

## Update Notes

## Update Summary

<b>Announcement</b>	7/25/2023	<a href="#">STI Nucleic Acid Testing Change Notice</a>
<b>Update Existing Test</b>	7/11/2023	<a href="#">AIRM - "Amylase Isoenzymes with Reflex to Macroamylase"</a>
<b>Update Existing Test</b>	7/18/2023	<a href="#">BIACT - "Bile Acids, Total"</a>
<b>Update Existing Test</b>	7/18/2023	<a href="#">COATD - "Complete Atopic Dermatitis Panel"</a>
<b>Update Existing Test</b>	7/25/2023	<a href="#">HIVUL - "HIV-1 RNA Ultraquant"</a>
<b>Update Existing Test</b>	7/11/2023	<a href="#">NTELO - "Collagen Cross Linked N Telopeptide (NTX), 24H U w/Creat"</a>
<b>Update Existing Test</b>	7/11/2023	<a href="#">NTXUR - "Collagen Cross Linked N Telopeptide, Urine with Creatinine"</a>
<b>Update Existing Test</b>	7/17/2023	<a href="#">PARID - "Parasite Identification, Worm"</a>
<b>Update Existing Test</b>	7/11/2023	<a href="#">TSI - "Thyroid Stimulating IgG (TSI)"</a>
<b>Inactivate Test With Replacement</b>	7/25/2023	<a href="#">CHGTM - "Chlamydia and Neisseria Nucleic Acid by TMA" replaced by COPCR - "Chlamydia and Neisseria Testing by PCR"</a>
<b>Inactivate Test With Replacement</b>	7/25/2023	<a href="#">CHRNA - "Chlamydia trachomatis Nucleic Acid by TMA" replaced by CHPCR - "Chlamydia Trachomatis Testing by PCR"</a>
<b>Inactivate Test With Replacement</b>	7/25/2023	<a href="#">GCRNA - "Neisseria gonorrhoeae Nucleic Acid by TMA" replaced by GCPCR - "Neisseria Gonorrhoeae Testing by PCR"</a>
<b>Inactivate Test With Replacement</b>	7/25/2023	<a href="#">TRIVA - "Trichomonas vaginalis RNA, Qualitative" replaced by TVPCR - "Trichomonas vaginalis Testing by PCR"</a>
<b>Inactivate Test Without Replacement</b>	7/25/2023	<a href="#">C208E - "Allergen - Tetanus Toxoid (RC208) IgE"</a>
<b>Inactivate Test Without Replacement</b>	7/25/2023	<a href="#">F267E - "Allergen - Cardamon (RF267) IgE"</a>
<b>Inactivate Test Without Replacement</b>	7/25/2023	<a href="#">F281E - "Allergen - Curry (F281) IgE"</a>
<b>Inactivate Test Without Replacement</b>	7/25/2023	<a href="#">F298E - "Allergen - Tragacanth (F298) IgE"</a>
<b>Inactivate Test Without Replacement</b>	7/11/2023	<a href="#">NTXS - "N-telopeptide, Serum"</a>

## Announcement

Warde Laboratory is switching platforms for nucleic acid testing of the STI pathogens *N. gonorrhoeae*, *C. trachomatis*, and *T. vaginalis*. Starting in July/Aug 2023, this testing will be performed on the Abbott Alinity m platform using the Alinity m STI Amp Kit. All three pathogens can be detected from a single Abbott Multi-Collect tube, which Warde will provide to clients. Additional information about the new test build and ordering process will be provided over the next few months. This notice is intended to allow clients time to wind down ordering of Aptima collection tubes as they will no longer be accepted for STI nucleic acid testing.

Alinity m STI Amp Kit specimen sources and stability:

Specimen	Room Temp Stability	Refrigerated Stability	Frozen Stability
Vaginal Swab	14 days	14 days	60 days
Rectal Swab	14 days	14 days	60 days
Oropharyngeal Swab	14 days	14 days	60 days
First Catch Urine	14 days	14 days	60 days

First catch urine should be collected in an IATA screw-capped container and transferred to the Multi-Collect Tube via transfer pipet within 24 hr. No additional specimen sources or media types will be accepted for testing for these pathogens. All specimens should be shipped refrigerated.

## Update Existing Test

<b>Effective Date</b>	7/11/2023
<b>Name</b>	Amylase Isoenzymes with Reflex to Macroamylase
<b>Code</b>	AIRM
<b>Interface Order Code</b>	3700045
<b>Legacy Code</b>	AIRM
<b>Notes</b>	Update to performing lab, LOINC

## Required Testing Changes

<b>Performing Laboratory</b>	Quest SJC		
<b>Result Code</b>	<b>Name</b>	<b>LOINC Code</b>	<b>AOE/Prompt<sup>2</sup></b>
3700046	Amylase	1798-8	No
3700047	Pancreatic Isoenzyme	1805-1	No
3700048	Salivary Isoenzymes	1809-3	No
3700049	Macroamylase	15358-5	No

Update Existing Test	
Effective Date	7/18/2023
Name	Bile Acids, Total
Code	BIACT
Interface Order Code	3717900
Legacy Code	BILEACTSP
Notes	Update to specimen required, alternate specimen, rejection criteria, stability, methodology, reference range, performing laboratory
Required Testing Changes	
Specimen Required	<p>Patient Preparation: <b>Patient should fast for eight hours prior to collection.</b></p> <p>Collect: Serum separator tube (SST)</p> <p>Specimen Preparation: <b>Allow sample to clot completely at room temperature before centrifugation.</b> Centrifuge and separate serum from cells and send 1.0 mL serum in a screw capped plastic vial.</p> <p>Minimum Volume: 0.5 mL</p> <p>Transport Temperature: Refrigerated</p>
Alternate Specimen	<p>Serum: Red top</p> <p><b>Plasma: Lavender EDTA or Green lithium heparin</b></p>
Rejection Criteria	<b>Hemolyzed samples or hemolysis, body fluids.</b>
Stability	<p><b>Room temperature: 8 hours</b></p> <p><b>Refrigerated: 14 days</b></p> <p><b>Frozen: 90 days</b></p>
Methodology	Quantitative Enzyme Immunoassay
Reference Range	<b>0 - 10 mcgmol/L</b>
Performing Laboratory	Quest SJC

Update Existing Test	
Effective Date	7/18/2023
Name	Complete Atopic Dermatitis Panel
Code	COATD
Interface Order Code	3300231
Legacy Code	COATD
Notes	Malassezia Mix IgE/Manganese Superoxide Dismutase IgE: Result comment changes, Class discontinued - will be sent as TNP

Update Existing Test	
Effective Date	7/25/2023
Name	HIV-1 RNA Ultraquant
Code	HIVUL
Interface Order Code	3041700
Legacy Code	HIVULTRA
Notes	<p><b>HIV Viral Load Testing Notification</b></p> <p>The purpose of this notification is to inform clients of an upcoming change to the HIV-1 RNA, Ultra Quantitative viral load (HIVUL) test report. Currently, reports for specimens resulted as <b>Not detected</b> for HIV-1 contain the value <i>&lt;20 copies/mL</i> in the <b>HIV-1 RNA Quantitative</b> result field, indicating a viral load below the assay limit of detection (LOD). In order to meet certain state reporting requirements, specimens resulted as <b>Not detected</b> for HIV-1 will now contain the value <i>0 copies/mL</i> in the <b>HIV-1 RNA Quantitative</b> result field. Specimens determined to contain HIV-1 RNA will still be called <b>Detected</b> and the viral load will be reported in the <b>HIV-1 RNA Quantitative</b> result field. Specimens with very low viral loads between 1-19 copies/mL will continue to be reported as <b>Detected</b> with <i>&lt;20 copies/mL</i> reported in the result field. There is no change to the performance of the HIV-1 RNA assay. Results for all specimens prior to this change will remain unchanged. As indicated in the report messages, a <b>Not detected</b> result does not rule out infection.</p>

Update Existing Test	
Effective Date	7/11/2023
Name	Collagen Cross Linked N Telo peptide (NTX), 24H U w/Creat
Code	NTELO
Interface Order Code	3700491
Legacy Code	NTELO
Notes	Update to performing laboratory
Required Testing Changes	
Performing Laboratory	Quest SJC

Update Existing Test	
Effective Date	7/11/2023
Name	Collagen Cross Linked N Telo peptide, Urine with Creatinine
Code	NTXUR
Interface Order Code	3715700
Legacy Code	NTXURSP
Notes	Update to performing laboratory
Required Testing Changes	
Performing Laboratory	Quest SJC

Update Existing Test	
Effective Date	7/17/2023
Name	Parasite Identification, Worm
Code	PARID
Interface Order Code	3427500
Legacy Code	PARIQ
Notes	Update to specimen requirement and rejection criteria
Required Testing Changes	
Specimen Required	<p>Collect: Suspect nematode, cestode, trematode or other parasite</p> <p><b>Specimen Preparation: Submit worm in saline and other parasites in 70% alcohol as soon as possible in a screw capped plastic container that is leak proof. Specify specimen source.</b></p> <p><b>Transport Temperature: Contact reference laboratory</b></p>
Rejection Criteria	Stool sample, pinworm paddle, arthropods

Update Existing Test	
Effective Date	7/11/2023
Name	Thyroid Stimulating IgG (TSI)
Code	TSI
Interface Order Code	3426720
Legacy Code	TSIQ
Notes	
Required Testing Changes	
Rejection Criteria	Gross hemolysis, lipemia, icterus, plasma.

Inactivate Test With Replacement	
<b>Effective Date</b>	7/25/2023
Inactivated Test	
<b>Name</b>	Chlamydia and Neisseria Nucleic Acid by TMA
<b>Code</b>	CHGTM
<b>Legacy Code<sup>1</sup></b>	CHGCRNA
<b>Interface Order Code</b>	3091010
<b>Notes</b>	
Replacement Test	
<b>Name</b>	Chlamydia and Neisseria Testing by PCR
<b>Code</b>	COPCR
<b>CPT Code(s)</b>	87491, 87591
<b>Notes</b>	
Specimen Requirements	
<b>Specimen Required</b>	<p>Collect: Variable specimen types</p> <p>Specimen Preparation: Vaginal swab, endocervical swab, first catch urine, rectal swab, oropharyngeal swab. Swab specimens must be collected using the Alinity m Multi-Colect Collection Kit. Urine specimens must be first catch and the swab can be discarded. Patients should not have urinated more than one hour prior to collection.</p> <p>Minimum Volume: Determined by specimen type</p> <p>Transport Temperature: Varies see stability</p>
<b>Alternate Specimen</b>	Urine may be collected in a screw capped plastic container but must be transferred to the Alinity m Multi-Collect Collection Kit with 24 hours.
<b>Rejection Criteria</b>	Specimens submitted with the white cleaning swab or with two swabs. Swabs in any media (e.g., M4, UTM, or Aptima media) other than the Alinity m Multi-Collect Collection Kit. Urine specimens where the liquid level in the urine transport tube does not fall within the clear fill window of the transport tube label (do not overfill). Urine specimens in sterile containers that have exceeded the 24 hour stability. Specimens collected in liquid cytology containers or media will not be tested.
<b>Stability</b>	<p>Swab/urine in Multi-Collect</p> <p>Room temperature: 14 days</p> <p>Refrigerated: 14 days</p> <p>Frozen: 60 days</p> <p>Urine</p> <p>Room temperature: Unacceptable</p>

Refrigerated: 24 hours  
Frozen: 4 days

## Performing Information

<b>Methodology</b>	Polymerase Chain Reaction (PCR)
<b>Reference Range</b>	Not detected
<b>Performed Days</b>	Monday - Friday
<b>Turnaround Time</b>	3 - 5 days
<b>Performing Laboratory</b>	Warde Medical Laboratory

## Interface Information

<b>Legacy Code<sup>1</sup></b>	COPCR		
<b>Interface Order Code</b>	3000499		
<b>Result Code</b>	<b>Name</b>	<b>LOINC Code</b>	<b>AOE/Prompt<sup>2</sup></b>
3000503	Specimen Source	Not available	<b>Yes</b>
3000507	Chlamydia trachomatis	Not available	No
3000508	Neisseria gonorrhoeae	Not available	No

Inactivate Test With Replacement	
<b>Effective Date</b>	7/25/2023
Inactivated Test	
<b>Name</b>	Chlamydia trachomatis Nucleic Acid by TMA
<b>Code</b>	CHRNA
<b>Legacy Code<sup>1</sup></b>	CHRNA
<b>Interface Order Code</b>	3091100
<b>Notes</b>	
Replacement Test	
<b>Name</b>	Chlamydia Trachomatis Testing by PCR
<b>Code</b>	CHPCR
<b>CPT Code(s)</b>	87491
<b>Notes</b>	
Specimen Requirements	
<b>Specimen Required</b>	<p>Collect: Variable specimen types</p> <p>Specimen Preparation: Endocervical swab, first catch urine, rectal swab, oropharyngeal swab. Swab specimens must be collected using the Alinity m Multi-Collect Collection Kit. Urine specimens must be first catch and the swab can be discarded. Patients should not have urinated more than 1 hour prior</p> <p>Minimum Volume: Determined by specimen type</p> <p>Transport Temperature: Specimen in Multi-Collect tubes should be shipped refrigerated.</p>
<b>Alternate Specimen</b>	Urine may be collected in an screw capped plastic container but must be transferred to the Alinity m Multi-Collect collection kit with 24 hours.
<b>Rejection Criteria</b>	Specimens submitted with the white cleaning swab or with two swabs. Swabs in any media (e.g., M4, UTM, or Aptima media) other than the Alinity m Multi-Collect Collection Kit. Urine specimens where the liquid level in the urine transport tube does not fall within the clear fill window of the transport tube label (do not overfill). Urine specimens in sterile in sterile containers that have exceeded the 24 hour stability. Specimens collected in liquid cytology containers or media will not be tested.
<b>Stability</b>	<p>Swab/urine in Multi-Collect</p> <p>Room temperature: 14 days</p> <p>Refrigerated: 14 days</p> <p>Frozen: 60 days</p> <p>Urine</p> <p>Room temperature: Unacceptable</p>



Refrigerated: 24 hours  
Frozen: 4 days

## Performing Information

<b>Methodology</b>	Polymerase Chain Reaction (PCR)
<b>Reference Range</b>	Not detected
<b>Performed Days</b>	Monday - Friday
<b>Turnaround Time</b>	3 - 5 days
<b>Performing Laboratory</b>	Warde Medical Laboratory

## Interface Information

<b>Legacy Code<sup>1</sup></b>	CHPCR		
<b>Interface Order Code</b>	3000492		
<b>Result Code</b>	<b>Name</b>	<b>LOINC Code</b>	<b>AOE/Prompt<sup>2</sup></b>
3000496	Specimen Source	Not available	<b>Yes</b>
3000498	Chlamydia trachomatis	Not available	No

Inactivate Test With Replacement	
<b>Effective Date</b>	7/25/2023
Inactivated Test	
<b>Name</b>	Neisseria gonorrhoeae Nucleic Acid by TMA
<b>Code</b>	GCRNA
<b>Legacy Code<sup>1</sup></b>	GCRNA
<b>Interface Order Code</b>	3091200
<b>Notes</b>	
Replacement Test	
<b>Name</b>	Neisseria Gonorrhoeae Testing by PCR
<b>Code</b>	GCPCR
<b>CPT Code(s)</b>	87591
<b>Notes</b>	
Specimen Requirements	
<b>Specimen Required</b>	<p>Collect: Variable specimen types</p> <p>Specimen Preparation: Endocervical swab, first catch urine, rectal swab, oropharyngeal swab specimens.</p> <p>Swab specimens must be collected using the Alinity m Multi-Collect Collection Kit. Urine specimens must be first catch and the swab can be discarded. Patients should not have urinated more than 1 hr prior to collection.</p>
<b>Alternate Specimen</b>	Urine may be collected in an screw capped plastic container but must be transferred to the Alinity m Mult-Collect Collection Kit with 24 hours.
<b>Rejection Criteria</b>	Specimens submitted with the white cleaning swab or with two swabs. Swabs in any media (e.g., M4, UTM, or Aptima media) other than the Alinity m Multi-Collect Collection Kit. Urine specimens where the liquid level in the urine transport tube does not fall within the clear fill window of the transport tube label (do not overfill). Urine specimens in sterile containers that have exceeded the 24 hour stability. Specimens collected in liquid cytology containers or media will not be tested.
<b>Stability</b>	<p>Swab/urine in Multi-Collect</p> <p>Room temperature: 14 days</p> <p>Refrigerated: 14 days</p> <p>Frozen: 60 days</p> <p>Urine</p> <p>Room temperature: Unacceptable</p> <p>Refrigerated: 24 hours</p> <p>Frozen: 4 days</p>
Performing Information	

<b>Methodology</b>	Polymerase Chain Reaction (PCR)		
<b>Reference Range</b>	Not detected		
<b>Performed Days</b>	Monday - Friday		
<b>Turnaround Time</b>	3 - 5 days		
<b>Performing Laboratory</b>	Warde Medical Laboratory		
<b>Interface Information</b>			
<b>Legacy Code<sup>1</sup></b>	GCPCR		
<b>Interface Order Code</b>	3000482		
<b>Result Code</b>	<b>Name</b>	<b>LOINC Code</b>	<b>AOE/Prompt<sup>2</sup></b>
3000488	Specimen Source	Not available	<b>Yes</b>
3000491	Neisseria gonorrhoeae	Not available	No

Inactivate Test With Replacement	
<b>Effective Date</b>	7/25/2023
Inactivated Test	
<b>Name</b>	Trichomonas vaginalis RNA, Qualitative
<b>Code</b>	TRIVA
<b>Legacy Code<sup>1</sup></b>	TRIVA
<b>Interface Order Code</b>	3093500
<b>Notes</b>	
Replacement Test	
<b>Name</b>	Trichomonas vaginalis Testing by PCR
<b>Code</b>	TVPCR
<b>CPT Code(s)</b>	87661
<b>Notes</b>	
Specimen Requirements	
<b>Specimen Required</b>	<p>Collect: Variable specimen types</p> <p>Specimen Preparation: Endocervical swab, first catch urine, rectal swab, oropharyngeal swab. Swab specimens must be collected using the Alinity m Multi-Collect Collection Kit. Urine specimens must be first catch and the swab can be discarded. Patients should not have urinated more than 1 hour prior to collection.</p> <p>Minimum Volume: Determined by specimen type</p> <p>Transport Temperature: Specimens in Multi-Collect tubes should be shipped refrigerated.</p>
<b>Alternate Specimen</b>	Urine may be collected in an screw capped plastic container but must be transferred to the Alinity m Multi-Collect Collection Kit with 24 hours.
<b>Rejection Criteria</b>	Specimens submitted with the white cleaning swab or with two swabs. Swabs in any media (e.g., M4, UTM, or Aptima media) other than the Alinity m Multi-Collect Collection Kit. Urine specimens where the liquid level in the urine transport tube does not fall within the clear fill window of the transport tube label (do not overfill). Urine specimens in sterile containers that have exceeded the 24 hour stability. Specimens collected in liquid cytology containers or media will not be tested.
<b>Stability</b>	<p>Swab/urine in Multi-Collect</p> <p>Room temperature: 14 days</p> <p>Refrigerated: 14 days</p> <p>Frozen: 60 days</p> <p>Urine</p> <p>Room temperature: Unacceptable</p> <p>Refrigerated: 24 hours</p>

	Frozen: 4 days		
<b>Performing Information</b>			
<b>Methodology</b>	Polymerase Chain Reaction (PCR)		
<b>Reference Range</b>	Not detected		
<b>Performed Days</b>	Monday - Friday		
<b>Turnaround Time</b>	3 - 5 days		
<b>Performing Laboratory</b>	Warde Medical Laboratory		
<b>Interface Information</b>			
<b>Legacy Code<sup>1</sup></b>	TVPCR		
<b>Interface Order Code</b>	3000471		
<b>Result Code</b>	<b>Name</b>	<b>LOINC Code</b>	<b>AOE/Prompt<sup>2</sup></b>
3000474	Specimen Source	Not available	Yes
3000481	Trichomonas vaginalis	Not available	No

Inactivate Test Without Replacement	
Effective Date	7/25/2023
Name	Allergen - Tetanus Toxoid (RC208) IgE
Code	C208E
Legacy Code	C208E
Interface Code	3723770
Notes	

Inactivate Test Without Replacement	
Effective Date	7/25/2023
Name	Allergen - Cardamon (RF267) IgE
Code	F267E
Legacy Code	F267E
Interface Code	3723850
Notes	

Inactivate Test Without Replacement	
Effective Date	7/25/2023
Name	Allergen - Curry (F281) IgE
Code	F281E
Legacy Code	F281E
Interface Code	3723920
Notes	Suggested alternatives: RF317 Coriander IgE, PEPCE Cayenne IgE, F280 Black Pepper IgE

Inactivate Test Without Replacement	
Effective Date	7/25/2023
Name	Allergen - Tragacanth (F298) IgE
Code	F298E
Legacy Code	F298E
Interface Code	3723950
Notes	Suggested alternate is RF297 Gum Arabic

Inactivate Test Without Replacement	
Effective Date	7/11/2023
Name	N-telopeptide, Serum
Code	NTXS
Legacy Code	NTXS
Interface Code	3717980
Notes	

Reportable Range Update: Due to manufacturer's reagent issues, the following tests (see below) have had their upper reportable ranges changed from 100 kU/L to 50 kU/L.

Warde Test Code	Interface Order Code	Test Name
ARTIE	3351050	Artichoke IgE
CHAME	3350130	Cheese American IgE
CHCOE	3351230	Cheese Cottage IgE
BEBLE	3350520	Bean Black IgE
ANNSE	3350610	Annatto Seed IgE
JACHI	3300044	Jalapeno/Chipotle IgE
RDMAE	3350760	Maple Red (Acer Rubrum) IgE
HICSE	3350320	Hickory Shagbark (Carya Ovata) IgE
TURME	3351350	Turmeric IgE
SUGCE	3350490	Sugar Cane IgE
BABLE	3350100	Bass Black IgE
WBLFE	3351670	Walnut Black Food (J Nigra) IgE
VENIG	3300055	Venison IgE
PEROE	3350040	Perch Ocean IgE
NECT	3300272	Nectarine IgE
ZUCSE	3350350	Zucchini IgE
TAPIE	3350990	Tapioca IgE
SUSQE	3351170	Squash Summer IgE
BEAPE	3350930	Bean Pinto IgE
PEPCE	3351020	Pepper Cayenne IgE
MAPSE	3351410	Maple Sugar Tree (Acer Saccharum) IgE
WPOPL	3350010	Poplar White (Populus Alba) IgE
RHODE	3350070	Rhodotorula IgE
SMCOE	3350380	Smut Corn (Ustilago Maydis) IgE
PAVAE	3350410	Paecilomyces Varoitii IgE
HESAE	3351320	Helminthosporium Sativum/Drechslera IgE
GUXAE	3350640	Gum Xanthan IgE
MAYFL	3300047	Mayfly (Ephemeroptera) IgE
OAKRE	3351700	Oak Red (Quercus Rubra) IgE
WILBE	3350870	Willow Black (Salix Nigra) IgE
HORHA	3300015	Horse Hair IgE
ASPEF	3300041	Aspergillus Flavus IgE