTS Reagent Dropper. Break ampoule in ATTS Reagent Dropper by firmly squeezing the vial with finger and thumb. Break ampoule close to its center one time only. DO NOT MANIPULATE DROPPER ANY FURTHER AS THE PLASTIC MAY PUNCTURE AND INJURY MAY OCCUR. Dispense reagent from ATTS Reagent Dropper into Sample Collection Tube (SCT). Peel wrapper to expose patient swab. Remove swab. Discard wrapper.

Prior to vaginal sample collection, label the Sample Collection Tube (SCT) with the patient identification information. Include the time and date sample was collected.
Place the patient in position for a pelvic examination. Insert an UNLUBRICATED speculum (WITHOUT JELLY OR WATER) into the vagina to permit visualization of the posterior vaginal fornix.

Using the sterile polyester (Dacron™) swab, obtain a sample from the posterior vaginal fornix. Twist or roll swab against the vaginal wall two or three times, ensuring the entire circumference of the swab has touched the vaginal wall. Swab the lateral vaginal wall while removing the swab. Immediately place the swab into the Sample collection Tube (SCT) containing the ATTS reagent.

With the swab touching the BOTTOM of the collection tube, grasp the pre-scored handle of the swab just above the top of the tube and bend until the swab breaks. When the swab is fully inserted into the collection tube, the score mark on the swab is approximately 1 cm above the collection tube. Discard the broken handle into an infectious waste container. Place the cap over the exposed end of the swab and firmly press the cap onto the tube. The cap will snap onto the tube when it is properly sealed. For specimen collection, use ONLY the AFFIRM™ VPIII Ambient Temperature Transport System. Separate swabs should be used for other tests, e.g. culture or wet mount samples.

Testing for the following must be specifically requested when suspected (use of specialized media and techniques is required).

Genital Lesions - Vulval, Penile, Topical
Herpes simplex virus: HSV Culture, Rapid or HSV Culture w/reflex Typing
Chlamydia trachomatis L1, L2, L3 (Lymphogranuloma-venereum: LGV):
Treponema pallidum (Syphilis Screen; RPR reflex to TPPA)

Vaginitis
Candida sp (Culture or Gram Stain)
Trichomonas vaginalis: Culture or Trichomonas vaginalis Molecular Amplification Assay

Bacterial Vaginosis
Mixed anaerobic and aerobic organisms (Wet Mount for Clue cells; Vaginosis Gram Stain, Bacterial Vaginosis/Vaginitis Panel, BV NAAT)

Urethritis
Neisseria gonorrhoeae: GC Screen Culture, GC Molecular Amplification Assay
Chlamydia trachomatis: Chlamydia Molecular Amplification Assay

Cervicitis
Neisseria gonorrhoeae: GC Screen Culture, GC Molecular Amplification Assay
Chlamydia trachomatis: Chlamydia Molecular Amplification Assay
Herpes simplex virus: Herpes Culture

NOTES: In the laboratory setting, only the most common etiologies are routinely searched for and specialized methods are available to screen for pathogens. These systems include use of specialized media for selective or enrichment cultures, wet mounts, specialized stains and/or gram stains. To facilitate appropriate workup, a close communication must exist between the laboratory and the clinicians who must relay clinical suspicions as to etiologies.

Group B Strep Culture – Prenatal Screen, Test No. 4615

CDC recommends that both vaginal and rectal swabs be submitted (as one culture) to increase sensitivity. This procedure is designed for use with prenatal specimens from expectant mothers and is not intended to detect pathogens other than Group B Streptococci.

Group A Strep Culture, Test No. 4704

Use culture swab in transport medium to obtain throat specimens. Rub the sterile swab firmly over the back of the throat (posterior pharynx), both tonsils or tonsillar fossa, and any area of inflammation. Once the specimen is collected, the swab should be placed into the transport medium.

Group A Direct Antigen w/Reflex Culture (Test No. 74119) will quickly detect Group A *Streptococcus* and can be used to screen patients for this organism. This test can only be performed with swabs transported in specific transport media (liquid). If negative it will reflex to culture. Culture, Group A Strep (Test No. 4704) should be ordered for culture.

Specimens should be stored at room temperature until and during transport to the laboratory.

Evaluation of Specimens from the Upper Respiratory Tract

Potentially pathogenic bacteria are commonly present as normal flora of the oral cavity and nasopharynx of asymptomatic patients. Cultures of the upper respiratory tract provide limited information to the clinician except in well-proven situations and may provide misleading information unless results are carefully interpreted. The Infectious Disease Division will work up cultures from these sites to best meet the need of the patient and the clinician and to provide the most clinically pertinent information needed for patient care.

Pharyngitis: The most common cause of bacterial pharyngitis is Group A *Streptococcus*. Therapy is indicated to alleviate symptoms and to abrogate post-streptococcal rheumatic fever. Available Rapid Group A Strep antigen detection systems are often not sensitive enough to stand alone and may require cultural confirmation when negative (culture confirmation of negative screens is no longer recommended in adults). *Arcanobacterium haemolyticum* is a rare cause of pharyngitis, often presenting with a scarlatiform rash. Other beta-hemolytic strep have been associated with pharyngitis, but do not usually require therapy. Other bacteria, mycoplasma, chlamydia, and viruses have either not been proven to be sole etiologies of pharyngitis or these are organisms for whom test methods are neither practical nor warranted.

Culture and identification of organisms in the pharynx (other than the Group A Strep or *Arcanobacterium*) provide the clinician with limited and potentially misleading information.

Diphtheria and *Neisseria gonorrhoeae* (GC) can present as pharyngitis and cultures for these should be specifically requested when suspected (use of specialized media necessary).

Sinusitis: Cultures of nasal and nasopharyngeal swabs may be misleading in the search for etiologies of sinusitis, unless purulence and organisms are noted on direct Gram Stain evaluation. The most adequate specimens for appropriate laboratory diagnosis of sinusitis are needle aspirates or surgical collection of material from sinus cavities (usually most helpful in chronic sinusitis). Nasopharyngeal swabs will only be fully processed for routine microbiology if purulence (pus) is present and the etiology(ies) are noted on the direct Gram Stain of the material (even in such instances there may be poor predictability/specificity of the culture results).

Otitis Media: Appropriate specimens include effusion from the middle ear but not nasal or nasopharyngeal swabs.

NOTE: Cultures of nasal and nasopharyngeal passages are NOT useful in diagnosis of otitis or pneumonia (they may even be misleading); they may also be misleading in the search for etiologies of sinusitis, unless purulence and organisms are noted on direct Gram Stain evaluation. Nasal and nasopharyngeal bacterial cultures are thus contra-indicated except in the diagnosis of whooping cough and possibly diphtheria, or (in instances where purulent discharge is present) to find the etiology of sinusitis.

References:

1. Carroll, K. and L. Reimer. 1996. Microbiology and laboratory diagnosis of upper respiratory tract infections. Clin. Infect. Dis. 23:442-8.
2. Dowell, SF., et.al. 1998. Principles of judicious use of antimicrobial agents for pediatric upper respiratory tract infections. Pediatrics. 101; 1:163-165.
3. Jousimies-Somer, HR, et.al. 1989. Comparison of the nasal bacterial floras in two groups of healthy subjects and in patients with acute maxillary sinusitis. J. Clin. Microbiol. 27:2736-43.
4. Red Book. 1994. Group A Streptococcal Infection. pp 430-9.
5. Schwartz, B., et.al. 1998. Pharyngitis - principles of judicious use of antimicrobial agents. Pediatrics. 101; 1:171-174.
6. Steele, RW and WR Wilson. 1996. Challenges in the management of upper respiratory tract infection. Infections in Medicine (supplement), pp 26-32.
7. Todd, JK. 1988. the sore throat - pharyngitis and epiglottitis. In, Infectious Syndromes of the Head and Neck; Infectious Dis. Clin. North Amer. 2:1, pp 149-62.

Mycobacterium Culture, Blood (Should be limited to immunocompromised patients only), **Test No. 6399**
(Acid Fast Bacilli Culture, Blood)

Venipuncture -- Due to the presence of skin microflora, special precautions must be followed when collecting a blood culture. Wipe the venipuncture area with 70% alcohol, and then apply 2% iodine to the site. For maximal effectiveness allow the site to dry for 1 to 2 minutes. Iodophors or chlorhexidine may be substituted if desired. The intended venipuncture site should not be touched unless the finger used for palpation is similarly disinfected. After collection, iodine should be removed with the use of alcohol, because many patients are sensitive to iodine. *Caution:* For patients who are sensitive to iodine, wipe site twice with 2 separate alcohol swabs. **Do not** palpate the prepared area after cleaning with ungloved fingers.

Specimen Collection -- Specimens must be collected into an **Isolator tube.** Wipe the stopper with 2% iodine and allow drying prior to specimen collection. After the tube is filled with blood, invert several times to assure adequate mixing of the anticoagulant. For optimal results, the tube should be filled completely. Specimens should be stored at room temperature until and during transport to the laboratory. Deliver to the laboratory ASAP.

Mycobacterium Culture, Miscellaneous, Test No. 8173
(Acid Fast Bacilli Culture & Smear)
Specimen:

Sputum (expectorated, induced) – Submit no more than three consecutive specimens in 8 to 24 hour intervals, with at least one being an early morning specimen. For follow-up of patients (M. tuberculosis) on therapy, collect at monthly intervals beginning 3 weeks after initiation of therapy until two consecutive specimens are negative on culture. Instruct patient to rinse mouth and gargle with water prior to collection. Avoid contamination of sputum with nebulizer reservoir water when collecting induced sputum.

Bronchial Washings and Bronchoalveolar Lavage Fluids – Should be generally obtained before brushing or biopsy specimen to avoid excess blood in the recovered fluid. Avoid contamination of bronchoscope with tap water (may cause false positive smear or culture result).

Gastric Lavage Fluid – Fasting and early morning specimens are recommended (in order to obtain sputum swallowed during sleep) on each of 3 consecutive days. Neutralize as soon as possible (within 2 hours) with 100 mg of sodium carbonate up to 15 ml of specimen. Alternatively, add an equal volume of 7.5% to 8% sodium bicarbonate solution to the specimen.

Urine – Collect entire first morning specimen. 3 separate specimens on at least three consecutive days are recommended.

Tissue and Biopsy – Submit sample as large as possible in sterile container with a small amount of nonbacteriostatic sterile saline or Middlebrook 7H9 broth. Always indicate if specimen is from a superficial lesion.

Bone Marrow - Submit refrigerated in an Isolator tube (supply #6074).

CSF - Submit cerebrospinal fluid in a sterile screw cap containe without fixative. Keep at room temperature.

Sterile Body Fluids - Submit refrigerated in an Isolator tube (supply #6074) or sterile container. Yellow-top (SPS) tubes and green-top (sodium heparin) tubes are no longer acceptable as they are not supported for these specimens by the manufacturer.

Body Fluid, Abscess Content: Submit as much as possible. Collect in sterile container or Isolator tube.

Stool – Recommended only for patients with AIDS.

Transportation:
For optimal recovery, specimens should be delivered to laboratory within 24 hours of the collection and kept at 2-8°C.

Volume (minimum amount):		**Optimal Amount:**
Respiratory specimens	3 mL	>5 mL
Gastric Lavage	5 mL	>5 mL
Urine	10 mL	50 mL
Body Fluids	5 mL	As much as possible
Abscess content	1 mL	As much as possible
Stool	1 gm	≥1 g

Unacceptable Specimens:
Swabs (acceptable only if specimen cannot be collected by other means); 24 hour or pooled urine or respiratory specimens; Specimen in a preservative or a fixative; Tissue, biopsy, bronchial brushings in a dry container (dried out specimens); Skin scraping, nail, hair; Blood collected in red-top tube, EDTA, ACD, Heparin, SPS or Citrate; Frozen specimens. If there are any further questions on specimen collection, please contact the Mycobacteriology Department at 602-839-3481.

Mycobacterium Smear, Test No. 8036
(Acid Fast Bacilli Stain)

Includes Fluorochrome screen. Submit specimen as above. Indicate specimen source on specimen vial and on the test request form. Smear will be included in all Mycobacterium culture requests.

Special Susceptibility Testing
When a Rapid Growing Mycobacterium is isolated on culture, susceptibility will automatically be performed on sterile body site specimens and on all members of the *M. fortuitum M. chelonae* group, regardless of source. The susceptibility will be repeated on subsequent isolates after 30 days.

When a *Nocardia* is isolated on culture, susceptibility will automatically be performed on sterile body site specimens and from any other site if seen in direct Gram Stain. The susceptibility will be repeated on subsequent isolates after 30 days.

Mycology, Test No. 8176, 708177, 8321, 70808
Specimen Collection
Respiratory secretions, body fluids, tissue, CSF, urine, contact lens fluid or contact lens: Submit specimen in a sterile leak proof container.
Hair, nail, skin scraping: Submit on folded black paper inserted into an envelope or between 2 slides or in a leak proof container. Remove hair with forceps, scrape skin or scalp scales, clip nails and include keratin scrapings. Keep at room temperature.
Specimens from mucosal surfaces: Throat, eye, urogenital tract, wound and ear may be submitted on a culture swab in a transport system or in a sterile leak proof container.
Blood: Collect into Isolator tube.
Bone Marrow: Collect into Isolator tube.
Transportation: For optimal recovery, specimens should be delivered to laboratory within 24 hours of the collection. Hold and transport specimen refrigerated with exception of dermatological specimens (hair, nail and skin scraping) and blood which should be kept at room temperature.

Yeast culture, Test No. 708177: Only suitable for isolation of yeast. Culture is held for 5 days and it is recommended only for specimens from mucosal surfaces, skin or nail.

Fungus culture (Fungus culture, Miscellaneous), Test No. 8176: Culture is held for 3 weeks. Culture for both yeast and mould.

Dermatophyte screen, Test No. 708086: Culture is held for 3 weeks. Culture for Dermatophytes and Agents of Onychomycosis (No other types of organisms will be reported even if isolated)

Blood culture, fungus, Test No. 8321: Culture is held for 3 weeks. Culture for Yeast and Mould.

Pneumocystis DFA, Test No. 7212: Submit lower respiratory secretions or lung tissue in sterile container. Please tightly secure bronchial (lavage) specimen traps before submitting to avoid leakage during transport. (This organism is now defined as a fungus).

Yeast Susceptibilities, Test No. 900379

Mycoplasma/Ureaplasma Cultures, Test No. 7174, 15409

Specimens for either genital or respiratory mycoplasma/ureaplasma must be obtained with a sterile swab and transported to the laboratory in Multi Microbe Media (M4) to optimize recovery of these fastidious organisms. Please note storage and expiration information on transport vials. Indicate the specimen source on the test request form and sample container.

For Mycoplasma Culture, Respiratory, order Test No. 7174; for Mycoplasma (Ureaplasma) Culture, Genital, order Test No. 15409.

Mycoplasma genitalium 907271 – FDA cleared molecular test.

Nasopharyngeal Culture, Test No. 4618

Nasopharyngeal cultures are best taken with the mini-tipped swabs. The swab is carefully inserted through the nose to the posterior nasopharynx where it is gently rotated. It should remain in this position for several seconds. The withdrawal should be slow to minimize irritation. Specimens should be stored at room temperature until and during transport to the laboratory. **Acceptable only if pus is present – refer to "Evaluation of Specimens from the Upper Respiratory Tract" under Group A Strep Screen.**

Neisseria gonorrhoeae Cultures (Culture, GC Screen) Test No. 4785

Charcoal swabs are provided for the isolation of *Neisseria gonorrhoeae* from eye, synovial fluid, rectal, pharyngeal, and genital sites.

Ocular Infection Specimens

Normally, specimens from the eye are collected by an ophthalmologist and require delicate processing. Specimen size or volume is also usually very small so that great care must be taken during collection and transfer to the laboratory. Thus it is often necessary to have the appropriate media inoculated immediately after specimen collection by the clinician and then submitted to the laboratory. Media are available from the laboratory and should be requested in advance so that appropriate arrangements can be made for delivery. Media outdates quickly and unused media should be returned to the laboratory for replacement with fresh media unless other arrangements have been made. Because the conjunctiva is commonly contaminated, cultures of conjunctiva should be used as a control measure and in helping with the interpretation of cultures of more invasive specimen collections.

Conjunctiva and Lid Margin: A pre-moistened cotton or calcium alginate swab can be used to roll over the conjunctiva. Collect specimens before initiating antimicrobial therapy. Both left and right eye conjunctiva should be cultured using separate swabs, even if unilateral conjunctivitis is suspected. Swabs can be submitted in appropriate transport media to be processed by the laboratory or, alternatively, inoculate directly to agar plates following instructions provided with media. Label all plates and/or transport vials appropriately, including specific information as to exact collection site for each specimen. Scrapings smeared onto clean glass microscope slides may also be submitted by following instructions provided.

Bacterial keratitis: Obtain corneal scrapings and culture directly onto appropriate media following instructions provided. Collect at least one conjunctival culture as a control. (Refer to Culture, Corneal Scraping – Test No. 900017)

Bacterial endophthalmitis: Obtain aspirate and culture directly onto appropriate media following instructions provided. Alternatively, the aspirate can be inoculated into a nonbacteriostatic fluid transport media (0.5-1.0 mL) in a tightly-sealed tube and sent for culture (the specimen will be centrifuged and the pellet evaluated). (Refer to Culture, Corneal Scraping – Test No. 900017)

Cellulitis: Follow procedures for Wound Cultures.

Lacrimal gland (Dacryoadenitis): Using a pre-moistened swab, collect purulent discharge as with conjunctival specimens. Submit in appropriate transport medium. Conjunctival culture should be obtained as a control.

Dacryocystitis: Press lacrimal sac to remove exudate and using a pre-moistened swab, collect for culture and smear. Specimens collected by swab can be submitted in appropriate transport media. Conjunctival culture should be obtained as a control.

Canaliculitis: Compress inner aspect of the eyelid to express pus and follow instructions for culture with conjunctival specimens. Conjunctival culture should be obtained as a control.

Recommendation for Diagnosis of Diarrheal Disease (when clinically needed)

Background

Laboratory detection of bacterial pathogens in stools remains in the 2-4% rate, while detection of parasites has fallen to below 1%. Clinical practice guidelines for the diagnosis of infectious diarrheas in adults and pediatrics have been published by the Infectious Disease Society of America, the American College of Gastroenterology, as well as other pediatric groups. These guidelines recommend that laboratory evaluation of stools from patients should not be ordered routinely but reserved for the appropriate clinical and epidemiologic setting as described below.

Practice Statement

Laboratory evaluation of stools for diagnosing adult and pediatric diarrheal disease should be done when patient symptoms include at least one of the following:

- Severe diarrhea
- Temperature of >38.5°C or 101.3°F
- Passage of bloody stools
- Stools positive for leukocytes, lactoferrin, or hemoccult testing
- Persistent diarrhea which has not been treated with antibacterial agents empirically

Clinical Approach: Select laboratory studies that best match the patient condition:

Community-acquired or traveler's diarrhea of ≤7 day's duration

- Strongly Consider:
  - Routine Bacterial Stool Culture for *Salmonella*, *Shigella*, *Campylobacter*, and *Shiga Toxin* (*E. coli* 0157:H7, et. al.)
- Other Clinical Considerations/Situations:
  - *Clostridium difficile* toxin assay or PCR if patient has history of antimicrobial therapy, chemotherapy within recent weeks of onset, or has protracted diarrhea and is on a proton pump inhibitor
  - *Giardia* Ag EIA if patient has history of daycare (child), is a hiker/camper or is an immunocompromised patient
  - *Cryptosporidium* by DFA only if outbreak is known to be occurring

Community-acquired or traveler's diarrhea that is >7 days duration

- Strongly Consider:
  - Routine Bacterial Stool Culture for *Salmonella, Shigella, Campylobacter*, and *Shiga Toxin* (E. coli 0157:H7, et. al.)
  - *Giardia* Ag EIA
- Other Clinical Considerations/Situations:
  - *Cryptosporidium* by DFA only if outbreak is known to be occurring
  - *Cystoisospora* and *Cyclospora* only if outbreak is known to be occurring
- **Full ova and parasite studies should be requested ONLY** on patients with diarrhea and relevant travel history, patients who have recently been residents of a developing country, and patients in an area of the United States where parasites other than *Giardia* are found.
  - Single O&P full exam only if tests above returned negative and diarrhea persists (especially in immunocompromised patients or those who have been associated with developing countries)
  - Repeat O&P full exam (x2 collected on separate days one to two days apart) if initial O&P exam is negative and symptoms persist

Hospital-associated diarrhea with onset >3 days after admission

- *Clostridium difficile* toxin assay by PCR. If test is negative, and patient has bloody stool, is immunocompromised, or is an infant:
  - *Routine Bacterial Stool Culture for Salmonella, Shigella, Campylobacter, and Shiga Toxin (E. coli 0157:H7, et. al.)*
  - *Giardia* Ag EIA if patient has history of daycare (child), is a hiker/camper or is an immunocompromised patient
  - *Cryptosporidium* by DFA only if outbreak is known to be occurring

HIV or severely immunocompromised patient: Depending on immune status of patient and his/her condition, more rapid progression of testing may have to be pursued and special situations may have to be evaluated. An Infectious Disease consult should be considered.

References

Guerrant et. al. Infectious Disease Society of America Guidelines: Practice guidelines for the management of infectious diarrhea. Clinical Infect Dis, 2001;32:331-350.
Dupont et. al. Guidelines on acute infectious diarrheas in adults. Am J Gastroenterology, 1997;92:1962-1975.
Church et. al. Practice guidelines for ordering stool cultures in a pediatric population. Am J Pathol, 1995;103:149-153

Parasitology

Ova and Parasites, Stool, Test No. 4792

The stool specimen is ideally placed in the O & P vials within 15 minutes, but up to 60 minutes is acceptable. Specimens received in incorrect medium are unacceptable and will not be processed. Collection dates must be recorded on specimen vials.

Stools for Ova and Parasites should be shipped in an Ova and Parasite Total-Fix™ - 5 gm minimum of stool in the vial). Place stool into vial to bring the liquid level up to the black fill-line. Carefully mix the specimen with the spoon attached to the vial cap, tighten the cap and shake vigorously to ensure that the specimen is adequately mixed. Do not overfill. When submitting multiple samples, use the large general specimen bag. Specimens should be stored at room temperature until and during transport to the laboratory. **Do not use expired vial**.

Specimens for parasite testing which are submitted in Cary Blair or any other transport medium specifically designed for bacterial pathogens cannot be processed, because this is an incorrect preservative medium for the detection of parasites.

Barium masks parasitic infections; specimens submitted from patients on whom barium exams have been performed must be collected 10 days post barium x-rays.

Paired vials of 10% Formalin and PVA will be accepted but are not provided by the laboratory. Both vials need to be submitted at the same time to ensure a comprehensive evaluation and result. Single vials of formalin and PVA represent an incomplete specimen.

Ova and Parasites, Urine, Test No. 8164

For Schistosomes, collect mid-day urine or a 24-hour collection in a clean container without preservatives. Peak egg excretion occurs between Noon and 3 PM. 24-hour collection will be rejected if >48 hours old. For Filariasis, collect a voided specimen in a clean container.

For *T. vaginalis*, collect first voided urine (particularly after a prostatic massage in males), centrifuge specimen and submit in Trichosel™ Broth and order Test No. 5575

Giardia / Cryptosporidium Exam, Test No. 900007:

Submit 5 grams of stool specimen in Total-Fix™ vial. Keep at room temperature (20-25°C). Alternatively, stool in 10% formalin will be accepted.

Giardia Antigen, EIA, Stool, Test No. 15338: Submit 10 grams of stool in a Total-Fix™ vial. Alternatively, stool in 10% formalin will be accepted.

Pinworm Exam, Test No. 4620: CLEAR tape preparation on a clear glass slide (in a plastic container) or pinworm paddle kit are appropriate for submission of specimens for pinworm examination. To facilitate diagnosis, please use the pinworm paddle. Do not collect stool. Collect early morning just prior to morning routine. The instructions for its proper use are:

Do not use if package is not intact.

1. Hold the paddle by the cap and remove it from the tube.
2. Separate the buttocks and press the tacky surface against several areas of the perianal region.
3. Replace the paddle in the tube for transport to the laboratory; specimens should be refrigerated if examination is to be delayed for more than one day.

Parasite ID, Test No. 4640: Submit worms in formalin 70% alcohol.

Arthropod (Insect) ID, Test No. 900718: Submit insect in formalin or 70% alcohol.

Pneumocystis DFA, Test No. 7212: Submit lower respiratory secretions or lung tissue in sterile container. Please tightly secure bronchial (lavage) specimen traps before submitting to avoid leakage during transport. (This organism is now defined as a fungus).

***Trichomonas vaginalis* Culture, Test No. 5575:** Submit vaginal swab in Trichosel™ broth.

Cyclospora/Cystoisospora (Isospora), Test No. 4644: Submit 5 gm stool in Total-Fix™ vial. Stool in 10% formalin will also be accepted.

Microsporidia Exam, Test No. 3880: 1 gm stool or 2 mL duodenal aspirate in Total-Fix™ vial. Specimen in 10% formalin will also be accepted.

Coccidia Exam, Test No. 900834: May be requested to test for Cyclospora Cystiosospora (Isospora), and Microsporidia.

Spinal Fluid Culture (Culture, CSF w/Gram Stain), Test No. 4405

The prompt delivery of specimens to the laboratory is critical for the recovery of fastidious organisms such as *Haemophilus influenzae* or *Neisseria meningitidis*. Specimens should be stored at room temperature until and during transport to the laboratory. **Do not refrigerate** spinal fluid prior to transport.

Lower Respiratory:

Sputum Culture, Test No. 4011

Instruct the patient to obtain material from a deep cough that is expectorated into a sterile container. Be sure that the cap is tightly sealed on the container once the specimen is collected.

Evaluation of Lower Respiratory Tract Specimens for Bacterial Etiologies of Pneumonia

Infections of the lower respiratory tract include acute and chronic bronchitis and community-acquired as well as nosocomially-acquired pneumonias. The value of microbiologic analysis of respiratory secretions as a diagnostic tool has been questioned, especially when obtained in a routine fashion. Culture of sputum collected via expectoration or endotracheal suction is severely limited due to poor sensitivity and specificity and without appropriate screening can lead to incorrect diagnosis and therapy. It is important therefore to understand the limitations as well as the values of such studies for appropriate result interpretation. When appropriate, it is also important to consider other means (such as cultures of blood and pleural effusion) in trying to document an etiologic agent of pneumonia.

Acute bronchitis results from inflammation of the bronchial tree as well as the trachea. Bacteria may be present whether or not infection is present and often represents upper airway colonization rather than lower tract infection. There is no evidence that microbiologic analysis (gram stain or culture) of sputum is of any diagnostic value in the determination of etiologies of acute bronchitis.

Pneumonia, a clinical diagnosis requiring appropriate X-ray findings, is an inflammatory disease of the lungs with alveolar involvement. The oropharyngeal environment normally harbors aerobic as well as anaerobic microorganisms. Colonization with potentially pathogenic species may occur during seasonal changes or with increased exposure. Thus, opportunity for colonization with *Streptococcus pneumoniae* and *Haemophilus influenzae* may increase significantly in adults with children recently enrolled in daycare centers. Colonization with Gram-negative bacilli increases in patients hospitalized with acute illnesses, being treated with broad spectrum antimicrobics, or suffering from diabetes or chronic alcoholism. Thus, use of culture results of throat, nasopharyngeal or other upper respiratory specimens are contra-indicated, as are those of inadequate sputum specimens.

To obtain a satisfactory sputum sample, the patient must be productive (have sputum) and must be instructed carefully to "raise sputum" or "cough deeply from within the chest". Failure to do so frequently results in collection of unsatisfactory "salivary" specimens that are not representative of lower respiratory tract secretions. It is mandatory that the patient be instructed in how to obtain the specimen and the instructor remain with the patient (coaching him/her) until the specimen is collected. It may also be helpful to have the patient rinse the mouth out with some water prior to the attempt to raise sputum.

Bronchiectasis is one of the chronic obstructive pulmonary diseases (COPD). Order **Culture, Bronchiectasis with Gram Stain – Test No. 902244.**

In bronchiectasis, there is an abnormal stretching and enlarging of the respiratory passages caused by mucus which accumulates and becomes stuck in airways. The blockage can cause inflammation and infection leading to a continuing cycle of infection and blocked airways. The mucus may become discolored, foul smelling and bloody. Antimicrobials are used to control the infection in conjunction with techniques to help remove the mucus and bronchodilator medicines to open the airways.

Cultures are examined for pure culture of a single bacterial type, organisms which are seen as predominant in the specimen Gram stain, as well as *Pseudomonas aeruginosa*, *Staphylococcus aureus* (including MRSA), *Haemophilus influenzae*, enteric Gram negative

rods, and *Burkholderia cepacia*. If fungus, AFB, or *Nocardia* are recovered they will be identified but, if those etiologies are suspected, specific fungal/*Nocardia*, and AFB cultures should be requested.

Cystic Fibrosis patients order Culture, Cystic Fibrosis – Test No. 900717.
Intended only for evaluation and medical care of the respiratory tract of patients with Cystic Fibrosis. Instruct patient to obtain material from a deep cough that is expectorated into a sterile container. Container must be tightly sealed. If the patient cannot produce a cough, use a culture swab in transport media to obtain the specimen. Store and transport refrigerated.

All expectorated/induced sputum for routine culture (Test No. 4011) will be screened microscopically for acceptability and rejected if criteria based on oropharyngeal contamination (squamous epithelial cells) and presence of lower tract secretions (leukocytes: PMN's or macrophage) are not met.

Other potential etiologies of lower respiratory infections are not normally detected in routine culture. The etiologies listed below require different diagnostic methods (cultural, serological, and molecular) if and when available or clinically necessary:

a. *Mycoplasma pneumoniae*: IgG and IgM serologies on acute and convalescent sera, but not routinely recommended.
b. *Chlamydia pneumoniae*: Available diagnostic tests not presently recommended although microimmunofluorescent antibody studies on acute and convalescent sera may be useful.
c. *Legionella*: Culture, urine antigens on selected cases, serology on acute and convalescent sera only - single sera not normally appropriate (See Legionella).

For Mycobacteriology (AFB), Mycology (Fungus), and Parasitology, see appropriate section of manual. For other special considerations, call the Microbiology Department at Sonora Quest Laboratories for recommendations.

MRSA Screen Culture, Test No. 901617.
This culture is for the culture/isolation of Methicillin-resistant *Staphylococcus aureus* (MRSA) for surveillance or investigation of a suspected outbreak.

Stool Culture, Test No. 803107
If enteric pathogens are to be detected by the Microbiology laboratory, adherence to appropriate guidelines for specimen collection and transport is imperative. Place the specimen into a C&S (for culture) vial as soon as possible. Stools in transport media should be held at room temperature. The minimum volume of liquid stools should be at least equal to 1 teaspoon (5 mL), or a pea-sized piece of formed stool that has been collected in a clean container. Repeat cultures (>2) for diagnostic testing should be discouraged without prior consultation due to the limited yield provided by additional specimens. For routine stool culture, order Test No. 803107 – Culture, Stool. If stool is not available, a rectal swab in an appropriate culturette may be substituted as a specimen for bacterial and viral culture, but it is not as good, particularly for diagnosis in adults. Swabs are not acceptable for detection of parasites, toxin, or viral antigens.

Stool for *Clostridium difficile* toxin assay, and ELISA must be sent to the laboratory without any added preservatives or liquids. Stool for Rotavirus EIA, Test No. 8162, requires a refrigerated specimen. Stools are not routinely cultured for Yersinia (Test No. 4660), or Vibrio (Test No. 4058), and those must be requested specifically, if clinically warranted. For Occult Blood Guaiac Diagnostic, Stool (Test No's. 4031 and 4034), and Occult Blood Immunochemical Diagnostic (Test No's. 11290 and 11293) refer to Test Directory for specific requirements.

Urine Culture, Test No. 704705
A clean-catch, midstream specimen is required to confirm bacteriuria. The Urine C&S Transport Tube gray top vacutainer is used to eliminate quantitative changes that occur in the bacterial population of urine during transport to the laboratory. The following are the steps for collection of a urine specimen for culture.

Urine Culture specimens received more than 24 hours past collection without a preservative are not acceptable and the test will not be performed. Unpreserved urines must be refrigerated immediately and maintained at 2-8 °C.

To ensure clinically relevant results based on specimen quality, the laboratory will only culture urine from a clean or sterile cup/container when a culture order is received with the specimen or an ordered urinalysis reflexes to a culture (based on previously defined criteria).

Instructions for the Female Patient:

1. Wash hands thoroughly.
2. Tear open package of towelette, and wash the vulva and the perianal areas passing the towelette from front to back.
3. Remove clean plastic container from packaging.
4. Start to urinate directly into the toilet. Stop, position container and collect urine sample. Do not touch the container to the genital area. Do not fill specimen cup to the top.

Instructions for the Male Patient:

1. Wash hands thoroughly.
2. Tear open package of towelette, completely retract the foreskin and wash the glans penis.
3. Remove clean plastic container from packaging.
4. Start to urinate directly into the toilet. Stop, position container and collect urine sample. Do not touch the container to the genital area. Do not fill specimen cup to the top.

Inoculation of the Urine C&S Transport Tube:

Each kit includes a Vacutainer brand urine preservative tube and a transfer unit sealed in a see-through plastic pouch.

1. Submerge tip of transfer unit in specimen.
2. Push tube into holder all the way. Hold in position until flow stops.
3. Remove tube, leaving holder in specimen container. Shake tube to dissolve preservative and send to the laboratory.

Catheterized Urine, Test No. 4647

Because of the potential of contamination and colonization of urines collected from indwelling urinary catheters, such specimens are considered differently than those collected by a single, straight catheterized specimen. Catheterized urine specimens need to be noted as collected by single catheter or from an indwelling catheter. Any specimen noted simply as "catheterized" will be assumed to have been collected through an indwelling catheter and will be treated the same as a clean-catch in terms of culture and workup. To ensure clinically relevant results based on specimen quality, the laboratory will only culture urine from a clean or sterile cup/container when a culture order is received with the specimen or an ordered urinalysis reflexes to a culture (based on previously defined criteria).

Ileal loop or indwelling catheters: The urine specimen should not be from the drainage bag. The only proper method of collection is by needle puncture of the catheter and aspiration of urine into a sterile syringe (the catheter site of collection must be properly cleansed prior to performing the procedure).

1. Aseptically cleanse septum port or, if no port available, the distal end of catheter tubing with alcohol (at junction of catheter and drainage tube). If patient is receiving continuous prophylactic irrigation of the bladder, the irrigant should be discontinued for at least 45 minutes prior to collection.
2. Insert sterile needle (25 gauge) into catheter at an angle.
3. Aspirate 1 or 2 mL of urine and aseptically transfer to sterile transport tube or a small sterile container. Label with patient information and transport.

CAUTION: DO NOT FORCE ANY URINE BACK INTO THE BLADDER.

Prostate Culture, Test No. 900802

Any of the following specimens may be submitted individually or together for the Prostate Culture; Test No. 900802:

1. Voided Bladder Urine (labeled as VB1, VB2, VB3). Submit refrigerated in sterile container, or if >3 mL, submit in Urine C&S Transport Tube (grey-top).
2. Expressed Prostatic Secretion (EPS) fluid submitted in a sterile container or on a swab.
3. If "Rule out G/C" is required, a Charcoal Swab MUST also be submitted.

Label all specimens and submit together as one culture with one requisition.

Wet Prep Exam Test No. 704002

Refer to Candida Vaginitis section above

Wound Culture, Test No. 4188, 4763

For aerobic only wound culture, order Test No. 4188. For deep wounds, non-contaminated sites, with a request for anaerobic culture also, order Test No. 4763. Samples should be stored at room temperature until and during transport to the laboratory. Submit adequate specimen on swab supplied by the laboratory or fluid material in anaerobic transport. Gram stains are included.

PRESCRIPTION DRUG MONITORING (PAIN MANAGEMENT)

Why Monitor Your Patients?

Protect your patients

We recognize that behind every specimen and result there is a human life – a life whose quality may be improved when pain medications are used as you prescribed. For patients with chronic and recurring pain, opioids not only relieve suffering, but also should support normal daily functioning, alleviate stress, and improve sleep. Periodic urine drug testing (UDT) with prescription drug monitoring (PDM) can help you to:

- Monitor your patient treatment plan
- Manage pain therapy safety and availability for your patients by assisting with regulatory compliance

A number of opioid medications have been linked to increasing risks of diversion (passing the drug on to others for sale or use), noncompliance, and abuse.

Monitor Drug Use

If you prescribe scheduled medications, including pain medications, balancing the needs of your patients and your practice can be challenging. One step you can take is proactive drug treatment monitoring with UDT, which helps to:

- Supplement patient self-reporting with documented lab results
- Identify drug compliance
- Detect illicit substances
- Detect drug substitution or supplementation

Prescription Drug Monitoring (Pain Management) Profiles

Profiles with reflex confirmation are available with and without medMATCH™. medMATCH™ reports compare prescribed drugs to test results. medMATCH™ report comments are present when drug test results may be the result of metabolism of one or more drugs or when results are inconsistent with prescribed medication(s) listed. medMATCH™ report comments may be blank when drug results are consistent with prescribed medication(s) listed.

Please refer to the next page for a listing of our available Prescription Drug Monitoring profiles and individual drug detections.

Drug Name	Screen	Screen/Confirm	Confirm Only	With medMATCH Screen/Confirm	With medMATCH Confirm Only
Alcohol Metabolite		906285	906511	906330	906512
Amphetamines	92222	906325	906299	906324	906264
Amphetamines d/l Isomers (w/ Meth.)		906847	906509	906848	906510
Barbiturates		906323	906300	906322	906265
Benzodiazepines	92224	906319	906301	906318	906266
Buprenorphine	4685U	906513	906274	906316	906286
Carisoprodol		906816	906287		906275
Cocaine Metabolite	92225	906329	906302	906328	906267
Fentanyl		906801	706289	906883	906276
Gabapentin			906290		906277
Heroin Metabolite		906291	906516	906278	906514
Marijuana Metabolite	92227	906315	906303	906314	906268
MDMA/MDA		906292	906518	906279	906517
Methadone Metabolite (EDDP)	92229	706313	906304	906312	906269
Methylphenidate			906294		906332
Opiates	92230	906334		906333	
Expanded Opiates/Includes Oxycodone			906281		906335
Oxycodone	92231	906327	906306	906326	706271
Phencyclidine	92232	706321	906307	906320	906272
Pregabalin			906295		906282
Synthetic Cannabinoids, Ql			906364		
Tapentadol			906296		906331
Tramadol		906823	706297		906283
Tricyclic Antidepressant			906298		906284

	4 Drug Profile	9 Drug Profile	9 Drug Profile	11 Drug Profile
Profile:	**906258 Screen/Confirm**	**906254 Screen/Confirm**	**906508 Screen/Confirm With d/l Isomers**	**906818 Screen/Confirm**
Profile:	**906253 Screen/Confirm With medMATCH**	**906249 Screen/Confirm With medMATCH**	**906507 Screen/Confirm w/ d/l Isomers With medMATCH**	
Amphetamines		X		X
Amphetamines d/l Isomers (w/ Methamphetamines)			X	
Barbiturates		X	X	X
Benzodiazepines	X	X	X	X
Carisoprodol				X
Cocaine Metabolite	X	X	X	X
Marijuana Metabolite		X	X	X
Methadone Metabolite (EDDP)		X	X	X
Opiates	X	X	X	X
Oxycodone	X	X	X	X
Phencyclidine		X	X	X
Tramadol				X

The College of American Pathologists requires that all samples include 2 FORMS of patient identification on EVERY container at time of collection. The information provided in this General Information section is for informational purposes only and is subject to change. Please contact our Client Services Department at 602.685.5050 to confirm any of the information presented within.

Specimen Requirements for Profiles: 30 mL room temperature urine preferred, transported in a Drug Collection Kit (supply #8954) or sterile urine container (7 mL minimum).

Specimen Requirements for Individually Ordered Tests: 20 mL room temperature urine preferred, transported in a Drug Collection Kit (supply #8954) or sterile urine container (7 mL minimum).

All reflex and confirmation tests will be performed at an additional charge. Prescription Drug Monitoring Requisitions are preferred when ordering any of the testing listed above. Please contact us at 1.800.766.6721, ext. 5285 or email SQLMarketing@SonoraQuest.com to obtain these test requisitions. You can also contact your Account Manager for additional information on our Prescription Drug Monitoring offering. .**Oral Swab Prescription Drug Monitoring Testing**

Specimen Requirements: 3 mL oral fluid submitted in an Oral-Eze® collection device (supply #27140). Follow instructions provided with collection kit. It is preferred that a completed Sonora Quest Laboratories Oral Fluid Substance Monitoring test requisition be submitted with the sample. Please contact us at 1.800.766.6721, ext. 5285 or email SQLMarketing@SonoraQuest.com to obtain these test requisitions. You can also contact your Account Manager for additional information on our Prescription Drug Monitoring offering.

Method: Liquid Chromatography/Tandem Mass Spectrometry
Setup: Days, Evenings & Nights: Monday - Sunday
Reports: 5-10 Days

Test Name	Test Code
PDM, Oral Swab, Monitoring Panel 1, with confirmation	906775
PDM, Oral Swab, Alcohol Metabolite, with Confirmation	906776
PDM, Oral Swab, Amphetamines, with Confirmation	906777
PDM, Oral Swab, Barbiturates, with Confirmation	906778
PDM, Oral Swab, Benzodiazepines, with Confirmation	906779
PDM, Oral Swab, Cocaine, with Confirmation	906780
PDM, Oral Swab, Marijuana, with Confirmation	906781
PDM, Oral Swab, MDMA, with Confirmation	906782
PDM, Oral Swab, Meprobamate, with Confirmation	906783
PDM, Oral Swab, Methadone, with Confirmation	906784
PDM, Oral Swab, Methylphenidate, with Confirmation	906785
PDM, Oral Swab, Naltrexone, with Confirmation	906786
PDM, Oral Swab, Nicotine, with Confirmation	906787
PDM, Oral Swab, Opioids, with Confirmation	906788
PDM, Oral Swab, PCP, with Confirmation	906789
PDM, Oral Sab, Zolpidem, with Confirmation	906790

Oral-Eze® Collection Instructions

1. Collect - Oral Swab Drug Testing must be submitted using Oral-Eze® Collection Device (Supply #27140). Insert the Oral-Eze® collection pad between the patient's lower cheek and gum.

2. Check - Remove the device when the indicator window on the handle turns blue.

3. Detach - Eject the collection pad from the handle and insert the collection pad into the transport tube. Dispose of the handle.

4. Cap and Submit - Press the cap until completely sealed and submit the transport tube with the requisition.

TOXICOLOGY

General Information
Sonora Quest Laboratories provides clinical toxicological and special chemistry testing services using state-of-the-art technology including Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS), Enzyme Immunoassay (EIA), Inductively Coupled Plasma Mass Spectrophotometry (ICP/MS), Gas Chromatography - Flame Ionization Detection (GC/FID), and Gas Chromatography Mass Spectrometry (GC/MS). Sonora Quest Laboratories meets the OSHA guidelines for blood lead testing.

Trace Elements

Copper, Zinc, and Iodine
Serum or plasma are acceptable specimens. Serum must be collected and transported in certified trace metal-free navy blue top tubes with no anticoagulant (red and white label). Plasma must be collected and transported in certified trace metal-free navy blue top (EDTA or heparin) tubes (lavender or white label).

Patients should refrain from taking vitamins or mineral supplements for at least 3 days before specimen collection. See individual test requirements.

For both serum and plasma, be sure to gently mix the specimen promptly after phlebotomy. Separate the plasma or serum from cells and transfer the separated plasma or serum to another plastic, certified metal-free transport tube within two hours of collection. Use powderless gloves. Firmly replace the cap on the transport tube and label with specimen type. Transport the specimen refrigerated. Be sure to confirm that the specific tubes used are free of the trace element in question. Metal free transport tubes are available from Sonora Quest Laboratories (supply #23994 for serum; supply #23995 for plasma).

Lead
Whole blood collected in either a tan-top (K2 EDTA), royal blue top (EDTA), or royal blue top (sodium heparin, lead-free) tube is the preferred and recommended specimen. Specimens in non-trace element tubes such as whole blood collected in lavender top (EDTA) tubes or capillary blood collected a lavender (EDTA, capillary) tubes are accepted, but may not accurately reflect the patient's lead concentration. All elevated blood lead results are reported to the local state health department. Please visit www.SonoraQuest.com for more information on blood lead cutoffs and recommended retest and treatment procedures.

Meconium Drug Screen

Plastic urine collection containers should be used to collect meconium. A complete (approximately 5 gram) meconium sample requires multiple collections takes several hours or days after birth. Meconium should be collected, pooled, and stored until an adequate amount of sample has been obtained.

Meconium Drug Screen Limits of Detection (Cut-offs)	
Drug Class	**Cut-off (ng/g)**
Amphetamines	100
Cocaine Metabolite	100
Methadone	50
Opiates	100
THC	30

Urine Screens
Specimens can be collected at several Sonora Quest Laboratories Patient Service Centers or subcontracted collection sites. Please visit www.SonoraQuest.com for a current listing. Information *Sonora Quest Laboratories does not perform employee drug screening or forensic drug testing.*

Urine Drug Screen

Urine Drug Screen Limits of Detection (Cut-offs)	
Drug Class	**Cut-off**
Alcohol (Ethyl)	50 mg/dL
Amphetamines	500 ng/mL
Barbituates	200 ng/mL
Benzodiazepine	200 ng/mL
Buprenorphine	10 ng/mL
Cannabinoid	20 or 50 ng/mL
Cocaine Metabolite	150 ng/mL
Ecstasy	500 ng/mL
Fentanyl	1 ng/mL
Methadone	300 ng/mL
Opiate	300 ng/mL
Oxycodone	100 ng/mL
Phencyclidine	25 ng/mL

Urine Volatile Screen

Urine Volatiles Limit of Detection (Cut-offs)	
Volatile	**Cut-off (mg/dL)**
Acetone	10
Isopropanol	10
Methanol	10
Ethanol	10

Urine Overdose Screen

The Urine Overdose Screen supports the evaluation of patients suspected of poisoning by unknown toxicants, typically presenting to an emergency department or an inpatient medical toxicology service. This test is not suitable for use in prescription drug monitoring, routine monitoring for illicit drugs, or workplace drug testing.

This assay is run primarily by LCqTOF, an advanced, high-resolution mass spectrophotometric technique. In instances of instrument downtime, the laboratory will perform this testing by GCMS, a less sensitive, but gold standard methodology. The limits of detection for LCqTOF and GC/MS are below. New drugs will be added to these lists periodically.

Overdose Screen by Mass Spectrometry - LCqTOF Limits of Detection (Cut-offs)			
Drug or Drug Product	**Cut-off (ng/mL)**	**Drug or Drug Product**	**Cut-off (ng/mL)**
6-Acetylmorphine	10	Lamotrigine	10
Acebutolol	10	Levamisole	2.5
Acetaminophen	10	Levetiracetam	5
Acetyl fentanyl	10	Levorphanol	2.5
Alprazolam	1	Lidocaine	100
Amitriptyline	2.5	Lorazepam glucuronide	50
Amobarbital	50	m-Chlorophenylpiperazine (mCPP)	10
Amphetamine	50	MDEA	2.5
Aripiprazole	10	MDMA	10
Atenolol	5	Mescaline	50

Atomoxetine	10	Metformin	25
Atropine	10	Methadone	1
Baclofen	50	Methamphetamine	25
Barbital	100	Methocarbamol	5
Benzoylecgonine	10	Methylprednisolone	50
Benztropine (mesylate)	10	Metoclopramide	1
Betaxolol	10	Metoprolol	10
Bisoprolol	5	Mitragynine	2.5
Buprenorphine	5	Morphine	25
Bupropion	1	Morphine-6-beta-D-glucuronide	50
Buspirone	2.5	Nadolol	25
Butabarbital	50	Nafcillin	5
Butalbital	50	Naloxone	10
Caffeine	25	N-desmethyltapentadol	10
Carbamazepine	10	Nicotine	10
Carbamazepine-10, 11-epoxide	1	Nordiazepam	1
Carisoprodol	5	Norfentanyl	25
Celiprolol	2.5	Norketamine	5
Citalopram	2.5	Normeperidine	10
Clindamycin	2.5	Noroxycodone	25
Clobazam	1	Norpropoxyphene	100
Clonazepam	2.5	O-desmethylvenlafaxine	5
Clonidine	2.5	Olanzapine	2.5
Cocaethylene	5	Ondansetron	2.5
Cocaine	5	Oxazepam	2.5
Codeine	10	Oxcarbazepine	2.5
Cotinine	10	Oxprenolol	2.5
Cyclobenzaprine	2.5	Oxycodone	10
Cyclopropyl fentanyl	5	Oxymorphone	25
Cyproheptadine	1	Pentobarbital	50
Dapsone	10	Pentoxifylline	5
Dextrorphan and/or levorphanol	2.5	Phencyclidine	5
Diazepam	1	Phenibut	100
Dihydrocodeine	10	Phenobarbital	100
Diphenhydramine	10	Phentermine	2.5
Dobutamine	10	Phenylpropanolamine	10
Doxepin	50	Pindolol	5
Doxylamine	100	Pregabalin	2.5
Duloxetine	25	Promethazine	2.5
Ecgonine methyl ester	50	Propoxyphene	2.5
EDDP	1	Propranolol	50

Ephedrine	1	Pseudoephedrine	1
Esmolol	2.5	Psilocin	5
Fentanyl	2.5	Psilocybin	25
Fluconazole	5	Ranitidine	2.5
Flunitrazepam	5	Ropinirole	5
Fluoxetine	10	Secobarbital	100
Gabapentin	5	Sumatriptan	10
Gemfibrozil	10	Tapentadol	5
Guaifenesin	100	Temazepam	1
Guanfacine	5	THC-COOH	50
Heroin	5	THC-OH	50
Hydrocodone	2.5	Timolol	2.5
Hydromorphone	25	Tramadol	2.5
α-Hydroxyalprazolam	5	Trazodone	2.5
Labetalol	25	Triazolam	2.5
		Xylazine	2.5

Overdose Screen by Mass Spectrometry - GC/MS Limits of Detection (Cut-offs)			
Drug or Drug Product	**Cut-off (ng/mL)**	**Drug or Drug Product**	**Cut-off (ng/mL)**
10,11-Carbamazepine Epoxide	2,000	Imipramine	50
1-Benzylpiperazine	100	Isoniazid	2,000
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	100	Isotonitazene	10,000
3,4-Methylenedioxypyrovalerone (MDPV)	100	JWH-018	2,000
3-Trifluoromethylphenyl-piperazine (3-TFMPP)	100	Ketamine	50
4-Aminopyridine	1,000	Labetalol	10,000
4-Fluoro-Isobutyryl Fentanyl	500	Lacosamide	100
6-Monoacetylmorphine	250	Lamotrigine	1,000
7-Aminoclonazepam	5,000	Levamisole	100
7-Aminoflunitrazepam	1,000	Levetiracetam	2,000
Acetaminophen	2,000	Levorphanol	50
Acetylsalicylic Acid	2,000	Lidocaine	100
Alprazolam	500	Lofexidine	500
Amantadine	50	Loxapine	250
Amitriptyline	50	m-Chlorophenylpiperazine	50
Amobarbital	250	Memantine	50
Amoxapine	2,000	Meperidine	50
Amphetamine	100	Mephedrone	250
Antipyrine	100	Mephobarbital	50
Atenolol	40,000	Meprobamate	250

Atomoxetine	500	Mescaline	250
Atropine	100	Metaxalone	250
Baclofen	10,000	Methadone	100
Barbital	2,000	Methamphetamine	100
Benzoylecgonine	5,000	Methaqualone	50
Benztropine (Mesylate)	50	Methcathinone	250
Brompheniramine	100	Methocarbamol	2,000
Brorphine	10,000	Methylenedioxyamphetamine (MDA)	100
Bupivacaine	250	Methylenedioxymethamphetamine (MDMA)	100
Buprenorphine	10,000	Methylephedrine	250
Bupropion	500	Methylphenidate	50
Buspirone	5,000	Methylprednisolone	10,000
Butabarbital	100	Metoclopramide	500
Butalbital	100	Metoprolol	10,000
Caffeine	50	Metronidazole	500
Carbamazepine	250	Midazolam	250
Carisoprodol	250	Milnacipran	250
Cathinone	250	Mirtazapine	50
Chloroquine	2,000	Mitragynine	10,000
Chlorpheniramine	50	Morphine	5,000
Chlorpromazine	250	Naproxen	20,000
Citalopram / Escitalopram	100	Nicotine	50
Clindamycin	40,000	Nordiazepam	250
Clobazam	250	Norhydroxyzine	250
Clomipramine	100	Norketamine	100
Clonazepam	5,000	Noroxycodone	5,000
Clonidine	500	Norpropoxyphene	2,000
Clozapine	500	Norquetiapine	500
Cocaethylene	250	Nortriptyline	100
Cocaine	100	O-Desmethylvenlafaxine	250
Codeine	250	Olanzapine	500
Cotinine	100	Orphenadrine	50
Cyclobenzaprine	100	Oxazepam	2,000
Cyclopropyl Fentanyl	1,000	Oxcarbazepine	500
Cyproheptadine	50	Oxycodone	2,000
Dapsone	2,000	Oxymorphone	5,000
Desalkylflurazepam	250	Paroxetine	1,000
Desipramine	100	Pentobarbital	100
Desmethylclozapine	1,000	Pentoxifylline	250
Desmethyldoxepin	250	Phencyclidine (PCP)	50
Desomorphine	100	Phendimetrazine	100

Dextromethorphan	100	Phenibut	20,000
Dextrorphan	250	Phenobarbital	500
Diacetylmorphine	250	Phentermine	250
Diazepam	100	Phenylbutazone	250
Diclofenac	2,000	Phenytoin	500
Dicyclomine	100	Pramipexole	500
Diethylpropion	250	Promethazine	100
Dihydrocodeine	100	Promethazine Sulfoxide	100
Diltiazem	1,000	Propofol	5,000
Diphenhydramine	100	Propoxyphene	250
Doxepin	100	Propranolol	2,000
Doxylamine	100	Pyrilamine	250
Ecgonine Methyl Ester	100	Quetiapine	40,000
EDDP	50	Remifentanil	500
Ephedrine / Pseudoephedrine	250	Ropinirole	250
Esmolol	10,000	Rufinamide	1,000
Etizolam	2,000	Salicylamide	250
Felbamate	500	Secobarbital	250
Fentanyl	500	Sertraline	50
Flecainide	250	Silodosin	50,000
Fluconazole	50	Sitagliptin	60,000
Flunitrazepam	1,000	Sumatriptan	5,000
Fluoxetine	250	Temazepam	1,000
Flurazepam	500	Ticlopidine	50
Gabapentin	2,000	Tizanidine	5,000
Gemfibrozil	10,000	Topiramate	250
Glutethimide	250	Tramadol	100
Guaifenesin	100	Trazodone	10,000
Haloperidol	2,000	Trihexyphenidyl	100
Hydrocodone	50	Trimethoprim	2,000
Hydromorphone	1,000	Valproic Acid	1,000
Hydroxybaclofen	2,000	Venlafaxine	250
Hydroxybupropion	500	Verapamil	5,000
Hydroxychloroquine	80,000	Vortioxetine	1,000
Hydroxyzine	5,000	Xylazine	250
Ibuprofen	250	Zolpidem	1,000
		Zonisamide	500

Turnaround Time

Urine drug screening is performed each day, Monday through Friday. Negative screens are normally available the day after they are received. If a screening test result requires confirmation, it will add additional testing time, generally from 48-72 hours.

Clinical Drug Screen Panels (Not intended for Prescription Drug Monitoring)

		Alcohol (ethyl)	Amphetamines	Barbiturate	Benzodiazepine	Cannabinoid	Cannabinoid	Cocaine Metabolite	Creatinine	Ecstasy	Methadone	Opiate	Oxycodone	pH	Phencyclidine
	Cut-off	50 mg/dL	500 ng/mL	200 ng/mL	200 ng/mL	20 ng/mL	50 ng/mL	150 ng/mL	1-300 mg/dL	500 ng/mL	300 ng/mL	300 ng/mL	100 ng/mL	-2-12	25 ng/mL
Test Name	**Test Code**														
Drug Screen 11-Test, Urine	**906640**	X	X	X	X		X	X	X	X	X	X	X	X	X
Drug Screen 11-Test, Urine Including THC 20	**906642**	X	X	X	X	X		X	X	X	X	X	X	X	X
Drug Screen 11-Test, Urine w/ Reflex Confirmation	**906641**	X	X	X	X		X	X	X	X	X	X	X	X	X
Drug Screen 10-Test, Urine w/ Reflex Oxycodone Confirmation	**801073**	X	X	X	X		X	X	X		X	X	X	X	X
Drug Screen 10-Test, Urine w/ Reflex Confirmation	**102011**	X	X	X	X		X	X	X		X	X	X	X	X
Drug Screen 9-Test, Urine w/Reflex Confirmation	**15802**	X	X	X	X		X	X	X		X	X		X	X
Drug Screen 9-Test, Urine w/ Reflex Oxycodone Confirmation	**801996**	X	X	X	X			X	X			X	X	X	X
Drug Screen 9-Test, Urine w/ Reflex Alcohol Confirmation	**2885**	X	X	X	X		X	X	X		X	X		X	X
Drug Screen 9-Test, Urine	**25802**	X	X	X	X		X	X	X		X	X		X	X
Drug Screen 9-Test, Urine Including THC 20	**102811**	X	X	X	X	X		X	X		X	X		X	X
Drug Screen 8-Test, Urine Including THC 20	**702806**		X	X	X	X		X	X		X	X		X	X
Drug Screen 8-Test, Urine w/Reflex Alcohol & THC Confirmation	**6777**	X	X	X	X		X	X	X			X		X	X
Drug Screen 8-Test, Urine w/ Reflex Confirmation	**902382**		X	X	X		X	X	X		X	X		X	X
Drug Screen 8-Test, Urine Including Alcohol	**902364**	X	X	X	X			X	X		X	X		X	X
Drug Screen 8-Test, Urine	**5799**		X	X	X		X	X	X		X	X		X	X
Drug Screen 7-Test, Urine w/ Reflex Alcohol	**5800**	X	X	X	X			X	X			X		X	X

The College of American Pathologists requires that all samples include 2 FORMS of patient identification on EVERY container at time of collection. The information provided in this General Information section is for informational purposes only and is subject to change. Please contact our Client Services Department at 602.685.5050 to confirm any of the information presented within.

Confirmation															
Drug Screen 7-Test, Urine w/ Reflex Confirmation	**704904**		**X**	**X**	**X**		**X**	**X**	**X**			**X**		**X**	**X**
Drug Screen 7-Test, Urine Including Alcohol	**803047**	**X**	**X**	**X**	**X**		**X**	**X**	**X**			**X**		**X**	
Drug Screen 7-Test, Urine	**5756**		**X**	**X**	**X**			**X**	**X**		X	**X**		**X**	**X**
Drug Screen 6-Test, Urine w/ Reflex Oxycodone Confirmation	**802465**		**X**				**X**	**X**	**X**			**X**	**X**	**X**	**X**
Drug Screen 6-Test, Urine Including Oxycodone	**904014**		**X**		**X**		**X**	**X**	**X**			**X**	**X**	**X**	
Drug Screen 6-Test, Urine	**900552**		**X**	**X**	**X**			**X**	**X**		X	**X**		**X**	
Drug Screen 6-Test, Urine Including THC	**20436**		**X**	**X**	**X**		**X**	**X**	**X**			**X**		**X**	
Drug Screen 5-Test, Urine	**99307**		**X**				**X**	**X**	**X**			**X**		**X**	**X**
Drug Screen 5-Test, Urine Including THC 20	**702442**	**X**	**X**			**X**		**X**	**X**			**X**		**X**	
Drug Screen 5-Test, Urine w/ Reflex Confirmation	**902383**		**X**				**X**	**X**	**X**			**X**		**X**	**X**

Clinical Drug Screen Components/Individually Orderable Tests (Not intended for Prescription Drug Monitoring)

Test Name	Test Code
Alcohol Screen, Urine	2136
Alcohol Screen, Urine w/ Reflex Confirmation	903498
Amphetamine Screen, Urine	903489
Amphetamine Screen, Urine w/ Reflex Confirmation	903497
Barbiturate Screen, Urine	903490
Barbiturate Screen, Urine w/ Reflex Confirmation	903505
Benzodiazepine Screen, Urine	903491
Benzodiazepine Screen, Urine w/ Reflex Confirmation	903499
Buprenorphine Screen, Urine	907054
Buprenorphine Screen, Urine w/ Reflex Confirmation	907218
Cannabinoid (THC20) Screen, Urine	928249
Cannabinoid (THC20) Screen, Urine w/ Reflex Confirmation	905833
Cannabinoid (THC50) Screen, Urine	102280
Cannabinoid (THC50) Screen, Urine w/ Reflex Confirmation	703500
Cocaine Screen, Urine	903493

Cocaine Screen, Urine w/ Reflex Confirmation	903501
Ecstasy Screen (MDMA), Urine	905195
Ecstasy Screen (MDMA), Urine w/ Reflex Confirmation	905832
Fentanyl Screen, Urine	907055
Fentanyl Screen, Urine w/ Reflex Confirmation	906801
Methadone Screen, Urine	903494
Methadone Screen, Urine w/ Reflex Confirmation	903502
Opiate and Oxycodone Screen, Urine	903916
Opiate Screen, Urine	906649
Opiate Screen, Urine w/ Reflex Confirmation	302354
Oxycodone Screen, Urine	903915
Oxycodone Screen, Urine w/ Reflex Confirmation	91149
Phencyclidine Screen, Urine	903495
Phencyclidine Screen, Urine w/ Reflex Confirmation	903503

VIROLOGY

General Specimen Collection
All swabs for virus culture must be transported in Universal Transport Media (UTM), Multi-microbe media (M4) or other specific viral transport media (VTM). Tissue specimens should be placed in viral or universal transport media for transport. Fluids should be transported in a sterile container and **should not be diluted** with viral or universal transport media. All specimens should be transported to the laboratory within 24 hours. It is important that specimens be refrigerated (2-8°C) during storage and transport. DO NOT USE EXPIRED MEDIA. DO NOT FREEZE.

Viral culture sensitivity is dependent on collecting the proper specimen and rapid transport to the laboratory. Improper specimen types, improper collection of specimens, and delayed transport may decrease the ability for viral detection. The source of the specimen must be provided on the sample or the test request when ordering any virus culture, otherwise results may be delayed.

The following is a simplified schematic for determination of viruses commonly associated with corresponding disease symptoms and the recommended specimens for maximizing virus identification.

	Sepsis/Fever/Meningitis	**Croup/Pneumonia/Resp. Distress**	**Diarrhea**
Viruses	Enteroviruses	Influenza A and B	Coronavirus
Associated	Coxsackievirus	RSV	Rotavirus
	Echovirus	Parainfluenza	Norovirus
	Poliovirus	Adenovirus	Adenovirus 40 & 41
Specimen	Throat Swab	Nasopharyngeal swab/aspirate	Non-Formed Stool
	and rectal swab or stool	and/or throat swab	(not swab)
	or CSF (Molecular testing)		
Preferred Test	*Throat and Rectal swab -- Virus Culture, Sepsis** *CSF -- nucleic acid amplification*	*Influenza A/B and RSV, Qualitative, Real-Time RT-PCR (Nasopharyngeal swab in UTM/VTM only)* *Respiratory Virus Culture and DFA* or *Influenza A & B Virus DFA and Culture*	EIA or nucleic acid detection
	**Culture identifies Enterovirus family and does not differentiate between Coxsackie, Echovirus, Poliovirus, or strains of Enterovirus.*		

VIROLOGY TEST MENU
Do not submit specimens for Virology testing if there is a suspicion of viral hemorrhagic fever (Ebola, Marburg, etc.), avian influenza, severe acute respiratory syndrome (SARS), Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV), Measles, or other high-risk infectious agents. Contact your local health department for testing options.

Respiratory Symptoms
Influenza A/B and RSV, Qualitative, Real-Time RT-PCR (Test No. 906336)
Respiratory Virus Culture and DFA (Test No. 8155)
Influenza A & B Rapid Antigen Screen (Test No. 903345)
RSV Rapid Antigen Screen (Test No. 903346)
Influenza A & B Virus DFA and Culture (Test No. 4576)
SARS-CoV-2 (Test No. 907080)

SARS-CoV-2 & Influenza A/B (Test No. 907258)

Fever/Meningitis Symptoms
Virus Culture, Enteroviruses -- Throat and Rectal Swab (Test No. 900039), CSF (nucleic acid amplification).

Immunocompromised Host/Body Fluids/Tissues
Full Virus Culture - Recommended for immunocompromised hosts and body fluids, tissues, Test includes: Adenovirus, Enterovirus, and Herpes Simplex Virus (types 1 and 2)(Test No. 708169) NOTE: This test code does not include CMV. Please see below for CMV Culture test information.

CMV Culture - throat swab and/or urine specimens recommended (Test No. 708144)

Skin Lesions
VZV/HSV Culture and DFA - Recommended for all non-oral/non-genital skin lesions (Test No. 8158)

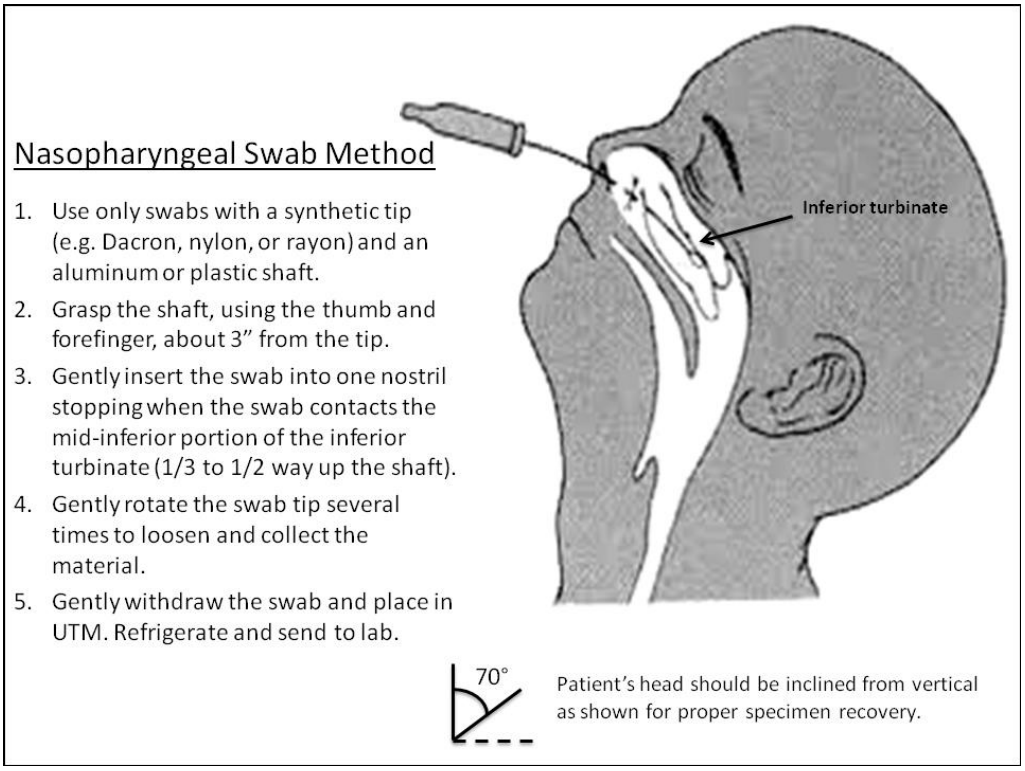
Genital/Oral Lesions
HSV Virus Culture with typing (Test No. 8181)

Diarrhea
Rotavirus ImmunoCard (Test No. 8162)
Clostridium difficile Toxin EIA (Test No. 9171)
Clostridium difficile Toxin B Gene PCR (Test No. 905221)

Chlamydia trachomatis
Chlamydia trachomatis Amplified Molecular Assay (Test No. 903150) – Aptima Collection Devices Only

Virology Respiratory Specimens
The most appropriate specimen for routine use is a properly collected nasopharyngeal swab (see diagram) combined with a throat swab placed in the same UTM. Unlike bacterial bronchitis and pneumonia, much virus shedding occurs in the throat. Throat swabs are useful for early stages of CNS disease caused by Enteroviruses.

Note: Although the nasopharyngeal swab is effective and may be used for both viral isolation and detection by Direct Immunofluorescence and/or Direct Enzyme Immunoassay, nasal washes or suction from infants may also be used for isolation of Respiratory Syncytial Virus. **Nasal or naris swabs are not adequate for respiratory virus isolations.**



Rectal Specimens

For the isolation of Enteroviruses that are associated with CNS disease, rashes, undifferentiated febrile illness, myocarditis and pericarditis, a properly collected rectal swab SUBMITTED IN CONJUNCTION WITH A NASOPHARYNGEAL/THROAT SWAB are suitable.

Rectal swab collection procedure:

1. Moisten a sterile shaft polyester, dacron or rayon fiber swab with UTM (Supply #20011).
2. Insert into the rectum and rub the mucosa until it is soiled or fecal material adheres to it when withdrawn.
3. Place swab in UTM and break off shaft.
4. Secure cap tightly on UTM vial.
5. Keep the specimen refrigerated until pickup by courier. DO NOT FREEZE.

CMV Urine Collection

The patient should collect 5 to 10 mL of midstream voided urine into a urine collection cup. Do not add UTM. Keep refrigerated until pickup. Transport as soon as possible at 2-8°C.

Cerebral Spinal Fluid (CSF) Collection

Nucleic acid amplification is the methodology of choice for the diagnosis of viral meningitis/encephalitis from CSF specimens.

CSF has a low diagnostic yield. Viruses are present in CSF for only a short time and in relatively low titer. Positive results may be obtained in aseptic meningitis although the yield in encephalitis is negligible. In CNS disease, the diagnostic yield can be increased by also submitting throat and rectal specimens.

Collect 1-3 mL of CSF in a sterile tube. DO NOT ADD TRANSPORT MEDIA.

Genital Collection

For Herpes, use a speculum so that vaginal lesions can be seen and sampled. If lesions are not present but screening is indicated, swab vaginal vault with polyester, dacron, or rayon fiber swab and place in UTM.

In pregnancy, sample endocervix by inserting dacron or rayon swab and rotating gently. Place polyester, dacron, or rayon fiber swab in UTM.

NOTE: Keep the specimens refrigerated until pickup by courier. DO NOT FREEZE.

Skin and Mucous Membrane

Break open lesions and "ring" vesicle vigorously with swab. Collecting fluid and cellular components from the vesicle. Place swab in VTM. DO NOT PREP SKIN WITH IODINE OR ALCOHOL.

Tissue

Small biopsy specimens may be placed directly into a tube of UTM. Alternatively, specimens may be placed in a clean, dry, leak-proof container with a small amount of sterile saline. Call the Virology Department for the handling and preparation of larger specimens. Transport and store at 2-8°C and deliver to laboratory as soon as possible. DO NOT FREEZE.

Conjunctival and Corneal Lesions

In conjunctivitis, remove any exudate before swabbing the conjunctiva sample. Place the polyester, dacron, or rayon fiber swab in UTM. Scrapings can be substituted if desired. Collect corneal samples by scraping ulcers with Kimura spatula under slit lamp guidance. These scrapings are placed directly into UTM. A polyester, dacron, or rayon fiber swab moistened with UTM may also be gently applied to the lesion and placed into the UTM tube. Store and transport at 2-8°C. DO NOT FREEZE.

SUPPLIES

Necessary supplies and containers for submission of specimens are provided at no additional charge. The laboratory will provide centrifuges to clients upon request. **Supplies will be provided by Sonora Quest Laboratories for the purpose of collection and transportation of specimens referred to us for analysis. Sonora Quest Laboratories WILL NOT provide supplies for any other purposes.** Such limitations are necessary to comply with applicable laws. Your acceptance of these supplies is an acknowledgment of your agreement to the above conditions.

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If you are already ordering supplies through our Quanum™ solution, you may continue to do so; however, note that this is not an option in all Quanum™ versions. Our Provider Portal is available to all clients, regardless if you utilize Quanum™.

If you are unable to order supplies through our Provider Portal and order by faxing a client supply requisition, please follow these helpful tips to ensure our fulfillment team can process your order as quickly as possible:

- Include all the following:
    - Your Sonora Quest account number
    - Your facility name and address
    - Your name and contact info (phone and/or email)
- Indicate the quantity in the QTY column next to each item you order
- Write as clearly as possible and do not use highlighter to avoid any delays to clarify your order
- Avoid writing in additional items if you do not have the supply number; instead, contact us for clarification using the info below

For questions regarding supplies please contact us by email at Supplies@SonoraQuest.com, or call 602.685.5264 (toll-free 800.766.6721, ext. 5264) or 520.784.8004 (toll-free 800.266.8101).