Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2020 UPDATE C

Update Notes/
Effective immediately, due to a nationwide supply shortage for Hologic Urine Aptima Combo II media, we cannot accept urine in a sterile container for CHGTM, CHRNA, GCRNA, MUPCR, and TRIVA. We subsequently cannot supply our clients with the urine collection kits at this time. We can accept urine in the Urine Aptima Combo II media if you still have any in stock.

Update Summary		
Update Existing Test	9/9/2020	CHGTM - "Chlamydia and Neisseria Nucleic Acid by TMA"
Update Existing Test	9/9/2020	CHRNA - "Chlamydia trachomatis Nucleic Acid by TMA"
Update Existing Test	9/9/2020	EASRT - "Ehrlichia and Anaplasma Species by Real-Time PCR"
Update Existing Test	9/9/2020	FUKAU - "Ustekinumab and Anti-Ustek Antibody, Serum"
Update Existing Test	9/9/2020	GCRNA - "Neisseria gonorrhoeae Nucleic Acid by TMA"
Update Existing Test	9/9/2020	HLB57 - "HLA-B*5701 Associate Variant Genotyping"
Update Existing Test	9/29/2020	JAKCR - "JAK2 V617F Cascading Reflex"
Update Existing Test	9/9/2020	MUPCR - "SureSwab®, Mycoplasma/Ureaplasma Panel, PCR"
Update Existing Test	9/9/2020	PETHB - "Phosphatidylethanol (Peth), Whole Blood"
Update Existing Test	9/9/2020	TCDB - "C. diff toxin B gene (tcdB)PCR"
Update Existing Test	9/9/2020	TRIVA - "Trichomonas vaginalis RNA, Qualitative"
Inactivate Test With Replacement	9/9/2020	COVLR - "SARS-CoV-2 RNA (COVID-19), Qualitative NAAT" replaced by COVQ - "SARS-CoV-2 RNA (COVID-19), Qualitative NAAT"
Inactivate Test With Replacement	9/9/2020	HPCRS - "Helicobacter pylori w Reflex to Susceptibility" replaced by HEOBA - "Helicobacter pylori Culture with Reflex to Susceptibility"
Inactivate Test Without Replacement	9/9/2020	GINPP - "Gastrointestinal Pathogen Panel, PCR, Feces"
Inactivate Test Without Replacement	9/9/2020	RF344 - "Sage IgE"
Inactivate Test Without Replacement	9/9/2020	RO201 - "Tobacco Leaf IgE"

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Update Existing Test	
Effective Date	9/9/2020
Name	Chlamydia and Neisseria Nucleic Acid by TMA
Code	CHGTM
Interface Order Code	3091010
Legacy Code	CHGCRNA
Notes	
Required Testing Changes	
Specimen Required	Specimen source required for testing. Endocervical, vaginal or male urethral swab specimens in APTIMA Combo II transport medium. First catch urine in APTIMA Combo II Urine Transport Tube. Liquid level must fall between the two black indicator lines. Minimum 2.0 mL **Aptima Combo II Urine transport media is currently unavailable.**
Alternate Specimen	Endocervical, vaginal or male urethral swab in M4 and M5 viral transport tube- 0.4 mL minimum Endocervical, vaginal or male urethral swab in Gen-Probe Pace 2 swab transport tubes- 0.4 mL minimum Endocervical, vaginal or male urethral swab in BD ProbeTec ET CT/GC Diluent- 0.4 mL minimum Endocervical, vaginal or male urethral swab in BD ProbeTec Dry Swab system

Update Existing Test	
Effective Date	9/9/2020
Name	Chlamydia trachomatis Nucleic Acid by TMA
Code	CHRNA
Interface Order Code	3091100
Legacy Code	CHRNA
Notes	
Required Testing Changes	
Specimen Required	Specimen source required for testing. Endocervical, vaginal, or male urethral swab specimens in APTIMA Combo II transport medium. First catch urine in APTIMA Combo II Urine Transport Tube. Liquid level must fall between the two black indicator lines. Minimum 2.0 mL. Dedicated specimens are required. If Chlamydia and Neisseria are both ordered one sample may be sent. Specimens used in other assay will not be tested. **Aptima Combo II Urine transport media is currently unavailable.**
Alternate Specimen	Endocervical, vaginal or male urethral swab in M4 and M5 viral transport tube- 0.4 mL minimum Endocervical, vaginal or male urethral swab in Gen-Probe Pace 2 swab transport tubes- 0.4 mL minimum Endocervical, vaginal or male urethral swab in BD ProbeTec ET CT/GC Diluent- 0.4 mL minimum Endocervical, vaginal or male urethral swab in BD ProbeTec Dry Swab system

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Update Existing Test	
Effective Date	9/9/2020
Name	Ehrlichia and Anaplasma Species by Real-Time PCR
Code	EASRT
Interface Order Code	3600090
Legacy Code	EASRT
Notes	TAT changes.
Required Testing Changes	
Turnaround Time	**3 - 8 days**

Update Existing Test			
Effective Date	9/9/2020		
Name	Ustekinumab and Anti-Ustek Antibody, Serum		
Code	FUKAU		
Interface Order Code	3800208		
Legacy Code	FUKAU		
Notes	Interface Order Code update.		
Required Testing Changes			
Interface Order Code	**3800208**		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt²**
3800117	Ustekinumab	87408-1	No
3800118	Anti-Ustekinumab Ab	88992-3	No

Update Existing Test	
Effective Date	9/9/2020
Name	Neisseria gonorrhoeae Nucleic Acid by TMA
Code	GCRNA
Interface Order Code	3091200
Legacy Code	GCRNA
Notes	
Required Testing Changes	
Specimen Required	Specimen source required for testing. Endocervical, vaginal or male urethral swab specimens in APTIMA Combo II transport medium. First catch urine in APTIMA Combo II Urine Transport Tube. Liquid level must fall between the two black indicator lines. Minimum 2.0 mL urine in sterile specimen cup. Dedicated specimens are required. If Chlamydia and Neisseria are both ordered on sample may be sent. Specimens used in other assays will not be tested. **Aptima Combo II Urine Transport media is currently unavailable.**

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Update Existing Test	
Effective Date	9/9/2020
Name	HLA-B*5701 Associate Variant Genotyping
Code	HLB57
Interface Order Code	3621200
Legacy Code	HLB57
Notes	TAT changes.
Required Testing Changes	
Turnaround Time	**6 - 12 days**

Update Existing Test			
Effective Date	9/29/2020		
Name	JAK2 V617F Cascading Reflex		
Code	JAKCR		
Interface Order Code	3400380		
Legacy Code	JAKCR		
Notes	Additional components added for Billing.		
Required Testing Changes			
Result Code	**Name**	**LOINC Code**	**AOE/Prompt²**
3400381	Clinical Indication:	55752-0	**Yes**
3400382	Specimen Source:	31208-2	**Yes**
3400383	Block/Specimen ID:	52463-7	**Yes**
3400384	JAK2 V617F Mutation	43399-5	No
3400385	CALR Exon 9 Mutation	77174-1	No
3400386	JAK2 Exon 12 Mutation	55300-8	No
3400387	MPL Exon 10 Mutation	62947-7	No
3400388	CSF3R Exon 14/17 Mutation	92674-1	No
3400389	Gene	48018-6	No
3400390	Amino Acid	48005-3	No
3400391	Mutation Frequency	81258-6	No
3400392	Mutation Type	48019-4	No
3400393	Exon	47999-8	No
3400394	Nucleotide Change	48004-6	No
3400395	Reference	81256-0	No
3400396	Interpretation	50398-7	No
3400397	Assay Details	8266-9	No
3400405	**Billing Only - CALR Exon 9 Mutation**	**Not available**	**No**
3400406	**Billing Only - JAK2 Exon 12 Mutation**	**Not available**	**No**
3400407	**Billing Only - MPL Exon 10 Mutation**	**Not available**	**No**
3400408	**Billing Only - CSF3R Exon 14/17 Mutation**	**Not available**	**No**

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Update Existing Test	
Effective Date	9/9/2020
Name	SureSwab®, Mycoplasma/Ureaplasma Panel, PCR
Code	MUPCR
Interface Order Code	3400019
Legacy Code	MUPCR
Notes	
Required Testing Changes	
Alternate Specimen	Urine: Male urine collected in an Aptima Urine Specimen Transport tube. Collect a first-catch urine in a urine cup (preservative free). Transfer 2.0 mL of urine to an Aptima Urine Specimen Transport tube within 24 hours of collection. Fluid levels should be between the black lines on the tube label. Male Urethral swab: Follow instructions in the Aptima Unisex Swab Specimen Collection kit. Please Note: **Aptima Combo II Urine transport media is currently unavailable.**

Update Existing Test	
Effective Date	9/9/2020
Name	Phosphatidylethanol (Peth), Whole Blood
Code	PETHB
Interface Order Code	3600171
Legacy Code	PETHB
Notes	
Required Testing Changes	
Reference Range	**See report.**

Update Existing Test	
Effective Date	9/9/2020
Name	C. diff toxin B gene (tcdB)PCR
Code	TCDB
Interface Order Code	3621000
Legacy Code	TCDB
Notes	Stability changes.
Required Testing Changes	
Stability	Room temperature: 48 hours; Refrigerated: 5 days; **Frozen: 1 week**

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Update Existing Test	
Effective Date	8/31/2020
Name	Trichomonas vaginalis RNA, Qualitative
Code	TRIVA
Interface Order Code	3093500
Legacy Code	TRIVA
Notes	
Required Testing Changes	
Specimen Required	Specimen source required. Collect endocervical, vaginal or male urethral swab and place in Aptima Combo II transport media. First void urine in Aptima urine transport tube. Liquid level must fall between the two black indicator lines. Dedicated specimens are required. **Aptima Combo II Urine transport media is currently unavailable.**
Alternate Specimen	No alternate specimen at this time.

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Inactivate Test With Replacement			
Effective Date	9/9/2020		
Inactivated Test			
Name	SARS-CoV-2 RNA (COVID-19), Qualitative NAAT		
Code	COVLR		
Legacy Code[1]	COVLR		
Interface Order Code	3400259		
Notes			
Replacement Test			
Name	SARS-CoV-2 RNA (COVID-19), Qualitative NAAT		
Code	COVQ		
CPT Code(s)	87635		
Notes	This code should be used for lower respiratory specimens. All nasopharnygeal specimens should be ordered as **COVW.**		
Specimen Requirements			
Specimen Required	Please send 0.85 bronchoalveolar lavage/wash frozen in a screw-capped plastic container. Please send each specimen in a separate plastic bag.		
Alternate Specimen	Nasopharyngeal aspirate/wash, tracheal aspirate, or sputum		
Rejection Criteria	Amies liquid or gel transport used for bacterial cultures.		
Stability	Room temperature; 5 days; Refrigerated: 5 days; Frozen: Acceptable		
Performing Information			
Methodology	Nucleic Acid Amplification Test (NAAT), includes PCR or TMA		
Reference Range	Not detected		
Performed Days	Sunday-Saturday		
Turnaround Time	2 - 3 days (may be impacted by high volume)		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	COVQ		
Interface Order Code	3400589		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400591	First Test? ***Acceptable responses:*** Yes No Not Given	95417-2	**Yes**
3400592	Employed in Healthcare? ***Acceptable responses:*** Yes	95418-0	**Yes**

	No Not Given		
3400593	Symptomatic? ***Acceptable responses:*** Yes No Not Given	95419-8	**Yes**
3400594	Date of Symptom Onset ***Acceptable responses:*** MM/DD/YYYY Not Given	65222-2	**Yes**
3400595	Hospitalized? ***Acceptable responses:*** Yes No Not Given	77974-4	**Yes**
3400596	ICU? ***Acceptable responses:*** Yes No Not Given	95420-6	**Yes**
3400597	Congregate care setting? ***Acceptable responses:*** Yes No Not Given	95421-4	**Yes**
3400598	Pregnant? ***Acceptable responses:*** Yes No Not Given	82810-3	**Yes**
3400599	Race ***Acceptable responses:*** Asian Black or African American American Indian or Alaska Native Other Race Native Hawaiian or Other Pacific Islander White	32624-9	**Yes**
3400601	Ethnicity ***Acceptable responses:*** Hispanic Non-Hispanic Not Given	42784-9	**Yes**
3400602	Source ***Acceptable responses:*** Nasopharyngeal Oropharyngeal NP/OP Bronchial lavage/wash NP aspirate/wash Sputum/Tracheal aspirate Mid Turbinate Anterior Nares Not Given	31208-2	**Yes**

3400603	SARS-CoV-2 RNA (COVID-19), Qualitative NAAT	94500-6	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 31 Y

Referral Testing

Collected: 09/09/2020 08:58 Received: 09/09/2020 08:58

Test Name	Result	Flag	Ref-Ranges	Units	Site
SARS-CoV-2 RNA (COVID-19), Qualitative NAAT					
First Test?	Yes				QCRL
Employed in Healthcare?	No				QCRL
Symptomatic?	Yes				QCRL
Date of Symptom Onset	09/08/2020				QCRL
Hospitalized?	No				QCRL
ICU?	No				QCRL
Congregate care setting?	No				QCRL
Pregnant?	Not Given				QCRL
Race	Other Race				QCRL
Ethnicity	Not Given				QCRL
Source	Nasopharyngeal				QCRL
SARS-CoV-2 RNA (COVID-19), Qualitative NAAT	NOT DETECTED				QCRL

A Not Detected (negative) test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. A negative result does not rule out the possibility of COVID-19 and should not be used as the sole basis for treatment or patient management decisions. If COVID-19 is still suspected, based on exposure history together with other clinical findings, re-testing should be considered in consultation with public health authorities. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.

REFERENCE RANGE: NOT DETECTED

Please review the 'Fact Sheets' and FDA authorized labeling available for health care providers and patients using the following websites:
https://www.questdiagnostics.com/home/Covid-19/HCP/QuestIVD/fact-sheet.html
https://www.questdiagnostics.com/home/Covid-19/Patients/QuestIVD/fact-sheet.html

This test has been authorized by the FDA under an Emergency Use Authorization (EUA) for use by

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 31 Y

Referral Testing

Collected: 09/09/2020 08:58 Received: 09/09/2020 08:58

Test Name	Result	Flag	Ref-Ranges	Units	Site

Authorized laboratories.

Due to the current public health emergency, Quest Diagnostics is receiving a high volume of samples from a wide variety of swabs and media for COVID-19 testing. In order to serve patients during this public health crisis, samples from appropriate clinical sources are being tested. Negative test results derived from specimens received in non-commercially manufactured viral collection and transport media, or in media and sample collection kits not yet authorized by FDA for COVID-19 testing should be cautiously evaluated and the patient potentially subjected to extra precautions such as additional clinical monitoring, including collection of an additional specimen.

Methodology: Nucleic Acid Amplification Test (NAAT) includes PCR or TMA

Additional information about COVID-19 can be found at the Quest Diagnostics website: www.QuestDiagnostics.com/Covid19

Test Performed at:
Quest Diagnostics Infectious Disease, Inc.
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 H J Batterman MD

Performing Site:
QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

Inactivate Test With Replacement			
Effective Date	8/31/2020		
Inactivated Test			
Name	Helicobacter pylori w Reflex to Susceptibility		
Code	HPCRS		
Legacy Code[1]	HPCRS		
Interface Order Code	3400180		
Notes			
Replacement Test			
Name	Helicobacter pylori Culture with Reflex to Susceptibility		
Code	HEOBA		
CPT Code(s)	87081, 87205, plus 87181 x 5, if reflexed to Susceptibility, at additional cost		
Notes			
Specimen Requirements			
Specimen Required	Send 3 mm gastric/Antral or duodenal biopsy (no minimum) in Brucella broth or equivalent with 10-20% glycerol. Do not send in a swab container. Send frozen -70°C.		
Alternate Specimen	Broth with our without glycerol 2- 8 C Sterile non-bacteriostatic saline 2 - 8 C		
Rejection Criteria	Transport swab with or without gel; stool		
Stability	Room temperature: Unacceptable; Refrigerated: 48 hours; Frozen -70 C: 5 days		
Performing Information			
Methodology	Culture		
Reference Range	Not Isolated		
Performed Days	Sunday - Saturday		
Turnaround Time	10 - 12 days		
Performing Laboratory	Quest Infectious Disease		
Interface Information			
Legacy Code[1]	HEOBA		
Interface Order Code	3400451		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400452	Source:	31208-2	**Yes**
3400453	Status	8251-1	No
3400454	Gram Stain	664-3	No
3400455	Culture	587-6	No
3400456	Amoxicillin	16-6	No
3400457	Clarithromycin	189-1	No
3400458	Levofloxacin	20396-8	No

3400459	Metronidazole	327-7	No
3400460	Tetracycline	496-0	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 31 Y

Referral Testing

Collected: 09/08/2020 16:44 Received: 09/08/2020 16:44

Test Name	Result	Flag	Ref-Ranges	Units	Site
Helicobacter pylori Culture with Reflex to Susceptibility					
Source:	Gastric			FINAL	QCRL
Status	FINAL				QCRL
Gram Stain	NO CURVED GRAM-NEGATIVE BACILLI SEEN				QCRL
Culture	NOT ISOLATED				QCRL
REFERENCE RANGE: NOT ISOLATED					
Test Performed at: Quest Diagnostics Infectious Disease, Inc. 33608 Ortega Highway San Juan Capistrano, CA 92675-2042 H J Batterman MD					
Amoxicillin	.				QCRL
Clarithromycin	.				QCRL
Levofloxacin	.				QCRL
Metronidazole	.				QCRL
Tetracycline	.				QCRL

Performing Site:
QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

B708000050
WX0000003039
Printed D&T: 09/09/20 08:58

Ordered By: CLIENT CLIENT
WX00000000001595

William G. Finn, M.D. - Medical Director
Form: MM RL1

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 31 Y

Referral Testing

Collected: 09/08/2020 16:29 Received: 09/08/2020 16:29

Test Name	Result	Flag	Ref-Ranges	Units	Site
Helicobacter pylori Culture with Reflex to Susceptibility					
Source:	Gastric				QCRL
Status	FINAL				QCRL
Gram Stain	CURVED GRAM-NEGATIVE BACILLI SEEN				QCRL
Culture	**ISOLATED**	**AB**			QCRL

REFERENCE RANGE: NOT ISOLATED

Test Performed at:
Quest Diagnostics Infectious Disease, Inc.
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 H J Batterman MD

Amoxicillin	0.125 S				QCRL
Clarithromycin	0.250 S				QCRL
Levofloxacin	0.125 S				QCRL
Metronidazole	0.125 S				QCRL
Tetracycline	0.250 S				QCRL

MIC values are expressed in mcg/mL.

S=Susceptible, I=Intermediate, R=Resistant

All breakpoints are based on FDA, CLSI, or EUCAST guidelines. Only the MIC value is reported when an FDA, CLSI, or EUCAST guideline is not available.

Test Performed at:
Quest Diagnostics Infectious Disease, Inc.
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 H J Batterman MD

Performing Site:
QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2020 UPDATE C

Inactivate Test Without Replacement	
Effective Date	8/31/2020
Name	Gastrointestinal Pathogen Panel, PCR, Feces
Code	GINPP
Legacy Code	GINPP
Interface Code	3800016
Notes	Due to lack of available reagent kits, this test will be temporarily inactivated until further notice.

Inactivate Test Without Replacement	
Effective Date	9/9/2020
Name	Sage IgE
Code	RF344
Legacy Code	RARF344
Interface Code	3063440
Notes	Manufacturer discontinuing reagent.

Inactivate Test Without Replacement	
Effective Date	9/9/2020
Name	Tobacco Leaf IgE
Code	RO201
Legacy Code	RARO201
Interface Code	3062900
Notes	Manufacturer discontinuing reagent.