Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## AUGUST 2020

| Update Notes |
|---|
| |

| Update Summary | | |
|---|---|---|
| **New Test Activation** | 8/25/2020 | CRMWS - "Collapsin Response-Mediator Protein-IgG, Western Blot, Ser" |
| **New Test Activation** | 8/25/2020 | CSHCP - "Cashew Nut IgE Component Panel" |
| **New Test Activation** | 8/25/2020 | DULOX - "Duloxetine, Serum" |
| **New Test Activation** | 8/25/2020 | EGUCT - "Ethyl Glucuronide, Umbilical Cord Tissue, Qualitative" |
| **New Test Activation** | 8/25/2020 | FUKAU - "Ustekinumab and Anti-Ustek Antibody, Serum" |
| **New Test Activation** | 8/25/2020 | HZLCP - "Hazelnut IgE Component Panel" |
| **New Test Activation** | 8/25/2020 | MGPMD - "MGMT Promoter Methylation Detection" |
| **New Test Activation** | 7/28/2020 | UCOPE - "Clin Urine Expanded Opioid Confirm" |
| **New Test Activation** | 8/25/2020 | WLNCP - "Walnut IgE Component Panel" |
| **Update Existing Test** | 8/17/2020 | ASPCF - "Aspergillus Ab by CF" |
| **Update Existing Test** | 8/17/2020 | CHROA - " Chromogranin A, Serum" |
| **Update Existing Test** | 8/17/2020 | FAPIA - "Fungal Antibodies (ID)" |
| **Update Existing Test** | 6/11/2020 | FMP3 - "MyoMarker 3 Profile" |
| **Update Existing Test** | 8/17/2020 | HISID - "Histoplasma Abs (ID)" |
| **Update Existing Test** | 8/17/2020 | HPIDA - "Histoplasma Abs (CF/ID)" |
| **Update Existing Test** | 7/21/2020 | ULEGA - "Legionella Urinary Antigen" |
| **Inactivate Test With Replacement** | 7/13/2020 | HGRIT - "HIV-1 Genotype (RTI, PI, Integrase Inhibitors)" replaced by HIVTO - "HIV-1 Genotype (RTI, PI, Integrase Inhibitors)" |
| **Inactivate Test With Replacement** | 8/17/2020 | TULGM - "F.tularensis Antibody,IgG/IgM" replaced by FTGMR - "Francisella tularensis Ab, IgG/M w/ Reflex to Agglutination" |

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## AUGUST 2020

| New Test Activation | | | |
|---|---|---|---|
| **Effective Date** | 8/25/2020 | | |
| **Name** | Collapsin Response-Mediator Protein-IgG, Western Blot, Ser | | |
| **Code** | CRMWS | | |
| **CPT Code(s)** | 84182 | | |
| **Notes** | | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | Draw blood in a red-top tube. Centrifuge, remove serum from cells and send 1.5 mL serum (1.0 mL minimum) refrigerated in a screw-capped plastic vial. | | |
| **Rejection Criteria** | Gross hemolysis, gross lipemia, gross icterus | | |
| **Stability** | Room temperature: 72 hours; Refrigerated: 28 days; Frozen: 28 days | | |
| **Performing Information** | | | |
| **Methodology** | Chemiluminescence | | |
| **Reference Range** | Negative | | |
| **Performed Days** | Monday - Thursday | | |
| **Turnaround Time** | 7-12 days | | |
| **Performing Laboratory** | Mayo Clinic Laboratories | | |
| **Interface Information** | | | |
| **Legacy Code[1]** | CRMWS | | |
| **Interface Order Code** | 3800119 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt[2]** |
| 3800119 | Collapsin Response-Mediator Protein-IgG, Western Blot, Ser | 47401-5 | 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: 07/13/2020 09:35 Received: 07/13/2020 09:35

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| Collapsin Response-Mediator Protein-IgG, Western Blot, Ser | Negative | | Negative | | MMRL |

```
------------------ADDITIONAL INFORMATION------------------
This test was developed and its performance characteristics
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

## AUGUST 2020

| New Test Activation | | | |
|---|---|---|---|
| **Effective Date** | 8/25/2020 | | |
| **Name** | Cashew Nut IgE Component Panel | | |
| **Code** | CSHCP | | |
| **CPT Code(s)** | 86008 | | |
| **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) refrigerated in a screw-capped plastic vial. | | |
| **Alternate Specimen** | Serum: Red-top | | |
| **Stability** | Room temperature: Unacceptable; Refrigerated: 7 days; Frozen: 14 days | | |
| **Performing Information** | | | |
| **Methodology** | Fluorescent Enzyme Immunoassay | | |
| **Reference Range** | See report | | |
| **Performed Days** | Monday - Friday | | |
| **Turnaround Time** | 1 - 3 days | | |
| **Performing Laboratory** | Warde Medical Laboratory | | |
| **Interface Information** | | | |
| **Legacy Code[1]** | CSHCP | | |
| **Interface Order Code** | 3000079 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt[2]** |
| 3000105 | Ana o 3 (f443) | 82539-8 | No |
| 3000106 | Ana o 3 Class | 82540-6 | No |
| 3069000 | Allergy Interpretation | 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

## Allergy Testing - Panels

Collected: 07/12/2020 09:37 Received: 07/13/2020 09:37

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Cashew Nut IgE Component Panel** | | | | | |
| Ana o 3 (f443) | <0.10 | | <0.10 | kU/L | WMRL |
| Ana o 3 Class | CLASS 0 | | | | WMRL |

Sensitization to Ana 03 may indicate an increased risk of systemic allergic response upon exposure to cashew. Patients may be allergic to other nuts, such as pistachio, walnut, and peanut. Reactivity to whole cashew with negative Ana 03 results may be explained by sensitization to other cashew nut storage proteins or lipid transfer protein, pollen proteins, or cross-reacting carbohydrate determinants.

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| Allergy Interpretation | See Below | | | | WMRL |

| CLASS | kU/L | Level of Allergen Specific IgE Antibody |
|---|---|---|
| 0 | <0.10 | Undetectable |
| 0/1 | 0.10 - 0.34 | Very Low Level |
| 1 | 0.35 - 0.69 | Low Level |
| 2 | 0.70 - 3.49 | Moderate Level |
| 3 | 3.50 - 17.4 | High Level |
| 4 | 17.5 - 49.9 | Very High Level |
| 5 | 50.0 - 100.0 | Very High Level |
| 6 | >100.0 | Very High Level |

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

B513000011
WX0000003039
Printed D&T: 07/13/20 09:37

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## AUGUST 2020

| New Test Activation | | | |
|---|---|---|---|
| **Effective Date** | 8/25/2020 | | |
| **Name** | Duloxetine, Serum | | |
| **Code** | DULOX | | |
| **CPT Code(s)** | 80332 (G0480) | | |
| **Notes** | | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | Draw blood in a red-top tube. Centrifuge, remove serum from cells and send 1.0 mL serum (0.5 mL minimum) refrigerated in a screw-capped plastic vial. Serum requires light protection at room temperature. | | |
| **Alternate Specimen** | Plasma: Lavender EDTA. Plasma requires light protection at room temperature. | | |
| **Rejection Criteria** | Polymer gel separation tube (SST or PST). | | |
| **Stability** | Room temperature: 30 days; Refrigerated: 30 days; Frozen: 12 months | | |
| **Performing Information** | | | |
| **Methodology** | High Performance LIquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS) | | |
| **Reference Range** | Duloxetine Reporting Limit: 3 ng/mL | | |
| **Performed Days** | Varies | | |
| **Turnaround Time** | 10 days | | |
| **Performing Laboratory** | NMS Labs | | |
| **Interface Information** | | | |
| **Legacy Code[1]** | DULOX | | |
| **Interface Order Code** | 3300034 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt[2]** |
| 3300034 | Duloxetine, Serum | 46227-5 | 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: 07/10/2020 12:00 Received: 07/13/2020 08:58

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| Duloxetine, Serum | 10 | | | ng/mL | NMRL |

Reporting Limit: 3.0 ng/mL
Synonym(s): Cymbalta(R)
Steady-state trough plasma concentrations after
5 days of oral therapy were:
20 mg twice daily: 4 to 22 ng/mL
30 mg twice daily: 8 to 48 ng/mL
40 mg twice daily: 12 to 60 ng/mL.
Analysis by High Performance Liquid Chromatography/
Tandem Mass Spectrometry (LC-MS/MS)
This test was developed and its performance
characteristics determined by NMS Labs. It has not
been cleared or approved by the US Food and Drug
Administration.

Testing performed at NMS Labs, Inc.
200 Welsh Road
Horsham, PA 19044-2208
CLIA 39D0197898

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

B513000000
WX0000003039
Printed D&T: 07/13/20 08:59

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## AUGUST 2020

| New Test Activation | | | |
|---|---|---|---|
| **Effective Date** | 8/25/2020 | | |
| **Name** | Ethyl Glucuronide, Umbilical Cord Tissue, Qualitative | | |
| **Code** | EGUCT | | |
| **CPT Code(s)** | 80321 (G0480) | | |
| **Notes** | | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | Collect at least 8 inches of Umbilical Cord. Ensure no ethanol-containing personal care products are used or nearby during collection. Drain and discard any blood. Rinse the exterior of the cord segment with normal saline or water. Pat the cord dry and send in a urine collection cup. | | |
| **Rejection Criteria** | Cords soaking in blood or other fluid. Formalin fixed or decomposed tissue. | | |
| **Stability** | Room temperature: 1 week; Refrigerated: 3 weeks; Frozen: 1 year | | |
| **Performing Information** | | | |
| **Methodology** | Qualitative Liquid Chromatography/Tandem Mass Spectrometry | | |
| **Reference Range** | Ethyl Glucuronide cutoff: 5 ng/g | | |
| **Performed Days** | Tuesday, Thursday, Saturday | | |
| **Turnaround Time** | 2 - 6 days | | |
| **Performing Laboratory** | ARUP Reference Laboratory | | |
| **Interface Information** | | | |
| **Legacy Code[1]** | EGUCT | | |
| **Interface Order Code** | 3600177 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt[2]** |
| 3600177 | Ethyl Glucuronide, Umbilical Cord Tissue, Qualitative | 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: 07/11/2020 11:12 Received: 07/13/2020 09:01

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| Ethyl Glucuronide, Umbilical Cord Tissue, Qualitative | Not Detected | | Cutoff 5 | ng/g | ARRL |

INTERPRETIVE INFORMATION: Ethyl Glucuronide, Umbilical Cord Tissue, Qualitative
Methodology: Qualitative Liquid Chromatography-Tandem Mass Spectrometry

This test is designed to detect and document exposure that occurred during approximately the last trimester of a full term pregnancy, to ethyl glucuronide, a common ethanol (alcohol) metabolite. Alternative testing is available to detect other drug exposures. The pattern and frequency of alcohol used by the mother cannot be determined by this test. A negative result does not exclude the possibility that a mother used alcohol during pregnancy. Detection of alcohol in umbilical cord tissue depends on extent of maternal use, as well as stability, unique characteristics of alcohol deposition in umbilical cord tissue, and the performance of the analytical method. Detection of alcohol in umbilical cord tissue does not insinuate impairment and may not affect outcomes for the infant. Interpretive questions should be directed to the laboratory.

Caution must be used when collecting specimen to ensure no ethanol-containing personal care products (i.e., hand sanitizers, wipes, mouthwash) are used directly on the specimen or nearby during collection.

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

## AUGUST 2020

| New Test Activation | | | |
|---|---|---|---|
| **Effective Date** | 8/25/2020 | | |
| **Name** | Ustekinumab and Anti-Ustek Antibody, Serum | | |
| **Code** | FUKAU | | |
| **CPT Code(s)** | 80299 (Ustekinumab); 82397 (Antibody) | | |
| **Notes** | | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | Draw blood in a plain red-top tube. Centrifuge, separate serum from cells and send 3.0 mL serum (1.0 mL minimum) frozen in a screw-capped plastic vial. | | |
| **Rejection Criteria** | Gross hemolysis, Gross lipemia, Gross icterus | | |
| **Stability** | Room temperature: 14 days; Refrigerated: 14 days; Frozen: 14 days | | |
| **Performing Information** | | | |
| **Methodology** | Electrochemiluminescence immuoassay (ECLIA) | | |
| **Reference Range** | By report | | |
| **Performed Days** | Wednesday | | |
| **Turnaround Time** | 12 - 17 days | | |
| **Performing Laboratory** | Mayo Clinic Laboratories | | |
| **Interface Information** | | | |
| **Legacy Code[1]** | FUKAU | | |
| **Interface Order Code** | 3800115 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt[2]** |
| 3800117 | Ustekinumab | 87408-1 | No |
| 3800118 | Anti-Ustekinumab Ab | 88992-3 | 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: 07/10/2020 07:00 Received: 07/13/2020 09:03

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Ustekinumab and Anti-Ustek Ab, Serum** | | | | | |
| Ustekinumab | 5.5 | | | ug/mL | MMRL |
| Anti-Ustekinumab Ab | 1.5 | | | ng/mL | MMRL |

Test Performed by:
Esoterix Endocrinology
4301 Lost Hills Road
Calabasas Hills, CA 91301

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

B513000002
WX0000003039
Printed D&T: 07/13/20 09:05

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## AUGUST 2020

| New Test Activation | | | |
|---|---|---|---|
| **Effective Date** | 8/25/2020 | | |
| **Name** | Hazelnut IgE Component Panel | | |
| **Code** | HZLCP | | |
| **CPT Code(s)** | 86008 x 4 | | |
| **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) refrigerated in a screw-capped plastic vial. | | |
| **Alternate Specimen** | Serum: Red-top | | |
| **Stability** | Room temperature: Unacceptable; Refrigerated: 7 days; Frozen: 14 days | | |
| **Performing Information** | | | |
| **Methodology** | Fluorescent Enzyme Immunoassay | | |
| **Reference Range** | See report | | |
| **Performed Days** | Monday - Friday | | |
| **Turnaround Time** | 1 - 3 days | | |
| **Performing Laboratory** | Warde Medical Laboratory | | |
| **Interface Information** | | | |
| **Legacy Code[1]** | HZLCP | | |
| **Interface Order Code** | 3000077 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt[2]** |
| 3000124 | Cor a 1 (f428) | 69421-6 | No |
| 3000125 | Cor a 1 Class | 81995-3 | No |
| 3000126 | Cor a 8 (f425) | 58753-5 | No |
| 3000127 | Cor a 8 Class | 81993-8 | No |
| 3000128 | Cor a 9 (f440) | 65765-0 | No |
| 3000129 | Cor a 9 Class | 82002-7 | No |
| 3000132 | Cor a 14 (f439) | 81788-2 | No |
| 3000133 | Cor a 14 Class | 82569-5 | No |
| 3069000 | Allergy Interpretation | 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

## Allergy Testing - Panels

Collected: 07/13/2020 09:06 Received: 07/13/2020 09:06

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Hazelnut IgE Component Panel** | | | | | |
| Cor a 1 (f428) | <0.10 | | <0.10 | kU/L | WMRL |
| Cor a 1 Class | CLASS 0 | | | | WMRL |
| Cor a 8 (f425) | <0.10 | | <0.10 | kU/L | WMRL |
| Cor a 8 Class | CLASS 0 | | | | WMRL |
| Cor a 9 (f440) | <0.10 | | <0.10 | kU/L | WMRL |
| Cor a 9 Class | CLASS 0 | | | | WMRL |
| Cor a 14 (f439) | <0.10 | | <0.10 | kU/L | WMRL |
| Cor a 14 Class | CLASS 0 | | | | WMRL |

Sensitization to Cor a 9 and Cor a 14 may indicate an increased risk of systemic allergic response upon exposure to hazelnut. Patients may be allergic to peanuts and other tree nuts (walnut and Brazil nut). Sensitization to Cor a 1 alone is typically associated with local reactions. Cor a 1 may be associated with cross-reactivity and sensitization to birch pollen. Sensitization to Cor a 8 is associated with systemic allergic reactions or local oral symptoms as well as symptoms to other lipid transfer protein containing food such as peach, lettuce, peanut, walnut, and cherry. Reactivity to whole hazelnut without reactivity to hazelnut components may be explained by sensitization to other hazelnut storage proteins, cross reactivity with pollen proteins, or cross-reactive carbohydrates.

Allergy Interpretation — See Below — WMRL

| CLASS | kU/L | Level of Allergen Specific IgE Antibody |
|---|---|---|
| 0 | <0.10 | Undetectable |
| 0/1 | 0.10 - 0.34 | Very Low Level |
| 1 | 0.35 - 0.69 | Low Level |
| 2 | 0.70 - 3.49 | Moderate Level |
| 3 | 3.50 - 17.4 | High Level |
| 4 | 17.5 - 49.9 | Very High Level |
| 5 | 50.0 - 100.0 | Very High Level |
| 6 | >100.0 | Very High Level |

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

B513000003
WX0000003039
Printed D&T: 07/13/20 09:07

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## AUGUST 2020

| New Test Activation | | | |
|---|---|---|---|
| **Effective Date** | 8/25/2020 | | |
| **Name** | MGMT Promoter Methylation Detection | | |
| **Code** | MGPMD | | |
| **CPT Code(s)** | 81287, 88381 | | |
| **Notes** | | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | Tumor Tissue: Formalin fix (10% neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Transport tissue block and 5 unstained 5 micron slides. | | |
| **Rejection Criteria** | Specimens fixed in alternative fixatives<br>Heavy metal fixatives (B-4 or B-5)<br>Decalcified specimens<br>Less than 25% tumor | | |
| **Stability** | Room temperature: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable | | |
| **Performing Information** | | | |
| **Methodology** | Polymerase Chain Reaction/MassARRAY/MAL-DI-TOF | | |
| **Reference Range** | By report | | |
| **Performed Days** | DNA Isolation: Sunday - Saturday; Assay: Varies | | |
| **Turnaround Time** | 10 - 14 days | | |
| **Performing Laboratory** | ARUP Reference Laboratory | | |
| **Interface Information** | | | |
| **Legacy Code[1]** | MGPMD | | |
| **Interface Order Code** | 3600174 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt[2]** |
| 3600175 | Block ID | 57723-9 | No |
| 3600176 | MGMT Promoter Methylation Dection Result | 60252-4 | 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: 07/13/2020 09:08 Received: 07/13/2020 09:08

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **MGMT Promoter Methylation Dection** | | | | | |
| Block ID | TEST9876 | | | | ARRL |

Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Julio C. Delgado, MD, MS

| | | | | |
|---|---|---|---|---|
| MGMT Promoter Methylation Dection Result | **Detected** | **AB** | | ARRL |

MGMT promoter methylation was detected.

This result has been reviewed and approved by Georgios Deftereos, M.D.
INTERPRETIVE INFORMATION: MGMT Promoter Methylation Detection
CHARACTERISTICS: This assay is designed to detect MGMT promoter methylation. MGMT promoter methylation status is a prognostic biomarker in patients with high grade gliomas and is useful in treatment decisions. For specific treatment recommendations please refer to NCCN Clinical Practice Guidelines in Oncology for Central Nervous System Cancers (www.nccn.org).

METHODOLOGY: Genomic DNA is isolated from microscopically-guided dissection of tumor tissue. Bisulfite conversion and subsequent polymerase chain reaction (PCR) amplification of region of interest is followed by enzymatic cleavage at thymine residues. The resulting fragments, which differ in molecular mass based on CpG site methylation status, are analyzed by MassARRAY matrix-assisted laser desorption/ionization (MALDI) time-of-flight (TOF) mass spectrometry to determine CpG methylation status. Methylation status of MGMT promoter CpG sites 72-83 and 86-89 is evaluated. Total methylation is calculated as an average across listed CpG sites. Total methylation of 0-9 percent is reported as "Not detected" 10-29 percent as "Low level" and equal or more than 30 percent as "Detected".

LIMITATIONS: Methylation at locations other than those listed above will not be detected.

ANALYTICAL SENSITIVITY: 5 percent methylation.

CLINICAL DISCLAIMER: Results of this test must always be

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

## Referral Testing

Collected: 07/13/2020 09:08 Received: 07/13/2020 09:08

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|

interpreted within the clinical context and other relevant data and should not be used alone for a diagnosis of malignancy.

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## AUGUST 2020

| New Test Activation | |
|---|---|
| **Effective Date** | 7/28/2020 |
| **Name** | Clin Urine Expanded Opioid Confirm |
| **Code** | UCOPE |
| **CPT Code(s)** | 80361, 80365 (Opiates); 80348, 80362 (Buprenorphine & Metabolite); 80354 (Fentanyl & Metabolite); 80373 (Tramadol & Metabolite) (G0480) |
| **Notes** | |
| **Specimen Requirements** | |
| **Specimen Required** | Collect random urine. Mix well and send 20.0 mL urine (4.0 mL) refrigerated in a screw-capped plastic urine container. |
| **Rejection Criteria** | Urine with preservative, vacutainer cup |
| **Stability** | Room temperature: 48 hours; Refrigerated: 14 days; Frozen: 14 days |
| **Performing Information** | |
| **Methodology** | Liquid Chromatography - Tandem Mass Spectrometry |
| **Reference Range** | **Confirmation (LC/MS/MS) Decision Limits**<br>Fentanyl 1 ng/mL<br>Norfentanyl 1 ng/mL<br>Morphine 25 ng/mL<br>Codeine 25 ng/mL<br>Hydrocodone 25 ng/mL<br>Hydromorphone 25 ng/mL<br>Oxycodone 25 ng/mL<br>Oxymorphone 25 ng/mL<br>Naloxone 5 ng/mL<br>Buprenorphine 5 ng/mL<br>Norbuprenorphine 5 ng/mL<br>Tramadol 5 ng/mL<br>O-desmethyltramadol 5 ng/mL |
| **Performed Days** | Sunday - Friday |
| **Turnaround Time** | 4 days |
| **Performing Laboratory** | Warde Medical Laboratory |
| **Interface Information** | |
| **Legacy Code[1]** | UCOPE |
| **Interface Order Code** | 3000811 |

| Result Code | Name | LOINC Code | AOE/Prompt[2] |
|---|---|---|---|
| 3000812 | Fentanyl | 58381-5 | No |
| 3000813 | Norfentanyl | 58383-1 | No |
| 3000814 | Morphine | 16251-1 | No |
| 3000815 | Codeine | 16250-3 | No |
| 3000816 | Hydrocodone | 16252-9 | No |

| | | | |
|---|---|---|---|
| 3000817 | Hydromorphone | 16998-7 | No |
| 3000818 | Oxycodone | 16249-5 | No |
| 3000819 | Oxymorphone | 17395-5 | No |
| 3000820 | Naloxone | 77207-9 | No |
| 3000821 | Buprenorphine | 49752-9 | No |
| 3000822 | Norbuprenorphine | 49751-1 | No |
| 3000823 | Tramadol | 20561-7 | No |
| 3000824 | O-desmethyltramadol | 86453-8 | No |
| 3000825 | Creatinine | 2161-8 | No |
| 3000826 | Adulterant | 58715-4 | No |

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT**
WX0000003039 M 12/05/1988

Collected: 06/30/2020 13:04 Received: 06/30/2020 13:04

## Clinical Urine Expanded Opioid Confirm

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| Fentanyl | 25 | | | ng/mL | WMRL |
| Norfentanyl | 35 | | | ng/mL | WMRL |
| Morphine | 1256 | | | ng/mL | WMRL |
| The morphine/codeine in this urine could have resulted from eating foods containing poppy seeds. | | | | | |
| Codeine | 122 | | | ng/mL | WMRL |
| Hydrocodone | Negative | | | ng/mL | WMRL |
| Hydromorphone | Negative | | | ng/mL | WMRL |
| Oxycodone | Negative | | | ng/mL | WMRL |
| Oxymorphone | Negative | | | ng/mL | WMRL |
| Naloxone | Negative | | | ng/mL | WMRL |
| Buprenorphine | Negative | | | ng/mL | WMRL |
| Norbuprenorphine | Negative | | | ng/mL | WMRL |
| Tramadol | Negative | | | ng/mL | WMRL |
| O-desmethyltramadol | Negative | | | ng/mL | WMRL |
| Creatinine | 25 | | 20-250 | mg/dL | WMRL |
| Adulterant | Negative | | | | WMRL |

Confirmation (LC/MS/MS) Decision Limits

| | |
|---|---|
| Fentanyl | 1 ng/mL |
| Norfentanyl | 1 ng/mL |
| Morphine | 25 ng/mL |
| Codeine | 25 ng/mL |
| Hydrocodone | 25 ng/mL |
| Hydromorphone | 25 ng/mL |
| Oxycodone | 25 ng/mL |
| Oxymorphone | 25 ng/mL |
| Naloxone | 5 ng/mL |
| Buprenorphine | 5 ng/mL |
| Norbuprenorphine | 5 ng/mL |
| Tramadol | 5 ng/mL |
| O-desmethyltramadol | 5 ng/mL |

Adulterant Decision Limit:
General Oxidants 200 ug/mL

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT**
WX0000003039 M 12/05/1988

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|

The adulterant assay tests for General Oxidants, including Chromates and Nitrites. Adulterants are substances either ingested or added directly to a urine specimen to prevent the detection of drug use.

If applicable, any drug confirmation testing reported here was developed and the performance characteristics determined by Warde Medical Laboratory. This confirmation testing has not been cleared or approved by the FDA. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for patient testing purposes. It should not be regarded as investigational or for research.

Performing Site:
WMRL: Warde Medical Laboratory 300 West Textile Road Ann Arbor MI 48108 (800)876-6522

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## AUGUST 2020

| New Test Activation | | | |
|---|---|---|---|
| **Effective Date** | 8/25/2020 | | |
| **Name** | Walnut IgE Component Panel | | |
| **Code** | WLNCP | | |
| **CPT Code(s)** | 86008 x 2 | | |
| **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) refrigerated in a screw-capped plastic vial. | | |
| **Alternate Specimen** | Serum: Red-top | | |
| **Stability** | Room temperature: Unacceptable; Refrigerated: 7 days; Frozen: 14 days | | |
| **Performing Information** | | | |
| **Methodology** | Fluorescent Enzyme Immunoassay | | |
| **Reference Range** | By report | | |
| **Performed Days** | Monday - Friday | | |
| **Turnaround Time** | 1 - 3 days | | |
| **Performing Laboratory** | Warde Medical Laboratory | | |
| **Interface Information** | | | |
| **Legacy Code[1]** | WLNCP | | |
| **Interface Order Code** | 3000078 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt[2]** |
| 3000116 | Jug r 1 (f441) | 81790-8 | No |
| 3000117 | Jug r 1 Class | 82545-5 | No |
| 3000118 | Jug r 3 (f442) | 81789-0 | No |
| 3000119 | Jug r 3 Class | 81790-8 | No |
| 3069000 | Allergy Interpretation | 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

## Allergy Testing - Panels

Collected: 07/13/2020 09:12 Received: 07/13/2020 09:12

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Walnut IgE Component Panel** | | | | | |
| Jug r 1 (f441) | <0.10 | | <0.10 | kU/L | WMRL |
| Jug r 1 Class | CLASS 0 | | | | WMRL |
| Jug r 3 (f442) | <0.10 | | <0.10 | kU/L | WMRL |
| Jug r 3 Class | CLASS 0 | | | | WMRL |

Sensitization to Jug r 1 may indicate an increased risk of systemic allergic response upon exposure to walnut. Patients may be allergic to other nuts or seeds, including pecan, hazelnut, and cashew. Sensitization to Jug r 3 has been associated with both systemic and local reactions. Patients may react to other lipid transfer protein containing foods, such as peach, other nuts, apple, or grapes. Reactivity to whole walnut with negative Jug r 1 and Jug r 3 results may be explained by sensitization to other walnut storage proteins, cross reactivity with pollen proteins, or cross-reactive carbohydrates.

Allergy Interpretation — See Below — WMRL

| CLASS | kU/L | Level of Allergen Specific IgE Antibody |
|---|---|---|
| 0 | <0.10 | Undetectable |
| 0/1 | 0.10 - 0.34 | Very Low Level |
| 1 | 0.35 - 0.69 | Low Level |
| 2 | 0.70 - 3.49 | Moderate Level |
| 3 | 3.50 - 17.4 | High Level |
| 4 | 17.5 - 49.9 | Very High Level |
| 5 | 50.0 - 100.0 | Very High Level |
| 6 | >100.0 | Very High Level |

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

B513000005
WX0000003039
Printed D&T: 07/13/20 09:12

Ordered By: CLIENT CLIENT
WX00000000001595

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## AUGUST 2020

| Update Existing Test | |
|---|---|
| **Effective Date** | 8/17/2020 |
| **Name** | Aspergillus Ab by CF |
| **Code** | ASPCF |
| **Interface Order Code** | 3680160 |
| **Legacy Code** | ASPABCFARP |
| **Notes** | Minimum volume changes |
| **Required Testing Changes** | |
| **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**) refrigerated in a screw-capped plastic vial. |

| Update Existing Test | | | |
|---|---|---|---|
| **Effective Date** | 8/17/2020 | | |
| **Name** | Chromogranin A | | |
| **Code** | CHROA | | |
| **Interface Order Code** | 3420100 | | |
| **Legacy Code** | CHROMAQ | | |
| **Notes** | | | |
| **Required Testing Changes** | | | |
| **Name** | Chromogranin A, Serum | | |
| **Specimen Required** | Draw blood in a plain red-top tube. Centrifuge, separate and send 1.0 mL serum (0.5 mL minimum) **frozen** in a screw-capped plastic vial. | | |
| **Alternate Specimen** | Serum: SST | | |
| **Stability** | Room temperature: 48 hours; Refrigerated: **3 days**; Frozen: **4 weeks** | | |
| **Methodology** | **Immunofluorescence assay** | | |
| **Reference Range** | **0 - 103 ng/mL** | | |
| **Performed Days** | Monday, Wednesday, Friday, **Sunday** | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt[2]** |
| 3420100 | **Chromogranin A, Serum** | 9811-1 | No |

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## AUGUST 2020

| Update Existing Test | |
|---|---|
| **Effective Date** | 8/17/2020 |
| **Name** | Fungal Antibodies (ID) |
| **Code** | FAPIA |
| **Interface Order Code** | 3682945 |
| **Legacy Code** | FAPIDARP |
| **Notes** | Turnaround changes |
| **Required Testing Changes** | |
| **Turnaround Time** | **4 - 7 days** |

| Update Existing Test | | | |
|---|---|---|---|
| **Effective Date** | 6/11/2020 | | |
| **Name** | MyoMarker Panel 3 | | |
| **Code** | FMP3 | | |
| **Interface Order Code** | 3800044 | | |
| **Legacy Code** | FMP3 | | |
| **Notes** | Methodology Changes and Resulting name changes. | | |
| **Required Testing Changes** | | | |
| **Name** | **MyoMarker 3 Profile** | | |
| **Methodology** | Enzyme-linked Immunosorbent Assay (ELISA) | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt[2]** |
| 3800045 | Anti-Jo-1 Ab | 35333-4 | No |
| 3800046 | **Anti-PL-7 Ab** | 33772-5 | No |
| 3800047 | **Anti-PL-12 Ab** | 33771-7 | No |
| 3800048 | **Anti-EJ Ab** | 45149-2 | No |
| 3800049 | **Anti-OJ Ab** | 45152-6 | No |
| 3800050 | **Anti-SRP Ab** | 33921-8 | No |
| 3800051 | **Anti-MI-2 Ab** | 18485-3 | No |
| 3800052 | **Anti-TIF1 Gamma Ab** | 88739-8 | No |
| 3800053 | **MDA-5 Ab (CADM-140)** | 88725-7 | No |
| 3800054 | **Anti-NXP-2 (P140) Ab** | 82425-0 | No |
| 3800055 | Anti-PM/Scl-100 Ab | 61120-2 | No |
| 3800056 | **Anti-U3 RNP (Fibrillarin)** | 49963-2 | No |
| 3800057 | **Anti-U2 RNP Ab** | 68549-5 | No |
| 3800058 | Anti-U1-RNP Ab | 57662-9 | No |
| 3800059 | **Anti-Ku Ab** | 18484-6 | No |
| 3800060 | Anti-SS-A 52 kD Ab, IgG | 56549-9 | No |

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## AUGUST 2020

| Update Existing Test | |
|---|---|
| **Effective Date** | 8/17/2020 |
| **Name** | Histoplasma Abs (ID) |
| **Code** | HISID |
| **Interface Order Code** | 3680860 |
| **Legacy Code** | HISABIDARP |
| **Notes** | Minimum volume and turnaround changes |
| **Required Testing Changes** | |
| **Specimen Required** | Draw blood in a SST. Centrifuge, separate serum from cells within 2 hours and send 0.5 mL serum (**0.2 mL minimum**) refrigerated in a screw-capped plastic vial. |
| **Turnaround Time** | **4 - 7 days** |

| Update Existing Test | |
|---|---|
| **Effective Date** | 8/17/2020 |
| **Name** | Histoplasma Abs (CF/ID) |
| **Code** | HPIDA |
| **Interface Order Code** | 3683110 |
| **Legacy Code** | HISTABCFID |
| **Notes** | Minimum volume and turnaround changes |
| **Required Testing Changes** | |
| **Specimen Required** | Draw blood in a SST. Centrifuge, separate serum from cells within 2 hours and send 1.0 mL serum (**0.5 mL minimum**) refrigerated in a screw-capped plastic vial. |
| **Turnaround Time** | **4 - 7 days** |

| Update Existing Test | |
|---|---|
| **Effective Date** | 7/21/2020 |
| **Name** | Legionella Urinary Antigen |
| **Code** | ULEGA |
| **Interface Order Code** | 3002030 |
| **Legacy Code** | ULEGAG |
| **Notes** | Reference Range and performed days changes |
| **Required Testing Changes** | |
| **Reference Range** | **Negative** |
| **Performed Days** | **Monday - Friday** |

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## AUGUST 2020

| Inactivate Test With Replacement | | | |
|---|---|---|---|
| **Effective Date** | 7/13/2020 | | |
| **Inactivated Test** | | | |
| **Name** | HIV-1 Genotype (RTI, PI, Integrase Inhibitors) | | |
| **Code** | HGRIT | | |
| **Legacy Code[1]** | HGRIT | | |
| **Interface Order Code** | 3431201 | | |
| **Notes** | | | |
| | | | |
| **Replacement Test** | | | |
| **Name** | HIV-1 Genotype (RTI, PI, Integrase Inhibitors) | | |
| **Code** | HIVTO | | |
| **CPT Code(s)** | 87900, 87901, 87906 | | |
| **Notes** | | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | Draw blood in a lavender EDTA. Centrifuge and separate plasma from cells within 24 hours. Send 5.0 mL plasma (1.6 mL minimum) frozen in a screw-capped plastic vial. | | |
| **Rejection Criteria** | Gross hemolysis, lipemia, serum, whole blood, heparinized plasma | | |
| **Stability** | Room temperature: 24 hours; Refrigerated: 5 days; Frozen: 35 days | | |
| **Performing Information** | | | |
| **Methodology** | Reverse Transcriptase Polymerase Chain Reaction (TR-PCR), Sequencing | | |
| **Reference Range** | By report | | |
| **Performed Days** | Monday - Saturday | | |
| **Turnaround Time** | 6 - 11 days | | |
| **Performing Laboratory** | Quest SJC | | |
| **Interface Information** | | | |
| **Legacy Code[1]** | HIVTO | | |
| **Interface Order Code** | 3400342 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt[2]** |
| 3400343 | HIV-1 Genotype | 48558-1 | No |
| 3400344 | Value of Last Viral Load | 19146-0 | **Yes** |
| 3400345 | Date Viral Load Collected | 33882-2 | **Yes** |
| 3400346 | Raltegravir Resistance | 72525-9 | No |
| 3400347 | Elvitegravir Resistance | 72536-7 | No |
| 3400348 | Dolutegravir Resistance | 72857-6 | No |
| 3400349 | Bictegravir Resistance | 90080-3 | 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: 07/09/2020 08:00 Received: 07/13/2020 09:13

| 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 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.

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 | 23 | | | | QCRL |
| Date Viral Load Collected | 6/30/2020 | | | | QCRL |
| Raltegravir Resistance | NOT PREDICTED | | | | QCRL |
| Elvitegravir Resistance | NOT PREDICTED | | | | QCRL |
| Dolutegravir Resistance | NOT PREDICTED | | | | QCRL |
| Bictegravir Resistance | NOT PREDICTED | | | | QCRL |

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

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

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## AUGUST 2020

| Inactivate Test With Replacement | | | |
|---|---|---|---|
| **Effective Date** | 8/17/2020 | | |
| **Inactivated Test** | | | |
| **Name** | F.tularensis Antibody,IgG/IgM | | |
| **Code** | TULGM | | |
| **Legacy Code[1]** | TULABGMARP | | |
| **Interface Order Code** | 3619900 | | |
| **Notes** | | | |
| | | | |
| **Replacement Test** | | | |
| **Name** | Francisella tularensis Ab, IgG/M w/ Reflex to Agglutination | | |
| **Code** | FTGMR | | |
| **CPT Code(s)** | 86668 x 2, plus 86000 if reflexed to agglutination, at an additional fee | | |
| **Notes** | | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | Draw blood in a SST. Centrifuge, separate serum from cells within 2 hours and send 1.0 mL serum (0.6 mL minimum) refrigerated in a screw-capped plastic vial. | | |
| **Alternate Specimen** | Plasma: Red top | | |
| **Stability** | Room temperature: 48 hours; Refrigerated: 14 days; Frozen: 1 month | | |
| **Performing Information** | | | |
| **Methodology** | Semi-quantitative Enzyme-Linked Immunosorbent Assay | | |
| **Reference Range** | By report | | |
| **Performed Days** | Monday, Wednesday, Friday | | |
| **Turnaround Time** | 2 - 8 days | | |
| **Performing Laboratory** | ARUP Reference Laboratory | | |
| **Interface Information** | | | |
| **Legacy Code[1]** | FTGMR | | |
| **Interface Order Code** | 3600178 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt[2]** |
| 3600179 | Francisella tularensis Ab, IgG | 70121-9 | No |
| 3600181 | Francisella tularensis Ab, IgM | 16878-1 | No |
| 3600182 | F. tularensis Ab by Agglutination | 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: 07/11/2020 11:00 Received: 07/13/2020 12:36

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Francisella tularensis Ab IgG/M w/ reflex to Agglutination** | | | | | |
| Francisella tularensis Ab, IgG | 0 | | <=9 | U/mL | ARRL |

```
INTERPRETATIVE DATA: Francisella tularensis
                     Antibody, IgG

  9 U/mL or less..... Negative - No significant
                      level of IgG antibody to
                      Francisella tularensis
                      detected.
  10 - 15 U/mL.....Equivocal - Questionable
                      Presence of IgG antibody
                      to Francisella tularensis.
                      Repeat testing in 10-14
                      days may be helpful.
  16 U/mL or greater...Positive - Presence of
                      IgG antibody to
                      Francisella tularensis
                      detected, suggestive of
                      current or past
                      exposure/Immunization.

Cross reactivity with Brucella and Yersinia antibodies may
occur. Therefore, results should be interpreted with
caution and correlated with clinical information. The best
evidence for current infection is a significant change on
two appropriately timed specimens, where both tests are
performed in the same laboratory at the same time.

Test developed and characteristics determined by ARUP
Laboratories. See Compliance Statement D: aruplab.com/CS
```

| | | | | | |
|---|---|---|---|---|---|
| Francisella tularensis Ab, IgM | 0 | | <=9 | U/mL | ARRL |

```
INTERPRETIVE DATA: Francisella tularensis
                   Antibody, IgM

   9 U/mL or less..... Negative - No significant
                       level of IgM antibody to
                       Francisella tularensis
                       detected.
  10 - 15 U/mL..... Equivocal - Questionable
                       presence of IgM antibody
                       to Francisella tularensis.
                       Repeat testing in 10-14
                       days may be helpful.
  16 U/mL..... Positive - Presence of
```

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: 07/11/2020 11:00 Received: 07/13/2020 12:36

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| | IgM antibody to Francisella tularensis detected, suggestive of current or recent exposure/Immunization. | | | | |

Cross reactivity with Brucella and Yersinia antibodies may occur. Therefore, results should be interpreted with caution and correlated with clinical information. The best evidence for current infection is a significant change on two appropriately timed specimens, where both tests are performed in the same laboratory at the same time.

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

F. tularensis Ab by Agglutination .TNP ARRL

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

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

## Referral Testing

Collected: 07/10/2020 06:09 Received: 07/13/2020 12:33

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Francisella tularensis Ab IgG/M w/ reflex to Agglutination** | | | | | |
| Francisella tularensis Ab, IgG | 0 | | <=9 | U/mL | ARRL |

INTERPRETATIVE DATA: Francisella tularensis Antibody, IgG

9 U/mL or less..... Negative - No significant level of IgG antibody to Francisella tularensis detected.
10 - 15 U/mL.....Equivocal - Questionable Presence of IgG antibody to Francisella tularensis. Repeat testing in 10-14 days may be helpful.
16 U/mL or greater...Positive - Presence of IgG antibody to Francisella tularensis detected, suggestive of current or past exposure/Immunization.

Cross reactivity with Brucella and Yersinia antibodies may occur. Therefore, results should be interpreted with caution and correlated with clinical information. The best evidence for current infection is a significant change on two appropriately timed specimens, where both tests are performed in the same laboratory at the same time.

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement D: aruplab.com/CS

| | | | | | |
|---|---|---|---|---|---|
| Francisella tularensis Ab, IgM | **10** | **H** | <=9 | U/mL | ARRL |

INTERPRETIVE DATA: Francisella tularensis Antibody, IgM

9 U/mL or less..... Negative - No significant level of IgM antibody to Francisella tularensis detected.
10 - 15 U/mL..... Equivocal - Questionable presence of IgM antibody to Francisella tularensis. Repeat testing in 10-14 days may be helpful.
16 U/mL..... Positive - Presence of

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: 07/10/2020 06:09 Received: 07/13/2020 12:33

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| | IgM antibody to Francisella tularensis detected, suggestive of current or recent exposure/Immunization. | | | | |

Cross reactivity with Brucella and Yersinia antibodies may occur. Therefore, results should be interpreted with caution and correlated with clinical information. The best evidence for current infection is a significant change on two appropriately timed specimens, where both tests are performed in the same laboratory at the same time.

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

| | | | | | |
|---|---|---|---|---|---|
| F. tularensis Ab by Agglutination | **1:40** | **H** | <1:20 | | ARRL |

INTERPRETIVE INFORMATION: Francisella tularensis Ab Agglutination

Testing was performed by direct agglutination (DA). DA measures total antibody and does not distinguish between IgG and IgM.
In the presence of compatible symptoms, a Francisella tularensis antibody titer of 1:160 or greater in an acute specimen supports a presumptive diagnosis of tularemia. However, a titer greater than or equal to 1:160 may also reflect past infection. An equivocal titer may be due to crossreactive antibodies (Brucella and Yersinia), past infection, or very recent infection. A four-fold rise in titer between acute and convalescent sera is required for definitive serologic diagnosis of tularemia.
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Performing Site:
ARRL: ARUP REFERENCE LAB 500 Chipeta Way Salt Lake City UT 841081221