Sonora Quest Laboratories™
A Subsidiary of Laboratory Sciences of Arizona

2018 Reference Manual Updates

(January 2018 to date)

The enclosed Client Grams include updated and supplemental information to our most recently published Reference Manual (2018) and are intended to be incorporated into or filed with your Reference Manual until the next annual edition is available.

You will receive all future Client Grams with your laboratory reports. If you would like to receive Client Grams via email, please contact your Account Manager or email us at SQLMarketing@SonoraQuest.com.

Please note these changes in your Reference Manual to ensure you have the most accurate test information. You may also visit SonoraQuest.com to use our Searchable Test Menu.

If you have any questions please call our Customer Solutions Department at 602.685.5285 or 520.784.8050.

The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

Sonora Quest Laboratories™
A Subsidiary of Laboratory Sciences of Arizona

Client Gram – Laboratory Updates
December 2017 – Volume 35

ANNOUNCEMENT: Beta-2-Microglobulin Reagent Backorder and Temporary Redirect

Beginning the week of December 18, we will be sending samples submitted for test 2003 - Beta-2-Microglobulin to Quest Diagnostics for testing due to a reagent backorder. We anticipate that we may not receive reagent until February, 2018. Please note that the Quest Diagnostics test is performed by nephelometry, has an adult reference range of ≤2.51 mg/L, and that pricing and CPT coding are the same as our in-house test. Please note that, due to the short notice of the reagent backorder, we are unable to provide rebaseline testing between the two methodologies.

An update will be sent as soon as reagent has been received and testing at Sonora Quest Laboratories has resumed.

ASSAY CHANGES:

<table>
<tr><td>Test 906033</td><td colspan="3">Old Name: Respiratory Panel, Qualitative Multiplex PCR
New Name: Viral Respiratory Panel, Qualitative Multiplex PCR</td></tr>
<tr><td>Effective:</td><td colspan="3">12/20/17</td></tr>
<tr><td>Method:</td><td colspan="3">Microarray Hybridization, Reverse Transcription Polymerase Chain Reaction (PCR)</td></tr>
<tr><td>Reports:</td><td colspan="3">1-2 Days</td></tr>
<tr><td>CPT*:</td><td colspan="3">87633</td></tr>
<tr><td>Comment:</td><td colspan="3">Please note this panel will test for: Adenovirus, Human Metapneumovirus, Influenza A Virus, Influenza A/H1 Virus, Influenza A/H3 Virus, Influenza B Virus, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, Respiratory Syncytial Virus A
Respiratory Syncytial Virus B, and Rhinovirus.

Also note this panel will no longer test for: Bordetella pertussis, Chlamydophila pneumoniae, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Rhinovirus/Enterovirus, or Mycoplasma pneumoniae.</td></tr>
<tr><td>Interface Mapping:</td><td>Result Code
10096033
20096033
20906033
30096033
40096033
50096033
60096033
61090633
70906033
80906033
90906033
91906033
92906033</td><td colspan="2">Result Name
Influenza B Virus
Parainfluenza Virus 1
Adenovirus
Parainfluenza Virus 2
Parainfluenza Virus 3
Parainfluenza Virus 4
Respiratory Syncytial Virus A
Respiratory Syncytial Virus B
Human Metapneumovirus
Rhinovirus
Influenza A Virus
Influenza A/H1 Virus
Influenza A/H3 Virus</td></tr>
<tr><td></td><td colspan="3">Ask at order entry question:</td></tr>
<tr><td></td><td>Result Code
10906033

99990000</td><td>Result Name
Source:

Other:</td><td>Response Options
Nasopharyngeal Swab
Nasopharyngeal
Nasal
Other - please specify
Not specified
No Source Provided
Text</td></tr>
</table>

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Client Gram – Laboratory Updates
January 2018 – Volume 1

Update: Additional Information Regarding Possible Biotin Interference in Immunoassay Testing

In Client Gram vol. 32 (2017), we announced that effective December 4, 2017, the following result comment was added to reports for the tests listed below:

Some immunoassays, particularly hormones, may be falsely increased or decreased in patients taking therapeutic doses of biotin. Such results should therefore be interpreted cautiously in patients taking biotin.

Effective immediately, the comment has been discontinued from being included in the reports due to conflicts with some client EMR systems.

However, the importance of understanding the potential effects of biotin on patient results has not changed. Below is additional information intended to enhance the understanding of this potential impact:

Due to the use of biotin-streptavidin complexes in assay design, the presence of high levels of circulating biotin may interfere with the measurement of some analytes determined by immunoassay. These include thyroid and reproductive hormones as well as other analytes including 25OH-Vitamin D and cardiac biomarkers (see list of impacted tests below). The level of interference is unpredictable, varying by assay and the amount of biotin in the specimen.

Common supplements that contain biotin include those claimed to improve hair, nail and skin health, of which single doses may include greater than 300 times the recommended daily intake of 300 µg/day. Alternative names for biotin in health products may include “Vitamin B7”, “Vitamin H” or “Coenzyme R”.

At normal daily intake (~300 µg/day), interference is unlikely. However, specimens from patients that take high-dose supplements are most likely to exhibit clinically-significant interference. The half-life of biotin is short but variable - sufficient clearance prior to specimen collection is usually attained by avoiding biotin supplements for at least 8 hours prior to specimen collection, with some reports suggesting avoiding biotin supplements for as long as 24 to 72 hours to eliminate potential interference.

It is recommended that the ordering provider should: 1) Prior to collecting specimens for testing, question all patients on their intake of biotin, to include use of skin, nail, and hair care products. 2) Delay testing where possible in patients that have recently taken biotin supplements. 3) Repeat testing after an appropriate biotin clearance interval if results are not consistent with clinical presentation.

Additionally, the following reminder will be added to the specimen requirements of all affected tests:

“Due to potential assay interference, do not collect samples from patients receiving high dose biotin therapy (i.e. >5 mg/day) until at least 8 hours (optimally 24 to 72 hours) following the last dose.”

Impacted tests:

Test	Name
8918	Alpha-Fetoprotein, Tumor Marker
3129	CA 125
9928	CA 15-3
3698	CA 19-9
8599	Carcinoembryonic Antigen (CEA)
900329	Cortisol Baseline and 30 Minutes
8138	Cortisol PM
702790	Cortisol Post Dexamethasone (Multiple Specimen)

2796	Cortisol Post Dexamethasone (Single Specimen)
9863	Cortisol response to ACTH (2 Spec.)
8039	Cortisol response to ACTH (3 Spec.)
8137	Cortisol, AM
8046	C-Peptide
5030	Creatine Kinase, MB Fraction
900912	Cyclic Citrullinated Peptide
9189	DHEA Sulfate
9196	Erythropoietin
9201	Estradiol
20013	Estradiol, FSH, LH
9210	Ferritin
8015	Folate
9060	Folate RBC with Hematocrit
9215	FSH
1114	FSH and LH
7249	FSH,LH,Testosterone Total
15355	hCG Quant, Tumor Marker
8030	hCG Quantitative
2960	Hepatitis B Core Antibody, IgM
9260	IgE
3059	Insulin Response to Glucose, 6 Hour (7 Specimens)
9265	Insulin, Fasting
8340	Intact PTH
9275	Luteinizing Hormone
900722	NT proBRAIN Natriuretic Peptide
8025	Pregnancy, Qualitative
9325	Progesterone
8035	Prolactin
8501	Prostate Specific Ag (PSA), Total
11061	PSA, Post-Prostatectomy
15055	PSA, Total and Free
901845	PSA, Total, 2.5 ng/mL Cutoff
102846	PTH Intact and Calcium
901071	Sirolimus
9346	T3 Free Non-Dialysis
8093	T3 Total
8899	T4 Free Non-Dialysis
9345	Testosterone, Total
9410	Thyroglobulin
8045	Thyroxine (T4)
902303	Troponin T
38055	TSH with Reflex Free T4
8055	TSH, High Sensitivity
8060	Vitamin B12
8065	Vitamin B12 and Folate

ANNOUNCEMENT: Update to Aptima Vaginal Swab (Orange Label)

In order to increase the versatility of sample collections and testing, our vendor for Aptima collection kits, Hologic, has implemented a new swab to be used for multiple specimen types, replacing the orange label vaginal swab.

You may continue to use any Aptima Vaginal Swab Collection Kit inventory that you have remaining as long as it has not exceeded the manufacturer's expiration date. Once your inventory is depleted, please order the Aptima Multitest Swab Specimen Collection Kit – Stock # 34893. This new stock will be available for ordering beginning January 22, 2018. The Aptima Vaginal Swab will continue to be available until stock is depleted.

- Current Stock #23960 – Aptima Vaginal Swab – Available until stock is depleted
- **New Stock #34893 – Aptima Multitest Swab – Available January 22, 2018**

Please see below for additional changes in the test setup to accommodate multiple specimen source locations for this new device.

ASSAY CHANGES:

Test 903150 **Test 903151** **Test 904767** **Test 904768**	**Chlamydia trachomatis, Aptima Device** **N. gonorrhoeae, Aptima Device** **Chlamydia trachomatis/N. gonorrhoeae, Aptima Device** **Trichomonas vaginalis, Aptima Device**		
Effective:	1/22/18		
Comment:	**Please ensure the source for these tests is entered correctly on the sample and in your EMR at point of order entry or provided on the requisition. Please note, The Aptima Urine Specimen and Aptima Unisex Swab continue to be appropriate collection devices for these tests.**		
Interface Mapping:	Ask at order entry question:		
	Result Code 99904767	**Result Name** Source	**Response Options (Acceptable sources for these tests – see below for Rectal or Throat)** Cervical Endocervix Male-Urethral Urine Vaginal

Test 904627 **Test 906560** **Test 903460**	**C. trachomatis TMA, Rectal** **Neisseria gonorrhoeae RNA, TMA, Rectal** **C. trachomatis/N. gonorrhoeae RNA, TMA, Rectal**
Effective:	1/22/18
Comment:	**Please ensure the source of Rectal is noted on the sample before submitting for testing and note the new supply code above for this device.**

Test 904629 **Test 904630** **Test 903478**	**C. trachomatis RNA, TMA, Throat** **N. gonorrhoeae RNA, TMA, Throat** **Chlamydia trachomatis/Neisseria gonorrhoeae RNA, TMA, Throat**
Effective:	1/22/18
Comment:	**Please ensure the source of Throat is noted on the sample before submitting for testing and note the new supply code above for this device.**

NOTE:

Eye/Conjunctival testing is available by culture only.

- Chlamydia Trachomatis, Culture, Test 906820 requires the sample be submitted in viral transport media.
- Culture, GC Screen, Culture, Test 4785 requires the sample be submitted on charcoal swab.

Please refer to the Reference Manual or test directory on SonoraQuest.com for additional testing options.

Sonora Quest Laboratories™
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Client Gram – Laboratory Updates
January 2018 – Volume 3

ANNOUNCEMENT: Reminder Regarding Critical Result Obligations

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))". The College of American Pathologists (CAP), our accrediting agency, requires a laboratory policy implementing this regulation.

Certain test results have been identified as potentially life threatening when their values fall outside established reference ranges. When such results occur, they are flagged as critical values and communicated to the appropriate ordering provider/individual immediately - 24 hours a day and 7 days a week.

In order to effectively report these results to the ordering provider/individual, we must have a means of contact established for after-hours calls. If you do not currently have an after-hours number on file with us please contact our Sales Support Department at 602.685.5285, 520.784.8050, or toll-free at 800.766.6721, ext. 5285.

Effective January 11, 2018, if our Client Service Department is unable to contact the appropriate provider/individual after 3 attempts, the results will be faxed to the ordering entity requesting confirmation of receipt and that a means of contact be placed on file.

Alternate Process for Reporting Critical Values:
We understand that some clients treat patients whose test results routinely have panic or alert values and choose to only receive notification by telephone during certain hours. You may request exceptions to Sonora Quest Laboratories Critical Value Reporting Policy through your Account Manager or through our Sales Support Department at 602.685.5285, 520.784.8050, or toll-free at 800.766.6721, ext. 5285.

ANNOUNCEMENT: Coccidioides Comp Fix Testing Delays

Due to reagent backorder, Coccidioides Comp Fix results are currently delayed. This impacts the following tests:

- 1063 – Coccidioides Complement Fixation
- 901098 – Coccidioides Monitoring Panel (Comp Fix)
- 1061 – Coccidioides Panel (Cocci IgM & IgG) w/reflex Confirm (IMDF) w/reflex Comp Fix (Titer)

Specimens are being stored frozen and will be tested once reagent is available. An update will be sent once testing has resumed.

DISCONTINUED TESTS:

Test 906741	**Epidermal Growth Factor Receptor (EGFR) Mutation Analysis**
Effective:	1/8/18
Comment:	Test has been discontinued. The recommended alternative test is: 906807 - Targeted Gene Panel with Fusions, Lung Cancer.

Test 803715	**EGFR Mut, ROS1, ALK**
Effective:	1/8/18
Comment:	Test has been discontinued. The recommended alternative test is: 906807 - Targeted Gene Panel with Fusions, Lung Cancer.

Test 10730	**Gabapentin, Serum**
Effective:	1/15/18
Comment:	Test has been discontinued The recommended alternative test is: 906290 - PDM Gabapentin, Quantitative, Urine.

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NEW ASSAYS:

Test 906745	**MYvantage™, Hereditary Comprehensive Cancer Panel**		
Available:	1/16/18		
Important Notes:	Testing will not be performed until prior-authorization or payment has been received. Please contact our Pre-Authorization Concierge Service at 1.866.GENE.INFO (436.3463) for more information. Please note that MYvantage testing is not eligible for coverage by the AHCCCS program. If submitting a MYvantage test request for an AHCCCS patient, a Notice of AHCCCS Non-Coverage form must accompany the Hereditary Cancer test requisition. This form can be obtained at SonoraQuest.com/HereditaryCancer or by contacting our Sales Support Department at 1.800.766.6721, ext. 5285.		
Specimen:	5 mL room temperature whole blood in an EDTA lavender-top tube or yellow-top ACD tube (2 mL minimum). Include report of results for family member with known mutation. It is preferred that a completed Sonora Quest Laboratories Hereditary Cancer test requisition be submitted with the sample in order for testing to be performed. Please contact us at 1.800.766.6721, ext. 5285 or email SQLMarketing@SonoraQuest.com to obtain Hereditary Cancer test requisitions. If ordering through Quanum (formerly Care360) or an EMR, please complete a Hereditary Cancer Patient & Family Clinical History form (supply #34863) available by faxing a Client Supply Request Form to 602-685-5402 or 520-296-5607, or by ordering online through our Healthcare Provider Portal at SonoraQuest.com. Fax the completed Hereditary Cancer test requisition and information form to 1.855.422.5181 prior to sample submission to the laboratory.		
Method:	Massively Parallel Sequencing		
Reference Ranges:	See Report		
Setup:	Days: Tuesday, Thursday, & Saturday		
Reports:	14-21 days from completed pre-authorization		
CPT*:	Breast: 81432, 81433 or Colon: 81435, 81436 CPT coding is dependent on patient history and the payer being billed.		
Price:	Client: $3,175.00 Patient: $3,175.00		
Interface Mapping:	**Result Code** 39906541 40906541 41906541 42906541 43906541 44906541	**Result Name** Reviewer Resource Method and Limitation Additional Information Comments Result	
	Potential Reflexes:		
	Test Code: Result Code:	10906745 10906700	Path Variant (Reflexed) Interpretation
	Test Code: Result Codes:	20906745 22906541 23906541 24906541 25906541	Variant 1 (Reflexed) Gene Variant 1 Classification 1 Lifetime Risk 1

	Test Code: Result Codes:	30906745 27906541 28906541 29906541 30906541	Variant 2 (Reflexed) Gene Variant 2 Classification 2 Lifetime Risk 2
	Test Code: Result Codes:	40906745 32906541 33906541 34906541 35906541	Variant 3 (Reflexed) Gene Variant 3 Classification 3 Lifetime Risk 3
	Test Code: Result Codes:	50906745 37906541 38906541	VUS (Reflexed) Other Variants Information on VUS
Comment:	This panel provides comprehensive analysis of 34 hereditary cancer predisposition genes related to breast, ovarian, colon, skin and other cancer types to guide management. It is intended for use in both male and female patients with personal history of early onset cancer, a rare cancer, bilateral cancer, or multiple primary cancers, with family history of multiple generations of cancers, or when suspected genetic explanations are not covered by a targeted panel.		

Test 906840	**GIvantage™, Hereditary Colorectal Cancer Panel**
Available:	1/16/18
Important Notes:	Testing will not be performed until pre-authorization or payment has been received. Please contact our Pre-Authorization Concierge Service at 1.866.GENE.INFO (436.3463) for more information. Please note that MYvantage testing is not eligible for coverage by the AHCCCS program. If submitting a MYvantage test request for an AHCCCS patient, a Notice of AHCCCS Non-Coverage form must accompany the Hereditary Cancer test requisition. This form can be obtained at SonoraQuest.com/HereditaryCancer or by contacting our Sales Support Department at 1.800.766.6721, ext. 5285.
Specimen:	5 mL room temperature whole blood in an EDTA lavender-top tube or yellow-top ACD tube (2 mL minimum). Include report of results for family member with known mutation. It is preferred that a completed Sonora Quest Laboratories Hereditary Cancer test requisition be submitted with the sample in order for testing to be performed. Please contact us at 1.800.766.6721, ext. 5285 or email SQLMarketing@SonoraQuest.com to obtain Hereditary Cancer test requisitions. If ordering through Quanum (formerly Care360) or an EMR, please complete a Hereditary Cancer Patient & Family Clinical History form (supply #34863) available by faxing a Client Supply Request Form to 602-685-5402 or 520-296-5607, or by ordering online through our Healthcare Provider Portal at SonoraQuest.com. Fax the completed Hereditary Cancer test requisition or information form to 1.855.422.5181 prior to sample submission to the laboratory.
Method:	Massively Parallel Sequencing
Reference Ranges:	See Report
Setup:	Days: Tuesday, Thursday, & Saturday
Reports:	12 days from completed pre-authorization
CPT*:	81435, 81436
Price:	Client: $3,075.00 Patient: $3,075.00

Interface Mapping:	**Result Code** 44906541 39906541 40906541 41906541 42906541 43906541	**Result Name** Result Reviewer Resource Method and Limitation Additional Information Comments	
	Potential Reflexes:		
	Test Code: Result Code:	10906840 10906700	Path Variant (Reflexed) Interpretation
	Test Code: Result Codes:	20906840 22906541 23906541 24906541 25906541	Variant 1 (Reflexed) Gene Variant 1 Classification 1 Lifetime Risk 1
	Test Code: Result Codes:	30906840 27906541 28906541 29906541 30906541	Variant 2 (Reflexed) Gene Variant 2 Classification 2 Lifetime Risk 2
	Test Code: Result Codes:	40906840 32906541 33906541 34906541 35906541	Variant 3 (Reflexed) Gene Variant 3 Classification 3 Lifetime Risk 3
	Test Code: Result Codes:	50906840 37906541 38906541	VUS (Reflexed) Other Variants Information on VUS
Comment:	This targeted panel includes 13 cancer genes related to colon, gastric, and pancreatic cancers and polyposis, among other cancer types. It consists mostly of high-penetrant genes for which NCCN has provided medical management recommendations.		

Test 906541	**Lynch Syndrome Panel**
Available:	1/16/18
Important Notes:	Testing will not be performed until pre-authorization or payment has been received. Please contact our Pre-Authorization Concierge Service at 1.866.GENE.INFO (436.3463) for more information. Please note that MYvantage testing is not eligible for coverage by the AHCCCS program. If submitting a MYvantage test request for an AHCCCS patient, a Notice of AHCCCS Non-Coverage form must accompany the Hereditary Cancer test requisition. This form can be obtained at SonoraQuest.com/HereditaryCancer or by contacting our Sales Support Department at 1.800.766.6721, ext. 5285.
Specimen:	5 mL room temperature whole blood in an EDTA lavender-top tube or yellow-top ACD tube (2 mL minimum). Include report of results for family member with known mutation.

<table>
<tr><td>Specimen (continued):</td><td colspan="3">It is preferred that a completed Sonora Quest Laboratories Hereditary Cancer test requisition be submitted with the sample in order for testing to be performed. Please contact us at 1.800.766.6721, ext. 5285 or email SQLMarketing@SonoraQuest.com to obtain Hereditary Cancer test requisitions. If ordering through Quanum (formerly Care360) or an EMR, please complete a Hereditary Cancer Patient & Family Clinical History form (supply #34863) available by faxing a Client Supply Request Form to 602-685-5402 or 520-296-5607, or by ordering online through our Healthcare Provider Portal at SonoraQuest.com. Fax the completed Hereditary Cancer test requisition and information form to 1.855.422.5181 prior to sample submission to the laboratory.</td></tr>
<tr><td>Method:</td><td colspan="3">Massively Parallel Sequencing</td></tr>
<tr><td>Reference Ranges:</td><td colspan="3">See Report</td></tr>
<tr><td>Setup:</td><td colspan="3">Days: Tuesday, Thursday, & Saturday</td></tr>
<tr><td>Reports:</td><td colspan="3">12 days from completed pre-authorization</td></tr>
<tr><td>CPT*:</td><td colspan="3">81295, 81297, 81292, 81294, 81298, 81300, 81317, 81319, 81403</td></tr>
<tr><td>Price:</td><td colspan="3">Client: $3,500.00 Patient: $3,500.00</td></tr>
<tr><td>Interface Mapping:</td><td colspan="3"><table>
<tr><td>Result Code</td><td>Result Name</td></tr>
<tr><td>44906541</td><td>Result</td></tr>
<tr><td>39906541</td><td>Reviewer</td></tr>
<tr><td>40906541</td><td>Resource</td></tr>
<tr><td>41906541</td><td>Method and Limitation</td></tr>
<tr><td>42906541</td><td>Additional Information</td></tr>
<tr><td>43906541</td><td>Comments</td></tr>
</table>
Potential Reflexes:
<table>
<tr><td>Test Code:
Result Code:</td><td>20906541
10906700</td><td>Variant (Reflexed)
Interpretation</td></tr>
<tr><td>Test Code:
Result Codes:</td><td>21906541
22906541
23906541
24906541
25906541</td><td>Variant 1 (Reflexed)
Gene
Variant 1
Classification 1
Lifetime Risk 1</td></tr>
<tr><td>Test Code:
Result Codes:</td><td>26906541
27906541
28906541
29906541
30906541</td><td>Variant 2 (Reflexed)
Gene
Variant 2
Classification 2
Lifetime Risk 2</td></tr>
<tr><td>Test Code:
Result Codes:</td><td>31906541
32906541
33906541
34906541
35906541</td><td>Variant 3 (Reflexed)
Gene
Variant 3
Classification 3
Lifetime Risk 3</td></tr>
<tr><td>Test Code:
Result Codes:</td><td>36906541
37906541
38906541</td><td>VUS (Reflexed)
Other Variants
Information on VUS</td></tr>
</table></td></tr>
<tr><td>Comment:</td><td colspan="3">Lynch syndrome is the most common form of hereditary colon cancer predisposition, accounting for 2% to 4% of all colorectal and endometrial cancer cases. This test detects pathogenic variants in the MLH1, MSH2, MSH6, PMS2, and EPCAM (dosage ONLY) genes.</td></tr>
</table>

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UPDATE: Beta-2-Microglobulin Reagent Backorder and Temporary Redirect

In Client Gram volume 35 (December 2017) it was announced that we would be sending samples submitted for test 2003 - Beta-2-Microglobulin to Quest Diagnostics for testing due to a reagent backorder. Reagent has been received and testing will resume at Sonora Quest Laboratories beginning Wednesday, January 17.

UPDATE: Coccidioides Comp Fix Testing Delays

In Client Gram volume 3, it was announced that Coccidioides Comp Fix results would be delayed due to reagent backorder. Reagent has been received and testing has resumed. Slight delays in reporting may occur over the next week or two as we work through the backlog. This impacts the following tests:

- 1063 – Coccidioides Complement Fixation
- 901098 – Coccidioides Monitoring Panel (Comp Fix)
- 1061 – Coccidioides Panel (Cocci IgM & IgG) w/reflex Confirm (IMDF) w/reflex Comp Fix (Titer)

ANNOUNCEMENT: Enhanced SonoraQuest.com Test Directory Now Available

We are excited to announce that our online Test Directory has been redesigned and now contains more helpful information and resources. In addition to specimen requirements, CPT codes, and methodology, our new Test Directory now displays:

- Reference ranges
- Setup days
- Result turnaround time
- EMR interface mapping
- LOINC codes

Additionally, the following features will be available in the coming weeks:

- Related resources: links to provider and patient educational materials
- The option to search by test categories (i.e., Allergy, Gastroenterology, etc.)
- Links to related tests in search results

Finally, while our 2018 Reference Manual will be available in February, our enhanced online Test Directory provides you with all the information from the printed guide and more. Our online Test Directory is updated daily, so you always have access to the most current information.

Please visit https://www.sonoraquest.com/test-directory/ to utilize our new Test Directory.

ASSAY CHANGES:

Test 8015	**Folate**
Effective:	1/22/18
Reference Ranges:	≥ 4.0 ng/mL

BILLING CHANGES:

Test 701843	**HLA Typing for Celiac Disease**
Effective:	2/1/18
CPT*:	81382 (x2), 81376 (x2)
Price:	Client: $650.00 Patient: $650.00

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Sonora Quest Laboratories™
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Client Gram – Laboratory Updates
January 2018 – Volume 6

ANNOUNCEMENT: SCHEDULED APPLICATION SERVER MAINTENANCE

On Sunday, January 28, 2018, Sonora Quest Laboratories will be performing application server maintenance. As a result, all computer systems will be unavailable beginning at 6:00 PM until approximately 11:00 PM.

During this period, our Client Services Representatives will not have access to computerized information or patient results. All reporting will resume by normal processes once our systems are operational. Quanum (formerly Care360) users will have uninterrupted access to patient results that were completed prior to 6:00 PM Sunday. Quanum (formerly Care360) will be updated with results completed during the down-time once the server maintenance is completed.

STAT courier services and STAT testing will remain available during this time and will be reported manually by phone via our established down-time processes.

During the down-time, please contact us as follows:

- Client Services: 602.685.5050
- Logistics (for pick-ups including Mobile Diagnostic Services STAT phlebotomy requests): 602.685.5052

ASSAY CHANGES:

Test 906820	**Chlamydia Trachomatis, Culture**		
Effective:	2/12/18		
Interface Mapping:	Ask at order entry question:		
	Result Code 99906820	**Result Name** Source:	**Response Options** Free Text

Test 9185	**Complement, Total (CH50)**
Effective:	2/5/18
Method:	Liposome

Test 902968	**First Trimester Screen, hCG**		
Effective:	1/15/18		
Comment:	Please note the below ask at order entry question has been removed.		
Interface Mapping:	Ask at order entry question:		
	Result Code 19901714	**Result Name** Insulin Dependent Diabetic	**Response Options** Free Text

Test 901714	**First Trimester Screen, H-hCG**		
Effective:	1/15/18		
Comment:	Please note the below ask at order entry question has been removed.		
Interface Mapping:	Ask at order entry question:		
	Result Code	**Result Name**	**Response Options**
	19901714	Insulin Dependent Diabetic	Free Text

Test 8176	**Fungus Culture, Miscellaneous**
Effective:	Immediately
Specimen:	Bone Marrow: Submit refrigerated in an Isolator Tube (supply order #6074). Sterile Body Fluids: Submit refrigerated in an Isolator Tube (supply order #6074). Other Specimens: Submit in a sterile container.

Test 905601	**Hepatitis C Viral RNA, QT Real Time PCR w/RFX to QL TMA**
Effective:	1/29/18
Specimen:	5 mL [x2] of plasma from a lavender-top (EDTA) tube. Aliquot plasma into a plastic vial. Ship refrigerated.
Method:	Real-Time Polymerase Chain Reaction

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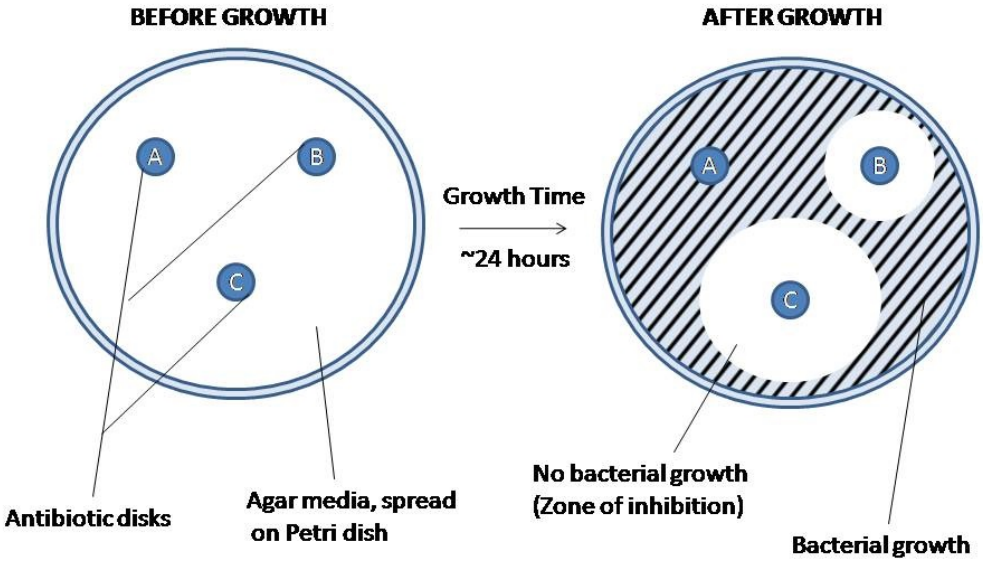
ANNOUNCEMENT: Backorder of the Gram-negative Antimicrobial Susceptibility Test (AST)

bioMerieux, the manufacturer of our primary antimicrobial susceptibility test for Gram-negative bacteria, has projected a 2-3 week backorder on their product.

Sonora Quest Laboratories will be temporarily converting to the disk diffusion method for urine, wound, and respiratory cultures during this backorder. Utilization of this method will most likely increase the result turnaround time by 12-24 hours. AST results will be limited to the interpretation: (S) susceptible, (I) intermediate or (R) resistant (the minimum inhibitory concentration (MIC) will not be determined nor listed in the result).



NOTE: Cultures from sterile sites (blood, CSF, tissues, and sterile body fluids) will continue to be reported using broth microdilution, which will provide an interpretation (S, I, or R) and an MIC value.

Please contact our Microbiology department at 602.685.5135 with any questions.

ASSAY CHANGES:

Test 11411	**Vitamin K, Plasma**
Effective:	2/19/18
Specimen:	3 mL frozen plasma from a lavender-top (EDTA) tube (1.5 mL minimum). Centrifuge as soon as possible. Pour into an amber light protected transport vial and freeze immediately. If amber tube not available wrap tube in aluminum foil to protect from light. Overnight fasting is preferred. Place in specimen bag with a frozen label applied and transport frozen.
Method:	Chromatography

Test 904992	**Quad Screen**		
Effective:	2/5/18		
Interface Mapping:	**Result Code**	**Result Name**	
	10901714	Interpretation	
	20904992	Risk for ONTD	
	30904992	Age Risk Down Syndrome	
	40904992	MSS Down Syndrome Risk	
	50904992	MSS Trisomy 18 Risk	
	60904992	Calculated Gestational Age	
	70904992	AFP, Serum	
	80904992	AFP MoM	
	90904992	hCG, Serum	
	11904992	hCG MoM	
	12904992	Estriol, Free	
	13904992	Estriol MoM	
	14904992	Inhibin A, Dimeric	
	15904992	Inhibin A MoM	
	31904992	Comments	
	32904992	Comment	
	Ask at order entry questions:		
	Result Code	**Result Name**	**Response Options**
	18901714	Number of Fetuses:	1, 2, or 3
	19901714	Insulin Dependent Diabetic:	Yes, No, or Unknown
	21901714	Repeat Specimen:	Yes, No, or Unknown
	23901714	Brief History (NTD):	Free Text
	24901714	Prev Pregnancy Down Syndrome:	Yes, No, or Unknown
	26901714	Donor Egg:	Yes, No, or Unknown
	27901714	Donor Age: Egg Retrieval:	MM/DD/YYYY
	12901714	Date of Birth:	MM/DD/YYYY
	13901714	Collection Date:	MM/DD/YYYY
	15901714	Estimated Date of Delivery:	MM/DD/YYYY
	16901714	EDD Determined by:	Free Text
	17901714	Mother's Ethnic Origin:	Asian, Black, Caucasian, Hispanic, Other, or Unknown
	22902968	Hx of Neural Tube Defects:	Yes, No, or Unknown
	14901714	Maternal Weight:	Numeric
	99903305	Cigarette Smoker	Yes, No, or Unknown

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DISCONTINUED TEST:

Test 905359	**Syphilis Treponemal Antibody Screen**
Effective:	2/19/18
Comment:	Test is being discontinued based upon requirements from our accrediting agency. Requests for this test will be automatically replaced with Test 905363, Syphilis Screen w/reflex RPR and Titer or TPPA. Please see below for all test and mapping information.

REPLACEMENT TEST:

Test 905363	**Syphilis Screen w/reflex RPR and Titer or TPPA**		
Specimen:	1 mL refrigerated serum from a serum separator tube (SST) (0.1 mL min).		
Method:	Chemiluminescent Immunoassay		
Reference Range:	Nonreactive		
Setup:	Evenings & Nights: Monday - Sunday		
Reports:	1-3 Days		
CPT*:	Screen: 86780; RPR Reflex: 86592; RPR Titer Reflex: 86593; TP-PA Reflex: 86780		
Price:	Client: $ 30.00 Patient: $ 45.00		
Interface Mapping:	**Result Code** 10905359 11905359	**Result Name** Syphilis Antibody Total Syphilis Antibody Result	
	Potential Reflexes:		
	Test Code: Result Code:	5376 10001054	RPR Screen w/Reflex to RPR Titer RPR Screen
	Test Code: Result Code:	201055 10001055	RPR Titer RPR Titer
	Test Code: Result Code:	900780 10900780	Treponema pallidum Antibody – PA Treponema pallidum Antibody - PA
Comment:	If Syphilis Screen is Reactive, then RPR Screen w/Reflex to RPR Titer (5376) will be performed. If RPR is nonreactive, then Treponema pallidum Antibody - PA (900780) will be performed. Reflex testing will be performed at an additional charge.		

*The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

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Sonora Quest Laboratories™
A Subsidiary of Laboratory Sciences of Arizona

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ANNOUNCEMENT: CPT Coding Effective January 1, 2018

The American Medical Association (AMA) has made Current Procedural Terminology (CPT) code changes to the 2018 edition of the CPT coding manual. In addition, the CMS has also made changes to Healthcare Common Procedure Coding System (HCPCS) codes.

Sonora Quest Laboratories has implemented these changes effective January 1, 2018. The changes for 2018 affect the way we bill some of our tests. Please note these changes will not impact our service offerings or how you order them, but simply how we will bill third party payers.

The summary below outlines the 2018 CPT code changes that affect Sonora Quest Laboratories published test offerings. These tests may also be included in panels or profiles.

Test Code	Test Name	2017 CPT*	2018 CPT*
803103	Allergen Food Panel	86003 x18	86003 x15, 86008 x3
906050	Allergen, Cow's Milk (F2), IgE w/Reflex Components	Screen: 86003 Reflex: 86003 x3	Screen: 86003 Reflex: 86008 x3
906049	Allergen, Egg White (F1), IgE w/Reflex Components	Screen: 86003 Reflex: 86003 x2	Screen: 86003 Reflex: 86008 x2
91682	Allergen, Food Panel w/Reflex Peanut, Egg, Milk Components	86003 x15	Screen: 86003 x15 Reflex: 86008 x5
91747	Allergen, Peanut (F13), IgE w/Reflex Components	Screen: 86003 Reflex: 86003 x5	Screen: 86003 Reflex: 86008 x5
904539	Alpha Lactalbumin (F76), IgE	86003	86008
904538	Beta Lactoglobulin (F77), IgE	86003	86008
903042	Casein (F78), IgE	86003	86008
91683	Childhood Allergy Profile with Reflexes	Screen: 86003 x16, 82785 Reflexes: 86003 x5, 86003 x2, 86003 x3	Screen: 86003 x16, 82785 Reflexes: 86008 x5, 86008 x2, 86008 x3
91372	Egg Component Panel	86003 x2	86008 x2
91403	Milk Component Panel	86003 x3	86008 x3
707799	Milk Panel	86003 x5	86003 x2, 86008 x3
902287	Ovalbumin (F232), IgE	86003	86008
905210	Ovomucoid (F233), IgE	86003	86008
906382	PDM, CYP450 3A4 Genotype, Qual	81401	81230
906381	PDM, CYP450 3A4/3A5 Genotype, Qual	81401, 81479	81230, 81231
906383	PDM, CYP450 3A5 Genotype, Qual	81479	81231
91681	Peanut Component Panel	86003 x5	86008 x5
902136	TPMT Genotype	81401	81335
906694	Zika Virus RNA Qualitative Real-Time RT-PCR	87798	87662

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Sonora Quest Laboratories™
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UPDATE: Backorder of the Gram-negative Antimicrobial Susceptibility Test (AST)

The backorder on our primary antimicrobial susceptibility product for Gram-negative bacteria announced in Client Gram volume 7 is no longer in effect. Sonora Quest Laboratories has converted back to providing the Minimum Inhibitory Concentration (MIC) susceptibility method for urine, wound, and respiratory cultures.

Please contact our Microbiology department at 602.685.5135 with any questions.

UPDATE: Additional Information Regarding Possible Biotin Interference in Immunoassay Testing

In Client Gram vol. 1 (2018), a list of tests was provided that may be impacted if the patient is receiving high dose biotin therapy. The following additional tests have been identified as being potentially affected:

901491 - B-Type Natriuretic Peptide
102555 - Hepatitis A Antibody, IgM
102562 - Hepatitis A Antibody, Total
8020 - Hepatitis B Surface Antigen w/Rflx Confirmation

The following reminder will be added to the specimen requirements of these and all affected tests:

“Due to potential assay interference, do not collect samples from patients receiving high dose biotin therapy (i.e. >5 mg/day) until at least 8 hours (optimally 24 to 72 hours) following the last dose.”

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ANNOUNCEMENT: SCHEDULED APPLICATION SERVER MAINTENANCE

On Sunday, February 25, 2018, Sonora Quest Laboratories will be performing application server maintenance. As a result, all computer systems will be unavailable beginning at 6:00 PM until approximately 11:00 PM.

During this period, our Client Services Representatives will not have access to computerized information or patient results. All reporting will resume by normal processes once our systems are operational. Quanum (formerly Care360) users will have uninterrupted access to patient results that were completed prior to 6:00 PM Sunday. Quanum (formerly Care360) will be updated with results completed during the down-time once the server maintenance is completed.

STAT courier services and STAT testing will remain available during this time and will be reported manually by phone via our established down-time processes.

During the down-time, please contact us as follows:

- Client Services: 602.685.5050
- Logistics (for pick-ups including Mobile Diagnostic Services STAT phlebotomy requests): 602.685.5052

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UPDATE: Coccidioides Comp Fix Testing Delays

In Client Gram volume 5, it was announced that reports for Coccidioides Comp Fix results would be slightly delayed as we worked through the backlog from a reagent backorder. All testing has now resumed to normal turnaround times. This pertains the following tests:

- 1063 – Coccidioides Complement Fixation
- 901098 – Coccidioides Monitoring Panel (Comp Fix)
- 1061 – Coccidioides Panel (Cocci IgM & IgG) w/reflex Confirm (IMDF) w/reflex Comp Fix (Titer)

ASSAY CHANGES:

Test 701303	**Natural Killer Cells** [Includes Lymphocytes, Absolute Cells, CD3-CD16+CD56+ Absolute Cells, CD3-CD16+CD56+ Percent Positive]	
Effective:	3/12/18	
Specimen:	5 mL room temperature whole blood in an EDTA lavender-top tube (1 mL minimum).	
Setup:	Days: Monday – Saturday	
Results:	3 Days	
Price:	Client: $80.85 Patient: $107.46	
Interface Mapping:	Result Code 10005672 11003116 11005677 11003010	Result Name CD16/56, Absolute Lymphocyte, Absolute CD16/56, Percent WBC
Comment:	Testing will be performed at our main laboratory in Tempe.	

Test 905574	**T & B Cells, Total** [Includes Lymphocytes, Absolute Cells, CD19, Absolute Cells, CD19+ Percent Positive, CD3, Absolute Cells, CD3 Percent Positive]	
Effective:	3/12/18	
Specimen:	5 mL room temperature whole blood in an EDTA lavender-top tube (1 mL minimum).	
Setup:	Days: Monday – Saturday	
Results:	3 Days	
Price:	Client: $193.00 Patient: $241.20	
Interface Mapping:	Result Code 10005648 10005658 10005660 10005662 11003116 11003010	Result Name CD19, Absolute CD19, Percent CD3, Absolute CD3, Percent Lymphocyte, Absolute WBC
Comment:	Testing will be performed at our main laboratory in Tempe.	

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ANNOUNCEMENT: InSure® Occult Blood Immunochemical Collection Kits

We are pleased to announce the availability of the InSure® ONE™ collection kits for occult blood immunochemical testing. InSure ONE kits offer substantially equivalent test performance to its sister test kit InSure FIT and is now more convenient than ever with only ONE collection required.[1,2,3] Greater convenience may lead to increased screening rates and move us closer to our shared commitment of increased screening and early detection.[4]

What this means for you:
We will begin distributing InSure ONE test kits (supply #18067) in March 2018. The new kit will include updated patient instructions to reflect the requirement of 2 samples from one bowel movement. No action is needed on your part. All supply orders will be filled using the InSure ONE kit starting March 19.

Increase colorectal cancer screening compliance with InSure ONE:

Easier to use
- InSure ONE is the only FIT that is performed using collection of water samples from one bowel movement
- NO stool collection or handling of feces required[4]
- There are no diet or drug restrictions associated with using InSure ONE[5]

Accurate
- FIT is supported by medical guidelines, including the American Cancer Society, the American College of Gastroenterology and the USPSTF, for use in colorectal cancer screening programs[5,6,7]
- InSure ONE reliably detects 50 ug Hb/g feces, in at least 95% positive readings[6]
- Reliable and accurate results can be obtained from testing a single bowel movement when compared to testing 2 separate bowel movements.[1,2,8]

Please contact your Sonora Quest Laboratories representative if you have questions.

References
1. InSure ONE K170548-Appendix A, Table 1 **2.** Insure ONE K170548-Appendix A, Table 2 **3.** InSure ONE K170548-Appendix A, Table 3 **4.** Young GP, et al., *J Med Screen* 2003;10:123-128 **5.** InSure FIT K002457-Instructions for Use (IFU) **6.** InSure ONE K170548-Instructions for Use (IFU) **7.** USPSTF Recommendation Statement *JAMA* 2016;315:2564-2575 **8.** InSure ONE K170548-Performance Testing-Clinical Study Summary Report, Tables 5 and 6

ASSAY CHANGES:

Test 11290 **Test 11293**	**InSure® Fecal Globin by Immunochemistry, Diagnostic** **InSure® Fecal Globin by Immunochemistry, Screening**
Effective:	3/19/18
Specimen:	Protect from light. Follow package instructions for proper collection. Inoculate each sample pad with a sampling of toilet water collected after a single bowel movement.

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