Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2021

Update Notes

Update Summary		
New Test Activation	3/23/2021	APIXA - "Apixaban"
Update Existing Test	3/29/2021	C57F - "CD57, CD3, CD8 Flow Cytometry"
Update Existing Test	2/24/2021	CYAN - "Cyanide, Whole Blood"
Update Existing Test	2/24/2021	HHV6D - "Herpesvirus 6 A and B DNA, Quant"
Update Existing Test	2/24/2021	LEGSP - "Legionella Species by Qual PCR"
Update Existing Test	2/24/2021	MYCP - "Mycoplasma pneumoniae by PCR"
Update Existing Test	2/24/2021	PB19 - "Parvovirus B-19 DNA (PCR)"
Update Existing Test	3/15/2021	RNAP3 - " RNA Polymerase III Antibody"
Update Existing Test	2/24/2021	TOXDN - "Toxoplasma gondii DNA (PCR)"
Update Existing Test	3/22/2021	U17CR - "17-OH Cortico w/Creat 24-HR Ur"
Update Existing Test	3/29/2021	UFE - "Iron-Urine"
Inactivate Test With Replacement	3/23/2021	QFTBP - "Quantiferon TB Plus" replaced by QFTBI - "Quantiferon TB Plus"
Inactivate Test Without Replacement	3/1/2021	K86 - "Trimellitic Anhydride, TMA IgE"
Inactivate Test Without Replacement	3/1/2021	RF247 - "Honey IgE"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2021

New Test Activation			
Effective Date	3/23/2021		
Name	Apixaban		
Code	APIXA		
CPT Code(s)	80299		
Notes			
Specimen Requirements			
Specimen Required	Send 1.0 mL (0.5 mL minimum) plasma collected in a 3.2 % sodium citrate tube.		
Rejection Criteria	Hemolysis, grossly lipemic, clotted and icteric samples		
Stability	Room temperature: Unacceptable; Refrigerated: Unacceptable; Frozen: 28 days		
Performing Information			
Methodology	Chromogenic		
Reference Range	See report		
Performed Days	Tuesday		
Turnaround Time	7 - 10 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	APIXA		
Interface Order Code	3400430		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400430	Apixaban	74214-8	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 32 Y

Referral Testing

Collected: 02/24/2021 15:48 Received: 02/24/2021 15:48

Test Name	Result	Flag	Ref-Ranges	Units	Site
Apixaban	8			ng/mL	QCRL

The predicted steady state peak and trough levels for Apixaban (5 mg bid) are 59-302 ng/mL and 22-177 ng/mL, respectively. The lower limit of detection for this assay is 30 ng/mL. For more information on this test, refer to the FAQ.

For additional information, please refer to http://education.QuestDiagnostics.com/faq/FAQ189 (This link is being provided for informational/ educational purposes only.)

This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Nichols Institute, Chantilly, VA. It has not been cleared or approved by the FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

Test Performed at:
Quest Diagnostics Chantilly
Nichols Institute, 14225 Newbrook Dr.
Chantilly, VA 20153-0841 P W Mason MD, PhD

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

C224000023
WX0000003039
Printed D&T: 02/24/21 15:50

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2021

Update Existing Test	
Effective Date	3/29/2021
Name	CD57, CD3, CD8 Flow Cytometry
Code	C57F
Interface Order Code	3434250
Legacy Code	C57F
Notes	
Required Testing Changes	
Rejection Criteria	**Gross hemolysis**
Specimen Required	*Collect:* Lavender EDTA Send 5.0 mL (**3.0 mL minimum**) whole blood at room temperature in a lavender EDTA tube. **Pediatric Specimens:** **1.0 mL (0.5 mL minimum) whole blood collected in lavender EDTA tube.** Specimen must be received at Warde Medical Laboratory the day of collection. **Absolute count results provided with this test code require a CBC to be performed. The stability of the CBC is 48 hours. Please provide CBC collected the same day as the submitted specimen.**

Update Existing Test	
Effective Date	2/24/2021
Name	Cyanide, Whole Blood
Code	CYAN
Interface Order Code	3680540
Legacy Code	CYANAR
Notes	
Required Testing Changes	
Specimen Required	*Collect:* Gray top tube **(Sodium fluoride/potassium oxalate)** Draw blood in a gray top tube (sodium fluoride/Potassium Oxalate). Send 1.0 mL (0.4 mL minimum) **refrigerated.**
Stability	Room temperature: Undetermined; **Refrigerated: 7 days**; **Frozen: 3 months**
Turnaround Time	**8 - 11 days**
Performing Laboratory	**NMS Labs**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2021

Update Existing Test	
Effective Date	2/24/2021
Name	Herpesvirus 6 A and B DNA, Quant
Code	HHV6D
Interface Order Code	3687000
Legacy Code	HHV6DNARP
Notes	Update to specimen requirements, alternate specimens, stability and rejection criteria.
Required Testing Changes	
Specimen Required	*Collect*: Lavender EDTA Centrifuge, separate plasma from cells and send 1.0 mL (0.5 mL minimum) plasma frozen in a screw capped plastic vial. **Specimen source is required.**
Alternate Specimen	**Serum: Serum separator tube (SST)** CSF **Tissue: Fresh tissue in a sterile screw capped plastic container or paraffin embedded tissue block. Tissue samples run with disclaimer.**
Rejection Criteria	Heparinized specimens, **tissue in optimal cutting temperature compound.**
Stability	*Plasma:* Room temperature: 24 hours; Refrigerated: 5 days; Frozen: 3 months *Paraffin embedded tissue:* Room temperature: Indefinite; Refrigerated: Indefinite; Frozen: Unacceptable

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2021

Update Existing Test	
Effective Date	2/24/2021
Name	Legionella Species by Qual PCR
Code	LEGSP
Interface Order Code	3620900
Legacy Code	LEPCR
Notes	Update to specimen requirements, alternate specimens, stability and rejection criteria.
Required Testing Changes	
Specimen Required	*Collect:* Respiratory specimen: Bronchoalveolar Lavage (BAL) Send 2.0 mL (0.5 mL minimum) BAL frozen in a sterile screw capped plastic container or in viral transport media (Microtest M4). Specimen source required.
Alternate Specimen	Bronchial brushings, nasopharyngeal swab in viral transport media, sputum, tracheal aspirates or pleural fluid. **Fresh tissue in sterile screw capped container or paraffin embedded tissue block. (Tissue samples run with disclaimer).**
Rejection Criteria	**Tissue in optimal cutting temperature compound.**
Stability	*Bronchoalveolar Lavage (BAL):* Room temperature: 24 hours; Refrigerated: 5 days; Frozen: 6 months *Paraffin embedded tissue:* Room temperature: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2021

Update Existing Test	
Effective Date	2/24/2021
Name	Mycoplasma pneumoniae by PCR
Code	MYCP
Interface Order Code	3686250
Legacy Code	MYCPDNAR
Notes	Update to specimen requirements, alternate specimens, stability and rejection criteria.
Required Testing Changes	
Specimen Required	*Collect:* Respiratory specimen (sputum) Send 2.0 mL (0.5 mL minimum) sputum frozen in a sterile screw capped plastic container or in viral transport media. Specimen source is required.
Alternate Specimen	Tracheal aspirates, nasopharyngeal swab in viral transport media, pleural fluid, Bronchoalveolar lavage (BAL), bronchial brushings or CSF (1.0 mL). **Fresh tissue in sterile screw capped container or paraffin embedded tissue block. (Tissue samples run with disclaimer).**
Rejection Criteria	**Tissues in optimal cutting temperature compound.**
Stability	*Respiratory Specimen (sputum):* Room temperature: 24 hours; Refrigerated: 5 days; Frozen: 1 year ***Paraffin embedded tissue:*** **Room temperature: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2021

Update Existing Test	
Effective Date	2/24/2021
Name	Parvovirus B-19 DNA (PCR)
Code	PB19
Interface Order Code	3688400
Legacy Code	PARVOD
Notes	Updates to specimen requirements, alternate specimen, stability and rejection criteria
Required Testing Changes	
Specimen Required	*Collect:* Lavender EDTA Centrifuge, separate **plasma** from cells and send 1.0 mL (0.5 mL minimum) **plasma** frozen in a screw capped plastic vial. **Specimen source required.**
Alternate Specimen	**Serum separator tube (SST),** CSF, amniotic fluid, **bone marrow**, synovial fluid. **Tissue (freeze immediately)** and paraffin embedded tissue block.
Rejection Criteria	**Heparinized specimens, tissues in optimal cutting temperature compound.**
Stability	*Plasma:* **Room temperature: 24 hours; Refrigerated: 5 days**; Frozen: 6 months ***Bone Marrow:*** **Room temperature: 7 days; Refrigerated: 7 days; Frozen: 7 days** ***Fresh Tissue:*** **Room temperature: Unacceptable; Refrigerated: Unacceptable; Frozen: 6 months** *Paraffin embedded tissue:* Room temperature; Indefinitely; **Refrigerated: Indefinitely**; **Frozen: Indefinitely**

Update Existing Test	
Effective Date	3/15/2021
Name	RNA Polymerase III
Code	RNAP3
Interface Order Code	3423040
Legacy Code	RNAP3Q
Notes	
Required Testing Changes	
Name	RNA Polymerase III Antibody
Specimen Required	Draw blood in a SST. Centrifuge, separate and send **1.0 mL** serum (**0.5 mL** minimum) refrigerated in a screw capped plastic vial.
Rejection Criteria	Gross hemolysis; **grossly lipemic**
Methodology	**Enzyme Linked Immunosorbent Immunoassay**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2021

Update Existing Test	
Effective Date	2/24/2021
Name	Toxoplasma gondii DNA (PCR)
Code	TOXDN
Interface Order Code	3687180
Legacy Code	TOXDNA
Notes	Updates to alternate specimen, rejection criteria and stability.
Required Testing Changes	
Specimen Required	*Collect:* Serum separator tube (SST) Centrifuge, separate serum from cells and send 1.0 mL (0.5 mL minimum) serum frozen in a screw capped plastic vial.
Alternate Specimen	Plasma: Lavender EDTA CSF, ocular fluid, amniotic fluid, **tissue (freeze immediately)**
Rejection Criteria	Heparinized specimens, **tissues in optimal cutting temperature compound**
Stability	*Serum:* Room temperature: 8 hours; Refrigerated: 5 days; **Frozen: 3 months** *Tissue:* Room temperature: Unacceptable; Refrigerated: Unacceptable; Frozen: 3 months

Update Existing Test	
Effective Date	3/22/2021
Name	17-OH Cortico w/Creat 24-HR Ur
Code	U17CR
Interface Order Code	3424960
Legacy Code	17OHCORQ
Notes	Updates to specimen requirements and alternate specimens.
Required Testing Changes	
Specimen Required	*Collect:* 24-hour urine (refrigerate during collection) Send 20 mL (10 mL minimum) of 24 hour urine preserved with 10 g Boric acid collected in a plastic urine container.
Alternate Specimen	**24 hour urine preserved with 25 mL of 50% acetic acid or 30 mL of 6N HCl acid submitted in a plastic urine container.**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2021

Update Existing Test	
Effective Date	3/29/2021
Name	Iron-Urine
Code	UFE
Interface Order Code	3504080
Legacy Code	UFE
Notes	Updates to specimen requirements, alternate specimens, performed days and TAT.
Required Testing Changes	
Specimen Required	*Collect:* 24 hour urine without preservatives Send 10.0 mL (6.0 mL minimum) **aliquot of 24 hour urine in a screw capped plastic container**. Please specify the total 24-hour urine volume on the container.
Alternate Specimen	**No other acceptable specimens.**
Performed Days	Tuesday, Thursday, **Saturday**
Turnaround Time	**3 - 5 days**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2021

Inactivate Test With Replacement	
Effective Date	3/23/2021
Inactivated Test	
Name	Quantiferon TB Plus
Code	QFTBP
Legacy Code[1]	QFTBP
Interface Order Code	3000005
Notes	
Replacement Test	
Name	Quantiferon TB Plus
Code	QFTBI
CPT Code(s)	86480
Notes	
Specimen Requirements	
Specimen Required	*Collect:* QuantiFERON® Collection Kit - Call Laboratory: QFT-NIL Control - 1.0 mL (0.8 mL minimum) whole blood (gray cap white ring*) QFT-TB1 Antigen- 1.0 mL (0.8 mL minimum) whole blood (green cap white ring*) QFT-TB2 Antigen- 1.0 mL (0.8 mL minimum) whole blood (yellow cap white ring*) QFT-Mitogen Control - 1.0 mL (0.8 mL minimum) whole blood (purple cap white ring*) **** High Altitude Collection Kit tubes have a cap with a yellow ring.*** 1 - For each patient, collect 1.0 mL of blood by venipuncture directly into each of the four QuantiFERON® - TB Gold Plus blood collection tubes. The black mark on the side of the tube indicates the 1.0 mL fill volume. Under or overfilling tubes my produce erroneous results. If a "butterfly needle" is being used to collect blood, a "purge" tube should be used to ensure that the tubing is filled with blood prior to the QFT-Plus Blood Collection Tubes being used. 2- Shake tubes 10 times immediately after filling the tube to ensure the entire surface of the tube is coated with blood to solubilize antigens in the tube walls. Overly energetic shaking may cause gel disruption and could lead to aberrant results. 3- Incubate all four (4) tubes upright at 37 °C for 16 - 24 hours. Incubation must commence within 16 hours of collections. **DO NOT REFRIGERATE or FREEZE WHOLE BLOOD SAMPLES.** 4 - After incubation, centrifuge 4 collection tubes for 15 minutes at 2000 - 3000 RCF (g). Spun samples are stable for 28 days at 2-8 °C (refrigerated). Transport refrigerated samples to Warde Medical Laboratory in the original collection tubes.
Rejection Criteria	Frozen tubes, unspun collection tubes, tubes with fill volumes below or above the black mark, specimens not in QuantiFERON® collection tubes, samples not incubated, or samples incubated in a water bath or heat block.

Stability	*Whole blood:* Room temperature: 16 hours from collection to 37 °C incubation Incubated and spun samples: 28 days at 2 - 8 °C Unspun samples: Unacceptable Frozen: Unacceptable
Performing Information	
Methodology	Chemiluminescence Immunoassay (CLIA)
Reference Range	Negative
Performed Days	Monday - Friday
Turnaround Time	3 days
Performing Laboratory	Warde Medical Laboratory
Interface Information	
Legacy Code[1]	QFTBI
Interface Order Code	3000244

Result Code	Name	LOINC Code	AOE/Prompt[2]
3000245	Nil	71776-9	No
3000246	Mitogen-Nil	71774-4	No
3000247	TB Ag 1 - Nil	64084-7	No
3000248	TB Ag 2 - Nil	64084-7	No
3000249	Quantiferon TB Plus	71773-6	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 32 Y

Immunology

Collected: 02/24/2021 15:55 Received: 02/24/2021 15:55

Test Name	Result	Flag	Ref-Ranges	Units	Site
Quantiferon TB Plus					
Nil	0.063			IU/mL	WMRL
Mitogen-Nil	5.740			IU/mL	WMRL
TB Ag 1 - Nil	0.080			IU/mL	WMRL
TB Ag 2 - Nil	0.060			IU/mL	WMRL
Quantiferon TB Plus	Negative				WMRL

A Negative result suggests that M. tuberculosis complex infection is not likely. However, a negative result does not rule out infection, particularly in patients with impaired immune function or patients suspected to have M. tuberculosis disease.

This test should not be used as the sole means for diagnosing or excluding active or latent tuberculosis. For more information, refer to the CDC guidelines for using interferon gamma release assays to detect Mycobacterium tuberculosis infection (MMWR 2010;59 (RR-05):1-25).

The preformance characteristics of the QFT-Plus test has not been evaluted in immune compromised patients, patients taking immunosuppressive drugs, pregnant women, and individuals younger than 18 years of age, Caution is warranted when evaluating QFT-Plus results from patients who have clinical conditions such as diabetes, silicosis, chronic renal failure, and hematological disorders (e.g., leukemia and lymphomas), or those with other specific malignancies(e.g.,carcinoma of the head or neck and lung).

Performing Site:
WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108

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

C224000025
WX0000003039
Printed D&T: 02/24/21 16:01

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MARCH 2021

Inactivate Test Without Replacement	
Effective Date	3/1/2021
Name	Trimellitic Anhydride, TMA IgE
Code	K86
Legacy Code	RAK86
Interface Code	3062580
Notes	

Inactivate Test Without Replacement	
Effective Date	3/1/2021
Name	Honey IgE
Code	RF247
Legacy Code	RARF247
Interface Code	3063300
Notes	