Warde Medical Laboratory

TEST DIRECTORY UPDATE

MOLECULAR/VIROLOGY UPDATE 2024

Update Notes

This update contains minor changes with no set due date. Please make changes as your time permits.

Update Summary

Update Existing Test	CFMPL - "Cystic Fibrosis Mutation Panel"
Update Existing Test	CHC - "Chlamydia Culture"
Update Existing Test	CHPCR - "Chlamydia Testing by PCR"
Update Existing Test	CMVQA - "Cytomegalovirus DNA, Quantitative"
Update Existing Test	COPCR - "Chlamydia and Neisseria Testing by PCR"
Update Existing Test	CVP - "Comprehensive Virus Panel"
Update Existing Test	CVPCR - "SAR-CoV-2 PCR"
Update Existing Test	EBQL - "Epstein-Barr Virus DNA PCR, Qualitative"
Update Existing Test	EBVQN - "Epstein-Barr Virus DNA PCR, Quantitative"
Update Existing Test	F2PM - "Prothrombin 20210A Mutation Analysis"
Update Existing Test	F5LM - "Factor V Leiden Mutation Analysis"
Update Existing Test	FLPCR - "Influenza Virus A and B PCR"
Update Existing Test	GCPCR - "Neisseria gonorrheae Testing by PCR"
Update Existing Test	HBVQL - "Hepatitis B Virus (HBV) DNA, Qualitative"
Update Existing Test	HBVQN - "Hepatitis B Virus (HBV) DNA, Quantitative"
Update Existing Test	HCVQL - "Hepatitis C Virus (HCV) RNA, Qualitative"
Update Existing Test	HIVUL - "HIV-1 RNA Ultraquant"
Update Existing Test	HSVC - "Herpes Culture"
Update Existing Test	RCVP - "Respiratory Comprehensive Virus Panel"
Update Existing Test	TCVP - "Tissue Comprehensive Virus Panel"
Update Existing Test	TVPCR - "Trichomonas vaginalis Testing by PCR"
Update Existing Test	VC - "Virus Culture"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MOLECULAR/VIROLOGY UPDATE 2024

Update Existing Test	
Name	Cystic Fibrosis Mutation Panel
Code	CFMPL
Interface Order Code	3070431
Legacy Code	CFMPL
Notes	Update to specimen requirements, rejection criteria, methodology, performed days, and example report on website.
Required Testing Changes	
Specimen Required	*Collect*: Lavender top tube *Specimen Preparation*: Send 3.0 mL whole blood. ***Minimum Volume*: 0.5 mL** *Transport Temperature*: Refrigerated
Rejection Criteria	**Serum, plasma, heparinized whole blood, tissue, non-dedicated specimen**
Methodology	Multiplex Polymerase Chain Reaction (PCR); **Luminex TA Sorting**
Performed Days	**Tuesday, Friday**

Update Existing Test	
Name	Chlamydia Culture
Code	CHC
Interface Order Code	3093000
Legacy Code	CHC
Notes	Update to alternate specimen.
Required Testing Changes	
Alternate Specimen	Place 2.0 mL (1.0 mL minimum) cul-de-sac fluids undiluted in a sterile screw capped container. 1) Nasal aspirates in vacuum trap, 1.0 mL (0.5 mL minimum) 2) Nasal wash in an IATA-approved sterile screw-capped plastic container, 2.0 mL (1.0 mL minimum) 3) Bronchoalveolar lavage/wash in an IATA-approved sterile, screw capped plastic container, 2.0 mL (1.0 mL minimum). **4) Placental, fallopian and/or uterine tissue specimens in saline or viral transport medium (snap frozen -20°C)** The Laboratory Director or Supervisor must approve testing of specimens other than those listed above.

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000073111 F 02/15/1985 39 Y

Molecular

Collected: 08/01/2024 13:53 Received: 08/01/2024 13:53

Test Name	Result	Flag	Ref-Ranges	Units	Site

Cystic Fibrosis Mutation Panel

Cystic Fibrosis Mutation Analysis — See Below — WMRL

Result: Normal Genotype

Interpretation:
This individual is negative for the 39 Cystic Fibrosis (CF) mutations included in this assay, indicating a reduced risk for CF. These results do not exclude all pathogenic CFTR mutations. An individual's residual risk after a negative test varies by ancestry (see table below).

Estimated carrier risk:

Ethnic group	Detection Rate	Risk Before Test	Residual Risk After Negative Test
Ashkenazi Jewish	94%	1/24	1 in 400
European Caucasian	91%	1/25	1 in 263
African American	68%	1/61	1 in 187
Hispanic American	74%	1/58	1 in 221
Asian American	49%	1/94	1 in 184

NOTE:
Limited information is available for individuals from other ethnic populations. Residual carrier risk after a negative test is modified by the presence of a positive family history of CF (i.e., having a first, second, or third degree relative affected with CF) and/or by a mixture of various ethnic groups. For these specific situations, accurate risk assessment requires standard Bayesian analysis and genetic counseling.

Methodology: Multiplex targeted amplification and direct mutation analysis using the Luminex analyzer was performed to test for the presence of 39 mutations within the CFTR gene (GenBank accession number NM_00492). A full list of mutations tested for by this assay can be found at the Warde Laboratory website:
(https://wardelab.com/resources/forms)
under "CFMPL Cystic Fibrosis Mutation Panel List of Variants Targeted".

Limitations: This assay does not include all known CF-causing pathogenic variants. The absence of a variant does not rule out the possibility of this individual being

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000073111 F 02/15/1985 39 Y

Molecular

Collected: 08/01/2024 13:53 Received: 08/01/2024 13:53

Test Name	Result	Flag	Ref-Ranges	Units	Site

a carrier of or affected with CF. The results of this test should not be used as the sole means for clinical diagnosis or patient management decisions.

Reported Date: 08/01/2024 13:54 CFMPL

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

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000072099 M 12/05/1988 35 Y

Molecular

Collected: 08/01/2024 13:57 Received: 08/01/2024 13:57

Test Name	Result	Flag	Ref-Ranges	Units	Site

Cystic Fibrosis Mutation Panel

Cystic Fibrosis Mutation Analysis	**See Below**	**AB**	WMRL

Result: Heterozygous for I507del mutation

Interpretation:
This patient is a cystic fibrosis (CF) carrier. The DNA of this patient contains one gene with the I507 deletion (c.1519_1521del) in the cystic fibrosis transmembrane conductance regulator (CFTR) gene and one normal CFTR gene. CF carriers do not exhibit a CF phenotype but the patient has a 1 in 2 chance of transmitting the CF gene to their child. Genetic counseling is recommended. CF testing of the partner may be indicated.

Methodology: Multiplex targeted amplification and direct mutation analysis using the Luminex analyzer was performed to test for the presence of 39 mutations within the CFTR gene (GenBank accession number NM_00492). A full list of mutations tested for by this assay can be found at the Warde Laboratory website:
(https://wardelab.com/resources/forms)
under "CFMPL Cystic Fibrosis Mutation Panel List of Variants Targeted".

Limitations: This assay does not include all known CF-causing pathogenic variants. The absence of a variant does not rule out the possibility of this individual being a carrier of or affected with CF. The results of this test should not be used as the sole means for clinical diagnosis or patient management decisions.

Reported Date: 08/01/2024 13:58 CFMPL

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

B601001079
WX0000072099
Printed D&T: 08/01/24 13:58

Ordered By: CLIENT CLIENT
WX00000000494009

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MOLECULAR/VIROLOGY UPDATE 2024

Update Existing Test	
Name	Chlamydia Testing by PCR
Code	CHPCR
Interface Order Code	3000492
Legacy Code	CHPCR
Notes	Update to rejection criteria and specimen preparation.
Required Testing Changes	
Specimen Required	*Collect*: Variable specimen types *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 less than 1 hour prior.** *Minimum Volume*: Determined by specimen type *Transport Temperature*: Specimen in Multi-Collect tubes should be shipped refrigerated.
Rejection Criteria	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. Male urethral swab

Update Existing Test	
Name	Cytomegalovirus DNA, Quantitative
Code	CMVQA
Interface Order Code	3092501
Legacy Code	CMVQA
Notes	Update to rejection criteria, methodology, reference range, and example report on website.
Required Testing Changes	
Rejection Criteria	**Whole Blood Specimens (plasma must be separated prior to receipt), shared specimens, specimens that do not meet the collection storage/handling conditions criteria above.**
Methodology	This test uses the polymerase chain reaction to amplify conserved regions of the cytomegalovirus (CMV) UL34 and UL80.5 genes. Real-time detection and quantification are used to determine the viral concentration. **The analytical measurement range is 30-10 million IU/mL (1.0 to 7.0 log 10 IU/mL). The qualitative limit of detection is 30 IU/mL (1.49 log 10 IU/mL) compared to the WHO International Standard.** Specimens reported as POSITIVE but <50 IU/mL contain detectable levels of CMV DNA but the viral load is below the limit of quantitation. A negative result does not rule out infection.
Reference Range	Not Detected **<30 IU/mL** **<1.48 log10 IU/mL**

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000072099 M 12/05/1988 35 Y

Molecular

Collected: 08/01/2024 13:50 Received: 08/01/2024 13:50

Test Name	Result	Flag	Ref-Ranges	Units	Site
Cytomegalovirus DNA, Quantitative					
Cytomegalovirus DNA, Qualitative	Not detected		Not detected		WMRL
Cytomegalovirus DNA, Quantitative	<30		<30	IU/mL	WMRL
Log Cytomegalovirus	<1.48		<1.48	Log (10) IU/mL	WMRL
CMV DNA (cp/mL)	<76		<76	Copies/mL	WMRL

This test uses a polymerase chain reaction (PCR) assay from Abbott Molecular Inc. to amplify and detected conserved regions of the cytomegalovirus (CMV) genome that have been extracted from plasma. Real-time detection and quantification are used to determine the viral concentration. The analytical measurement range is 30 IU/mL to 10 million IU/mL (1.48 to 7.00 log10 IU/mL). The lower limit of detection is 30 IU/mL (1.48 log10 IU/mL).

Specimens reported as DETECTED but <30 IU/mL contain detectable levels of CMV DNA but the viral load is less than the lower limit of quantitation (30 IU/mL). A negative result does not rule out infection.

Reported Date: 08/01/2024 13:50 CMVQA

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

B601001064
WX0000072099
Printed D&T: 08/01/24 13:50

Ordered By: CLIENT CLIENT
WX00000000494009

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1

Update Existing Test	
Name	Chlamydia and Neisseria Testing by PCR
Code	COPCR
Interface Order Code	3000499
Legacy Code	COPCR
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	*Collect*: Variable specimen types *Specimen Preparation*: Vaginal swab, 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 less than one hour prior to collection.** *Minimum Volume*: Determined by specimen type *Transport Temperature*: Varies, see stability

Update Existing Test	
Name	Comprehensive Virus Panel
Code	CVP
Interface Order Code	3000846
Legacy Code	CVP
Notes	Update to stability and example report on website.
Required Testing Changes	
Stability	Room temperature (18-25°C): 4 hours Refrigerated (2-8°C): 7 days **Frozen (-20°C): 14 days** Frozen (-70°C): 3 months

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000072099 M 12/05/1988 35 Y

Molecular

Collected: 08/01/2024 13:43 Received: 08/01/2024 13:43

Test Name	Result	Flag	Ref-Ranges	Units	Site
Comprehensive Virus Panel					
Client Source/ Not Reported	CSF				WMRL
Specimen Source	CSF				WMRL
Herpes simplex Type I	**DETECTED**	**AB**	Not detected		WMRL
Herpes simplex Type 2	**DETECTED**	**AB**	Not detected		WMRL
Varicella Zoster Virus	**DETECTED**	**AB**	Not detected		WMRL
Cytomegalovirus	**DETECTED**	**AB**	Not detected		WMRL
Adenovirus	**DETECTED**	**AB**	Not detected		WMRL
Enterovirus	**DETECTED**	**AB**	Not detected		WMRL

This specimen was tested for multiple viruses by individual PCR reactions. The nucleic acid targets may include the glycoprotein G gene of HSV-1, the glycoprotein G/J junction of HSV-2, the VZV open reading frame 62, the CMV DNA polymerase gene, the adenovirus hexon gene, the 5' non-translated region of the enterovirus genome, the 5' untranslated region of rhinovirus, and the RNA polymerase gene of norovirus.

The specific viruses tested depend on the specimen source and are indicated in the result field. The analytical sensitivity for these assays are 50 copies/mL for HSV-1, HSV-2, and VZV; 150 copies/mL for enterovirus; 200 copies/mL for adenovirus and rhinovirus; 600 copies/mL for CMV, and 100 copies/mL for norovirus.

This procedure utilizes multiple real-time polymerase chain reaction amplification and detection tests. A "Not detected" result does not rule out infection.

This test uses commercial reagents that have not been approved or cleared by the FDA. The FDA has determined that such clearance or approval is not necessary. The performance characteristics of this procedure were determined by Warde Medical Laboratory.

Rhinovirus	NO BILL				WMRL
Norovirus Group 1	NO BILL				WMRL
Norovirus Group 2	NO BILL				WMRL

Reported Date: 08/01/2024 13:44 CVP

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

B601001052
WX0000072099
Printed D&T: 08/01/24 13:44

Ordered By: CLIENT CLIENT
WX00000000494009

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MOLECULAR/VIROLOGY UPDATE 2024

Update Existing Test	
Name	SAR-CoV-2 PCR
Code	CVPCR
Interface Order Code	3000878
Legacy Code	CVPCR
Notes	Update to alternate specimen and example report on website.
Required Testing Changes	
Alternate Specimen	One oropharyngeal swab or NP/OP sent frozen in viral transport media. Nasal swab sent frozen in viral transport media. Our internal studies show that Phosphate Buffered Saline (PBS) and sterile saline do not interfere with the analytical performance of the COVID-19 assay. Liquid Amies buffer may decrease the analytical sensitivity of the assay and should be used only when other transport media are not available. **Bronchoalveolar lavage/wash in sterile, leak-proof container.**

Update Existing Test	
Name	Epstein-Barr Virus DNA PCR, Qualitative
Code	EBQL
Interface Order Code	3000075
Legacy Code	EBQL
Notes	Update to stability, rejection criteria, methodology, and example report on website.
Required Testing Changes	
Rejection Criteria	**Serum, heparinized plasma, whole blood, specimens submitted to repeated freeze-thaw cycles**
Stability	**Room temperature: 24 hours** **Refrigerated: 5 days** Frozen (-20°C): 30 days Frozen (-70°C): 6 months
Methodology	This test uses the polymerase chain reaction to amplify regions of the Epstein Barr Virus BLLF1 gene. Real-time detection and quantification are used to determine the viral concentration. **The qualitative limit of detection is 20 IU/mL (1.3 log (10) IU/mL).** **Specimens reported as "Detected" but <50 IU/mL, contain detectable levels of EB Virus DNA, but the viral load is below the limit of quantification.** A "Not Detected" result does not rule out infection.

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000073111 F 02/15/1985 39 Y

Molecular

Collected: 08/01/2024 13:45 Received: 08/01/2024 13:45

Test Name	Result	Flag	Ref-Ranges	Units	Site
SAR-CoV-2 PCR					
Specimen Source	Nasopharyngeal Swab				WMRL
SAR-CoV-2	Not detected		Not detected		WMRL

This test utilizes a real-time polymerase chain reaction procedure to amplify and detect conserved sequences in the N1 and N2 genes in the SARS-CoV-2 genome. The analytical sensitivity of this assay is 500 copies/mL. A "Not detected" result does not rule out infection.

This test uses commercial reagents that have not been approved or cleared by the FDA. The FDA has determined that such clearance or approval is not necessary. The performance characteristics of this procedure were determined by Warde Medical Laboratory.

Reported Date: 08/01/2024 13:46 CVPCR

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

B601001059
WX0000073111
Printed D&T: 08/01/24 13:46

Ordered By: CLIENT CLIENT
WX00000000409391

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000073111 F 02/15/1985 39 Y

Molecular

Collected: 08/01/2024 13:51 Received: 08/01/2024 13:51

Test Name	Result	Flag	Ref-Ranges	Units	Site
Epstein-Barr DNA PCR, Qualitative					
Epstein-Barr Virus DNA, Qualitative	**DETECTED**	**AB**	Not detected		WMRL

This test uses real-time polymerase chain reaction (PCR) from Abbott Molecular systems to amplify and detect regions of the Epstein Barr Virus genome extracted from plasma or CSF specimens. The qualitative limit of detection is 20 IU/mL (1.3 log(10) IU/mL). A "Not Detected" result does not rule out infection.

Reported Date: 08/01/2024 13:51 EBQL

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

B601001068
WX0000073111
Printed D&T: 08/01/24 13:51

Ordered By: CLIENT CLIENT
WX00000000409391

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MOLECULAR/VIROLOGY UPDATE 2024

Update Existing Test	
Name	Epstein-Barr Virus DNA PCR, Quantitative
Code	EBVQN
Interface Order Code	3000071
Legacy Code	EBVQN
Notes	Update to specimen stability, rejection criteria, methodology, reference range, and example report on website.
Required Testing Changes	
Rejection Criteria	**Serum, heparinized plasma, whole blood, specimens submitted to repeated freeze-thaw cycles**
Stability	**Room temperature: 24 hours** **Refrigerated: 5 days** Frozen (-20°C): 30 days Frozen (-70°C): 6 months
Methodology	Polymerase Chain Reaction (PCR) This test uses the polymerase chain reaction to amplify regions of the Epstein Barr Virus BLLF1 gene. Real-time detection and quantification are used to determine the viral concentration. **The analytical measurement range is 50 to 200 million IU/mL (1.7 to 8.3 log (10) IU/mL). The qualitative limit of detection is 20 IU/mL (1.3 log (10) IU/mL).** **Specimens reported as "DETECTED" but <50 IU/mL, contain detectable levels of EB Virus DNA but the viral load is below the limit of quantification.** A "NOT DETECTED" result does not rule out infection.
Reference Range	EBV Qualitative: Not Detected **EBV Quantitative: <50 IU/mL** **Log EBV: <1.7 log(10) IU/mL**

Update Existing Test	
Name	Prothrombin 20210A Mutation Analysis
Code	F2PM
Interface Order Code	3000308
Legacy Code	F2PM
Notes	Update to specimen requirements, rejection critiera, and performed days.
Required Testing Changes	
Specimen Required	*Collect*: Lavender EDTA *Specimen Preparation*: Send 5.0 mL whole blood ***Minimum Volume*: 0.5 mL** *Transport Temperature*: Refrigerated
Rejection Criteria	**Serum, plasma, heparinized whole blood, tissue, non-dedicated specimen**
Performed Days	**Monday, Wednesday, Friday**

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000072099 M 12/05/1988 35 Y

Molecular

Collected: 08/01/2024 13:52 Received: 08/01/2024 13:52

Test Name	Result	Flag	Ref-Ranges	Units	Site
Epstein-Barr Virus DNA PCR, Quantitative					
Epstein-Barr Virus DNA, Qualitative	Not detected		Not detected		WMRL
Epstein-Barr Virus DNA, Quantitative	<50		<50	IU/mL	WMRL
Log Epstein-Barr Virus DNA	<1.70		<1.70	Log (10) IU/mL	WMRL

This test uses real-time polymerase chain reaction (PCR) from Abbott Molecular systems to amplify and detect regions of the Epstein Barr Virus genome extracted from plasma or CSF specimens. Real-time detection and quantification are used to determine the viral concentration. The analytical measurement range is 50 to 200 million IU/mL (1.7 to 8.3 log(10) IU/mL). The qualitative limit of detection is 20 IU/mL (1.3 log(10) IU/mL).

Specimens reported as "DETECTED" but <50 IU/mL, contain detectable levels of EB Virus DNA, but the viral load is below the limit of quantification. A "Not Detected" result does not rule out infection.

Reported Date: 08/01/2024 13:52 EBVQN

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

B601001069
WX0000072099
Printed D&T: 08/01/24 13:52

Ordered By: CLIENT CLIENT
WX00000000494009

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MOLECULAR/VIROLOGY UPDATE 2024

Update Existing Test	
Name	Factor V Leiden Mutation Analysis
Code	F5LM
Interface Order Code	3000306
Legacy Code	F5LM
Notes	Update to specimen requirements and performed days.
Required Testing Changes	
Specimen Required	*Collect*: Lavender EDTA *Specimen Preparation*: Send 5.0 mL whole blood. ***Minimum Volume*: 0.5 mL** *Transport Temperature*: Refrigerated
Performed Days	**Monday, Wednesday, Friday**

Update Existing Test	
Name	Influenza Virus A and B PCR
Code	FLPCR
Interface Order Code	3091830
Legacy Code	FLUPCR
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	*Collect*: Variable specimen types *Specimen Preparation*: Specimen source is required. **NP and Throat swabs in viral transport medium.** Swabs in culturettes must be transferred to viral transport within 24 hours of collection. Bronchoalveolar lavage/wash in a sterile screw capped plastic container. Send 1.0 mL (0.5 mL minimum). Sputum undiluted in a sterile screw capped plastic container. Send 1.0 mL (0.5 mL minimum). Nasal aspirates in vacuum trap. 1.0 mL (0.5 mL minimum). Nasal washes in a sterile screw capped plastic container 1.0 mL (0.5 mL minimum). *Minimum Volume*: Determined by specimen type *Transport Temperature*: Varies by specimen type, **tissues must be sent frozen**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MOLECULAR/VIROLOGY UPDATE 2024

Update Existing Test	
Name	Neisseria gonorrheae Testing by PCR
Code	GCPCR
Interface Order Code	3000482
Legacy Code	GCPCR
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	*Collect*: Variable specimen types *Specimen Preparation*: Endocervical swab, first catch urine, rectal swab, oropharyngeal swab specimens. 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 less than 1 hour prior to collection.**

Update Existing Test	
Name	Hepatitis B Virus (HBV) DNA, Qualitative
Code	HBVQL
Interface Order Code	3092000
Legacy Code	HBVQUAL
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	*Collect*: Lavender EDTA *Specimen Preparation*: Centrifuge and separate from cells within 6 hours of collection. Send 3.0 mL plasma in a screw capped plastic vial. Dedicated specimens are required. Specimens used in other assays will not be tested. *Minimum Volume*: 2.5 mL ***Transport Temperature*: Frozen**

Update Existing Test	
Name	Hepatitis B Virus (HBV) DNA, Quantitative
Code	HBVQN
Interface Order Code	3041500
Legacy Code	HBVQUANT
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	*Collect*: Lavender EDTA *Specimen Preparation*: Centrifuge and separate plasma from cells within 6 hours of collection. Send 3.0 mL plasma in a screw capped plastic vial. Dedicated specimens are required. Specimens used in other assays will not be tested. *Minimum Volume*: 2.5 mL ***Transport Temperature*: Frozen**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MOLECULAR/VIROLOGY UPDATE 2024

Update Existing Test	
Name	Hepatitis C Virus (HCV) RNA, Qualitative
Code	HCVQL
Interface Order Code	3010550
Legacy Code	HCVQUAL
Notes	Update to performed days.
Required Testing Changes	
Performed Days	**Monday - Friday**

Update Existing Test	
Name	HIV-1 RNA Ultraquant
Code	HIVUL
Interface Order Code	3041700
Legacy Code	HIVULTRA
Notes	Update to example report on website.

Update Existing Test	
Name	Herpes Culture
Code	HSVC
Interface Order Code	3093600
Legacy Code	HSVC
Notes	Update to specimen requirements, stability, and rejection criteria.
Required Testing Changes	
Specimen Required	*Collect*: Variable specimen types *Specimen Preparation*: **Swab specimens in viral transport medium. 3.0 mL (1.0 mL minimum). Biopsy/tissue specimens in saline or viral transport medium (Snap frozen -20°C).** *Minimum Volume*: 1.0 mL *Transport Temperature*: Varies with specimen type, see stability
Rejection Criteria	The following specimen types will not be tested: CSF or body fluids; CNS tissue; Urine; Stool; **Whole blood, plasma, or serum**; Specimens in proprietary PCR transport media; Specimens in bacterial transport media, Stewart medium (Culturette), gel, or charcoal transports; Specimens in bacteriological blood culture media; Dry swabs, wooden swabs, calcium alginate swabs; Tissues received in transport media that has not been frozen (-20°C); Frozen specimens (except tissues); Specimens received in non-sterile or leaking containers.
Stability	**Swab:** Room temperature: 4 hours Refrigerated: 7 days **Frozen: Do Not Freeze (except tissue specimens)** Tissue and Biopsy: Room temperature: 4 hours Refrigerated: Unacceptable **Frozen (-20°C): 30 days** **Frozen (-70°C): 3 months**

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000073111 F 02/15/1985 39 Y

Molecular

Collected: 08/01/2024 13:59 Received: 08/01/2024 13:59

Test Name	Result	Flag	Ref-Ranges	Units	Site
HIV-1 RNA Ultraquant					
HIV-1 RNA Qualitative	**DETECTED**	**AB**	Not detected		WMRL
HIV-1 RNA Quantitative	**56**	**H**	<20	Copies/mL	WMRL
LOG HIV RNA	**1.75**	**H**	<1.30	Log (10) Copies/mL	WMRL
HIV-1 Date Received	8/1/24				WMRL
HIV-1 Date Completed	8/1/24				WMRL

This test utilizes a real-time reverse-transcriptase polymerase chain reaction (RT-PCR) assay from Abbott Molecular Systems to amplify and detect HIV-1 RNA genomic sequences that have been extracted from plasma or serum specimens. This test is intended for use alongside clinical presentation and other laboratory markers as an indicator of disease prognosis. This test may also aid in assessing the viral response to antiretroviral treatment as measured by changes in plasma or serum HIV-1 RNA levels. This test should not be used to establish a diagnosis of HIV-1 infection. The limit of detection and the lower limit of quantitation are 20 copies/mL (1.30 log copies/mL). The upper limit of quantitation is 10,000,000 copies/mL (7.00 log copies/mL).

Specimens reported as DETECTED but <20 copies/mL contain detectable level of HIV-1 RNA but the viral load is below the limit of quantitation. A "Not detected" result does not rule out infection.

Reported Date: 08/01/2024 14:00 HIVUL

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

B601001081
WX0000073111
Printed D&T: 08/01/24 14:00

Ordered By: CLIENT CLIENT
WX00000000409391

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1

Update Existing Test	
Name	Respiratory Comprehensive Virus Panel
Code	RCVP
Interface Order Code	3000859
Legacy Code	RCVP
Notes	Update to stability and example report on website.
Required Testing Changes	
Stability	Room temperature: 4 Hours Refrigerated (2-8°C): 7 Days **Frozen (-20°C): 14 days** Frozen (-70°C): 3 months

Update Existing Test	
Name	Tissue Comprehensive Virus Panel
Code	TCVP
Interface Order Code	3000827
Legacy Code	TCVP
Notes	Update to example report on website.

Update Existing Test	
Name	Trichomonas vaginalis Testing by PCR
Code	TVPCR
Interface Order Code	3000471
Legacy Code	TVPCR
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	*Collect*: Variable specimen types *Specimen Preparation*: Endocervical swab, first catch urine. 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 less than 1 hour prior to collection.** *Minimum Volume*: Determined by specimen type *Transport Temperature*: Specimens in Multi-Collect tubes should be shipped refrigerated.

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000073111 F 02/15/1985 39 Y

Molecular

Collected: 08/01/2024 13:48 Received: 08/01/2024 13:48

Test Name	Result	Flag	Ref-Ranges	Units	Site
Respiratory Comprehensive Virus Panel					
Specimen Source	Respiratory - Lower				WMRL
Herpes simplex Type I	Not detected		Not detected		WMRL
Herpes simplex Type 2	Not detected		Not detected		WMRL
Cytomegalovirus	Not detected		Not detected		WMRL
Adenovirus	Not detected		Not detected		WMRL
Enterovirus	Not detected		Not detected		WMRL
Influenza A	**DETECTED**	**AB**	Not detected		WMRL
Influenza B	Not detected		Not detected		WMRL
Respiratory Syncytial Virus	Not detected		Not detected		WMRL
Rhinovirus	Not detected		Not detected		WMRL
Parainfluenza 1	Not detected		Not detected		WMRL
Parainfluenza 2	Not detected		Not detected		WMRL
Parainfluenza 3	Not detected		Not detected		WMRL
SAR-CoV-2	Not detected		Not detected		WMRL

This specimen was tested for multiple viruses by individual PCR reactions. The nucleic acid targets include the glycoprotein G gene of HSV-1, the glycoprotein G/J junction of HSV-2, the CMV DNA polymerase gene, the adenovirus hexon gene, the 5' non-translated region of the enterovirus genome; the matrix gene from influenza A virus, the NS1 gene from influenza B, the HN gene of parainfluenza 1,2, and 3, the RSV RNA polymerase gene, the N1 and N2 genes of SARS-CoV-2, and the 5' untranslated region of rhinovirus.

The analytical sensitivity of these assays are 50 copies/mL for HSV-1, HSV-2; 100 copies/mL for influenza A and B and RSV; 150 copies/mL for enterovirus; 200 copies/mL for adenovirus, rhinovirus and parainfluenza 1,2, and 3; 600 copies/mL for CMV and 500 copies/mL for SARS-CoV2.

This procedure utilizes multiple real-time polymerase chain reaction amplification and detection tests. A "Not detected" result does not rule out infection. This test uses commercial reagents that have not been approved or cleared by the FDA. The FDA has determined that such clearance or approval is not necessary. The performance characteristics of this procedure were determined by Warde Medical Laboratory.

Reported Date: 08/01/2024 13:49 RCVP

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

B601001063
WX0000073111
Printed D&T: 08/01/24 13:49

Ordered By: CLIENT CLIENT
WX00000000409391

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000072099 M 12/05/1988 35 Y

Molecular

Collected: 08/01/2024 13:47 Received: 08/01/2024 13:47

Test Name	Result	Flag	Ref-Ranges	Units	Site
Tissue Comprehensive Virus Panel					
Client Source/ Not Reported	Lung Tissue				WMRL
Specimen Source	Lung Tissue				WMRL
Herpes simplex Type 1	Not detected		Not detected		WMRL
Herpes simplex Type 2	Not detected		Not detected		WMRL
Varicella Zoster Virus	NO BILL				WMRL
Cytomegalovirus	Not detected		Not detected		WMRL
Adenovirus	Not detected		Not detected		WMRL
Enterovirus	Not detected		Not detected		WMRL
Influenza A	Not detected		Not detected		WMRL
Influenza B	Not detected		Not detected		WMRL
Respiratory Syncytial Virus	Not detected		Not detected		WMRL
Rhinovirus	Not detected		Not detected		WMRL
Parainfluenza 1	Not detected		Not detected		WMRL
Parainfluenza 2	Not detected		Not detected		WMRL
Parainfluenza 3	Not detected		Not detected		WMRL

This specimen was tested for multiple viruses by individual PCR reactions. The nucleic acid targets include the glycoprotein G gene of HSV-1, the glycoprotein G/J junction of HSV-2, the VZV open reading frame 62, the adenovirus hexon gene, the 5' non-translated region of the enterovirus genome, the matrix gene from influenza A virus, the NS1 gene from influenza B, the HN gene of parainfluenza 1, 2, and 3, the RSV RNA polymerase gene, and the 5' untranslated region of rhinovirus.

The specific viruses tested depend on the specimen source and are indicated in the result field. The analytical sensitivity of theses assays are 50 copies/mL for HSV-1, HSV-2 and VZV; 100 copies/mL for Influenza A, Influenza B, and RSV; 150 copies/mL for enterovirus; and 200 copies/mL for adenovirus, rhinovirus, and parainfluenza 1, 2, and 3. This procedure utilizes multiple real-time polymerase chain reaction amplification and detection tests. A "Not detected" result does not rule out infection.

This test uses commercial reagents that have not been approved or cleared by the FDA. The FDA has determined that such clearance or approval is not necessary. The performance characteristics of this procedure were determined by Warde Medical Laboratory.

Reported Date: 08/01/2024 13:47 TCVP

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

B601001060
WX0000072099
Printed D&T: 08/01/24 13:47

Ordered By: CLIENT CLIENT
WX00000000494009

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000072099 M 12/05/1988 35 Y

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

B601001060
WX0000072099
Printed D&T: 08/01/24 13:47

Ordered By: CLIENT CLIENT
WX00000000494009

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MOLECULAR/VIROLOGY UPDATE 2024

Update Existing Test	
Name	Virus Culture
Code	VC
Interface Order Code	3093100
Legacy Code	VC
Notes	Update to specimen requirements, rejection criteria, and methodology.
Required Testing Changes	
Specimen Required	*Collect*: Variable specimen types *Specimen Preparation*: **Specimen source required.** **Swab specimens in viral transport medium.** **Biopsy/tissue specimens in saline or viral transport medium. (snap frozen -20°C).** **Body fluids undiluted in sterile leak-proof container. 2.0 mL (1.0 mL minimum).** *Minimum Volume*: Determined by specimen type *Transport Temperature*: Varies with specimen type, see stability
Rejection Criteria	CSF - Please reorder as Comprehensive Virus Detection (CVD). **Urine, stool, whole blood, or serum - Please reorder as CVD.** Specimens in Amplicor, EIA, Gen-Probe, or ProbeTec transport media. Specimens in bacterial transport media, Stewart medium (Culturette) and specimens in bacteriological blood culture media. Dry swabs, wooden swabs, calcium alginate swabs, and swabs in gel transports. Tissues received in transport media that has not been frozen (-20°C). Any specimen other than tissues frozen at temperatures warmer than -70°C. Specimens received in non-sterile or leaking containers. Swab specimens (respiratory) in viral transport medium Nasal washes (respiratory) in sterile, leak proof plastic container Nasal aspirates (respiratory) in vacuum trap Bronchoalveolar lavage/wash (respiratory) in sterile leak-proof container
Methodology	Standard tube cultures and monoclonal antibody staining. **Viruses that can be isolated include most Adenoviruses, most Enteroviruses, and Herpes Simplex Virus.**