

JUNE 2025

Update Summary

| opaace sammary | | |
|-------------------------------------|-----------|---|
| Update Existing Test | 6/23/2025 | ARIX - "Arixtra (Fondaparinux) Level" |
| Update Existing Test | 5/29/2025 | CVLPB - "Comprehensive Volatiles Panel, Blood" |
| Update Existing Test | 5/29/2025 | ENCS - "Encephalopathy, Autoimmune/Paraneoplastic Evaluation, Serum" |
| Update Existing Test | 6/10/2025 | HCVGT - "Hepatitis C Viral RNA Genotype" |
| Update Existing Test | 6/10/2025 | HCVRG - "HCV RNA, QN, Real Time PCR Reflex to Genotype" |
| Update Existing Test | 6/30/2025 | HTLVD - "HTLV I/II DNA, Qualitative, Real-Time PCR" |
| Update Existing Test | 6/10/2025 | HVGII - "HIV-1 Genotype (RTI, PI, Integrase Inhibitors)" |
| Update Existing Test | 5/29/2025 | KIDST - "Kidney Stone Diagnostic Prof" |
| Update Existing Test | 6/23/2025 | KRBC - "Potassium - RBC" |
| Update Existing Test | 6/24/2025 | RBCF - "RBC Folate" |
| Update Existing Test | 6/23/2025 | RIVAR - "Rivaroxaban" |
| Update Existing Test | 7/7/2025 | THIOT - "Thiothixene, Serum or Plasma" |
| Update Existing Test | 7/7/2025 | THIR - "Thioridazine and Metabolite, Serum/Plasma" |
| Inactivate Test With Replacement | 6/10/2025 | <u>CIABG - "Cutaneous Immunofl Ab IgG, Ser" replaced by CIFAS -</u> <u>"Cutaneous Immuonofluoresence, IgG and IgG4, Serum"</u> |
| Inactivate Test With Replacement | 6/24/2025 | TMHIV - "HIV-1 RNA, Qualitative Real-Time PCR" replaced by HIVUL - "HIV-1 RNA Ultraguant" |
| Inactivate Test Without Replacement | 5/29/2025 | COXA9 - "Coxsackie A Serotype 9 Titer" |
| Inactivate Test Without Replacement | 6/9/2025 | CRYAB - "Cryptococcus Ab" |
| Inactivate Test Without Replacement | 5/29/2025 | LCM - "LCM Antibody" |
| Inactivate Test Without Replacement | 5/29/2025 | UGAL - "Galactose (Quant) - Urine" |



| Update Existing Test | | | |
|---------------------------|---|--|--|
| Effective Date | 6/23/2025 | | |
| Name | Arixtra (Fondaparinux) Level | | |
| Code | ARIX | | |
| Interface Order Code | 3423100 | | |
| Legacy Code | ARIXQ | | |
| Notes | Update to rejection criteria. | | |
| Required Testing Changes | | | |
| Rejection Criteria | Specimens received room temperature or refrigerated. Hemolysis. | | |

| Update Existing Test | | | |
|--------------------------|--------------------------------------|--|--|
| Effective Date | 5/29/2025 | | |
| Name | Comprehensive Volatiles Panel, Blood | | |
| Code | CVLPB | | |
| Interface Order Code | 3300373 | | |
| Legacy Code | CVLPB | | |
| Notes | Update to CPT codes. | | |
| Required Testing Changes | | | |
| CPT Code(s) | 82441, 84600 x 4 | | |

| Update Existing Test | | | |
|--------------------------|---|--|--|
| Effective Date | 5/29/2025 | | |
| Name | Encephalopathy, Autoimmune/Paraneoplastic Evaluation, Serum | | |
| Code | ENCS | | |
| Interface Order Code | 3800079 | | |
| Legacy Code | ENCS | | |
| Notes | Update to CPT codes. | | |
| Required Testing Changes | | | |
| CPT Code(s) | 86255 x 23, 86341 | | |



| Update Existin | g Test | | |
|---------------------------|---|-------------------|---|
| Effective Date | 6/10/2025 | | |
| Name | Hepatitis C Vira | I RNA, Genotype | , LiPA |
| Code | | HCVGT | |
| Interface Order Code | 3 | 8400971 | |
| Legacy Code | | HCVGT | |
| Notes | Update to test name, result component name methodology, and reference range. | e, specimen requi | rements, rejection criteria, stability, |
| Required Testing Changes | | | |
| Name | Hepatitis C \ | /iral RNA Genoty | pe |
| | Collect: Lavender EDTA | | |
| | Specimen Preparation: Centrifuge and separa | ate plasma from | cells within 24 hours of collection. |
| Specimen Required | Send 2.0 mL plasma in a screw capped plastic | c vial. | |
| | Minimum Volume: 0.6 mL | | |
| | Transport Temperature: Refrigerated | | |
| Rejection Criteria | Unspun PPT Tubes, Unspun serum separator tube (SST), Unspun red top tube (no gel), Received | | |
| | room temperature, heparinized plasma, gross hemolysis, grossly lipimic. | | |
| | Room temperature: 72 hours | | |
| Stability | Refrigerated: 14 days | | |
| | Frozen: 30 days | | |
| Methodology | Real Time Polymerase Chain Reaction (RT-PCR) - Sequencing | | |
| Reference Range | Not detected | | |
| Result Code | Name | LOINC Code | AOE/Prompt |
| 3400971 | HCV RNA Genotype | 32286-7 | No |



| Update Existing Test | | | |
|--------------------------|---|------------|------------|
| Effective Date | 6/10/2025 | | |
| Name | HCV RNA, QN, Real Time PCR Reflex to Genotype LiPA | | |
| Code | | HCVRG | |
| Interface Order Code | 3 | 400966 | |
| Legacy Code | | HCVRG | |
| Notes | Update to test name, result component name, specimen requirements, alternate specimen, rejection criteria, and stability. | | |
| Required Testing Changes | | | |
| Name | HCV RNA, QN, Real Time PCR Reflex to Genotype | | |
| Specimen Required | <i>Collect:</i> Lavender EDTA <i>Specimen Preparation:</i> Centrifuge and separate plasma from cells within 24 hours of collection. Send 3.0 mL plasma in a screw capped plastic vial. <i>Minimum Volume:</i> 1.5 mL | | |
| | Transport Temperature: Refrigerated | | |
| Alternate Specimen | Plasma: Plasma preparation tube (PPT); Potassium EDTA (white top) Serum: Red top or Serum separator tube (SST) | | |
| Rejection Criteria | Unspun PPT tube, Unspun serum separator tube (SST), Unspun red-top tube (no gel), Received room temperature, heparinized plasma, gross hemolysis, grossly lipimic. | | |
| Stability | Room temperature: 72 hours Refrigerated: 14 days Frozen: 30 days | | |
| Result Code | Name | LOINC Code | AOE/Prompt |
| 3400967 | HCV RNA, QN, Real Time PCR | 11011-4 | No |
| 3400968 | HCV RNA, QN, Real Time PCR | 38180-6 | No |
| 3400969 | HCV RNA Genotype | 32286-7 | No |

| Update Existing Test | | | |
|--------------------------|--|--|--|
| Effective Date | 6/30/2025 | | |
| Name | HTLV I/II DNA, Qualitative, Real-Time PCR | | |
| Code | HTLVD | | |
| Interface Order Code | 3400829 | | |
| Legacy Code | HTLVD | | |
| Notes | Update to alternate specimen, performed days, and turnaround time. | | |
| Required Testing Changes | | | |
| Alternate Specimen | No alternate specimen listed. | | |
| Performed Days | Sunday - Saturday | | |
| Turnaround Time | 3 - 4 days | | |



| Update Existing Test | | | |
|--------------------------|--|--|--|
| Effective Date | 6/10/2025 | | |
| Name | HIV-1 Genotype (RTI, PI, Integrase Inhibitors) | | |
| Code | HVGII | | |
| Interface Order Code | 3400610 | | |
| Legacy Code | HVGII | | |
| Notes | Update to CPT codes. | | |
| Required Testing Changes | | | |
| CPT Code(s) | 87900, 87901, 87906 | | |

| Update Existing Test | | |
|--------------------------|-----------------------------------|--|
| Effective Date | 5/29/2025 | |
| Name | Kidney Stone Diagnostic Prof | |
| Code | KIDST | |
| Interface Order Code | 3717400 | |
| Legacy Code | KIDSTDX | |
| Notes | Update to New York approval. | |
| Required Testing Changes | | |
| New York Approval | New York DOH Approval Status: Yes | |

| Update Existing Test | | | |
|--------------------------|---|--|--|
| Effective Date | 6/23/2025 | | |
| Name | Potassium - RBC | | |
| Code | KRBC | | |
| Interface Order Code | 3718600 | | |
| Legacy Code | POTR | | |
| Notes | Update to specimen requirements. | | |
| Required Testing Changes | | | |
| Specimen Required | Collect: Green sodium heparin AND Lavender EDTA Specimen Preparation: Send 4.0 mL whole blood collected in a green sodium heparin tube AND 4.0 mL whole blood collected in Lavender EDTA tube. Both samplees must only be collected Mon-Thurs and must be received together for testing. Contact the lab prior to ordering for special logistics arrangements. | | |



| Update Existing | a Test |
|----------------------------|--|
| Effective Date | 6/24/2025 |
| Name | RBC Folate |
| Code | RBCF |
| Interface Order Code | 1000773 |
| Legacy Code | RBCF |
| Notes | Update to New York approval, specimen requirements, stability, and turnaround time. |
| Required Testing Cl | hanges |
| New York Approval | New York DOH Approval Status: Yes |
| Specimen Required | Patient Preparation: A hematocrit result is required. Provide a hematocrit from this collection with the sample submission. A hematocrit collected within 24 hours of the RBCF collection is also acceptable if the patient has not received a transfusion or experienced excessive bleeding in that 24 hour period. Please note: Methotrexate and leucovorin may interfere with assay. Specimen Preparation: Send 1 full EDTA whole blood (entire sample) in the original collection tube along with the hematocrit. Minimum Volume: 1.0 mL of well mixed aliquot of EDTA whole blood. Transport Temperature: Frozen |
| Stability | Room temperature: 8 hours Refrigerated: 24 hours Frozen: 2 months |
| Turnaround Time | 2 - 4 days |

| Update Existing Test | | |
|--------------------------|--|--|
| Effective Date | 6/23/2025 | |
| Name | Rivaroxaban | |
| Code | RIVAR | |
| Interface Order Code | 3400398 | |
| Legacy Code | RIVAR | |
| Notes | Update to rejection criteria. | |
| Required Testing Changes | | |
| Rejection Criteria | Samples received refrigerated or at room temperature. Hemolysis. | |



| Update Existing | g Test | | | |
|--------------------------|---|------------|------------|--|
| Effective Date | 7/7/2025 | | | |
| Name | Th | iothixene | | |
| Code | | ТНІОТ | | |
| Interface Order Code | 3 | 510400 | | |
| Legacy Code | | THIOT | | |
| Notes | Update to test name, result component name, CPT code, specimen requirements, turnaround time, and methodology. | | | |
| Required Testing Changes | | | | |
| Name | Thiothixene, Serum or Plasma | | | |
| CPT Code(s) | 80342 | | | |
| Specimen Required | Collect: Red top Specimen Preparation: Centrifuge, separate serum from cells within 2 hours and send serum in a screw capped plastic vial. Minimum Volume: 1.0 mL Transport Temperature: Refrigerated | | | |
| Methodology | Liquid Chromatography - Tandem Mass Spectrometry | | | |
| Turnaround Time | 4 - 6 days | | | |
| Result Code | Name | LOINC Code | AOE/Prompt | |
| 3510400 | Thiothixene, Serum/Plasma | 6696-9 | No | |

| Update Existing | g Test |
|----------------------------|--|
| Effective Date | 7/7/2025 |
| Name | Thioridazine and Metabolite, Serum/Plasma |
| Code | THIR |
| Interface Order Code | 3300480 |
| Legacy Code | THIR |
| Notes | Update to CPT code, specimen requirements, and methodology. |
| Required Testing Cl | hanges |
| CPT Code(s) | 80342 |
| Specimen Required | Collect: Red top Specimen Preparation: Centrifuge, separate serum from cells and send serum in a screw capped plastic vial. Minimum Volume: 1.0 mL Transport Temperature: Refrigerated |
| Methodology | Liquid Chromatography - Tandem Mass Spectrometry |



| Inactivate Test | With Replacement | | | |
|---------------------------|---|---|-----------------------------------|--|
| Effective Date | 6/10/2025 | | | |
| | Inactivated Test | | | |
| Name | Cutaneous In | nmunofl Ab IgG, S | Ser | |
| Code | | CIABG | | |
| Legacy Code | CIABM | | | |
| Interface Order Code | 3 | 800500 | | |
| Replacement Test | | | | |
| Name | Cutaneous Immuonoflu | Cutaneous Immuonofluoresence, IgG and IgG4, Serum | | |
| Code | | CIFAS | | |
| CPT Code(s) | 88346, 88350, plus 88346, 88350 if reflexed to | titer, at addition | al cost. | |
| Notes | New York DOH Approval Status: Yes | | | |
| Specimen Requiren | nents | | | |
| Specimen Required | <i>Collect:</i> Serum separator tube (SST) <i>Specimen Preparation:</i> Centrifuge, separate and send 2.0 mL serum refrigerated in a screw capped plastic vial. <i>Minimum Volume:</i> 0.5 mL <i>Transport Temperature:</i> Refrigerated | | | |
| Alternate Specimen | Serum: Red top | | | |
| Rejection Criteria | Grossly hemolyzed, lipemic or icteric specime | Grossly hemolyzed, lipemic or icteric specimens | | |
| Stability | Room temperature: 14 days Refrigerated: 14 days Frozen: 30 days | | | |
| Performing Informa | ation | | | |
| Methodology | Indirect Immunofluorescence using Rhesus r skin | nonkey esophagu substrate | is substrate and human NaCl split | |
| Reference Range | Negative Report includes presence and titer of circulating antibodies (BMZ, and ANA). If serum contains BMZ antibodies on split -skin subrate patterns will be reported as: (1) epidermal pattern, consistent with pemphigoid or (2) dermal pattern consistent with epidermolysis bullosa acquisita. | | | |
| Performed Days | Monday - Friday | | | |
| Turnaround Time | 4 - 9 days | | | |
| Performing Laboratory | | nic Laboratories | | |
| Interface Informati | on | | | |
| Legacy Code | - | CIFAS | | |
| Interface Order Code | | 800413 | | |
| Result Code | Name | LOINC Code | AOE/Prompt | |
| 3800520 | Cell Surface Ab IgG | 93233-5 | No | |
| 3800540 | Basement Membrane IgG | 29994-1 | No | |
| 3800570 | Primate Split Skin IgG | 104832-1 | No | |

Warde Medical Laboratory

TEST DIRECTORY UPDATE

| 3800414 | Cell Surface Ab IgG4 | | No |
|---------|------------------------------|----------|----|
| 3800416 | Basement Membrane IgG4 | | No |
| 3800417 | Primate Split Skin IgG4 | | No |
| 3800580 | Other | 48767-8 | No |
| 3800418 | Cell Surface Ab Titer, IgG | 104831-3 | No |
| 3800419 | Basement Membrane Titer, IgG | 104836-2 | No |
| 3800421 | Other | 48767-8 | No |



QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 EXAMPLE, REPORT W WX0000003827 M 07/08/1968 56 Y

| | | Referral Test | • | | | | |
|-------------------------|---|---|-----------|----------------------------------|-----------|--------------|----------------------|
| | | Collected: 0 | 5/20/2025 | 15:09 | Received: | 05/20/2025 | 15:09 |
| Test Name | 2 | <u>Result</u> | Flag | Ref-Ranges | <u>.</u> | <u>Units</u> | <u>Site</u> |
| Cell Surfac Basement | ous Immfluor. Ab, IgG/IgG4, S ce Ab IgG Membrane IgG olit Skin IgG | S Negative Positive SEE BELOW | AB AB | Negative Negative Negative | | | MMRL MMRL MMRL |
| Basement | RESULT: Positive; Epidermal p ce Ab IgG4 Membrane IgG4 blit Skin IgG4 | attern present Negative Positive SEE BELOW | AB AB | Negative Negative Negative | | | MMRL MMRL MMRL |
| Other | RESULT: Positive; Epidermal p | attern present See Comment | | | | | MMRL |
| | The observation of basement membrane zone deposition with IgG and/or IgG4 detected with cutaneous immunofluorescence on esophageal substrate and the epidermal side of the artefactual blister implies the presence of autoantibodies directed against antigens located anatomically above the lamina lucida, as may be seen in bullous/non-bullous pemphigoid and some forms of mucous membrane pemphigoid. This association has not been specifically validated with IgG4. Other tests including (a) lesional skin or mucous membrane biopsy for histopathological evaluation on sections from formalin-fixed, paraffin-embedded tissue; (b) perilesional skin or mucous membrane biopsy for cutaneous immunofluorescence testing (test code CIB); and (c) serum testing for bullous pemphigoid BP180 and BP230 (test code BPAB) antibodies by ELISA technique are recommended. | | | | | | |
| | 200 First Street SW, Rocheste Lab Director: Nikola A. Bauma | nn Ph.D.; CLIA# 241 | D0404292 | | | | MMRL |
| | ce Ab Titer, IgG Membrane Titer, IgG | Negative SEE BELOW | AB | Negative Negative | | | MMRL |

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

| H320000003 |
|-----------------------------|
| WX000003827 |
| Printed D&T: 05/20/25 15:09 |

Ordered By: KAJAL SITWALA, MD, PHD WX00000000002516



QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 EXAMPLE, REPORT W WX0000003827 M 07/08/1968 56 Y

| | | Referral Te | sting | | | | |
|------------------|--|---|--|--------------------------------------|-------------|--------------|-------------|
| | | Collected | d: 05/20/202 | 5 15:09 | Received: | 05/20/2025 | 15:09 |
| <u>Test Name</u> | RESULT: BMZ Positive Tit | Result er 1:80 | <u>Flag</u> | Ref-Range | <u>es l</u> | <u>Jnits</u> | <u>Site</u> |
| Other | | See Comment | | | | | MMRL |
| | The presence of serum ba detected by cutaneous im esophagus supports a dia subepithelial autoimmune Occasionally, low titer basement membrane zone I otherwise normal individ with the clinical presen findings on direct immun CIB), serum testing for T antibodies (test code BP subepithelial blistering RSBV) by indirect immuno indicated. | munofluorescence on p gnosis of an IgG-medi mucocutaneous bliste (less than or equal t gG antibodies may be uals. Results should tation, histopatholog ofluorescence testing bullous pemphigoid BF AB) by ELISA techniqu variant antibodies | primate iated ering diso to 1:80) seen in be correl gical find g (test co P180 and B ue, and ra (test code | rder. ated ings, de P230 | | | |
| | This test was developed determined by Mayo Clini requirements. This test the U.S. Food and Drug A | c in a manner consist has not been cleared | characteri tent with | stics CLIA | | | |
| | Test Performed by: Mayo Clinic Laboratories 200 First Street SW, Roc Lab Director: Nikola A. | hester, MN 55905 | | 2 | | | |
| | | | Rep | orted Date: | 05/20/2025 | 15:09 C | IFAS |

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

H320000003 WX0000003827 Printed D&T: 05/20/25 15:09 Ordered By: KAJAL SITWALA, MD, PHD WX0000000002516

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 2 OF 2



| Inactivate Test | With Replacement | | | |
|-----------------------|--|--|--|--|
| Effective Date | 6/24/2025 | | | |
| | Inactivated Test | | | |
| Name | HIV-1 RNA, Qualitative Real-Time PCR | | | |
| Code | TMHIV | | | |
| Legacy Code | TMAHIV | | | |
| Interface Order Code | 3424450 | | | |
| Replacement Test | | | | |
| Name | HIV-1 RNA Ultraquant | | | |
| Code | HIVUL | | | |
| CPT Code(s) | 87536 | | | |
| Notes | New York DOH Approval Status: Yes | | | |
| | NOTE: This is an existing test offered at Warde Medical Laboratory. | | | |
| Specimen Requiren | hents | | | |
| Specimen Required | <i>Collect</i> : Lavender EDTA <i>Specimen Preparation</i> : Centrifuge and separate plasma from cells within 6 hours of collection. Send 3.0 mL plasma in a screw capped plastic vial. Dedicated specimens are required. <i>Minimum Volume</i> : 2.5 mL <i>Transport Temperature</i> : Frozen | | | |
| Alternate Specimen | Plasma: Yellow ACD A | | | |
| Rejection Criteria | Serum specimens, shared specimens, specimens subjected to repeated freeze-thaw cycles, specimens that do not meet the handling/storage criteria listed above, gel based plasma separation media (PPT) | | | |
| Stability | Room temperature: Unacceptable Refrigerated: 3 days Frozen (-20°C): 3 days Frozen (-70°C): 6 weeks | | | |
| Performing Informa | | | | |
| Methodology | Abbott RealTime HIV-1 system uses an in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for the detection and quantitation of the diverse group M subtypes A-H as well as group O and N isolates. The lower limit of quantitation is 20 copies/mL (1.30 log copies/mL) and the upper limit of quantitation is 10,000,000 copies/mL (7.0 log copies/mL). The qualitative limit of detection is 20 copies/mL (1.30 log copies/mL). Specimens reported as DETECTED but <20 copies/mL contain detectable levels of HIV-1 RNA even though the viral load is below the limit of quantitation. | | | |
| Reference Range | HIV-1 RNA: Not detected HIV-1 RNA Quantitative: <20 copies/mL LOG HIV CP U/mL: <1.3 | | | |
| Performed Days | Monday - Friday | | | |
| Turnaround Time | 3 days | | | |
| Performing Laboratory | Warde Medical Laboratory | | | |
| Interface Information | on | | | |
| Legacy Code | HIVULTRA | | | |
| Interface Order Code | 3041700 | | | |

Warde Medical Laboratory

TEST DIRECTORY UPDATE

| Result Code | Name | LOINC Code | AOE/Prompt |
|-------------|------------------------|------------|------------|
| 3041720 | HIV-1 RNA Qualitative | 25835-0 | No |
| 3041740 | HIV-1 RNA Quantitative | 20447-9 | No |
| 3041760 | LOG HIV RNA | 29541-0 | No |
| 3041780 | HIV-1 Date Received | | No |
| 3041790 | HIV-1 Date Completed | | No |



JUNE 2025

Inactivate Test Without Replacement

| Effective Date | 5/29/2025 |
|----------------|---|
| Name | Coxsackie A Serotype 9 Titer |
| Code | COXA9 |
| Legacy Code | COXA9ARP |
| Interface Code | 3680520 |
| Notes | Test discontinued. Suggested alternative is test code COXAQ: Coxsackie A Antibodies, Serum. |

| Inactivate Tes | Inactivate Test Without Replacement | | |
|----------------|-------------------------------------|--|--|
| Effective Date | 6/9/2025 | | |
| Name | Cryptococcus Ab | | |
| Code | CRYAB | | |
| Legacy Code | CRYAB | | |
| Interface Code | 3501850 | | |
| Notes | Test discontinued. | | |

| Inactivate Tes | Inactivate Test Without Replacement | | |
|----------------|-------------------------------------|--|--|
| Effective Date | 5/29/2025 | | |
| Name | LCM Antibody | | |
| Code | LCM | | |
| Legacy Code | LCM | | |
| Interface Code | 3504220 | | |
| Notes | Test discontinued. | | |

| Inactivate Test Without Replacement | |
|-------------------------------------|---------------------------|
| Effective Date | 5/29/2025 |
| Name | Galactose (Quant) - Urine |
| Code | UGAL |
| Legacy Code | UGAL |
| Interface Code | 3502985 |
| Notes | Test discontinued. |