Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2021

Update Notes

Update Summary		
Update Existing Test	12/20/2021	3AG - "3a-Androstanediol Glucuronide"
Update Existing Test	12/13/2021	ALDMS - "Aldosterone, LC/MS/MS"
Update Existing Test	11/23/2021	DREN - "Direct Renin"
Update Existing Test	12/13/2021	ESTFL - "Estradiol, Free, LC/MS/MS"
Update Existing Test	11/23/2021	ESTRL – "Estriol, Serum"
Update Existing Test	12/20/2021	HEPXA - "Heparin Anti-Xa"
Update Existing Test	12/20/2021	IGA12 - "IgA Subclass 1 and 2"
Update Existing Test	11/23/2021	MBCFS - "Mycobacteria, Culture, with Fluorochrome Smear"
Update Existing Test	12/20/2021	SRALQ - "Serotonin Release Assay, LMWH"
Update Existing Test	12/20/2021	SRAQ - "Serot Rel Assay, Unfract Hep"
Inactivate Test With Replacement	12/20/2021	HIIGE - "HIV-1 Integrase Genotype" replaced by HVIGE - "HIV-1 Integrase Genotype"
Inactivate Test With Replacement	12/20/2021	HIVTO - "HIV-1 Genotype (RTI, PI, Integrase Inhibitors)" replaced by HVGII - "HIV-1 Genotype (RTI, PI, Integrase Inhibitors)"
Inactivate Test With Replacement	12/6/2021	STACH - "Stachybotrys chartarum/atra IgE*" replaced by STACE - "Stachybotrys chartarum/atra IgE"
Inactivate Test With Replacement	12/20/2021	STACP - "Stachybotrys Panel II" replaced by STAHP - "Stachybotrys Panel II"
Inactivate Test Without Replacement	12/31/2021	CASEA - "Casein IgA*"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2021

Update Existing Test	
Effective Date	12/20/2021
Name	3a-Androstanediol Glucuronide
Code	3AG
Interface Order Code	3501265
Legacy Code	3AG
Notes	Updates to patient preparation, rejection criteria, stability and TAT.
Required Testing Changes	
Specimen Required	*Patient Preparation:* **Overnight** fasting specimen is preferred *Collect:* Red top *Specimen Preparation:* Centrifuge, separate serum from cells and send 0.5 mL serum refrigerated in a screw capped plastic vial.
Rejection Criteria	**Moderately icteric**
Stability	Room temperature: **7 days** Refrigerated: 14 days Frozen (-20°C): 60 days Frozen (-70°C): **6 months**
Turnaround Time	**6 - 8 days**

Update Existing Test	
Effective Date	12/13/2021
Name	Aldosterone, LC/MS/MS
Code	ALDMS
Interface Order Code	3435340
Legacy Code	ALDMS
Notes	Updates to rejection criteria and performed days.
Required Testing Changes	
Rejection Criteria	Serum separator tube (SST), **moderate to gross hemolysis**
Performed Days	**Monday - Saturday**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2021

Update Existing Test	
Effective Date	11/23/2021
Name	Direct Renin
Code	DREN
Interface Order Code	1003995
Legacy Code	DREN
Notes	Updates to rejection criteria.
Required Testing Changes	
Rejection Criteria	Hemolyzed, grossly lipemic or icteric specimens, **Dark blue trace element EDTA**, non-frozen samples

Update Existing Test	
Effective Date	12/13/2021
Name	Estradiol, Free, LC/MS/MS
Code	ESTFL
Interface Order Code	3400086
Legacy Code	
Notes	Updates to transport temperature, rejection criteria and stability.
Required Testing Changes	
Specimen Required	*Specimen Preparation:* Centrifuge, remove serum from cells and send 1.0 mL serum in a screw capped plastic vial. *Transport Temperature:* **Frozen**
Rejection Criteria	Hemolysis, lipemia, serum separator tube (SST), **grossly icteric**
Stability	Room temperature: **24 hours** Refrigerated: 7 days Frozen: **28 days**

Update Existing Test	
Effective Date	11/23/2021
Name	Estriol, Serum
Code	ESTRL
Interface Order Code	3420240
Legacy Code	
Notes	Updates to stability.
Required Testing Changes	
Stability	Room temperature: **48 hours** Refrigerated: 7 days Frozen: 28 days

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2021

Update Existing Test	
Effective Date	12/20/2021
Name	Heparin Anti-Xa
Code	HEPXA
Interface Order Code	3424250
Legacy Code	HEPXAQ
Notes	Updates to stability.
Required Testing Changes	
Name	Heparin Anti-Xa
Stability	**Room temperature: Unacceptable** **Refrigerated: Unacceptable** **Frozen: 30 days**

Update Existing Test	
Effective Date	12/20/2021
Name	IgA Subclass 1 and 2
Code	IGA12
Interface Order Code	3718900
Legacy Code	IGASUB12
Notes	Updates to patient preparation, rejection criteria, stability, performed and TAT information.
Required Testing Changes	
Specimen Required	*Patient Preparation:* **Fasting preferred** *Collect:* Serum separator tube (SST) *Specimen Preparation:* Centrifuge, separate serum from cells and send 2.0 mL serum in a screw capped plastic vial.
Rejection Criteria	**Gross hemolysis; lipemia**
Stability	Room temperature: **5 days** Refrigerated: **15 days** Frozen: **30 days**
Performed Days	**Sunday, Thursday**
Turnaround Time	**4 - 6 days**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2021

Update Existing Test	
Effective Date	11/23/2021
Name	Mycobacteria, Culture, with Fluorochrome Smear
Code	MBCFS
Interface Order Code	3700535
Legacy Code	MBCFS
Notes	Updates to CPT codes.
Required Testing Changes	
CPT Code(s)	87116. 87206 billed on MC order. (Plus 87015, 87149, 87118, 87153, 87190 added as necessary at additional fees.)

Update Existing Test	
Effective Date	12/20/2021
Name	Serotonin Release Assay, LMWH
Code	SRALQ
Interface Order Code	3422600
Legacy Code	SRALMWHQ
Notes	Updates to stability.
Required Testing Changes	
Stability	Room temperature: **Unacceptable** Refrigerate: **Unacceptable** Frozen: 6 months

Update Existing Test	
Effective Date	12/20/2021
Name	Serot Rel Assay, Unfract Hep
Code	SRAQ
Interface Order Code	3422060
Legacy Code	SRAQ
Notes	Updates to stability.
Required Testing Changes	
Stability	Room temperature: **Unacceptable** Refrigerated: **Unacceptable** Frozen: 6 months

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2021

Inactivate Test With Replacement			
Effective Date	12/20/2021		
Inactivated Test			
Name	HIV-1 Integrase Genotype		
Code	HIIGE		
Legacy Code[1]	HIIGE		
Interface Order Code	3431211		
Notes			
Replacement Test			
Name	HIV-1 Integrase Genotype		
Code	HVIGE		
CPT Code(s)	87906		
Notes			
Specimen Requirements			
Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Centrifuge, separate plasma from cells within 6 hours of collection and send 2.0 mL plasma in a screw capped plastic vial. *Minimum Volume:* 0.6 mL *Transport Temperature*: Frozen		
Rejection Criteria	Serum, heparinized plasma, gross hemolysis, lipemia		
Stability	Room temperature: 24 hours Refrigerated: 6 days Frozen: 42 days		
Performing Information			
Methodology	Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), Sequencing		
Reference Range	See report		
Performed Days	Monday - Saturday		
Turnaround Time	6 - 10 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	HVIGE		
Interface Order Code	3400438		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400439	Value of Last Viral Load	Not available	**Yes**
3400440	Date of Load Collected	33882-2	**Yes**

3400441	Raltegravir Resistance	72525-9	No
3400442	Elvitegravir Resistance	72526-7	No
3400443	Dolutegravir Resistance	72857-6	No
3400444	Bictegravir Resistance	90080-3	No
3400445	Cabotgravir Resistance	96566-5	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: 11/22/2021 12:59 Received: 11/22/2021 12:59

Test Name	Result	Flag	Ref-Ranges	Units	Site
HIV-1 Integrase Genotype					
Value of Last Viral Load	12				QCRL
Date of Load Collected	11/21/2021				QCRL
Raltegravir Resistance	NOT PREDICTED				QCRL
Elvitegravir Resistance	NOT PREDICTED				QCRL
Dolutegravir Resistance	NOT PREDICTED				QCRL
Bictegravir Resistance	NOT PREDICTED				QCRL
Cabotgravir Resistance	NOT PREDICTED				QCRL

The Quest Diagnostics September 2021 Interpretation Algorithm

The method used in this test is RT-PCR and sequencing of the HIV-1 integrase gene. The phrases 'resistance predicted' and 'probable or emerging resistance' refer to the application of the interpretive rules. The FDA has not reviewed all of the interpretive rules used by the laboratory to predict drug resistance. FDA may not currently recognize some of the HIV gene mutations reported as predictive of drug resistance, but the laboratory considers these mutations to be associated with resistance to anti-viral drugs based on current clinical or scientific studies.

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

For more information on this test, go to:
http://education.questdiagnostics.com/faq/FAQ135
(This link is being provided for informational/educational purposes only.)

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

D122000000
WX0000003039
Printed D&T: 11/22/21 13:04

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2021

Inactivate Test With Replacement			
Effective Date	12/20/2021		
Inactivated Test			
Name	HIV-1 Genotype (RTI, PI, Integrase Inhibitors)		
Code	HIVTO		
Legacy Code[1]	HIVTO		
Interface Order Code	3400342		
Notes			
Replacement Test			
Name	HIV-1 Genotype (RTI, PI, Integrase Inhibitors)		
Code	HVGII		
CPT Code(s)	87900, 87901, 87906		
Notes			
Specimen Requirements			
Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Centrifuge and separate plasma from cells within 24 hours. Send 4.0 mL plasma in a screw capped plastic vial. *Minimum Volume:* 1.2 mL *Transport Temperature:* Frozen		
Rejection Criteria	Gross hemolysis, lipemia, serum, whole blood, heparinized plasma		
Stability	Room temperature: 24 hours Refrigerated: 6 days Frozen: 42 days		
Performing Information			
Methodology	Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) - Sequencing		
Reference Range	See report		
Performed Days	Monday - Saturday		
Turnaround Time	6 - 11 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	HVGII		
Interface Order Code	3400610		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400618	HIV 1 Genotype	48558-1	No
3400611	Value of Last Viral Load	Not available	**Yes**

3400612	Date Viral Load Collected	33882-2	**Yes**
3400613	Raltegravir Resistance	72525-9	No
3400614	Elvitegravir Resistance	72526-7	No
3400615	Dolutegravir Resistance	72857-6	No
3400616	Bictegravir Resistance	90080-3	No
3400617	Cabotegravir Resistance	96566-5	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: 11/23/2021 08:36 Received: 11/23/2021 08:36

Test Name	Result	Flag	Ref-Ranges	Units	Site

HIV-1 Genotype (RTI, PI, Integrase Inhibitors)

HIV 1 Genotype	NOT DETECTED				QCRL

The method used in this test is RT-PCR and sequencing
of the HIV-1 polymerase gene.

The phrases 'resistance predicted' and 'probable
or emerging resistance' refer to the application of
the interpretive rules. The FDA has not reviewed
all of the interpretive rules used by the laboratory
to predict drug resistance. FDA may not currently
recognize some of the HIV gene mutations reported as
predictive of drug resistance, but the laboratory
considers these mutations to be associated with
resistance to anti-viral drugs based on current
clinical or scientific studies. The test has been
validated pursuant to CLIA regulations and is not
considered investigational or for research use only.
Treatment decisions should be made in consideration of
all relevant clinical and laboratory findings and the
prescribing information for the drugs.

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

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

Value of Last Viral Load	45				QCRL
Date Viral Load Collected	11/11/2021				QCRL
Raltegravir Resistance	NOT PREDICTED				QCRL
Elvitegravir Resistance	NOT PREDICTED				QCRL
Dolutegravir Resistance	NOT PREDICTED				QCRL
Bictegravir Resistance	NOT PREDICTED				QCRL
Cabotegravir Resistance	NOT PREDICTED				QCRL

The Quest Diagnostics September 2021 Interpretation Algorithm

The method used in this test is RT-PCR and sequencing of

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 11/23/2021 08:36 Received: 11/23/2021 08:36

Test Name	Result	Flag	Ref-Ranges	Units	Site

the HIV-1 integrase gene. The phrases 'resistance predicted' and 'probable or emerging resistance' refer to the application of the interpretive rules. The FDA has not reviewed all of the interpretive rules used by the laboratory to predict drug resistance. FDA may not currently recognize some of the HIV gene mutations reported as predictive of drug resistance, but the laboratory considers these mutations to be associated with resistance to anti-viral drugs based on current clinical or scientific studies.

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

For more information on this test, go to:
http://education.questdiagnostics.com/faq/FAQ135
(This link is being provided for informational/educational purposes only.)

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2021

Inactivate Test With Replacement	
Effective Date	12/6/2021
Inactivated Test	
Name	Stachybotrys chartarum/atra IgE*
Code	STACH
Legacy Code[1]	STACH
Interface Order Code	3530440
Notes	
Replacement Test	
Name	Stachybotrys chartarum/atra IgE
Code	STACE
CPT Code(s)	86003
Notes	
Specimen Requirements	
Specimen Required	*Collect:* Red top *Specimen Preparation:* Centrifuge, separate serum from cells and send 0.5 mL serum in a screw capped plastic vial. *Minimum Volume:* 0.4 mL *Transport Temperature:* Refrigerated
Alternate Specimen	Serum separator tube (SST)
Rejection Criteria	Lipemia
Stability	Room temperature: 28 days Refrigerated: 28 days Frozen: 28 days
Performing Information	
Methodology	ImmunoCAP® FEIA
Reference Range	See report
Performed Days	Varies
Turnaround Time	3 - 4 days
Performing Laboratory	Viracor Eurofins
Interface Information	
Legacy Code[1]	STACE
Interface Order Code	3300265

Result Code	Name	LOINC Code	AOE/Prompt[2]
3300266	Stachybotrys chartarum/atra IgE*	19616-0	No

3300267	Class	Not available	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: 11/23/2021 08:41 Received: 11/23/2021 08:41

Test Name	Result	Flag	Ref-Ranges	Units	Site
Stachybotrys chartarum/atra IgE					
Stachybotrys chartarum/atra IgE*	**1.77**	**H**	<0.35	kU/L	VIRL
Class	2				VIRL

The test method is the Phadia ImmunoCAP allergen-specific IgE system.
CLASS INTERPRETATION <0.10 kU/L= 0, Negative; 0.10 - 0.34 kU/L= 0/1, Equivocal/Borderline; 0.35 - 0.69 kU/L=1, Low Positive; 0.70 - 3.49 kU/L=2, Moderate Positive; 3.50 - 17.49 kU/L=3, High Positive; 17.50 - 49.99 kU/L= 4, Very High Positive; 50.00 - 99.99 kU/L= 5, Very High Positive; >99.99 kU/L=6, Very High Positive
*This test was developed and its performance characteristics determined by Eurofins Viracor. It has not been cleared or approved by the U.S. Food and Drug Administration.

Testing Performed At:
Eurofins Viracor
1001 NW Technology Dr.
Lee's Summit MO 64086
Laboratory Director: Brock Neil Ph.D., BCLD (ABB)
CLIA#: 26D-0983643
Phone: 1(800)305-5198

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

Inactivate Test With Replacement			
Effective Date	12/20/2021		
Inactivated Test			
Name	Stachybotrys Panel II		
Code	STACP		
Legacy Code[1]	STACP		
Interface Order Code	3351440		
Notes			
Replacement Test			
Name	Stachybotrys Panel II		
Code	STAHP		
CPT Code(s)	86001 RUO, 86003		
Notes			
Specimen Requirements			
Specimen Required	*Collect:* Serum separator tube (SST) *Specimen Preparation:* Centrifuge, separate serum from cells and send 2.0 mL serum in a screw capped plastic vial. *Minimum Volume:* 1.0 mL *Transport Temperature*: Refrigerated		
Alternate Specimen	Serum: Red top		
Stability	Room temperature: 7 days Refrigerated: 28 days Frozen: >28 days		
Performing Information			
Methodology	Stachybotrys chartarum/atra IgE: ImmunoCAP® FEIA Stachybotrys chartarum/atra IgG: Enzyme Immunoassay (FEIA)		
Reference Range	See report		
Performed Days	Varies		
Turnaround Time	7 - 9 days		
Performing Laboratory	Viracor Eurofins		
Interface Information			
Legacy Code[1]	STAHP		
Interface Order Code	3300261		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3300262	Stachybotrys chartarum/atra IgE*	19616-0	No
3300264	Class	Not available	No

3300263	Stachybotrys chartarum/atra IgG*	42816-9	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: 11/23/2021 08:52 Received: 11/23/2021 08:52

Test Name	Result	Flag	Ref-Ranges	Units	Site
Stachybotrys Panel II					
Stachybotrys chartarum/atra IgE*	0.34		<0.35	kU/L	VIRL
Class	0/1				VIRL

The test method is the Phadia ImmunoCAP allergen-specific IgE system. CLASS INTERPRETATION <0.10 kU/L= 0, Negative; 0.10 - 0.34 kU/L= 0/1, Equivocal/Borderline; 0.35 - 0.69 kU/L=1, Low Positive; 0.70 - 3.49 kU/L=2, Moderate Positive; 3.50 - 17.49 kU/L=3, High Positive; 17.50 - 49.99 kU/L= 4, Very High Positive; 50.00 - 99.99 kU/L= 5, Very High Positive; >99.99 kU/L=6, Very High Positive

Stachybotrys chartarum/atra IgG*	11.0		<20.4	mcg/mL	VIRL

Antibody levels greater than the reference range indicate that the patient has been immunologically sensitized to the antigen. The significance of elevated IgG depends on the nature of the antigen and the patient's clinical history. The test method was the Phadia ImmunoCAP.
*This test was developed and its performance characteristics determined by Eurofins Viracor. It has not been cleared or approved by the U.S. Food and Drug Administration.

Testing Performed At:
Eurofins Viracor
1001 NW Technology Dr.
Lee's Summit MO 64086
Laboratory Director: Brock Neil Ph.D., BCLD (ABB)
CLIA#: 26D-0983643
Phone: 1(800)305-5198

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2021

Inactivate Test Without Replacement	
Effective Date	12/31/2021
Name	Casein IgA*
Code	CASEA
Legacy Code	CASEA
Interface Code	3350840
Notes	