Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020

Update Notes

Update Summary		
New Test Activation	5/26/2020	FRDIG - "Digoxin, Free, Serum"
New Test Activation	5/26/2020	HEPCR - "Hepatitis E Virus by Quantitative PCR"
New Website Listing	5/18/2020	INT1G - "Interleukin 1 beta"
New Website Listing	4/22/2020	INTBG - "Interferon-Beta IgG, MAID"
Update Existing Test	5/18/2020	BARGM - "Bartonella quintana IgG IgM Ab"
Update Existing Test	5/18/2020	COCID - "Coccidioides Ab (ID)"
Update Existing Test	4/22/2020	COVWD - "SARS-CoV-2 Qualitative"
Update Existing Test	5/18/2020	DHEA - "DHEA (Dehydroepiandrosterone), Unconjugated, LC/MS/MS"
Update Existing Test	5/18/2020	DIGI - "Digitoxin"
Update Existing Test	5/18/2020	FROC - "Fluoroquinolone-Resistant Organism, Culture"
Update Existing Test	5/18/2020	INT2R - "Interleukin-2 Receptor, Soluble, Serum"
Update Existing Test	5/18/2020	INT6 - "Interleukin 6, Serum"
Update Existing Test	5/18/2020	INTL8 - "Interleukin 8, Serum"
Update Existing Test	5/18/2020	PRINS - "Proinsulin, Intact"
Update Existing Test	5/4/2020	THIOS - "Thiopental and Metabolite Serum/Plasma"
Update Existing Test	5/18/2020	TNFA - "Tumor Necrosis Factor - Alpha, Serum"
Inactivate Test With Replacement	5/26/2020	APOEG - "Apo E Genotype for Alzheimer" replaced by APOE - "Admark® ApoE Genotype Analysis and Interpretation (Sympto)"
Inactivate Test With Replacement	5/4/2020	COV19 - "SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR" replaced by COVLR - "SARS-CoV-2 RNA (COVID-19), Qualitative NAAT"
Inactivate Test With Replacement	5/18/2020	PETH - "Phosphatidylethanol (PEth)" replaced by PETHB - "Phosphatidylethanol (PEth), Whole Blood"
Inactivate Test Without Replacement	4/17/2020	RC209 - "Chymopapain IgE"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020

New Test Activation			
Effective Date	5/26/2020		
Name	Digoxin, Free, Serum		
Code	FRDIG		
CPT Code(s)	80163		
Notes	Do not take biotin or any supplements containing biotin for 12 hours prior to testing.		
Specimen Requirements			
Specimen Required	Draw blood in a SST, 6-8 hours after last digoxin dose. Centrifuge within 2 hours of collection, remove serum from cells and send 1.0 mL serum (0.5 mL minimum) refrigerated in a screw-capped plastic vial.		
Alternate Specimen	Serum: Red-top		
Stability	Room temperature: Unacceptable; Refrigerated: 7 days; Frozen: 180 days		
Performing Information			
Methodology	Ultrafiltration followed by Electrochemiluminescent Immunoassay		
Reference Range	≥ 16 years 0.4 - 0.9 ng/mL Toxic Concentration ≥3.0 ng/mL		
Performed Days	Monday - Sunday		
Turnaround Time	2 - 3 days		
Performing Laboratory	Mayo Medical Laboratories		
Interface Information			
Legacy Code[1]	FRDIG		
Interface Order Code	3800080		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3800080	Digoxin, Free, S	3562-6	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 04/22/2020 17:13 Received: 04/22/2020 17:13

Test Name	Result	Flag	Ref-Ranges	Units	Site
Digoxin, Free, Serum	0.4		0.4-0.9	ng/mL	MMRL

>=3.0 ng/mL(Toxic concentration)

----------ADDITIONAL INFORMATION----------
This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Test Performed by:
Mayo Clinic Laboratories - Rochester Main Campus
200 First Street SW, Rochester, MN 55905
Lab Director: William G. Morice M.D. Ph.D.; CLIA# 24D0404292

Performing Site:
MMRL: MAYO MEDICAL REFERENCE LAB 3050 Superior Drive NW Rochester MN 55901

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020

New Test Activation			
Effective Date	5/26/2020		
Name	Hepatitis E Virus by Quantitative PCR		
Code	HEPCR		
CPT Code(s)	87799		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in a SST. Centrifuge, remove serum from cells and send 1.0 mL serum (0.5 mL minimum) frozen in a screw-capped plasic vial.		
Alternate Specimen	Plasma: Lavender EDTA		
Rejection Criteria	Heparinized specimens		
Stability	Room temperature: 24 hours; Refrigerated: 1 week; Frozen: 1 week		
Performing Information			
Methodology	Qualitative Polymerase Chain Reaction		
Reference Range	Not detected		
Performed Days	Monday, Thursday		
Turnaround Time	3 - 6 days		
Performing Laboratory	ARUP Reference Laboratory		
Interface Information			
Legacy Code[1]	HEPCR		
Interface Order Code	3600154		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3600155	Hepatitis E Quant by PCR, Source ***Acceptable Prompt Responses:*** Serum Plasma	31208-2	**Yes**
3600156	Hepatitis E Quant by PCR, IU/mL	69961-1	No
3600157	Hepatitis E Quant by PCR, Log IU/mL	78750-7	No
3600158	Hepatitis E Quant by PCR, Interp	48767-8	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 04/22/2020 17:22 Received: 04/22/2020 17:22

Test Name	Result	Flag	Ref-Ranges	Units	Site
Hepatitis E Virus by Quantitative PCR					
Hepatitis E Quant by PCR, Source	Plasma				ARRL
Hepatitis E Quant by PCR, IU/mL	<1,800			IU/mL	ARRL
Hepatitis E Quant by PCR, Log IU/mL	< 3.3			log IU/mL	ARRL
Hepatitis E Quant by PCR, Interp	Not Detected		Not Detected		ARRL

INTERPRETIVE INFORMATION: Hepatitis E Virus by Quantitative PCR
The quantitative range of this assay is 3.3- 8.3 log IU/mL (1,800- 180,000,000 IU/mL). One IU/mL of HEV RNA is approximately 2.25 copies/mL.

A negative result (less than 3.3 log IU/mL or less than 1,800 IU/mL) does not rule out the presence of PCR inhibitors in the patient specimen or HEV RNA concentrations below the level of detection of the test. Inhibition may also lead to underestimation of viral quantitation.

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: aruplab.com/CS
Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Julio C. Delgado, MD, MS

Performing Site:
ARRL: ARUP REFERENCE LAB 500 Chipeta Way Salt Lake City UT 841081221

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020

New Website Listing			
Effective Date	5/18/2020		
Name	Interleukin 1 beta		
Code	INT1G		
CPT Code(s)	83520		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in a SST. Centrifuge, remove serum from cells within 2 hours of collection and send 1.0 mL serum (0.4 mL) frozen in a screw-capped plastic vial. CRITICAL FROZEN.		
Alternate Specimen	Serum: Plain red		
Rejection Criteria	Refrigerated specimens, heat-inactivated specimens		
Stability	Room temperature: 30 minutes; Refrigerated: Unacceptable; Frozen: 1 year		
Performing Information			
Methodology	Quantitative Multiplex Bead Assay		
Reference Range	≤ 6.7 pg/mL Cytokine levels may demonstrate diurnal variation. For longitudinal comparison, it is recommended that cytokine levels be determined at the same time of day.		
Performed Days	Sunday-Saturday		
Turnaround Time	2-5 days		
Performing Laboratory	ARUP Reference Laboratory		
Interface Information			
Legacy Code[1]	INT1G		
Interface Order Code	3503990		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3503990	Interleukin 1 beta	13629-1	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000073111 F 02/15/1985 35 Y

Referral Testing

Collected: 04/22/2020 17:34 Received: 04/22/2020 17:34

Test Name	Result	Flag	Ref-Ranges	Units	Site
Interleukin 1 beta	<5		<=36	pg/mL	ARRL

INTERPRETIVE INFORMATION: Cytokines
Results are used to understand the pathophysiology of immune, infectious, or inflammatory disorders, or may be used for research purposes.
Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: aruplab.com/CS

Performing Site:
ARRL: ARUP REFERENCE LAB 500 Chipeta Way Salt Lake City UT 841081221

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

6422001478
WX0000073111
Printed D&T: 04/22/20 17:37

Ordered By: CLIENT CLIENT
WX00000000409391

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020

New Website Listing			
Effective Date	4/22/2020		
Name	Interferon-Beta IgG, MAID w/reflex to Neutralization		
Code	INTBG		
CPT Code(s)	83516 If Interferon - beta igG is positive, Nab Feron® Neutralizing Antibody Test will be added at an additional charge (86382)		
Notes	Collect at least 8 hours after interferon injection.		
Specimen Requirements			
Specimen Required	Draw blood in a SST. Centrifuge, remove serum from cells and send 1.5 mL serum (0.5 mL minimum) refrigerated in a screw-capped plastic vial.		
Alternate Specimen	Serum: Red-top		
Stability	Room temperature: 7 days; Refrigerated: 14 days; Frozen: 30 days		
Performing Information			
Methodology	Multi-Analyte Immunodetection (MAID)		
Reference Range	Negative		
Performed Days	Tuesday		
Turnaround Time	3-10 days		
Performing Laboratory	Quest Infectious Disease		
Interface Information			
Legacy Code[1]	INTFBAB		
Interface Order Code	3512660		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3512660	Interferon-Beta IgG, MAID w/reflex to Neutralization	27871-3	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000073111 F 02/15/1985 35 Y

Referral Testing

Collected: 04/22/2020 18:11 Received: 04/22/2020 18:11

Test Name	Result	Flag	Ref-Ranges	Units	Site
Interferon-Beta IgG, MAID	See Below				WMFD

```
Test                    Result    Flag   Ref Range
INTERFERON-BETA IgG, MAID (REFLEX TO NEUTRALIZATION)
INTERFERON-BETA USED
  FOR TREATMENT         BASELINE
INTERFERON-BETA IgG:    <1.6             <4.0 units

INTERPRETIVE CRITERIA:
                 <4.0 units  IgG not detected
           > or = 4.0 units  IgG detected

Some multiple sclerosis patients receiving
recombinant interferon-beta (IFNb) develop
IFNb-specific antibodies that may block the
therapeutic effect of the treatment. This assay
screens for IgG antibodies capable of binding to
IFNb; all samples with detectable IFNb binding
antibodies are then tested for IFNb neutralizing
antibodies using a bioassay. Approximately two
weeks are required to perform the neutralization
bioassay; those results will be reported
separately when available.

This test was developed and its analytical performance
characteristics have been determined by Quest Diagnostics
Infectious Disease. 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.

Performed at Quest Diagnostics Infectious Disease,
33608 Ortega Highway, San Juan Capistrano, CA 92675,
Hollis J. Batterman MD, Director, CLIA 05D0644251
```

Performing Site:
WMFD: FOCUS DIAGNOSTICS, INC. (QUEST DIAGNOSTICS) 11331 Valley View Street Cypress CA 906304717

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

6422001658
WX0000073111
Printed D&T: 04/22/20 18:13

Ordered By: CLIENT CLIENT
WX00000000409391

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020

Update Existing Test	
Effective Date	5/18/2020
Name	Bartonella quintana IgG IgM Ab
Code	BARGM
Interface Order Code	3704920
Legacy Code	BARTSP
Notes	Minimum volume change
Required Testing Changes	
Specimen Required	Draw blood in a SST. Centrifuge, separate serum from cells within 2 hours of collection and send 1.0 mL serum **(0.3 mL minimum)** refrigerated in a screw-capped plastic vial.

Update Existing Test	
Effective Date	5/18/2020
Name	Coccidioides Ab (ID)
Code	COCID
Interface Order Code	3680490
Legacy Code	COCABIDARP
Notes	Requested volume change
Required Testing Changes	
Specimen Required	Draw blood in a SST. Centrifuge, separate and send **0.5 mL serum (0.3 mL minimum)** refrigerated in a screw-capped plastic vial.

Update Existing Test	
Effective Date	4/22/2020
Name	SARS-CoV-2 Qualitative
Code	COVWD
Interface Order Code	3000065
Legacy Code	COVWD
Notes	CPT change
Required Testing Changes	
CPT Code(s)	**87635 (U0003)**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020

Update Existing Test	
Effective Date	5/18/2020
Name	DHEA (Dehydroepiandrosterone), Unconjugated, LC/MS/MS
Code	DHEA
Interface Order Code	3700510
Legacy Code	DHEA
Notes	Alternate specimen change
Required Testing Changes	
Specimen Required	Draw blood in a plain-red top tube. Centrifuge, separate serum from cells and send 0.5 mL serum (0.3 mL minimum) refrigerated in a screw-capped plastic vial. Overnight fasting is preferred
Alternate Specimen	**No other acceptable specimens.**
Rejection Criteria	**SST**

Update Existing Test			
Effective Date	5/18/2020		
Name	Digitoxin		
Code	DIGI		
Interface Order Code	3683100		
Legacy Code	DIGIARP		
Notes	Stability, Performed days, Reference Range, Turnaround Time, CPT4 Code changes and name change.		
Required Testing Changes			
Name	**Digitoxin Quantitative, Serum or Plasma**		
CPT Code(s)	80375 (G0480)		
Stability	Room temperature: **Undetermined**; Refrigerated: **1 week**; Frozen: **3 months**		
Methodology	**Quantitative Immunoassay**		
Reference Range	See report		
Performed Days	**Varies**		
Turnaround Time	**6-9 days**		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3683100	**Digitoxin Quantitative, Serum or Plasma**	3559-2	No

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020

Update Existing Test	
Effective Date	5/18/2020
Name	Fluoroquinolone-Resistant Organism, Culture
Code	FROC
Interface Order Code	3623200
Legacy Code	FROC
Notes	Performed days comment added
Required Testing Changes	
Performed Days	Sunday-Saturday **Negative reported at 4 days;** **Positives as soon as detected**

Update Existing Test	
Effective Date	5/18/2020
Name	Interleukin-2 Receptor (CD25), Soluble
Code	INT2R
Interface Order Code	3504010
Legacy Code	INT2R
Notes	Test name, minimum volume, reference range, alternate specimen, and performed days changes.
Required Testing Changes	
Name	**Interleukin-2 Receptor, Soluble, Serum**
Specimen Required	Draw blood in a SST. Centrifuge, remove serum from cells within 2 hours and send 1.0 mL serum **(0.4 mL minimum)** frozen in a screw-capped plastic vial. CRITICAL FROZEN.
Alternate Specimen	Serum: Red-top
Reference Range	**175.3-858.2 pg/mL** **Cytokine levels may demonstrate diurnal variation. For longitudinal comparison, it is recommended that cytokine levels be determined at the same time of day.**
Performed Days	**Sunday-Saturday**
Turnaround Time	**2-5 days**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020

Update Existing Test	
Effective Date	5/18/2020
Name	Interleukin 6
Code	INT6
Interface Order Code	3685840
Legacy Code	INT6A
Notes	Test name, minimum volume, alternate specimen, reference range and performed days changes.
Required Testing Changes	
Name	**Interleukin 6, Serum**
Specimen Required	Draw blood in a SST. Centrifuge, Separate serum from cells within 2 hours and send 1.0 mL serum **(0.4 mL minimum)** frozen in a screw-capped plastic vial. CRITICAL FROZEN.
Alternate Specimen	Serum: Red-top
Reference Range	**≤2.0 pg/mL** **Cytokine levels may demonstrate diurnal variation. For longitudinal comparison, it is recommended that cytokine levels be determined at the same time of day.**
Performed Days	**Sunday-Saturday**

Update Existing Test	
Effective Date	5/18/2020
Name	Interleukin 8
Code	INTL8
Interface Order Code	3684605
Legacy Code	INT8ARP
Notes	Test name, minimum volume, alternate specimen, reference range and performed days change.
Required Testing Changes	
Name	**Interleukin 8, Serum**
Specimen Required	Draw blood in a SST. Centrifuge, separate serum from cells within 2 hours and send 1.0 mL serum **(0.4 mL minimum)** frozen in a screw-capped plastic vial. CRITICAL FROZEN.
Alternate Specimen	Serum: Red-top
Reference Range	**≤3.0 pg/mL** **Cytokine levels may demonstrate diurnal variation. For longitudinal comparision, it is recommended that cytokine levels be determined at the same time of day.**
Performed Days	**Sunday-Saturday**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020

Update Existing Test	
Effective Date	5/18/2020
Name	Proinsulin, Intact
Code	PRINS
Interface Order Code	3681100
Legacy Code	PROINSARP
Notes	Specimen required updated
Required Testing Changes	
Name	Proinsulin, Intact
Specimen Required	Patient Preparation: Patient must fast 12-15 hours before collection. Draw blood in a SST. Centrifuge, separate serum from cells within 2 hours and send 1.0 mL serum (0.2 mL minimum) frozen in a screw-capped plastic vial. **CRITICAL FROZEN.**
Methodology	**Quantitative Chemiluminescent Immunoassay**

Update Existing Test	
Effective Date	5/4/2020
Name	Thiopental and Metabolite Serum/Plasma
Code	THIOS
Interface Order Code	3301520
Legacy Code	THIOS
Notes	Specimen requirement updated
Required Testing Changes	
Specimen Required	Draw blood in a plain red-top tube. Centrifuge, separate serum from cells and send 2.0 mL serum (0.7 mL minimum) frozen in a screw-capped plastic vial. **CRITICAL FROZEN**. **Send Monday through Wednesday only.**
Reference Range	See report

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020

Update Existing Test	
Effective Date	5/18/2020
Name	Tumor Necrosis Factor Alpha, S
Code	TNFA
Interface Order Code	3685260
Legacy Code	TNFARP
Notes	Test name, alternate specimen, reference range, performed days, turnaround time changes.
Required Testing Changes	
Name	**Tumor Necrosis Factor - Alpha, Serum**
Specimen Required	Draw blood in a SST. Centrifuge, separate serum from cells within 2 hours and send 1.0 ml serum **(0.4 mL minimum)** frozen in a screw-capped plastic vial.
Alternate Specimen	Serum: Red-top
Rejection Criteria	**Refrigerated specimens, heat-inactivated specimens**
Reference Range	**≤7.2 pg/mL** **Cytokine levels may demonstrate diunal variations. For longitudinal comparison, it is recommended that cytokine levels be determined at the same time of day.**
Performed Days	**Sunday-Saturday**
Turnaround Time	**2-6 days**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020

Inactivate Test With Replacement			
Effective Date	5/26/2020		
Inactivated Test			
Name	Apo E Genotype for Alzheimer		
Code	APOEG		
Legacy Code[1]	APOEALAT		
Interface Order Code	3500437		
Notes			
Replacement Test			
Name	Admark® ApoE Genotype Analysis and Interpretation (Sympto)		
Code	APOE		
CPT Code(s)	81401 ZB08V		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in a lavender EDTA tube. Send 10.0 mL whole bood (6.0 mL minimum) at room temperature.		
Rejection Criteria	Samples from patients less than 18 years old		
Stability	Room temperature: 10 days; Refrigerated: 10 days; Frozen: 90 days		
Performing Information			
Methodology	Restriction Fragment Length Polymorphism (RFLP)		
Reference Range	See report		
Performed Days	Varies		
Turnaround Time	10-16 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	APOE		
Interface Order Code	3400253		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400254	Interpretation	50398-7	No
3400255	Technical Results	42315-2	No
3400256	Comments	77202-0	No
3400258	Methods	49549-9	No
3400257	References	75608-0	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 04/22/2020 18:10 Received: 04/22/2020 18:10

Test Name	Result	Flag	Ref-Ranges	Units	Site

ADmark ApoE Genotype Analysis and Interpretation (Sympto)

Interpretation — See Note — QCRL

This individual does not possess an ApoE 4 allele.

Technical Results — See Note — QCRL

```
------------------------------------------------------------------------
Interpretive Result Table
------------------------------------------------------------------------
INTERPRETIVE RESULT: Negative
TEST: APOE
TECHNICAL RESULT: Alleles: 2 and 3
CLINICAL RELEVANCE: See Limitations of Analysis
------------------------------------------------------------------------
------------------------------------------------------------------------
```

Comments — See Note — QCRL

Comments: While this analysis did not identify an APOE allele associated with AD, a diagnosis of AD cannot be ruled out.

Clinical limitations: The frequency of the E4 allele in the APOE gene is reported to occur in 40-50% of individuals with Alzheimer's disease (1,2). This ApoE analysis is only appropriate for symptomatic individuals. Results cannot be interpreted for asymptomatic individuals and should not be used for predictive testing.

Background information: Alzheimer's disease (AD) is a heterogeneous disorder and is the most common cause of dementia. Memory failure is often the initial presenting sign in affected individuals. As the disease progresses, additional deficits develop including those in judgment and language. Psychiatric changes may also occur. In the late stages of the disease, physical functioning is impacted which leads to incapacitation. Diagnosis relies on the clinical picture as well as findings of amyloid plaques and neurofibrillary tangles in the brain (1) .
There are different types of AD based on the age of onset of symptoms and the presence of family history. The more common 'sporadic' late-onset AD (LOAD) is characterized with symptoms usually starting after 60 years old and lacking a clear mode of transmission. Alternatively, a smaller portion of AD cases have an onset prior to 60 years old with a strong family history. These are familial early-onset AD (EOAD) (1) .
The ApoE gene has been associated with AD. There are three major isoforms of ApoE, E2, E3 and E4, that are differentiated by either cysteine or arginine residues at positions 112 and 158. Specifically, the E4 allele is considered to be the risk factor for AD. These amino

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 04/22/2020 18:10 Received: 04/22/2020 18:10

Test Name	Result	Flag	Ref-Ranges	Units	Site

acid differences impact binding capabilities of ApoE protein with other cellular products including amyloid-beta peptides. An accumulation of amyloid-beta is observed in the brains of individuals with AD who carry the E4 allele (1). Although this allele appears to increase an individual's risk of AD, it is considered to be a reduced penetrant allele because it is not required to cause disease and it cannot predict one's risk to develop AD (3).
APOE gene information: MIM ID: +107741; Chromosome Location: 19q13.32
Phenotype information: MIM ID: #104310 for Alzheimer's disease

Methods — See Note — QCRL

ApoE genotyping was performed by restriction endonuclease digestion of PCR amplified genomic DNA.

Limitations of analysis: Although rare, false positive or false negative results may occur. All results should be interpreted in the context of clinical findings, relevant history, and other laboratory data.

References — See Note — QCRL

1. Liu, CC, et al. (2013) Nat Rev Neurol 9: 106-18. (PMID: 23296339)
2. Chouraki, V, et al. (2014) Adv Genet 87: 245-94. (PMID: 25311924)
3. Roberts, JS, et al. (2013) Prog Neurobiol 110: 89-101. (PMID: 23583530)

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

Laboratory oversight provided by Vivekananda Datta, M.D., Ph.D., CLIA license holder, Athena Diagnostics (CLIA# 22D0069726)

Testing performed at:
Athena Diagnostics 200 Forest Street Marlborough, MA 01752

Test Performed at:
Athena Diagnostics, Inc.
200 Forest Street, 2nd Floor
Marlborough, MA 01752 V Datta MD, PhD

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020

Inactivate Test With Replacement			
Effective Date	5/4/2020		
Inactivated Test			
Name	SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR		
Code	COV19		
Legacy Code[1]	COV19		
Interface Order Code	3400262		
Notes			
Replacement Test			
Name	SARS-CoV-2 RNA (COVID-19), Qualitative NAAT		
Code	COVLR		
CPT Code(s)	87635		
Notes	This code should be used for lower repiratory specimens. Quest has created a new code for SARS-CoV2 RNA testing. **All Nasopharyngeal specimens should continue to be ordered as COVWD for testing at Warde Medical Laboratory.**		
Specimen Requirements			
Specimen Required	Please send 0.85 bronchoalveolar lavage/wash frozen in a screw-capped plastic container. Please send each specimen in a separate plastic bag.		
Alternate Specimen	Nasopharyngeal aspirate/wash, tracheal aspirate, or sputum		
Rejection Criteria	Amies liquid or gel transport used for bacterial cultures.		
Stability	Room temperature: 5 days; Refrigerated: 5 days; Frozen: Acceptable		
Performing Information			
Methodology	Nucleic Acid Amplification Test (NAAT), includes PCR or TMA		
Reference Range	Not detected		
Performed Days	Sunday - Saturday		
Turnaround Time	2 - 3 days (may be impacted by high volume)		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	COVLR		
Interface Order Code	3400259		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400259	SARS-CoV-2 RNA (COVID-19), Qualitative NAAT	94500-6	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 04/22/2020 18:40 Received: 04/22/2020 18:40

Test Name	Result	Flag	Ref-Ranges	Units	Site
SARS-CoV-2 RNA (COVID-19), Qualitative NAAT	**DETECTED**	**AB**			QCRL

A Detected result is considered a positive test result for COVID-19. This indicates that RNA from SARS-CoV-2 (formerly 2019-nCoV) was detected, and the patient is infected with the virus and presumed to be contagious. If requested by public health authority, specimen will be sent for additional testing.
REFERENCE RANGE: NOT DETECTED

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

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

Methodology: Real-Time RT-PCR

Please review the 'Fact Sheets' for health care providers, and patients and the FDA authorized labeling available on the Quest website: www.QuestDiagnostics.com/Covid19.

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

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

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

B222000008
WX0000003039
Printed D&T: 04/22/20 18:41

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020

Inactivate Test With Replacement			
Effective Date	5/18/2020		
Inactivated Test			
Name	Phosphatidylethanol (PEth)		
Code	PETH		
Legacy Code[1]	PETH		
Interface Order Code	3623100		
Notes			
Replacement Test			
Name	Phosphatidylethanol (PEth), Whole Blood		
Code	PETHB		
CPT Code(s)	80321 (G0480)		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in a lavender EDTA tube. Send 1.0 mL whole bood (0.5 mL minimum) refrigerated.		
Alternate Specimen	Blood: Green lithium heparin, gray potassium oxalate		
Rejection Criteria	SST, plain red top, light blue sodium citrate, yellow (ACD or SPS)		
Stability	Room temperature: Unacceptable; Refrigerated: 2 weeks; Frozen: 1 month		
Performing Information			
Methodology	Quantitative Liquid Chromatography - Tandem Mass Spectrometry		
Reference Range	<10 ng/mL		
Performed Days	Sunday-Saturday		
Turnaround Time	3-6 days		
Performing Laboratory	ARUP Reference Laboratory		
Interface Information			
Legacy Code[1]	PETHB		
Interface Order Code	3600171		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3600172	PEth 16:0/18.1 (POPEth)	74661-0	No
3600173	PEth 16:0/18.2 (PLPEth)	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 31 Y

Referral Testing

Collected: 04/22/2020 18:42 Received: 04/22/2020 18:42

Test Name	Result	Flag	Ref-Ranges	Units	Site

Phosphatidylethanol (PEth), Whole Blood

PEth 16:0/18.1 (POPEth)	<10			ng/mL	ARRL

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INTERPRETIVE INFORMATION:Phosphatidylethanol (PEth), Whole
                         Blood
Phosphatidylethanol (PEth)
homologues                    Result Interpretation

PEth 16:0/18.1 (POPEth)
Less than 10 ng/mL.............Not detected
Less than 20 ng/mL.............Abstinence or light alcohol
                               consumption
20 - 200 ng/mL.................Moderate alcohol consumption
Greater than 200 ng/mL.........Heavy alcohol consumption or
                               chronic alcohol use

PEth 16:0/18.2 (PLPEth).........Reference ranges are not
well
                               established.
(Reference: W. Ulwelling and K Smith 2018 J. Forensic Sci)

Phosphatidylethanol (PEth) is a group of phospholipids
formed in the presence of ethanol, phospholipase D and
phosphatidylcholine. PEth is known to be a direct alcohol
biomarker. The predominant PEth homologues are PEth
16:0/18:1 (POPEth) and PEth 16:0/18:2 (PLPEth), which
account for 37-46% and 26-28% of the total PEth homologues,
respectively. PEth is incorporated into the phospholipid
membrane of red blood cells and has a general half-life of
4 - 10 days and a window of detection of 2-4 weeks.
However, the window of detection is longer in individuals
who chronically or excessively consume alcohol. The limit
of quantification is 10 ng/mL. Serial monitoring of PEth
may be helpful in monitoring alcohol abstinence over time.
PEth results should be interpreted in the context of the
patients clinical and behavioral history.  Patients with
advanced liver disease may have falsely elevated PEth
concentrations (Nguyen VL et al 2018, Alcoholism Clinical &
Experimental Research).


Test developed and characteristics determined by ARUP
Laboratories. See Compliance Statement B: aruplab.com/CS
Performed By: ARUP Laboratory
500 Chipeta Way
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LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 04/22/2020 18:42 Received: 04/22/2020 18:42

Test Name	Result	Flag	Ref-Ranges	Units	Site
Salt Lake City, UT 84108					
PEth 16:0/18.2 (PLPEth)	<10			ng/mL	ARRL

Performed By: ARUP Laboratory
500 Chipeta Way
Salt Lake City, UT 84108
Performed by ARUP Laboratories,
500 Chipeta Way, SLC,UT 84108 800-522-2787
www.aruplab.com, Julio Delgado, MD - Lab. Director

Performing Site:
ARRL: ARUP REFERENCE LAB 500 Chipeta Way Salt Lake City UT 841081221

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2020

Inactivate Test Without Replacement	
Effective Date	4/17/2020
Name	Chymopapain IgE
Code	RC209
Legacy Code	RARC209
Interface Code	3062380
Notes	