Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| Update Summary | | |
|---|---|---|
| **New Test Activation** | 2/27/2024 | F266E - "Mace IgE*" |
| **New Test Activation** | 2/27/2024 | FHIGE - "Fly, Horse (Tabanus spp) IgE*" |
| **New Test Activation** | 2/27/2024 | RUPIE - "Rabbit Urine Proteins IgE*" |
| **New Test Activation** | 2/27/2024 | STRAT - "Stratify JCV Ab (w/Index) w/Ref to Inhib Assay" |
| **Update Existing Test** | 2/20/2024 | 17HPR - "17-Hydroxypregnenolone" |
| **Update Existing Test** | 2/20/2024 | CHROA - "Chromogranin A, Serum" |
| **Update Existing Test** | 2/5/2024 | COPRU - "Copper, Random Urine" |
| **Update Existing Test** | 2/20/2024 | CSFLA - "Lactic Acid, CSF" |
| **Update Existing Test** | 2/5/2024 | CURBC - "Copper RBC" |
| **Update Existing Test** | 2/19/2024 | E1Q - "Estrone" |
| **Update Existing Test** | 2/19/2024 | ESTFL - "Estradiol, Free" |
| **Update Existing Test** | 2/20/2024 | ESTFR - "Estrogen, Fractionated, LC-TMS" |
| **Update Existing Test** | 2/20/2024 | FLUPH - "Fluphenazine (Prolixin)" |
| **Update Existing Test** | 3/4/2024 | KETMS - "Ketamine and Metabolite Serum/Plasma" |
| **Update Existing Test** | 2/20/2024 | LACPL - "Lactic Acid, Plasma" |
| **Update Existing Test** | 2/20/2024 | MEX - "Mexiletine (Mexitil)" |
| **Update Existing Test** | 2/20/2024 | TPHPV - "Cytology, ThinPrep Pap Test and HPV" |
| **Update Existing Test** | 2/5/2024 | UB2M - "Beta 2 Microglobulin, Random Urine" |
| **Update Existing Test** | 2/20/2024 | UHVA - "Homovanillic Acid (HVA), Urine" |
| **Update Existing Test** | 3/4/2024 | UKETA - "Ketamine and Metabolite, Urine" |
| **Update Existing Test** | 2/20/2024 | UVMHA - "VMA and HVA, Urine" |
| **Update Existing Test** | 2/5/2024 | ZNRBC - "Zinc, RBC" |
| **Inactivate Test With Replacement** | 2/20/2024 | ADACT - "Adalimumab Activity and Neutralizing Antibody" replaced by ADABQ - "Adalimumab/Ab to Adalimumab Quantitation" |
| **Inactivate Test With Replacement** | 2/6/2024 | AGAS - "Alpha-galactosidase, Serum" replaced by AGALS - "Alpha-Galactosidase, Serum" |
| **Inactivate Test With Replacement** | 2/20/2024 | BBRUV - "Borrelia burgdorferi VlsE1/pepC10 Ab w Reflex to Immunoblot" replaced by BBUVR - "Borrelia burgdorferi VlsE1/pepC10Ab w Reflex to IgG/M" |
| **Inactivate Test With Replacement** | 2/27/2024 | BIACT - "Bile Acids, Total" replaced by BILAT - "Bile Acids, Total" |
| **Inactivate Test With Replacement** | 2/6/2024 | BIOT - "Biotinidase" replaced by BIOTS - "Biotinidase, Serum" |
| **Inactivate Test With Replacement** | 2/6/2024 | LC1AA - "Liver Cytosol (LC-1) Autoantibodies" replaced by LCA1G - "Liver Cystolic Antigen Type 1 (LC-1) Ab, IgG" |
| **Inactivate Test With Replacement** | 2/6/2024 | NARCO - "Narcolepsy (HLA-DQB1*06:02) Genotyping" replaced by NARCG - "Narcolepsy HLA-DQ Genotyping (HLA-DQB1*06:02)" |
| **Inactivate Test With Replacement** | 2/5/2024 | UCUQ - "Copper 24 Hour Urine" replaced by C24U - "Copper, 24 Hour Urine" |

| | | |
|---|---|---|
| **Inactivate Test Without Replacement** | 2/19/2024 | ISOH - "Isohemagglutinin" |
| **Inactivate Test Without Replacement** | 2/20/2024 | ZPYRI - "Pyridinium" |

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| New Test Activation | | | |
|---|---|---|---|
| **Effective Date** | 2/27/2024 | | |
| **Name** | Mace IgE* | | |
| **Code** | F266E | | |
| **CPT Code(s)** | 86003 | | |
| **Notes** | New Test Activation<br>*New York DOH Approval Status:* Yes | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | *Collect:* Red top<br>*Specimen Preparation:* Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial.<br>*Minimum Volume:* 0.5 mL<br>*Transport Temperature:* Refrigerated | | |
| **Alternate Specimen** | Serum separator tube (SST) | | |
| **Rejection Criteria** | Lipemic specimens | | |
| **Stability** | Room temperature: 4 weeks<br>Refrigerated: 4 weeks<br>Frozen: 2 months | | |
| **Performing Information** | | | |
| **Methodology** | Fluorimetric Enzyme-linked Immunoassay (FEIA) | | |
| **Reference Range** | See Report | | |
| **Performed Days** | Monday - Friday | | |
| **Turnaround Time** | 3 - 5 days | | |
| **Performing Laboratory** | Viracor Eurofins | | |
| **Interface Information** | | | |
| **Legacy Code** | F266E | | |
| **Interface Order Code** | 3300324 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt²** |
| 3300326 | Mace IgE | 15280-1 | No |
| 3300327 | Mace IgE Class | 51553-6 | No |

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003826 F 12/05/1988 35 Y

## Referral Testing

Collected: 01/17/2024 08:59 Received: 01/17/2024 08:59

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Mace IgE*** | | | | | |
| Mace IgE | 0.10 | | <0.35 | kU/L | VIRL |
| Mace IgE Class | 0/1 | | | | VIRL |

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

Testing Performed At:
Eurofins Viracor, LLC
18000 W. 99th Street, Suite 10
Lenexa, KS 66219
Lab Director: Brock Neil, PhD BCLD (ABB)
CLIA # 26D-0983643
FLAG Interpretation: A = Abnormal, H = High, L = Low

**Reported Date:** 01/17/2024 08:59 F266E

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

F717000011
WX0000003826
Printed D&T: 01/17/24 08:59

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002353

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| New Test Activation | | | |
|---|---|---|---|
| **Effective Date** | 2/27/2024 | | |
| **Name** | Fly, Horse (Tabanus spp) IgE* | | |
| **Code** | FHIGE | | |
| **CPT Code(s)** | 86003 | | |
| **Notes** | New Test Activation<br>*New York DOH Approval Status:* Yes | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | *Collect:* Red top<br>*Specimen Preparation:* Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial.<br>*Minimum Volume:* 0.5 mL<br>*Transport Temperature:* Refrigerated | | |
| **Alternate Specimen** | Serum separator tube (SST) | | |
| **Rejection Criteria** | Lipemic specimens | | |
| **Stability** | Room temperature: 4 weeks<br>Refrigerated: 4 weeks<br>Frozen: 2 months | | |
| **Performing Information** | | | |
| **Methodology** | Fluorimetric Enzyme-linked Immunoassay (FEIA) | | |
| **Reference Range** | See Report | | |
| **Performed Days** | Monday – Friday | | |
| **Turnaround Time** | 3 - 5 days | | |
| **Performing Laboratory** | Viracor Eurofins | | |
| **Interface Information** | | | |
| **Legacy Code** | FHIGE | | |
| **Interface Order Code** | 3300321 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt²** |
| 3300322 | Horse Fly IgE | 6144-0 | No |
| 3300323 | Horse Fly IgE Class | 15717-2 | No |

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003827 M 07/08/1978 45 Y

## Referral Testing

Collected: 01/17/2024 08:56 Received: 01/17/2024 08:56

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Fly Horse (Tabanus spp) IgE*** | | | | | |
| Fly Horse IgE | <0.10 | | <0.35 | kU/L | VIRL |
| Fly Horse IgE Class | 0 | | | | VIRL |

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

Testing Performed At:
Eurofins Viracor, LLC
18000 W. 99th Street, Suite 10
Lenexa, KS 66219
Lab Director: Brock Neil, PhD BCLD (ABB)
CLIA # 26D-0983643
FLAG Interpretation: A = Abnormal, H = High, L = Low

**Reported Date:** 01/17/2024 08:56 FHIGE

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

F717000009
WX0000003827
Printed D&T: 01/17/24 08:57

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002365

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| New Test Activation | | | |
|---|---|---|---|
| **Effective Date** | 2/27/2024 | | |
| **Name** | Rabbit Urine Proteins IgE* | | |
| **Code** | RUPIE | | |
| **CPT Code(s)** | 86003 | | |
| **Notes** | New Test Activation<br>*New York DOH Approval Status:* Yes | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | *Collect:* Red top<br>*Specimen Preparation:* Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial.<br>*Minimum Volume:* 0.5 mL<br>*Transport Temperature:* Refrigerated | | |
| **Alternate Specimen** | Serum separator tube (SST) | | |
| **Rejection Criteria** | Lipemic specimens | | |
| **Stability** | Room temperature: 4 weeks<br>Refrigerated: 4 weeks<br>Frozen: 2 months | | |
| **Performing Information** | | | |
| **Methodology** | Fluorimetric Enzyme-linked Immunoassay (FEIA) | | |
| **Reference Range** | See Report | | |
| **Performed Days** | Monday - Friday | | |
| **Turnaround Time** | 3 - 5 days | | |
| **Performing Laboratory** | Viracor Eurofins | | |
| **Interface Information** | | | |
| **Legacy Code** | RUPIE | | |
| **Interface Order Code** | 3300328 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt²** |
| 3300329 | Rabbit Urine Proteins IgE | 10961-1 | No |
| 3300331 | Rabbit Urine Proteins IgE Class | 15973-1 | No |

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003827 M 07/08/1978 45 Y

## Referral Testing

Collected: 01/17/2024 08:57 Received: 01/17/2024 08:57

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Rabbit Urine Proteins IgE*** | | | | | |
| Rabbit Urine Proteins IgE | 0.25 | | <0.35 | kU/L | VIRL |
| Rabbit Urine Proteins IgE Class | 0/1 | | | | VIRL |

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

Testing Performed At:
Eurofins Viracor, LLC
18000 W. 99th Street, Suite 10
Lenexa, KS 66219
Lab Director: Brock Neil, PhD BCLD (ABB)
CLIA # 26D-0983643
FLAG Interpretation: A = Abnormal, H = High, L = Low

**Reported Date:** 01/17/2024 08:58 RUPIE

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

F717000010
WX0000003827
Printed D&T: 01/17/24 08:58

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002365

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| New Test Activation | | | |
|---|---|---|---|
| **Effective Date** | 2/27/2024 | | |
| **Name** | Stratify JCV Ab (w/Index) w/Ref to Inhib Assay | | |
| **Code** | STRAT | | |
| **CPT Code(s)** | 86711 | | |
| **Notes** | New Test Activation<br>*New York DOH Approval Status: Yes* | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | *Collect:* Serum Separator Tube (SST)<br>*Specimen Preparation:* Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial.<br>*Minimum Volume:* 0.5 mL<br>*Transport Temperature:* Refrigerated | | |
| **Alternate Specimen** | Plasma: Lavender EDTA | | |
| **Rejection Criteria** | Gross hemolysis, Grossly lipemic, Grossly icteric | | |
| **Stability** | Room temperature: 7 days<br>Refrigerated: 14 days<br>Frozen: 90 days | | |
| **Performing Information** | | | |
| **Methodology** | Immunoassay | | |
| **Reference Range** | Negative | | |
| **Performed Days** | Monday - Saturday | | |
| **Turnaround Time** | 4 - 8 days | | |
| **Performing Laboratory** | Quest SJC | | |
| **Interface Information** | | | |
| **Legacy Code** | STRAT | | |
| **Interface Order Code** | 3400812 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt²** |
| 3400813 | Index Value | 100977-8 | No |
| 3400814 | JCV Antibody | 70173-0 | No |
| 3400828 | Stratify JCV Antibody Inhibition Assay | 70173-0 | No |

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003826 F 12/05/1988 35 Y

## Referral Testing

Collected: 01/17/2024 08:54 Received: 01/17/2024 08:54

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Stratify JCV Ab (w/Index) w/Ref to Inhib Assay** | | | | | |
| Index Value | **0.35** | **H** | | | QCRL |
| JCV Antibody | **INDETERMINATE** | **AB** | | | QCRL |

See Inhibition Assay result below for the final
antibody result.

Index interpretive criteria:
<0.20 negative
0.20-0.40 indeterminate
>0.40 positive

INTERPRETATION

Negative: Antibodies to JCV not detected.

Indeterminate: Low level reactivity detected, see
Inhibition Assay result below for the final
antibody result.

Positive: Antibodies to JC virus (JCV) detected indicating
the patient has been exposed to JCV at an
undetermined time.

The STRATIFY JCV Antibody Test is an enzyme-linked
immunosorbent assay (ELISA) designed to detect JCV
antibodies to help identify individuals who have been
exposed to the virus. Samples with low level reactivity
in the detection assay are retested in a confirmation
(inhibition) assay to confirm presence or absence of
JCV-specific antibodies.

Retrospective analyses of post marketing data from
various sources, including observational studies and
spontaneous reports obtained worldwide, suggest that
the risk of developing PML may be associated with
relative levels of serum anti-JCV antibody as measured
by anti-JCV antibody index.1

1TYSABRI(natalizumab)US Prescribing Information

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003826 F 12/05/1988 35 Y

## Referral Testing

Collected: 01/17/2024 08:54 Received: 01/17/2024 08:54

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| Stratify JCV Antibody Inhibition Assay | **FINAL RSLT: POSITIVE** | **AB** | | | QCRL |

```
REFERENCE RANGE: NEGATIVE

INTERPRETATION
Positive: Antibodies to JC virus (JCV) detected
          indicating the patient has been exposed
          to JCV at an undetermined time
Negative: Antibodies to JCV not detected
Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
```

**Reported Date:** 01/17/2024 08:55 STRAT

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

F717000007
WX0000003826
Printed D&T: 01/17/24 08:55

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002353

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/20/2024 |
| **Name** | 17-Hydroxypregnenolone |
| **Code** | 17HPR |
| **Interface Order Code** | 3684940 |
| **Legacy Code** | 17OHPREA |
| **Notes** | Update to turnaround time. |
| **Required Testing Changes** | |
| **Turnaround Time** | **3 - 7 days** |

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/20/2024 |
| **Name** | Chromogranin A, Serum |
| **Code** | CHROA |
| **Interface Order Code** | 3420100 |
| **Legacy Code** | CHROMAQ |
| **Notes** | Update to stability and reference range. |
| **Required Testing Changes** | |
| **Stability** | Room temperature: 48 hours<br>Refrigerated: 3 days<br>**Frozen: 3 months** |
| **Reference Range** | **0 - 187 ng/mL** |

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/5/2024 |
| **Name** | Copper, Random Urine |
| **Code** | COPRU |
| **Interface Order Code** | 3700000 |
| **Legacy Code** | COPRU |
| **Notes** | Update to performing laboratory. |
| **Required Testing Changes** | |
| **Performing Laboratory** | **Quest SJC** |

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/20/2024 |
| **Name** | Lactic Acid, CSF |
| **Code** | CSFLA |
| **Interface Order Code** | 3504190 |
| **Legacy Code** | CSFLAC |
| **Notes** | Update to rejection criteria and stability. |
| **Required Testing Changes** | |
| **Rejection Criteria** | **Hemolyzed specimen.** |
| **Stability** | After separation from cellular material:<br>**Room temperature: 2 hours**<br>**Refrigerated: 3 days**<br>**Frozen: 4 months**<br>**One freeze/thaw cycle is acceptable** |

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/5/2024 |
| **Name** | Copper RBC |
| **Code** | CURBC |
| **Interface Order Code** | 3711640 |
| **Legacy Code** | COPBLSP |
| **Notes** | Update to performing laboratory. |
| **Required Testing Changes** | |
| **Performing Laboratory** | **Quest SJC** |

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/19/2024 |
| **Name** | Estrone |
| **Code** | E1Q |
| **Interface Order Code** | 3400039 |
| **Legacy Code** | E1Q |
| **Notes** | Update to stability. |
| **Required Testing Changes** | |
| **Stability** | **Room temperature: 72 hours**<br>**Refrigerated: 30 days**<br>**Frozen: 1 year** |

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/19/2024 |
| **Name** | Estradiol, Free |
| **Code** | ESTFL |
| **Interface Order Code** | 3400086 |
| **Legacy Code** | ESTFL |
| **Notes** | Update to rejection criteria. |
| **Required Testing Changes** | |
| **Rejection Criteria** | **Serum separator tube (SST); hemolysis; grossly icteric** |

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/20/2024 |
| **Name** | Estrogen, Fractionated, LC-TMS |
| **Code** | ESTFR |
| **Interface Order Code** | 3685650 |
| **Legacy Code** | ESTRFARP |
| **Notes** | Update to turnaround time. |
| **Required Testing Changes** | |
| **Turnaround Time** | **3 - 7 days** |

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/20/2024 |
| **Name** | Fluphenazine (Prolixin) |
| **Code** | FLUPH |
| **Interface Order Code** | 3502860 |
| **Legacy Code** | FLUPHEN |
| **Notes** | Update to turnaround time. |
| **Required Testing Changes** | |
| **Turnaround Time** | **3 - 10 days** |

| Update Existing Test | |
|---|---|
| **Effective Date** | 3/4/2024 |
| **Name** | Ketamine and Metabolite Serum/Plasma |
| **Code** | KETMS |
| **Interface Order Code** | 3301320 |
| **Legacy Code** | KETMS |
| **Notes** | Update to specimen requirement and methodology |
| **Required Testing Changes** | |
| **Specimen Required** | *Collect:* Red top<br>*Specimen Preparation:* **Separate serum from cells and send 2.0 mL serum in a screw capped plastic vial.**<br>***Minimum Volume:*** **1.0 mL**<br>*Transport Temperature:* Refrigerated |
| **Methodology** | **Liquid Chromatography - Tandem Mass Spectrometry (LC/MS/MS)** |

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/20/2024 |
| **Name** | Lactic Acid, Plasma |
| **Code** | LACPL |
| **Interface Order Code** | 3600036 |
| **Legacy Code** | LACPL |
| **Notes** | Update to rejection criteria. |
| **Required Testing Changes** | |
| **Rejection Criteria** | **Hemolyzed,** EDTA, citrate, or iodoacetate as anticoagulants. **Tubes less than half full.** |

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/20/2024 |
| **Name** | Mexiletine (Mexitil) |
| **Code** | MEX |
| **Interface Order Code** | 3505000 |
| **Legacy Code** | MEX |
| **Notes** | Update to turnaround time. |
| **Required Testing Changes** | |
| **Turnaround Time** | **3 - 10 days** |

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/20/2024 |
| **Name** | Cytology, ThinPrep Pap Test and HPV |
| **Code** | TPHPV |
| **Interface Order Code** | 3662100 |
| **Legacy Code** | TPHPV |
| **Notes** | Update to CPT4 code. |
| **Required Testing Changes** | |
| **CPT Code(s)** | **Varies** |

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/5/2024 |
| **Name** | Beta 2 Microglobulin, Random Urine |
| **Code** | UB2M |
| **Interface Order Code** | 3719360 |
| **Legacy Code** | UB2MSP |
| **Notes** | Update to performing laboratory |
| **Required Testing Changes** | |
| **Performing Laboratory** | **Quest SJC** |

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/20/2024 |
| **Name** | Homovanillic Acid (HVA), Urine |
| **Code** | UHVA |
| **Interface Order Code** | 3686400 |
| **Legacy Code** | UHVARP |
| **Notes** | Update to turnaround time |
| **Required Testing Changes** | |
| **Turnaround Time** | **3 - 7 days** |

| Update Existing Test | |
|---|---|
| **Effective Date** | 3/4/2024 |
| **Name** | Ketamine and Metabolite, Urine |
| **Code** | UKETA |
| **Interface Order Code** | 3301360 |
| **Legacy Code** | UKETA |
| **Notes** | Update to methodology. |
| **Required Testing Changes** | |
| **Methodology** | **Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)** |

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/20/2024 |
| **Name** | VMA and HVA, Urine |
| **Code** | UVMHA |
| **Interface Order Code** | 3686500 |
| **Legacy Code** | UVMAHVARP |
| **Notes** | Update to turnaround time. |
| **Required Testing Changes** | |
| **Turnaround Time** | **3 - 7 days** |

| Update Existing Test | |
|---|---|
| **Effective Date** | 2/5/2024 |
| **Name** | Zinc, RBC |
| **Code** | ZNRBC |
| **Interface Order Code** | 3711650 |
| **Legacy Code** | ZINCRBCSP |
| **Notes** | Update to stability, performing laboratory. |
| **Required Testing Changes** | |
| **Stability** | Room temperature: 7 days<br>**Refrigerated: 10 days**<br>Frozen: Unacceptable |
| **Performing Laboratory** | **Quest SJC** |

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| Inactivate Test With Replacement | | | |
|---|---|---|---|
| **Effective Date** | 2/20/2024 | | |
| **Inactivated Test** | | | |
| **Name** | Adalimumab Activity and Neutralizing Antibody | | |
| **Code** | ADACT | | |
| **Legacy Code** | ADACT | | |
| **Interface Order Code** | 3618440 | | |
| **Replacement Test** | | | |
| **Name** | Adalimumab/Ab to Adalimumab Quantitation | | |
| **Code** | ADABQ | | |
| **CPT Code(s)** | 80145, 83520 | | |
| **Notes** | New York DOH Approval Status: No | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | *Patient Preparation:* Collect specimens prior to Adalimumab treatment. Avoid exposure to biotin (Vitamin B7) for 12 hours prior to specimen collection.<br>*Collect:* Serum separator tube (SST)<br>*Specimen Preparation:* Centrifuge, separate serum from cells as soon as possible or within 2 hours of collection and send 1.0 mL serum in a screw capped plastic vial.<br>*Minimum Volume:* 0.1 mL<br>*Transport Temperature:* Refrigerated | | |
| **Rejection Criteria** | Grossly hemolyzed, icteric or lipemic specimens | | |
| **Stability** | Room temperature: 2 days<br>Refrigerated: 14 days<br>Frozen: 1 month<br>Avoid repeated freeze/thaw cycles. | | |
| **Performing Information** | | | |
| **Methodology** | Quantitative Electrochemiluminescent Immunoassay | | |
| **Reference Range** | Adalimumab Quantitation: 0.4 ug/mL or greater<br>Antibodies to Adalimumab Quantitation: 19 ng/mL or less | | |
| **Performed Days** | Sunday - Saturday | | |
| **Turnaround Time** | 5 - 9 days | | |
| **Performing Laboratory** | ARUP Reference Laboratory | | |
| **Interface Information** | | | |
| **Legacy Code** | ADABQ | | |
| **Interface Order Code** | 3600373 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt²** |
| 3600374 | Adalimumab Quantitation | 86894-3 | No |
| 3600376 | Antibodies to Adalimumab Quantitation | 86895-0 | No |

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003826 F 12/05/1988 35 Y

## Referral Testing

Collected: 01/17/2024 08:55 Received: 01/17/2024 08:55

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Adalimumab/Ab to Adalimumab Quantitation** | | | | | |
| Adalimumab Quantitation | 5.0 | | >=0.4 | ug/mL | ARRL |

INTERPRETIVE INFORMATION: Adalimumab Quantitation

Results of 0.4 ug/mL or higher indicate the detection of adalimumab or an adalimumab biosimilar. Therapeutic level may vary depending on the disease being treated.

| | | | | | |
|---|---|---|---|---|---|
| Antibodies to Adalimumab Quantitation | **25** | **H** | <=19 | ng/mL | ARRL |

INTERPRETIVE INFORMATION: Antibodies to Adalimumab Quantitation
Results of 20 ng/mL or higher indicate the detection of antibodies against adalimumab or an adalimumab biosimilar. Interpret in the context of adalimumab or adalimumab biosimilar trough concentration to determine clinical significance and impact on treatment efficacy.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.
Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Jonathan R. Genzen, MD, PhD
CLIA Number: 46D0523979

**Reported Date:** 01/17/2024 08:55 ADABQ

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

F717000008
WX0000003826
Printed D&T: 01/17/24 08:56

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002353

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

| Inactivate Test With Replacement | | | |
|---|---|---|---|
| **Effective Date** | 2/6/2024 | | |
| **Inactivated Test** | | | |
| **Name** | Alpha-galactosidase, Serum | | |
| **Code** | AGAS | | |
| **Legacy Code** | AGASM | | |
| **Interface Order Code** | 3805600 | | |
| **Replacement Test** | | | |
| **Name** | Alpha-Galactosidase, Serum | | |
| **Code** | AGALS | | |
| **CPT Code(s)** | 82657 | | |
| **Notes** | New York DOH Approval Status: Yes | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | *Collect:* Serum separator tube (SST)<br>*Specimen Preparation:* Centrifuge, separate serum from cells and send 2.0 mL serum in a screw capped plastic vial. Sex of patient is required for interpretation.<br>*Minimum Volume:* 0.2 mL<br>*Transport Temperature:* Frozen | | |
| **Alternate Specimen** | Serum: Red top | | |
| **Rejection Criteria** | Gross hemolysis, gross lipemia, gross icterus | | |
| **Stability** | Room temperature: Unacceptable<br>Refrigerated: 24 hours<br>Frozen: 14 days | | |
| **Performing Information** | | | |
| **Methodology** | Alpha-galactosidase is a lysosomal enzyme active at an acidic pH. The enzyme hydrolyzes artificial substrates such as 4-methylumbelliferyl and alpha-D galactopyranoside. The 4-methylumbelliferone liberated is measured by fluorometry. | | |
| **Reference Range** | 0.074 - 0.457 U/L<br><br>Note: Results from this assay are not useful for carrier determination. Carriers usually have levels in the normal range. | | |
| **Performed Days** | Tuesday, Friday | | |
| **Turnaround Time** | 6 - 10 days | | |
| **Performing Laboratory** | Mayo Clinic Laboratories | | |
| **Interface Information** | | | |
| **Legacy Code** | AGALS | | |
| **Interface Order Code** | 3800353 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt²** |
| 3800354 | Alpha-Galactosidase S | 1813-5 | No |
| 3800356 | Interpretation | 59462-2 | No |
| 3800357 | Reviewed By | 18771-6 | No |

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003827 M 07/08/1978 45 Y

## Referral Testing

Collected: 01/17/2024 08:48 Received: 01/17/2024 08:48

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Alpha-Galactosidase, Serum** | | | | | |
| Alpha-Galactosidase S | 0.085 | | 0.074-0.457 | U/L | MMRL |
| Interpretation | SEE BELOW | | | | MMRL |

*NEGATIVE* In this sample, the activity of
alpha-galactosidase is normal. These results indicate that
this individual is NOT affected with Fabry disease.

----------ADDITIONAL INFORMATION----------
Fluorometric Enzyme Assay
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.

Reviewed By SEE BELOW MMRL

RESULT: Rebecca Billings

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

**Reported Date:** 01/17/2024 08:48 AGALS

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

F717000004
WX0000003827
Printed D&T: 01/17/24 08:49

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002365

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| Inactivate Test With Replacement | | | |
|---|---|---|---|
| **Effective Date** | 2/20/2024 | | |
| **Inactivated Test** | | | |
| **Name** | Borrelia burgdorferi VlsE1/pepC10 Ab w Reflex to Immunoblot | | |
| **Code** | BBRUV | | |
| **Legacy Code** | BBRUV | | |
| **Interface Order Code** | 3600296 | | |
| **Replacement Test** | | | |
| **Name** | Borrelia burgdorferi VlsE1/pepC10Ab w Reflex to IgG/M | | |
| **Code** | BBUVR | | |
| **CPT Code(s)** | 86618 if reflexed add 86617 x 2 at additional cost | | |
| **Notes** | New York DOH Approval Status: Yes | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | *Collect:* Serum separator tube (SST)<br>*Specimen Preparation:* Centrifuge, separate serum from cells. Send 2.0 mL in a screw capped plastic vial.<br>*Minimum Volume:* 0.2 mL<br>*Transport Temperature:* Refrigerated | | |
| **Alternate Specimen** | Serum: Red top | | |
| **Rejection Criteria** | Plasma, cerebrospinal fluid (CSF), contaminated, heat-inactivated, hemolyzed, icteric, or lipemic specimens | | |
| **Stability** | Room temperature: 48 hours<br>Refrigerated: 10 days<br>Frozen: 1 month | | |
| **Performing Information** | | | |
| **Methodology** | Semi-quantitative Enzyme-Linked Immunosorbent Assay/Qualitative Immunoblot | | |
| **Reference Range** | .90 IV or less: Negative VlsE1 and pepC10 antibodies to B. burgdorferi not detected.<br>0.91 - 1.09 IV: Equivocal - Repeat testing in 10 - 14 days may be helpful.<br>1.10 IV or greater: Positive - VlsE1 and pepC10 antibodies to B. Burgdorferi detected. | | |
| **Performed Days** | Monday - Friday | | |
| **Turnaround Time** | 3 - 6 days | | |
| **Performing Laboratory** | ARUP Reference Laboratory | | |
| **Interface Information** | | | |
| **Legacy Code** | BBUVR | | |
| **Interface Order Code** | 3600367 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt²** |
| 3600368 | B. burgdorferi VlsE1/pepC10 Abs, ELISA | 100711-1 | No |
| 3600369 | B. burgdorferi IgG Immunoblot | 6320-6 | No |
| 3600371 | B. burgdorferi Antibody IgM Immunoblot | 6321-4 | No |
| 3600372 | Lyme Standard 2-Tier Testing Interp | 62342-1 | No |

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003827 M 07/08/1978 45 Y

## Referral Testing

Collected: 01/17/2024 08:53 Received: 01/17/2024 08:53

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Borrelia burgdorferi VlsE1/pepC10Ab w Reflex to IgG/M** | | | | | |
| B. burgdorferi VlsE1/pepC10 Abs, ELISA | **1.25** | **H** | <=0.90 | IV | ARRL |

```
REFERENCE INTERVAL: B. burgdorferi VlsE1/pepC10 Abs, ELISA

 0.90 IV or less.....Negative: VlsE1 and pepC10
                     antibodies to B. burgdorferi
                     not detected.

 0.91 - 1.09 IV.....Equivocal: Repeat testing in
                     10-14 days may be helpful.

 1.10 IV or greater.....Positive: VlsE1 and pepC10
                     antibodies to B. burgdorferi
                     detected.
Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Jonathan R. Genzen, MD, PhD
CLIA Number: 46D0523979
```

| | | | | | |
|---|---|---|---|---|---|
| B. burgdorferi IgG Immunoblot | **Positive** | **AB** | Negative | | ARRL |

```
INTERPRETIVE INFORMATION: B. burgdorferi IgG Immunoblot

For this assay, a positive result is reported when any 5 or
more of the following 10 bands are present: 18, 23, 28, 30,
39, 41, 45, 58, 66, or 93 kDa.  All other banding patterns
are reported as negative.
```

| | | | | | |
|---|---|---|---|---|---|
| B. burgdorferi Antibody IgM Immunoblot | **Positive** | **AB** | Negative | | ARRL |

```
INTERPRETIVE INFORMATION: B. burgdorferi Antibody IgM
                          Immunoblot

For this assay, a positive result is reported when any 2 or
more of the following bands are present: 23, 39, or 41 kDa.
 All other banding patterns are reported as negative.
```

| | | | | | |
|---|---|---|---|---|---|
| Lyme Standard 2-Tier Testing Interp | **Positive** | **AB** | Negative | | ARRL |

```
INTERPRETIVE INFORMATION: Lyme Standard 2-Tier, 2nd Tier

IgG: For this assay, a positive result is reported when any
```

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003827 M 07/08/1978 45 Y

## Referral Testing

Collected: 01/17/2024 08:53 Received: 01/17/2024 08:53

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

5 or more of the following 10 bands are present: 18, 23, 28, 30, 39, 41, 45, 58, 66, or 93 kDa. All other banding patterns are reported as negative.

IgM: For this assay, a positive result is reported when any 2 or more of the following bands are present: 23, 39, or 41 kDa. All other banding patterns are reported as negative.
Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Jonathan R. Genzen, MD, PhD
CLIA Number: 46D0523979

**Reported Date:** 01/17/2024 08:53 BBUVR

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| Inactivate Test With Replacement | | | |
|---|---|---|---|
| **Effective Date** | 2/27/2024 | | |
| **Inactivated Test** | | | |
| **Name** | Bile Acids, Total | | |
| **Code** | BIACT | | |
| **Legacy Code** | BILEACTSP | | |
| **Interface Order Code** | 3717900 | | |
| **Replacement Test** | | | |
| **Name** | Bile Acids, Total | | |
| **Code** | BILAT | | |
| **CPT Code(s)** | 82239 | | |
| **Notes** | New York DOH Approval Status: Yes | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | *Patient Preparation:* Patient should fast for eight hours prior to collection.<br>*Collect:* Serum separator tube (SST)<br>*Specimen Preparation:* Allow sample to clot completely at room temperature before centrifugation. Centrifuge and separate serum from cells within 1 hour of collection. Send 1.0 mL serum in a screw capped plastic vial.<br>*Minimum Volume:* 0.5 mL<br>*Transport Temperature:* Refrigerated | | |
| **Alternate Specimen** | Plasma: Lavender EDTA or Green lithium heparin | | |
| **Rejection Criteria** | Hemolyzed samples or hemolysis, body fluids | | |
| **Stability** | Room temperature: 8 hours<br>Refrigerated: 14 days<br>Frozen: 90 days | | |
| **Performing Information** | | | |
| **Methodology** | Quantitative Enzymatic Assay | | |
| **Reference Range** | 0 - 10 mcgmol/L | | |
| **Performed Days** | Sunday - Saturday | | |
| **Turnaround Time** | 3 - 5 days | | |
| **Performing Laboratory** | ARUP Reference Laboratory | | |
| **Interface Information** | | | |
| **Legacy Code** | BILAT | | |
| **Interface Order Code** | 3600347 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt²** |
| 3600347 | Bile Acids, Total | 14628-2 | No |

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003827 M 07/08/1978 45 Y

## Referral Testing

Collected: 01/17/2024 08:43 Received: 01/17/2024 08:43

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| Bile Acids, Total | 8 | | 0-10 | umol/L | ARRL |

INTERPRETIVE INFORMATION: Bile Acids, Total

Reference Interval applies to fasting specimens.
Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Jonathan R. Genzen, MD, PhD
CLIA Number: 46D0523979

**Reported Date:** 01/17/2024 08:43 BILAT

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

F717000001
WX0000003827
Printed D&T: 01/17/24 08:44

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002365

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| Inactivate Test With Replacement | | | |
|---|---|---|---|
| **Effective Date** | 2/6/2024 | | |
| **Inactivated Test** | | | |
| **Name** | Biotinidase | | |
| **Code** | BIOT | | |
| **Legacy Code** | BIOT | | |
| **Interface Order Code** | 3500562 | | |
| **Replacement Test** | | | |
| **Name** | Biotinidase, Serum | | |
| **Code** | BIOTS | | |
| **CPT Code(s)** | 82261 | | |
| **Notes** | New York DOH Approval Status: Yes | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | *Collect:* Serum: Red top<br>*Specimen Preparation:* Centrifuge, separate immediately after collection and send 1.0 mL serum in a screw capped plastic vial.<br>*Minimum Volume:* 0.5 mL<br>*Transport Temperature:* Frozen | | |
| **Alternate Specimen** | Serum separator tube (SST) | | |
| **Rejection Criteria** | Gross hemolysis | | |
| **Stability** | Room temperature: Unacceptable<br>Refrigerated: 5 days<br>Frozen: 21 days | | |
| **Performing Information** | | | |
| **Methodology** | Colorimetric | | |
| **Reference Range** | 3.5 - 13.8 U/mL | | |
| **Performed Days** | Monday, Thursday | | |
| **Turnaround Time** | 6 - 10 days | | |
| **Performing Laboratory** | Mayo Clinic Laboratories | | |
| **Interface Information** | | | |
| **Legacy Code** | BIOTS | | |
| **Interface Order Code** | 3800348 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt²** |
| 3800349 | Biotinidase, S | 1982-8 | No |
| 3800351 | Interpretation | 59462-2 | No |
| 3800352 | Reviewed By | 18771-6 | No |

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003827 M 07/08/1978 45 Y

## Referral Testing

Collected: 01/17/2024 08:46 Received: 01/17/2024 08:46

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Biotinidase, Serum** | | | | | |
| Biotinidase, S | 3.5 | | 3.5-13.8 | U/L | MMRL |
| Interpretation | SEE BELOW | | | | MMRL |

*NEGATIVE* In this sample, biotinidase activity is normal.
These results indicate this individual is not affected with
biotinidase deficiency.

----------ADDITIONAL INFORMATION----------
Colorimetric Enzyme Assay
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.

| | | |
|---|---|---|
| Reviewed By | SEE BELOW | MMRL |

RESULT: Rebecca Billings

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

**Reported Date:** 01/17/2024 08:47 BIOTS

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

F717000003
WX0000003827
Printed D&T: 01/17/24 08:47

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002365

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| Inactivate Test With Replacement | | | |
|---|---|---|---|
| **Effective Date** | 2/6/2024 | | |
| **Inactivated Test** | | | |
| **Name** | Liver Cytosol (LC-1) Autoantibodies | | |
| **Code** | LC1AA | | |
| **Legacy Code** | LC1AA | | |
| **Interface Order Code** | 3724300 | | |
| **Replacement Test** | | | |
| **Name** | Liver Cystolic Antigen Type 1 (LC-1) Ab, IgG | | |
| **Code** | LCA1G | | |
| **CPT Code(s)** | 84182 | | |
| **Notes** | New York DOH Approval Status: Yes | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | *Collect:* Serum separator tube (SST)<br>*Specimen Preparation:* Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial.<br>*Minimum Volume:* 0.3 mL<br>*Transport Temperature:* Refrigerated | | |
| **Rejection Criteria** | Contaminated, hemolyzed, or severely lipemic | | |
| **Stability** | Room temperature: 2 days<br>Refrigerated: 14 days<br>Frozen: 1 year | | |
| **Performing Information** | | | |
| **Methodology** | Qualitative Immunoblot | | |
| **Reference Range** | Negative | | |
| **Performed Days** | Tuesday | | |
| **Turnaround Time** | 3 - 10 days | | |
| **Performing Laboratory** | ARUP Reference Laboratory | | |
| **Interface Information** | | | |
| **Legacy Code** | LCA1G | | |
| **Interface Order Code** | 3600346 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt²** |
| 3600346 | Liver Cystolic Antigen Type 1 (LC-1) Ab, IgG | 13175-5 | No |

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003827 M 07/08/1978 45 Y

## Referral Testing

Collected: 01/17/2024 08:45 Received: 01/17/2024 08:45

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| Liver Cystolic Antigen Type 1 (LC-1) Ab, IgG | Negative | | Negative | | ARRL |

Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Jonathan R. Genzen, MD, PhD
CLIA Number: 46D0523979

**Reported Date:** 01/17/2024 08:46 LCA1G

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

F717000002
WX0000003827
Printed D&T: 01/17/24 08:46

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002365

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| Inactivate Test With Replacement | | | |
|---|---|---|---|
| **Effective Date** | 2/6/2024 | | |
| **Inactivated Test** | | | |
| **Name** | Narcolepsy (HLA-DQB1*06:02) Genotyping | | |
| **Code** | NARCO | | |
| **Legacy Code** | NARCO | | |
| **Interface Order Code** | 3621400 | | |
| **Replacement Test** | | | |
| **Name** | Narcolepsy HLA-DQ Genotyping (HLA-DQB1*06:02) | | |
| **Code** | NARCG | | |
| **CPT Code(s)** | 81383 | | |
| **Notes** | New York DOH Approval Status: Yes | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | *Collect:* Lavender EDTA<br>*Specimen Preparation:* Send 3.0 mL whole blood.<br>*Minimum Volume:* 1.0 mL<br>*Transport Temperature:* Refrigerated | | |
| **Alternate Specimen** | Whole blood: Yellow ACD A | | |
| **Rejection Criteria** | Yellow ACD B, heparinized specimens, clotted, grossly hemolyzed. | | |
| **Stability** | Room temperature: 72 hours<br>Refrigerated: 7 days<br>Frozen: Unacceptable | | |
| **Performing Information** | | | |
| **Methodology** | Polymerase Chain Reaction (PCR), Massively Parallel Sequencing, Sequence-Specific Oligonucleotide Probe Hybridization | | |
| **Reference Range** | See report | | |
| **Performed Days** | Monday - Friday | | |
| **Turnaround Time** | 10 - 17 days | | |
| **Performing Laboratory** | ARUP Reference Laboratory | | |
| **Interface Information** | | | |
| **Legacy Code** | NARCG | | |
| **Interface Order Code** | 3600362 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt²** |
| 3600363 | HLA-DQB1, Allele 1 | 57299-0 | No |
| 3600364 | HLA-DQB1, Allele 2 | 57299-0 | No |
| 3600366 | Narcolepsy HLA Interpretation | | No |

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003827 M 07/08/1978 45 Y

## Referral Testing

Collected: 01/17/2024 08:51 Received: 01/17/2024 08:51

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Narcolepsy HLA-DQ Genotyping (HLA-DQB1*06:02)** | | | | | |
| HLA-DQB1, Allele 1 | 06:02 | | | | ARRL |

Performed By: UUH Histocompatibility and Immunogenetic
417 Wakara Way
Suite 3220
Salt Lake City, UT 84108
CLIA Number: 46D0523979

| | | | | | |
|---|---|---|---|---|---|
| HLA-DQB1, Allele 2 | 06:02 | | | | ARRL |

Performed By: UUH Histocompatibility and Immunogenetic
417 Wakara Way
Suite 3220
Salt Lake City, UT 84108
CLIA Number: 46D0523979

| | | | | | |
|---|---|---|---|---|---|
| Narcolepsy HLA Interpretation | See Note | | | | ARRL |

Positive for HLA-DQB1*06:02, two copies.
The HLA-DQB1*06:02 allele, which is strongly associated with
narcolepsy, was detected. Two copies of the HLA-DQB1*06:02 allele double the risk for narcolepsy, compared to just one copy. This result is supportive of a clinical diagnosis of narcolepsy, but by itself does not establish a diagnosis. Medical screening and management of this individual should rely
on clinical findings.
Performed By: UUH Histocompatibility and Immunogenetic
417 Wakara Way
Suite 3220
Salt Lake City, UT 84108
CLIA Number: 46D0523979
BACKGROUND INFORMATION: Narcolepsy Genotyping
(HLA-DQB1*06:02)
Characteristics: Narcolepsy is a chronic neurological sleep disorder that manifests in excessive daytime sleepiness and difficulty in maintaining wakefulness. Narcolepsy type 1 is associated with cataplexy (the sudden loss of muscle tone triggered by strong emotions). Additionally, disturbed nighttime sleep, sleep paralysis, and hypnagogic hallucinations (occurring in the period between sleep and wakefulness) are common.

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003827 M 07/08/1978 45 Y

## Referral Testing

Collected: 01/17/2024 08:51 Received: 01/17/2024 08:51

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

Incidence: Varies, depending on ethnicity. It affects 0.02-0.05% of the populations in the US and Europe, it is most common in Japan (0.16-0.18%).

Inheritance: Multifactorial.

Cause: The HLA-DQB1*06:02 allele is strongly associated with narcolepsy, but by itself is not causative. Homozygosity for DQB1*06:02 allele doubles the risk, compared to heterozygous individuals.

Alleles Tested: HLA-DQB1 alleles.

Clinical Sensitivity: 85-95 percent depending on ethnicity. Greater than 98% of affected Caucasians with cataplexy have the HLA-DQB1*06:02 allele.

Clinical Specificity: Less than 1 percent; 15-25 percent of unaffected Caucasians carry the HLA-DQB1*06:02 allele.

Methodology: Polymerase Chain Reaction/Massively Parallel Sequencing, or Polymerase Chain Reaction/Sequence-Specific Oligonucleotide Probe Hybridization

Analytical Sensitivity and Specificity: 99 percent.

Limitations: Rare diagnostic errors may occur due to primer site mutations. Other genetic and nongenetic factors that influence narcolepsy disease are not evaluated. In cases where an HLA allele cannot be resolved unambiguously, the allele assignment will be reported as the most common, based on allele frequencies from the common, intermediate, and well-documented alleles catalogue version 3.0.0 (Hurley CK et al, 2020).

This test was developed and its performance characteristics determined by the Histocompatibility & Immunogenetics laboratory at the University of Utah Health. It has not been cleared or approved by the US Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Histocompatibility & Immunogenetics laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003827 M 07/08/1978 45 Y

## Referral Testing

Collected: 01/17/2024 08:51 Received: 01/17/2024 08:51

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

Performed at: Histocompatibility & Immunogenetics Laboratory, University of Utah Health, 417 Wakara Way, Suite 3220, Salt Lake City, UT 84108.
CLIA Number: 46D0679773

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

**Reported Date:** 01/17/2024 08:51 NARCG

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

F717000005
WX0000003827
Printed D&T: 01/17/24 08:52

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002365

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| Inactivate Test With Replacement | | | |
|---|---|---|---|
| **Effective Date** | 2/5/2024 | | |
| **Inactivated Test** | | | |
| **Name** | Copper 24 Hour Urine | | |
| **Code** | UCUQ | | |
| **Legacy Code** | UCOPSP | | |
| **Interface Order Code** | 3706125 | | |
| **Replacement Test** | | | |
| **Name** | Copper, 24 Hour Urine | | |
| **Code** | C24U | | |
| **CPT Code(s)** | 82525 | | |
| **Notes** | New York DOH Approval Status: Yes | | |
| **Specimen Requirements** | | | |
| **Specimen Required** | *Collect:* 24 hour urine in acid washed or metal free container<br>*Specimen Preparation:* Mix well and send 7.0 mL urine refrigerated in an acid washed screw-capped plastic container. Record total volume on specimen container and test requisition. Call lab for collection container.<br>*Minimum Volume:* 3.0 mL<br>*Transport Temperature:* Refrigerated | | |
| **Rejection Criteria** | Hemolysis, random urine, fecal contamination | | |
| **Stability** | Room temperature: 5 day<br>Refrigerated: 14 days<br>Frozen: 30 days | | |
| **Performing Information** | | | |
| **Methodology** | Inductively Coupled Plasma/Mass Spectrometry (ICP/MS) | | |
| **Reference Range** | 15 - 60 mcg/24 hr | | |
| **Performed Days** | Sunday, Wednesday, Friday | | |
| **Turnaround Time** | 3 - 5 days | | |
| **Performing Laboratory** | Quest SJC | | |
| **Interface Information** | | | |
| **Legacy Code** | C24U | | |
| **Interface Order Code** | 3400843 | | |
| **Result Code** | **Name** | **LOINC Code** | **AOE/Prompt²** |
| 3400844 | Urine Volume | 3167-4 | **Yes** |
| 3400846 | Collection Duration | 13362-9 | **Yes** |
| 3706130 | Copper, 24 Hour Urine | 5633-3 | No |

Warde Medical Laboratory

# LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

**EXAMPLE, REPORT W**
WX0000003826 F 12/05/1988 35 Y

## Referral Testing

Collected: 01/25/2024 08:13 Received: 01/25/2024 08:13

| Test Name | Result | Flag | Ref-Ranges | Units | Site |
|---|---|---|---|---|---|
| **Copper, 24 Hour Urine** | | | | | |
| Urine Volume | 1200 | | | | QCRL |
| Collection Duration | 24 | | | | QCRL |
| Copper, 24 Hour Urine | 30 | | 15-60 | mcg/24 h | QCRL |

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

Test Performed at:
MedFusion
2501 South State Highway 121, Suite 1100

**Reported Date:** 01/25/2024 08:14 C24U

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

F725000000
WX0000003826
Printed D&T: 01/25/24 08:14

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002353

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

Warde Medical Laboratory

# TEST DIRECTORY UPDATE

## FEBRUARY 2024

| Inactivate Test Without Replacement | |
|---|---|
| **Effective Date** | 2/19/2024 |
| **Name** | Isohemagglutinin |
| **Code** | ISOH |
| **Legacy Code** | ISOH |
| **Interface Code** | 3504110 |
| **Notes** | Test discontinued. |

| Inactivate Test Without Replacement | |
|---|---|
| **Effective Date** | 2/20/2024 |
| **Name** | Pyridinium |
| **Code** | ZPYRI |
| **Legacy Code** | PYRIDIN |
| **Interface Code** | 3509465 |
| **Notes** | Test discontinued. |