

Update Notes

Update Summary

New Test Activation	12/29/2020	TMAO - "TMAO (Trimethylamine N-Oxide)"
Update Existing Test	11/16/2020	ADAPF - "Adenosine Deaminase, Pleural Fluid"
Update Existing Test	12/14/2020	BRAFD - "BRAF Mutation Analysis"
Update Existing Test	12/21/2020	CALRA - "Calreticulin (CALR) Mutation Analysis"
Update Existing Test	12/14/2020	EGFR - "Epidermal Growth Factor Receptor (EGFR) Mutation Analysis"
Update Existing Test	11/25/2020	FLPCR - "Influenza Virus A and B PCR"
Update Existing Test	12/21/2020	HHQ - "Hemochromatosis, Hereditary"
Update Existing Test	12/21/2020	JAKCR - "JAK2 V617F Cascading Reflex"
Update Existing Test	12/14/2020	KRASA - "Kras Mutation Analysis"
Update Existing Test	11/25/2020	LIPFL - "Lipase, Fluid"
Update Existing Test	12/21/2020	MPLQL - "MPL Mutation Analysis"
Update Existing Test	11/25/2020	RVPCR - "Respiratory Syncytial Virus PCR"
Update Existing Test	12/21/2020	TCRGQ - "T Cell Rec Gamma Gene Rearrangement PCR"
Update Existing Test	12/21/2020	YCMIC - "Y Chromosome Microdeletion, DNA Analysis"
Inactivate Test With Replacement	12/8/2020	C6PEP - "Borrelia burgdorferi C6 Pept Ab" replaced by BBURV - "Borrelia burgdorferi VlsE1/pepC10 Abs, ELISA"
Inactivate Test With Replacement	12/14/2020	NRASM - "NRAS Mutation Analysis" replaced by NRMUA - "NRAS Mutation Analysis"

New Test Activation			
Effective Date	12/29/2020		
Name	TMAO (Trimethylamine N-Oxide)		
Code	TMAO		
CPT Code(s)	82542		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in red-top tube. Gently invert tube 5 times. DO NOT SHAKE . Allow specimen to clot completely (about 30 minutes). Centrifuge for 10 minutes. Separate serum from cells and send 1.0 mL serum (0.5 mL minimum) refrigerated in a screw-capped plastic vial.		
Rejection Criteria	Hemolysis		
Stability	Room temperature: 24 hours; Refrigerated: 7 days; Frozen: 3 months		
Performing Information			
Methodology	Liquid Chromatography - Tandem Mass Spectrometry (LC/MS/MS)		
Reference Range	< 6.2 uM		
Performed Days	Monday - Saturday		
Turnaround Time	6 - 8 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code ¹	TMAO		
Interface Order Code	3400281		
Result Code	Name	LOINC Code	AOE/Prompt ²
3400281	TMAO (Trimethylamine N-Oxide)	90360-9	No



LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 11/23/2020 08:30 Received: 11/25/2020 13:17

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: TMAO (Trimethylamine N-Oxide), 5.3, <6.2, uM, QCRL

Based on a population (N=4007) defined as ambulatory stable patients without acute coronary syndrome who underwent elective diagnostic coronary angiography (1) and a reference range study of apparently healthy donors (N=180), we have defined the following cut-offs for TMAO to assess relative risk of a cardiovascular event: A cut-off of <6.2 uM defines a population at optimal relative risk for a cardiovascular event relative to those above this level. 6.2-9.9 uM defines a population at moderate relative risk for a cardiovascular event (two-fold increased risk of MACE at 3 years) relative to those with TMAO <6.2 uM (1). Given the dose-dependent relationship between TMAO and cardiovascular event risk demonstrated across multiple clinical subgroups (2), those above the upper limit of the Cleveland HeartLab 95% population interval (>=10.0 uM) are defined as high relative risk for a cardiovascular event relative to those with TMAO <6.2 uM. (References: 1-Tang et al. N Engl J Med. 2013; 368:1575-1584. 2-Heianza Y, et al. J Am Heart Assoc. 2017;6(7)). This test is performed by a Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS) method. This test was developed and its performance characteristics determined by the Cleveland HeartLab, Inc. It has not been cleared or approved by the U.S. FDA. The Cleveland HeartLab is regulated under Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

Test Performed at:
Cleveland HeartLab, Inc
6701 Carnegie Avenue Suite 500
Cleveland, OH 44103-4623 B G Richendollar MD

Performing Site:

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

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

Update Existing Test	
Effective Date	11/16/2020
Name	Adenosine Deaminase, Pleural Fluid
Code	ADAPF
Interface Order Code	3619500
Legacy Code	ADAPF
Notes	Update to specimen volume requirements, stability and reference range.
Required Testing Changes	
Specimen Required	Collect pleural fluid and send 0.5 mL fluid (0.2 mL minimum) frozen in a screw-capped plastic vial.
Stability	Room temperature: 24 hours ; Refrigerated: 7 days; Frozen: 1 month
Reference Range	0.0 - 30.0 U/L

Update Existing Test	
Effective Date	12/14/2020
Name	BRAF Mutation Analysis
Code	BRAFD
Interface Order Code	3400399
Legacy Code	
Notes	Updates to specimen requirements, alternate specimen, stability and turnaround time.
Required Testing Changes	
Specimen Required	Send formalin fixed paraffin embedded tissue at room temperature. Please submit pathology report, tissue source and block id.
Alternate Specimen	Whole blood: 5.0 mL (3.0 mL minimum) EDTA or sodium heparin refrigerated. Bone Marrow: 3.0 mL (1.0 mL minimum) EDTA or sodium heparin, refrigerated. Slides: 8 (4 minimum) unstained, charged + slides
Stability	Tissue: Room temperature: Indefinite; Refrigerated: Indefinite; Frozen: Unacceptable Whole Blood: Room temperature: 72 hours; Refrigerated: 72 hours; Frozen: Unacceptable Slides: Room temperature: 5 years; Refrigerated: 5 years; Frozen: Unacceptable
Turnaround Time	6 - 8 days

Update Existing Test	
Effective Date	12/21/2020
Name	Calreticulin (CALR) Mutation Analysis
Code	CALRA
Interface Order Code	3700071
Legacy Code	CALRA
Notes	Updates to specimen requirements and alternate specimens.
Required Testing Changes	
Specimen Required	Draw blood in a lavender tube. Send 5.0 mL whole blood (3.0 mL minimum) at room temperature.
Alternate Specimen	Bone marrow: EDTA, 3.0 mL (1.0 mL minimum) or sodium heparin Cell pellets: Send fixed cell pellet collected in a plastic leak-proof container. Extracted DNA: from a CLIA-certified laboratory collected in a sterile leak-proof container. Whole blood: sodium heparin

Update Existing Test			
Effective Date	12/14/2020		
Name	EGFR Mutation Analysis		
Code	EGFR		
Interface Order Code	3423400		
Legacy Code	EGFRPCRQ		
Notes	Updates to name change, result component name changes, specimen requirements, alternate specimen and stability.		
Required Testing Changes			
Name	Epidermal Growth Factor Receptor (EGFR) Mutation Analysis		
Specimen Required	Formalin fixed paraffin embedded tissue block sent at room temperature.		
Alternate Specimen	Slide: 8 (4 minimum) unstained charged (+) slides. Cut one 3-5 microns tissue section for H & E stain. Cut 3-5 (10 microns) sections on non-charged regular glass slides for microdissection. The slide should not be baked or melted. A new blade must be used for each paraffin block, for cutting to prevent cross contamination.		
Stability	Block: Room temperature: 5 years ; Refrigerated: 5 years ; Frozen: Unacceptable		
Result Code	Name	LOINC Code	AOE/Prompt ²
3423410	Source	31208-2	No
3423420	Block/specimen ID	Not available	Yes
3423400	EGFR Mutation Analysis	21665-5	Yes

Update Existing Test

Effective Date	11/25/2020
Name	Influenza Virus A and B PCR
Code	FLPCR
Interface Order Code	3091830
Legacy Code	FLUPCR
Notes	Updates to specimen requirements.

Required Testing Changes

Specimen Required	<p>Specimen source is required. NP and Throat swabs in viral transport medium. If sending one sample for FLPCR and COVW (COVID testing) please send a minimum of 1.5 mL.</p> <p>Swabs in culettes must be transferred to viral transport within 24 hours of collection. Bronchoalveolar lavage/wash in an IATA-approved sterile screw-capped plastic container send 1.0 mL (0.5 mL minimum). Sputum undiluted in an IATA-approved sterile screw-capped plastic container send 1.0 mL (0.5 mL minimum). Nasal aspirates in vacuum trap send 1.0 mL (0.5 mL minimum). Nasal washes in an IATA-approved sterile screw-capped plastic container send 1.0 mL (0.5 mL minimum).</p> <p>NP/OP swab in Phosphate Buffered Saline or Sterile Saline.</p>
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Update Existing Test

Effective Date	12/21/2020
Name	Hemochromatosis, Hereditary
Code	HHQ
Interface Order Code	3426000
Legacy Code	HHQ
Notes	Updates to accepted alternate specimen.

Required Testing Changes

Alternate Specimen	Whole blood: yellow ACD tube
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Update Existing Test	
Effective Date	12/21/2020
Name	JAK2 V617F Cascading Reflex
Code	JAKCR
Interface Order Code	3400380
Legacy Code	
Notes	Updates to specimen requirements, alternate specimens and stability.
Required Testing Changes	
Specimen Required	Send 5.0 mL whole blood or 3.0 mL bone marrow collected in EDTA lavender top tube. Send room temperature.
Alternate Specimen	Whole blood: sodium heparin tube Extracted DNA from CLIA-certified laboratory Bone marrow: 3.0 mL (1.0 mL minimum), EDTA or sodium heparin
Stability	Whole blood, Bone marrow, Cell pellet: Room temperature: 7 days; Refrigerated: 7 days; Frozen: Unacceptable Extracted DNA: Room temperature: 7 days; Refrigerated: 14 days; Frozen: 1 year

Update Existing Test	
Effective Date	12/14/2020
Name	Kras Mutation Analysis
Code	KRASA
Interface Order Code	3423900
Legacy Code	KRASQ
Notes	
Required Testing Changes	
Specimen Required	Send paraffin-embedded, formalin-fixed tissue block at room temperature . Protect paraffin block from excessive heat and include surgical pathology report.
Alternate Specimen	Whole blood: 5.0 mL lavender EDTA (3.0 mL minimum) Bone marrow: 3.0 mL lavender EDTA (1.0 mL minimum) 8 (4 minimum) unstained, charged (+) slides
Stability	Tissue block: Room temperature: 5 years; Refrigerated: 5 years; Frozen: Unacceptable Whole blood and Bone marrow: Room temperature: 72 hours; Refrigerated: 72 hours; Frozen: Unacceptable Slides: Room temperature: 5 years; Refrigerated: 5 years; Frozen: Unacceptable
Performed Days	Sunday - Saturday
Turnaround Time	7 - 9 days

Update Existing Test	
Effective Date	11/25/2020
Name	Lipase, Fluid
Code	LIPFL
Interface Order Code	3619780
Legacy Code	LIPFL
Notes	Updates to specimen requirements and stability.
Required Testing Changes	
Specimen Required	Acceptable fluid types are Biliary/Hepatic, Drain, Pancreatic, Pericardial, Peritoneal/Ascites, Pleural or Synovial fluid. Centrifuge fluid to remove cellular material and send 1.0 mL fluid (0.5 mL minimum) at room temperature in a screw-capped plastic vial. Specimen source must be provided.
Stability	Room temperature: 7 days; Refrigerated: 7 days; Frozen: 2 months

Update Existing Test	
Effective Date	12/21/2020
Name	MPL Mutation Analysis
Code	MPLQL
Interface Order Code	3700139
Legacy Code	
Notes	Updates to specimen requirements and alternate specimens.
Required Testing Changes	
Specimen Required	Draw blood in a lavender EDTA. Send 5.0 mL whole blood (3.0 mL minimum) refrigerated.
Alternate Specimen	Bone marrow: Lavender EDTA, 3.0 mL (1.0 mL minimum) Cell pellets: Send fixed cell pellet collected in a plastic, screw-capped leak-proof vial. Extracted DNA: from a CLIA - certified laboratory collected in a sterile screw-capped leak-proof vial.

Update Existing Test	
Effective Date	11/25/2020
Name	Respiratory Syncytial Virus PCR
Code	RVPCR
Interface Order Code	3091910
Legacy Code	RSVPCR
Notes	
Required Testing Changes	
Specimen Required	<p>Specimen source is required. Throat plus NP swab in viral transport medium.</p> <p>If sending one sample for RVPCR and COVW (COVID testing) please send a minimum of 1.5 mL.</p> <p>Swabs in culturettes must be transferred to viral transport within 24 hours of collection. Bronchoalveolar lavage/wash in an IATA-approved sterile screw-capped plastic container. 1.0 mL (0.5 mL minimum). Sputum undiluted in an IATA-approved sterile screw-capped plastic container. 1.0 mL (0.5 mL minimum). Nasal Aspirates in vacuum trap. 1.0 mL (0.5 mL minimum). Nasal Washes in an IATA-approved sterile screw-capped plastic container. 1.0 mL (0.5 mL minimum).</p> <p>NP/OP swab in Phosphate Buffered saline or sterile saline.</p>

Update Existing Test

Effective Date	12/21/2020
Name	T Cell Rec Gamma Gene Rear PCR
Code	TCRGQ
Interface Order Code	3427200
Legacy Code	TCRGQ
Notes	Updates to alternative specimens and stability.

Required Testing Changes

Alternate Specimen	<p>Bone marrow: 3.0 mL (1.0 minimum) EDTA Paraffin block (room temperature), fresh/unfixed tissue sample (frozen -70°C) 8 (4 minimum) unstained charge (+) slides and include pathology report.</p>
Stability	<p>Whole blood/bone marrow: Room temperature: 7 days; Refrigerated: 7 days; Frozen; Unacceptable</p> <p>Paraffin block/slides: Room temperature: 5 years; Refrigerated: 5 years; Frozen: Unacceptable</p> <p>Fresh tissue: Frozen: (-70° Celsius) 1 year</p>

Update Existing Test

Effective Date	12/21/2020
Name	Y Chromosome Microdeletion, DNA Analysis
Code	YCMIC
Interface Order Code	3428900
Legacy Code	YCMIC
Notes	Updates to accepted alternate specimens.

Required Testing Changes

Alternate Specimen	Whole blood: Yellow ACD
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Inactivate Test With Replacement			
Effective Date	12/8/2020		
Inactivated Test			
Name	Borrelia burgdorf C6 Pept Ab		
Code	C6PEP		
Legacy Code ¹	C6PEPAR		
Interface Order Code	3685820		
Notes			
Replacement Test			
Name	Borrelia burgdorferi VlsE1/pepC10 Abs, ELISA		
Code	BBURV		
CPT Code(s)	86618		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in a SST. Centrifuge and separate serum from cells within 2 hours. Send 1.0 mL serum (0.2 mL minimum) refrigerated in a screw-capped plastic vial.		
Rejection Criteria	Plasma, CSF, Contaminated, heat-inactivated, hemolyzed, icteric, or lipemic specimens		
Stability	Room temperature: 48 hours; Refrigerated: 10 days; Frozen: 1 month		
Performing Information			
Methodology	Semi-quantitative Enzyme-Linked Immunosorbent Assay		
Reference Range	<p>0.90 IV or less: Negative - VlsE1 and pepC10 antibodies to B. burgdorferi not detected.</p> <p>0.91 - 1.09 IV: Equivocal - Repeat testing in 10 - 14 days may be helpful.</p> <p>1.10 IV or greater: Positive - VlsE1 and pepC10 antibodies to B. Burgdorferi detected.</p>		
Performed Days	Monday - Friday		
Turnaround Time	2 - 6 days		
Performing Laboratory	ARUP Reference Laboratory		
Interface Information			
Legacy Code ¹	BBURV		
Interface Order Code	3600169		
Result Code	Name	LOINC Code	AOE/Prompt ²
3600169	Borrelia burgdorferi VlsE1/pepC10 Abs, ELISA	5060-9	No



LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 11/23/2020 11:00 Received: 11/25/2020 13:24

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: Borrelia burgdorferi VlsE1/pepC10 Abs, ELISA, 1.00, 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: Tracy I. George, MD

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

Inactivate Test With Replacement			
Effective Date	12/14/2020		
Inactivated Test			
Name	NRAS Mutation Analysis		
Code	NRASM		
Legacy Code¹	NRASM		
Interface Order Code	3428850		
Notes			
Replacement Test			
Name	NRAS Mutation Analysis		
Code	NRMUA		
CPT Code(s)	81311 ZB0V6		
Notes			
Specimen Requirements			
Specimen Required	Formalin-fixed, parafin - embedded tissue block sent at room temperature. Include specimen source and pathology report.		
Alternate Specimen	Whole blood: 5.0 mL (3.0 minimum), EDTA or sodium heparin. Bone marrow: 3.0 mL (1.0 mL minimum), EDTA or sodium heparin. Slides: 8 (4 minimum) unstained charged + slides.		
Rejection Criteria	Gross hemolysis, clotted whole blood or bone marrow		
Stability	Whole blood, bone marrow: Room temperature: 72 hours; Refrigerated: 72 hours; Frozen: Unacceptable. Tissue Block: Room temperature: 5 years; Refrigerated: 5 years; Frozen: Unacceptable		
Performing Information			
Methodology	Polymerase Chain Reaction/Sequencing		
Reference Range	Not detected		
Performed Days	Tuesday - Saturday		
Turnaround Time	5 - 7 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code¹	NRMUA		
Interface Order Code	3400413		
Result Code	Name	LOINC Code	AOE/Prompt ²
3400414	Specimen Source	Not available	Yes
3400415	Paraffin Block Number:	Not available	Yes
3400416	NRAS Mutation Analysis	21719-0	No



LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 11/20/2020 11:12 Received: 11/25/2020 13:22

Test Name Result Flag Ref-Ranges Units Site

NRAS Mutation Analysis

Specimen Source Blood QCRL
Paraffin Block Number: 123456 QCRL
NRAS Mutation Analysis NOT DETECTED QCRL

Reference Range:
NOT DETECTED

Activating NRAS oncogenic mutations are detected in a wide variety of cancers, including colorectal carcinomas, melanomas and acute myeloid leukemias.

Nucleic acid was subjected to PCR-based sequencing of the NRAS gene in three separate reactions for exons 2, 3 and 4. In fixed tissue samples, the area of tumor was grossly macrodissected prior to DNA extraction. This assay will detect mutations that comprise approximately 15-20% of alleles within the analyzed area.

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

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

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