

JULY 2022

| Update Notes | |
|--------------|--|
| | |

| Update Summary | | |
|----------------------------------|-----------|----------------------------------------------------------------|
| Announcement | 7/1/2022 | Reagent Shortage Temporary Inactivation |
| Announcement | 7/1/2022 | Test Code Reactivated |
| Update Existing Test | 7/18/2022 | APHAG - "Anaplasma phagocytophilum DNA, Qualitative RT-PCR" |
| Update Existing Test | 7/1/2022 | CORTS - "Cortisol, Saliva, LC/MS/MS" |
| Update Existing Test | 7/1/2022 | HISPL - "Histamine, Plasma" |
| Update Existing Test | 7/1/2022 | JAK2Q - "JAK2 (V617F) Mutation, Quantitative (PCR)" |
| Update Existing Test | 7/18/2022 | LALA - "Limulus Amebocyte Lysate, Endotoxin" |
| Update Existing Test | 7/1/2022 | PMSCQ - "Anti-PM/Scl-100 Ab (RDL)" |
| Update Existing Test | 7/18/2022 | SLAA - "Soluble Liver Antigen Auto Abs" |
| Update Existing Test | 7/11/2022 | TIFLU - "Titanium, Fluid" |
| Update Existing Test | 7/1/2022 | VITD - "25-hydroxy Vitamin D" |
| Inactivate Test With Replacement | 7/6/2022 | HPVRA - "HPV RNA, Low and High Risk, ISH" replaced by HPVHL - |
| | | "HPV High/Low Risk ISH" |
| Inactivate Test With Replacement | 7/18/2022 | LYMPB - "Lyme Disease (Borrelia spp) DNA, Qual, RT-PCR, Blood" |
| | | replaced by BSDQL - "Borrelia Species DNA, Qual Real-Time PCR" |

Announcement

Test RETRT - Reticulin Antibody (IgG) Screen with Reflex to Titer is temporarily non-orderable due to reagent shortage. The suggested replacement is TTGG - Tissue Transglutaminase Antibody, IgG.

Announcement

Test code PNEJ - Pneumocystis Jirovecii by DFA is now orderable.

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| Update Existing Test | |
|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effective Date | 7/18/2022 |
| Name | Anaplasma phagocytophilum DNA, Qualitative RT-PCR |
| Code | APHAG |
| Interface Order Code | 3429050 |
| Legacy Code | APHAG |
| Notes | |
| Required Testing Change | es |
| Specimen Required | Collect: Lavender EDTA Specimen Preparation: Send 0.7 mL whole blood in original container. Minimum Volume: 0.3 mL Transport Temperature: Refrigerated |

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| Update Existing Test Effective Date | 7/1/2022 | |
|--------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Name | Cortisol, Saliva, LC/MS/MS | |
| Code | CORTS | |
| Interface Order Code | 3511840 | |
| Legacy Code | CORTSAL | |
| Notes | Updates to patient preparation, rejection criteria, acceptable specimens, stability and performed days. | |
| Required Testing Change | es es | |
| Specimen Required | Patient Preparation: Do not eat, drink, smoke, take oral medications, or use oral hygiene products for at least 60 minutes prior to collection and 10 minutes before beginning the collection process, rinse the mouth with water to avoid contamination. Collect: Salivette® Cortisol with blue screw cap Sample Preparation: Send 0.5 mL saliva collected in Salivette® Cortisol with blue screw cap Collection Instructions: 1- Remove the swab from the Salivette® 2- Place the swab in the mouth, e.g. in your cheek, where it should remain for 2 min without chewing. If an extremely small amount of saliva is produced, leave the swab in the mouth for longer. 3- Return the swab with the absorbed saliva to the Salivette®. 4- Replace the stopper. 5- Refrigerate the Salivette® immediately. Minimum Volume: 0.2 mL Transport Temperature: Refrigerated | |
| Alternate Specimen | Super SAL [™] Super SAL2 [™] | |
| Rejection Criteria | Hemolysis, white top Salivette® collection device | |
| Performed Days | Sunday, Monday, Tuesday, Thursday, Friday | |
| Stability | Room temperature: 7 days Refrigerated: 21 days Frozen: 180 days | |

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| Update Existing Test | |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effective Date | 7/1/2022 |
| Name | Histamine, Plasma |
| Code | HISPL |
| Interface Order Code | 3680810 |
| Legacy Code | HISTAPARP |
| Notes | Update to specimen preparation. |
| Required Testing Change | es e |
| Specimen Required | Specimen Preparation: Centrifuge, separate the upper two-thirds of the plasma portion and send 1.0 mL plasma in a screw capped plastic vial. CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. |

| Update Existing Test | | |
|-----------------------------|-------------------------------------------------------------------------------|--|
| Effective Date | 7/1/2022 | |
| Name | JAK2 (V617F) Mutation, Quantitative (PCR) | |
| Code | JAK2Q | |
| Interface Order Code | 3096210 | |
| Legacy Code | JAK2 | |
| Notes | Updates to stability and rejection criteria. | |
| Required Testing Changes | | |
| Rejection Criteria | Serum, plasma, bone marrow , heparinized whole blood, tissue specimens | |
| Stability | Room temperature: 24 hours Refrigerated: 14 days Frozen: Unacceptable | |

| Update Existing Test | | | |
|--------------------------|--------------------------------------------|------------------|-------------------------|
| Effective Date | 7/18/2022 | | |
| Name | Limulus ame | bocyte Lysate As | say |
| Code | | LALA | |
| Interface Order Code | | 3422360 | |
| Legacy Code | | LALQ | |
| Notes | Update to LOI | NC and name cha | ange. |
| Required Testing Changes | | | |
| Name | Limulus Amebocyte Lysate, Endotoxin | | |
| Result Code | Name | LOINC Code | AOE/Prompt ² |
| 3422360 | Limulus amebocyte Lysate Assay | 33643-8 | No |
| 3422370 | Source | 31208-2 | Yes |

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| Hadata Evistina Test | |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Update Existing Test Effective Date | 7/1/2022 |
| Name | Anti-PM/Scl-100 Ab (RDL) |
| Code | PMSCQ |
| Interface Order Code | 3423685 |
| Legacy Code | PMSCQ |
| Legacy Code | Updates to specimen requirements, minimum volume, stability, rejection criteria |
| Notes | opuates to speciment requirements, minimum volume, stability, rejection criteria |
| Required Testing Change | es s |
| Specimen Required | Collect: Serum separator tube (SST) Specimen Preparation: Centrifuge, separate serum from cells within 1 hour of collection and send 1.0 mL serum in a screw capped plastic vial. Minimum Volume: 0.3 mL Transport Temperature: Refrigerated |
| Alternate Specimen | Serum: Red top |
| Rejection Criteria | Gross hemolysis, bacterial contamination, lipemic, icteric, non-serum specimen types |
| Stability | Room temperature: 7 days Refrigerated: 14 days Frozen: 60 days |
| Turnaround Time | 14 – 24 days |
| Performed | Varies |

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| Update Existing Test | | | |
|-----------------------------|---------------------------------------------------------------------|--|--|
| Effective Date | 7/18/2022 | | |
| Name | Soluble Liver Antigen Auto Abs | | |
| Code | SLAA | | |
| Interface Order Code | 3711250 | | |
| Legacy Code | SLAAABSP | | |
| Notes | Updates to reference range, performed days and performing location. | | |
| Required Testing Changes | | | |
| Reference Range | <20.1 U Negative 20.1 - 24.9 U Equivocal | | |
| | ≥25.0 U Positive | | |
| Performed Days | Wednesday | | |
| Performing Location | Quest SJC | | |

| Update Existing Test | | |
|--------------------------|----------------------------------------------------------------------------------------------------------|--|
| Effective Date | 7/11/2022 | |
| Name | Titanium, Fluid | |
| Code | TIFLU | |
| Interface Order Code | 3300138 | |
| Legacy Code | TIFLU | |
| Notes | | |
| Required Testing Changes | | |
| Specimen Required | Specimen Preparation: Send 4.0 mL fluid in a plastic container (Acid washed or trace metal-free). | |

| Update Existing Test | | | |
|-------------------------|-------------------------------------------------------------------|--|--|
| Effective Date | 7/1/2022 | | |
| Name | 25-hydroxy Vitamin D | | |
| Code | VITD | | |
| Interface Order Code | 1007180 | | |
| Legacy Code | VITD25H | | |
| Notes | Update to performing location – correction from June 2022 update. | | |
| Required Testing Change | Required Testing Changes | | |
| Performing Laboratory | Quest Valencia | | |

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| Inactivate Test With Rep | lacement | |
|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Effective Date | 7/6/2022 | |
| | Inactivated Test | |
| Name | HPV RNA, Low and High Risk, ISH | |
| Code | HPVRA | |
| Legacy Code ¹ | HPVRA | |
| Interface Order Code | 3400161 | |
| Notes | | |
| | | |
| | Replacement Test | |
| Name | HPV High/Low Risk ISH | |
| Code | HPVHL | |
| CPT Code(s) | 88365, 88364 | |
| Notes | | |
| Specimen Requirements | | |
| Specimen Required | Patient Preparation: A pathology/diagnostic report and a brief history are required. Collect: Formalin-fixed, paraffin-embedded tissue block and slides Specimen Preparation: Send entire formalin-fixed, paraffin-embedded tissue block and 6 unstained glass, positively charged slides with 5(+ or -1)-microns formalin-fixed, paraffin-embedded tissue. Transport temperature: Room temperature New York DOH Approved: Yes | |
| Rejection Criteria | Wet/frozen tissue, cytology smears, nonformalin fixed tissue, nonparaffin embedded tissue, noncharged slides, ProbeOn slides | |
| Stability | Room temperature: Undetermined Refrigerated: Undetermined Frozen: Unacceptable | |
| Performing Information | | |
| Methodology | In-Situ Hydridization | |
| Reference Range | See report | |
| Performed Days | Monday - Friday | |
| Turnaround Time | 7 - 9 days | |

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| Performing Laboratory | Mayo Clinic Laboratories | | | |
|--------------------------|------------------------------------|---------------|-------------------------|--|
| Interface Information | | | | |
| Legacy Code ¹ | HPVHL | | | |
| Interface Order Code | 3800281 | | | |
| Result Code | Name | LOINC Code | AOE/Prompt ² | |
| 3800282 | Interpretation | 50595-8 | No | |
| 3800283 | Participated in the Interpretation | Not available | No | |
| 3800284 | Material Received | 81178-6 | No | |
| 3800285 | Disclaimer | 62364-5 | No | |
| 3800286 | Case Number | 80398-1 | No | |
| 3800287 | Report electronically signed by | 19135-5 | No | |

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LABORATORY REPORT

QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 **EXAMPLE, REPORT**

WX0000003481 F 12/08/1988 33 Y

Referral Testing

Collected: 06/28/2022 14:25 Received: 07/01/2022 08:01

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

HPV High/Low Risk ISH

Interpretation SEE BELOW MMRL

Source, specimen for Human Papilloma Virus (HPV) In Situ Hybridization (ISH) studies performed on paraffin-embedded tissue sections (SP15-1234-A1):

HPV (family 6) ISH is negative for types 6 and 11.

HPV (family 16) ISH is negative for types 16, 18, 31, 33, $$

and 51.

Participated in the Interpretation .TNP

Material Received SEE BELOW MMRL

A. SP15-1234: Source

1 block

Disclaimer SEE BELOW MMRL

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.

Case Number CR-22-50538

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

Report electronically signed by MICHELE DECKER

Performing Site:

MMRI

MMRI

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

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

D901000001 WX0000003481 Printed D&T: 07/01/22 11:00 Ordered By: CLIENT CLIENT WX00000000000002063

William G. Finn, M.D. - Medical Director Form: MM RL1 PAGE 1 OF 1



JULY 2022

| Inactivate Test With Rep | lacement | | | | | |
|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|--|
| Effective Date | 7/18/2022 | | | | | |
| | Inactivated Test | | | | | |
| Name | Lyme Disease (Borrelia spp) DNA, Qual, RT-PCR, Blood | | | | | |
| Code | LYMPB | | | | | |
| Legacy Code ¹ | LYMPB | | | | | |
| Interface Order Code | 3435320 | | | | | |
| Notes | | | | | | |
| | | | | | | |
| | Replacement Test | | | | | |
| Name | Borrelia Species DNA, Qual Real-Time PCR | | | | | |
| Code | BSDQL | | | | | |
| CPT Code(s) | 87801 | | | | | |
| Notes | | | | | | |
| Specimen Requirements | | | | | | |
| Specimen Required | Collect: Lavender EDTA Specimen Preparation: Send 1.0 mL whole blood in original tube or in a screw capped plastic vial. Minimum Volume 0.5 mL | | | | | |
| | Transport Temperature: Refrigerated | | | | | |
| Alternate Specimen | Whole blood: Yellow ACD solution A CSF, synovial fluid | | | | | |
| Stability | Room temperature: 48 hours Refrigerated: 7 days Frozen: Unacceptable | | | | | |
| Performing Information | | | | | | |
| Methodology | Real-Time Polymerase Chain Reaction (PCR) | | | | | |
| Reference Range | Not detected | | | | | |
| Performed Days | Monday - Saturday | | | | | |
| Turnaround Time | 2 - 5 days | | | | | |
| Performing Laboratory | Quest SJC | | | | | |

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| Interface Information | | | | | |
|--------------------------|----------------------------|---------------|-------------------------|--|--|
| Legacy Code ¹ | BSDQL | | | | |
| Interface Order Code | 3400641 | | | | |
| Result Code | Name | LOINC Code | AOE/Prompt ² | | |
| 3400642 | SOURCE | Not available | Yes | | |
| 3400643 | BORRELIA spp DNA, QL, Misc | 32667-8 | No | | |

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LABORATORY REPORT

Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT**

WX0000003039 M 12/05/1988 33 Y

Referral Testing

Collected: 07/01/2022 11:05 Received: 07/01/2022 11:05

Test Name Result Flag Ref-Ranges Units Site

Borrelia Species DNA, Qual Real-Time PCR

SOURCE Blood QCRL
BORRELIA spp DNA, QL, Misc NOT DETECTED QCRL

REFERENCE RANGE: NOT DETECTED

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

For additional information, please refer to https://education.questdiagnostics.com/faq/faq224 (This link is being provided for informational/educational purposes only.)

Test Performed at: Quest Diagnostics Nichols Institute 33608 Ortega Highway San Juan Capistrano, CA 92675-2042

I Maramica MD, PhD

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

D901000002 WX0000003039 Printed D&T: 07/01/22 11:06 Ordered By: CLIENT CLIENT WX0000000000001595

William G. Finn, M.D. - Medical Director Form: MM RL1 PAGE 1 OF 1