Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Summary

New Test Activation	5/21/2024	HPVRG - "HPV mRNA E6/E7, Rect w/Ref to Geno, 16, 18/45"
Update Existing Test	5/7/2024	ALPRZ - "Alprazolam (Xanax)"
Update Existing Test	5/7/2024	ANA - "ANA IFA with Titer and Pattern"
Update Existing Test	5/7/2024	ANAR - "ANA IFA with Reflex to Connective Tissue Disease Antibodies"
Update Existing Test	5/7/2024	ASCA - "Saccharomyces cerevisiae IgG IgA"
Update Existing Test	5/7/2024	BENZP - "Benzodiazepine Panel, Serum Quantitative"
Update Existing Test	5/7/2024	BLQA - "MyVista(R) Blastomyces QN Antigen EIA"
Update Existing Test	5/7/2024	CD03A - " Clinical Urine Drug Abuse Screen 3A"
Update Existing Test	5/7/2024	CD05A - "Clinical Urine Drug Abuse Screen 5A"
Update Existing Test	5/7/2024	CD08A - "Clinical Urine Drug Abuse Screen 8A"
Update Existing Test	5/7/2024	CD09A - "Clinical Urine Drug Abuse Screen 9A"
Update Existing Test	5/7/2024	CD10A - "Clinical Urine Drug Abuse Screen 10A"
Update Existing Test	5/7/2024	CHLRP - "Chlordiazepoxide (Librium)"
Update Existing Test	5/7/2024	CLOZA - "Clozapine (Clozaril)"
Update Existing Test	5/7/2024	CYCLO - "Cyclosporine"
Update Existing Test	5/7/2024	ENDOM - "Endomysial IgA Antibodies"
Update Existing Test	5/7/2024	EVROL - "Everolimus (Afinitor, Zortress)"
Update Existing Test	5/7/2024	FK506 - "Tacrolimus (FK506, Prograf)"
Update Existing Test	5/7/2024	GABAP - "Gabapentin (Neurontin)"
Update Existing Test	5/7/2024	IGG4 - "Immunoglobulin G Subclass 4"
Update Existing Test	5/7/2024	KLFLC - "Kappa-Lambda Quantitative Free Light Chains"
Update Existing Test	5/7/2024	LAMOT - "Lamotrigine (Lamictal)"
Update Existing Test	5/7/2024	LEVET - "Levetiracetam (Keppra)"
Update Existing Test	5/7/2024	LKMAB - "Liver-Kidney Microsome Ab"
Update Existing Test	5/7/2024	METHD - "Methadone, Serum, Quantitative"
Update Existing Test	5/7/2024	MYCG - "Mycoplasma IgG Ab"
Update Existing Test	5/7/2024	MYCGM - "Mycoplasma IgG/IgM Abs"
Update Existing Test	5/7/2024	MYCM - "Mycoplasma IgM Ab"
Update Existing Test	5/7/2024	PARGM - "Parvovirus B-19 IgG/IgM Antibody"
Update Existing Test	5/7/2024	PARVG - "Parvovirus B-19 IgG Antibodies"
Update Existing Test	5/7/2024	PARVM - "Parvovirus B-19 IgM Antibodies"
Update Existing Test	5/7/2024	PNJRP - "Pneumocystis jirovecii, Quan, Real-Time PCR"
Update Existing Test	5/7/2024	SIROL - "Sirolimus (Rapamycin)"
Update Existing Test	5/7/2024	SMAB - "Smooth Muscle (F-actin) IgG Ab"
Update Existing Test	5/7/2024	SMTH1 - "Methadone, Serum, Qualitative"

Update Existing Test	5/7/2024	TGIWB - "Total Glutathione in Whole Blood"
Update Existing Test	5/7/2024	TOPIR - "Topiramate (Topamax)"
Update Existing Test	5/7/2024	UCAMP - " Amphetamine, Urine, Clinical, LC/MS-MS Confirmation (Quantitative)"
Update Existing Test	5/7/2024	UCBAR - "Barbiturate, Urine, Clinical, GC/MS Confirmation (Quantitative)"
Update Existing Test	5/7/2024	UCBEN - "Benzodiazepine, Urine, Clinical, LC/MS/MS, Confirmation (Quantitative)"
Update Existing Test	5/7/2024	UCCOC - " Cocaine, Urine, Clinical, LC/MS-MS Confirmation (Quantitative)"
Update Existing Test	5/7/2024	UCETH - " Ethanol, Urine, Clinical, Confirmation (Qualitative)"
Update Existing Test	5/7/2024	UCMTH - " Methadone, Urine, Clinical, LC/MS-MS Confirmation (Quantitative)"
Update Existing Test	5/7/2024	UCOPT - " Opiate, Urine, Clinical, LC/MS-MS Confirmation (Quantitative)"
Update Existing Test	5/7/2024	UCPCP - " Phencyclidine, Urine, Clinical, LC/MS-MS Confirmation (Quantitative)"
Update Existing Test	5/7/2024	UCPRP - " Propoxyphene, Urine, Clinical, GC/MS Confirmation (Quantitative)"
Update Existing Test	5/7/2024	UCTHC - "THC, Urine, Clinical, GC/MS Confirmation (Quantitative)"
Update Existing Test	5/7/2024	UMAC1 - " 6-Acetylmorphine, Urine, Clinical, Quantitative"
Update Existing Test	5/7/2024	VARGM - "Varicella IgG/IgM Antibodies"
Update Existing Test	5/7/2024	VARM - "Varicella Zoster IgM Antibody"
Update Existing Test	5/7/2024	VOLAT - "Volatiles Screen"
Inactivate Test With Replacement	5/20/2024	CHAG - "Trypanosoma cruzi (Chagas' Disease) Ab, IgG" replaced by TRCAB - "Trypanosoma cruzi Ab, Total w/ Ref to Conf"
Inactivate Test With Replacement	5/28/2024	E1Q - "Estrone" replaced by EONE - "Estrone, LC/MS/MS"
Inactivate Test With Replacement	5/20/2024	IDHMF - "IDH1 and IDH2 Mutation Analysis FFPE Tissue" replaced by IDHMD - "IDH1 and IDH2 Mutation Detection "
Inactivate Test With Replacement	5/14/2024	NTELO - "Collagen Cross Linked N Telopeptide (NTX), 24H U w/Creat" replaced by NTELU - "Collagen Cross Linked N Telopeptide (NTx), 24H U"
Inactivate Test Without Replacement	5/20/2024	IDHMA - "IDH1 and IDH2 Mutation Analysis, exon 4"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

New Test Activation

Effective Date	5/21/2024
Name	HPV mRNA E6/E7, Rect w/Ref to Geno, 16, 18/45
Code	HPVRG
CPT Code(s)	87624, plus 87625 if reflexed, at an additional fee
Notes	New test listing

Specimen Requirements

New York Approval	New York DOH Approval Status: Yes
Specimen Required	*Collect:* Liquid cytology *Specimen Preparation:* Collect an anal-rectal sample with a wetted, non-lubricated Dacron/Polyester swab. Send 3.0 mL Dacron/Polyester swab collected in Liquid Cytology (PreservCyt®) Preservative (ThinPrep®). *Minimum Volume:* 1.5 mL *Transportation Temperature:* Room temperature
Alternate Specimen	Anal-rectal brush
Rejection Criteria	Cotton swab on a wooden stick, swab that is grossly contaminated with feces.
Stability	Room temperature: 30 days Refrigerated: 28 days Frozen: Unacceptable

Performing Information

Methodology	Transcription-Mediated Amplification (TMA)
Reference Range	Not detected
Performed Days	Monday, Wednesday, Friday
Turnaround Time	5-8 days
Performing Laboratory	Quest SJC

Interface Information

Legacy Code	HPVRG
Interface Order Code	3400851

Result Code	Name	LOINC Code	AOE/Prompt
3400907	HPV mRNA E6/E7, Rectal	74763-4	No
3400908	HPV 16 RNA, Anal-Rectal	77396-0	No
3400909	HPV 18/45 RNA, Anal-Rectal		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: 04/16/2024 14:56 Received: 04/16/2024 14:56

Test Name	Result	Flag	Ref-Ranges	Units	Site
HPV mRNA E6/E7, Rect w/Ref to Geno, 16, 18/45					
HPV mRNA E6/E7, Rectal	**DETECTED**	**AB**			QCRL

REFERENCE RANGE: NOT DETECTED

Methodology: Transcription-Mediated Amplification

This assay detects E6/E7 viral messenger RNA(mRNA) from 14 high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68).

The analytical performance characteristics of this assay have been determined by Quest Diagnostics. The modifications have not been cleared or approved by the U.S. Food and Drug Administration. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

For additional information, please refer to http://education.questdiagnostics.com/faq/FAQ129v1 (This link is being provided for informational/ educational purposes only).

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway

HPV 16 RNA, Anal-Rectal	**DETECTED**	**AB**			QCRL
HPV 18/45 RNA, Anal-Rectal	**DETECTED**	**AB**			QCRL

REFERENCE RANGE:
HPV 16 RNA: NOT DETECTED
HPV 18/45 RNA: NOT DETECTED

Methodology: Transcription Mediated Amplification

The analytical performance characteristics of this assay have been determined by Quest Diagnostics. The modifications have not been cleared or approved by the U.S. Food and Drug Administration. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

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

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 04/16/2024 14:56 Received: 04/16/2024 14:56

Test Name	Result	Flag	Ref-Ranges	Units	Site
Test Performed at: Quest Diagnostics Nichols Institute 33608 Ortega Highway					

Reported Date: 04/16/2024 14:56 HPVRG

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

G016000014
WX0000003826
Printed D&T: 04/16/24 14:57

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002353

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

Update Existing Test	
Effective Date	5/7/2024
Name	Alprazolam (Xanax)
Code	ALPRZ
Interface Order Code	1751100
Legacy Code	ALPRAZO
Notes	Update to specimen requirements
Required Testing Changes	
Specimen Required	*Collect*: Red top *Specimen Preparation*: Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial. *Minimum Volume*: **0.5 mL** *Transport Temperature*: Refrigerated

Update Existing Test	
Effective Date	5/7/2024
Name	ANA IFA with Titer and Pattern
Code	ANA
Interface Order Code	3000189
Legacy Code	ANA
Notes	Update to rejection criteria and specimen stability.
Required Testing Changes	
Rejection Criteria	Grossly hemolyzed, **heat-treated, microbially contaminated** or lipemic specimens, plasma
Stability	Room temperature: 8 hours Refrigerated: 7 days **Frozen: Undetermined**

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Update Existing Test	
Effective Date	5/7/2024
Name	ANA IFA with Reflex to Connective Tissue Disease Antibodies
Code	ANAR
Interface Order Code	3000178
Legacy Code	REFANA
Notes	Update to rejection criteria and specimen stability.
Required Testing Changes	
Rejection Criteria	Grossly hemolyzed, **heat-treated, microbially contaminated** or lipemic specimens, plasma
Stability	ANA: Room temperature: 8 hours Refrigerated 7 days **Frozen: Undetermined** Anti-ds DNA, Anti-SM, Anti-RNP, Anti-SSA, Anti-SSB, Anti-Scl-70, Jo-1 IgG: Room temperature: 8 hours Refrigerated: 14 days **Frozen: Undetermined**

Update Existing Test	
Effective Date	5/7/2024
Name	Saccharomyces cerevisiae IgG IgA
Code	ASCA
Interface Order Code	3017360
Legacy Code	ASCA
Notes	Update to rejection criteria and specimen stability.
Required Testing Changes	
Rejection Criteria	Grossly hemolyzed, **heat-treated, microbially contaminated** or lipemic specimens, plasma
Stability	Room Temperature: 8 hours Refrigerated: 48 hours **Frozen: Undetermined**

Update Existing Test	
Effective Date	5/7/2024
Name	Benzodiazepine Panel, Serum Quantitative
Code	BENZP
Interface Order Code	1750970
Legacy Code	BENZOP
Notes	Update to specimen requirements and reference range.
Required Testing Changes	
Specimen Required	*Collect:* Red top *Specimen Preparation:* Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial. *Minimum Volume:* **0.5 mL** *Transport Temperature:* Refrigerated
Reference Range	Therapeutic: Chlordiazepoxide: 100 – 3000 ng/mL Diazepam: 100 – 1000 ng/mL Nordiazepam: 100 – 1000 ng/mL N-Desalkylflurazepam: 30 – 150 ng/mL Oxazepam: 200 – 500 ng/mL Lorazepam: 50 – 240 ng/mL Alprazolam: 7 – 40 ng/mL Clonazepam: 15 – 60 ng/mL Temazepam: 50 – 1000 ng/mL Toxic: **sum of Diazepam + Nordiazepam: >5000 ng/mL** **Nordiazepam: >3000 ng/mL** **Diazepam: >3000 ng/mL** **N-Desalkylflurazepam: >300 ng/mL** **Oxazepam: NA** Lorazepam: >300 ng/mL Alprazolam: >100 ng/mL Clonazepam: >80 ng/mL **Temazepam: >3000 ng/mL**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	MyVista(R) Blastomyces QN Antigen EIA
Code	BLQA
Interface Order Code	3700035
Legacy Code	BLQA
Notes	Update to New York Approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: Yes**

Update Existing Test	
Effective Date	5/7/2024
Name	Drug Abuse Screen, Urine 3 Panel Screen
Code	CD03A
Interface Order Code	1845100
Legacy Code	CD03A
Notes	Update to test name and specimen requirements.
Required Testing Changes	
Name	**Clinical Urine Drug Abuse Screen 3A**
Specimen Required	*Collect*: **Random urine** *Specimen Preparation*: Send 30.0 mL urine in a screw capped plastic urine container. Pediatric: Newborn minimum requires 1.0 mL urine. **All positive screen results are considered presumptive results.** *Minimum Volume*: **15.0 mL** *Transport Temperature*: Refrigerated

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TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Clinical Urine Drug Abuse Screen 5A
Code	CD05A
Interface Order Code	1845180
Legacy Code	CD05A
Notes	Update to specimen requirements and methodology.
Required Testing Changes	
Specimen Required	*Collect*: Random Urine *Specimen Preparation*: Send 30.0 mL urine in a screw capped plastic urine container. Pediatric: Newborn minimum requires 1.0 mL urine. **All positive screen results are considered presumptive positives except for amphetamines and PCP, which are confirmed to ensure accuracy of screening result.** **This panel is NOT designed to detect low levels of buprenorphine, fentanyl, meperidine, oxycodone or tramadol. See the PNO3A panel if these tests are required.** *Minimum Volume*: 15.0 mL *Transport Temperature*: Refrigerated
Methodology	**Liquid Chromatography/Tandem Mass Spectrometry**

Update Existing Test	
Effective Date	5/7/2024
Name	Clinical Urine Drug Abuse Screen 8A
Code	CD08A
Interface Order Code	1845200
Legacy Code	CD08A
Notes	Update to specimen requirements and methodology.
Required Testing Changes	
Specimen Required	*Collect:* Random urine ***Specimen Preparation:*** **Send 30.0 mL urine in a screw capped plastic urine container. Newborn minimum requires 1.0 mL urine. All positive screen results are considered presumptive positives except for amphetamines and PCP, which are confirmed to ensure accuracy of screening result.** *Minimum Volume:* 15.0 mL *Transport Temperature:* Refrigerated This panel is NOT designed to detect low levels of buprenorphine, fentanyl, meperidine, oxycodone or tramadol. See the PN03A panel if these tests are required.
Methodology	**Enzyme Immunoassay; Gas Chromatography/Mass Spectrometry; Liquid Chromatography/Tandem Mass Spectrometry**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Clinical Urine Drug Abuse Screen 9A
Code	CD09A
Interface Order Code	1845220
Legacy Code	CD09A
Notes	Update to specimen requirements and methodology.
Required Testing Changes	
Specimen Required	*Collect*: Random urine *Specimen Preparation*: **Send 30.0 mL urine in a screw capped plastic urine container. Pediatric: Newborn minimum requires 1.0 mL urine.** **All positive screen results are considered presumptive results except for amphetamines and PCP, which are confirmed to ensure accuracy of screening result.** **This panel is NOT designed to detect low levels of buprenorphine, fentanyl, meperidine, oxycodone or tramadol. See the PN03A panel if these tests are required.** *Minimum Volume*: **15.0 mL** *Transport Temperature*: Refrigerated
Methodology	**Liquid Chromatography/Tandem Mass Spectrometry**

Update Existing Test	
Effective Date	5/7/2024
Name	Clinical Urine Drug Abuse Screen 10A
Code	CD10A
Interface Order Code	1845240
Legacy Code	CD10A
Notes	Update to specimen requirements and methodology.
Required Testing Changes	
Specimen Required	*Collect*: Random urine *Specimen Preparation*: **Send 30.0 mL urine in a screw capped plastic urine container. Pediatric: Newborn minimum requires 1.0 mL urine. All positive screen results are considered presumptive results except for amphetamines and PCP, which are confirmed to ensure accuracy of screening result.** **This panel is NOT designed to detect low levels of buprenorphine, fentanyl, meperidine, oxycodone or tramadol. See the PN03A panel if these tests are required.** *Minimum Volume*: **15.0 mL** *Transport Temperature*: Refrigerated
Methodology	**Liquid Chromatography/Tandem Mass Spectrometry**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Chlordiazepoxide (Librium)
Code	CHLRP
Interface Order Code	1750980
Legacy Code	CHLDP
Notes	Update to specimen requirements, alternate specimen, and stability.
Required Testing Changes	
Specimen Required	*Collect:* Red top *Specimen Preparation:* Centrifuge, separate serum from cells and send 1.0 mL serum refrigerated in an amber screw capped plastic vial. PROTECT FROM LIGHT. ***Minimum Volume:* 0.5 mL** *Transport Temperature:* Refrigerated
Alternate Specimen	**No alternate specimen listing.**
Stability	Room temperature: 48 hours **Refrigerated: 7 days** Frozen: 14 days

Update Existing Test	
Effective Date	5/7/2024
Name	Clozapine (Clozaril)
Code	CLOZA
Interface Order Code	1757000
Legacy Code	CLOZAP
Notes	Update to alternate specimen and stability.
Required Testing Changes	
Alternate Specimen	**No alternate listing.**
Stability	Room temperature: 48 hours **Refrigerated: 7 days** Frozen: 14 days

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Cyclosporine
Code	CYCLO
Interface Order Code	1757210
Legacy Code	CYCLO
Notes	Update to specimen requirements, stability and reference range.
Required Testing Changes	
Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Send 1.0 mL whole blood refrigerated. **CAUTION: The complexity of the clinical state, individual differences in sensitivity to the immunosuppressive and nephrotoxic effects of cyclosporine, the co-administration of other immunosuppressants, the type of transplant and a number of other factors will cause different requirements for optimal whole blood levels of cyclosporine. The reference ranges below are general guidelines and apply to trough specimens drawn just prior to a.m. dose.** ***Minimum Volume:*** **0.5 mL** *Transport Temperature:* Refrigerated
Stability	Room temperature: 24 hours **Refrigerated: 7 days** **Frozen: Unacceptable**
Reference Range	100 - 400 ng/mL Toxic: >700 ng/mL **Organ Kidney (w/Everolimus)** **Post Transplant (months)** **up to 1 100-200 ng/mL** **2 - 3 75 - 150 ng/mL** **4 - 5 50 - 100 ng/mL** **6 - 12 25 - 50 ng/mL** **Heart** **Up to 3 350 - 525** **>=4 145 - 350** **Liver 290 - 525**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Endomysial IgA Antibodies
Code	ENDOM
Interface Order Code	3083000
Legacy Code	ENDOMYS
Notes	Update to rejection criteria and specimen stability.
Required Testing Changes	
Rejection Criteria	Grossly hemolyzed, **heat-treated, microbially contaminated** or lipemic specimens, plasma
Stability	Room temperature: Unacceptable **Refrigerated: 7 days** **Frozen: Undetermined**

Update Existing Test	
Effective Date	5/7/2024
Name	Everolimus (Afinitor, Zortress)
Code	EVROL
Interface Order Code	1757640
Legacy Code	EVEROL
Notes	Update to stability and reference range.
Required Testing Changes	
Stability	Room temperature: 24 hours Refrigerated: 7 days **Frozen: 14 days**
Reference Range	3.0 - 8.0 ng/mL Critical value >15 ng/mL **Organ — Combined therapy with — Trough Level** **Kidney — Cyclosporine — 3.0 - 8.0 ng/mL** **Liver — Tacrolimus — 3.0 - 8.0 ng/mL**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Tacrolimus (FK506, Prograf)
Code	FK506
Interface Order Code	1757110
Legacy Code	FK506
Notes	Update to specimen requirements, stability, and reference range.
Required Testing Changes	
Specimen Required	*Collect*: Lavender EDTA *Specimen Preparation*: Send 1.0 mL whole blood. *Minimum Volume*: **0.5 mL** *Transport Temperature*: Refrigerated
Stability	Room temperature: 24 hours **Refrigerated: 7 days** **Frozen: Unacceptable**
Reference Range	5 - 20 ng/mL Toxic: >26 ng/mL Organ Post Transpl. (months) Trough Level Kidney Up to 3 7.0 - 20.0 ng/mL >3 5.0 - 15.0 ng/mL Heart Up to 3 10.0 - 20.0 ng/mL >3 5.0 - 15.0 ng/mL Liver Up to 12 5.0 - 20.0 ng/mL

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Gabapentin (Neurontin)
Code	GABAP
Interface Order Code	1751300
Legacy Code	GABA
Notes	Update to specimen requirements, alternate specimen, and stability.
Required Testing Changes	
Specimen Required	*Collect:* Red top *Specimen Preparation:* Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial. ***Minimum volume:* 0.5 mL** *Transport Temperature:* Refrigerated
Alternate Specimen	**No alternate specimen listing.**
Stability	Room temperature: 48 hours **Refrigerated: 7 days** Frozen: 14 days

Update Existing Test	
Effective Date	5/7/2024
Name	Immunoglobulin G Subclass 4
Code	IGG4
Interface Order Code	3004040
Legacy Code	IGG4
Notes	Update to specimen stability.
Required Testing Changes	
Stability	**Room temperature: Undetermined** Refrigerated: 8 days **Frozen: Undetermined**

Update Existing Test	
Effective Date	5/7/2024
Name	Kappa-Lambda Quantitative Free Light Chains
Code	KLFLC
Interface Order Code	1015200
Legacy Code	KLFLC
Notes	Update to specimen stability.
Required Testing Changes	
Stability	**Room temperature: Undetermined** Refrigerated: 21 days **Frozen: Undetermined**

Update Existing Test	
Effective Date	5/7/2024
Name	Lamotrigine (Lamictal)
Code	LAMOT
Interface Order Code	1756800
Legacy Code	LAMOTR
Notes	Update to specimen requirements, alternate specimen, and stability.
Required Testing Changes	
Specimen Required	*Collect:* Red top *Specimen Preparation:* Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial. ***Minimum Volume:* 0.5 mL** *Transport Temperature:* Refrigerated
Alternate Specimen	**No alternate specimen listing.**
Stability	Room temperature: 24 hours **Refrigerated: 7 days** Frozen: 14 days

Update Existing Test	
Effective Date	5/7/2024
Name	Levetiracetam (Keppra)
Code	LEVET
Interface Order Code	1751330
Legacy Code	LEVETRCTM
Notes	Update to specimen requirements, alternate specimen, and stability.
Required Testing Changes	
Specimen Required	*Collect:* Red top *Specimen Preparation:* Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial. ***Minimum Volume:* 0.5 mL** *Transport Temperature:* Refrigerated
Alternate Specimen	**No alternate specimen listing.**
Stability	Room temperature: 48 hours **Refrigerated: 7 days** Frozen: 14 days

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Liver-Kidney Microsome Ab
Code	LKMAB
Interface Order Code	3007540
Legacy Code	LKMAB
Notes	Update to rejection criteria and specimen stability.
Required Testing Changes	
Rejection Criteria	Grossly hemolyzed, **heat-treated, microbially contaminated** or lipemic specimens, plasma
Stability	Room temperature: 8 hours Refrigerated: 21 days **Frozen: Undetermined**

Update Existing Test	
Effective Date	5/7/2024
Name	Methadone, Serum, Quantitative
Code	METHD
Interface Order Code	1750760
Legacy Code	METHAD
Notes	Update to specimen requirements and specimen stability.
Required Testing Changes	
Specimen Required	*Collect*: Red top *Specimen Preparation*: Centrifuge, separate serum from cells and send **1.0 mL** serum in a screw capped plastic vial. *Minimum Volume*: **0.5 mL** *Transport Temperature*: Refrigerated
Stability	Room temperature: 48 hours Refrigerated: **7 days** Frozen: 14 days

Update Existing Test	
Effective Date	5/7/2024
Name	Mycoplasma IgG Ab
Code	MYCG
Interface Order Code	3003010
Legacy Code	MYCG
Notes	Update to specimen stability.
Required Testing Changes	
Stability	Room temperature: 8 hours Refrigerated: 48 hours **Frozen: Undetermined**

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TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Mycoplasma IgG/IgM Abs
Code	MYCGM
Interface Order Code	3003005
Legacy Code	MYCGM
Notes	Update to specimen stability.
Required Testing Changes	
Stability	Room temperature: 8 hours Refrigerated: 48 hours **Frozen: Undetermined**

Update Existing Test	
Effective Date	5/7/2024
Name	Mycoplasma IgM Ab
Code	MYCM
Interface Order Code	3003100
Legacy Code	MYCM
Notes	Update to specimen stability.
Required Testing Changes	
Stability	Room temperature: 8 hours Refrigerated: 48 hours **Frozen: Undetermined**

Update Existing Test	
Effective Date	5/7/2024
Name	Parvovirus B-19 IgG/IgM Antibody
Code	PARGM
Interface Order Code	3003500
Legacy Code	PARVGM
Notes	Update to specimen stability.
Required Testing Changes	
Stability	Room temperature: 8 hours Refrigerated: 48 hours Frozen: **Undetermined**

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TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Parvovirus B-19 IgG Antibodies
Code	PARVG
Interface Order Code	3003510
Legacy Code	PARVG
Notes	Update to specimen stability.
Required Testing Changes	
Stability	Room temperature: 8 hours Refrigerated: 48 hours Frozen: **Undetermined**

Update Existing Test	
Effective Date	5/7/2024
Name	Parvovirus B-19 IgM Antibodies
Code	PARVM
Interface Order Code	3003520
Legacy Code	PARVM
Notes	Update to specimen stability.
Required Testing Changes	
Stability	Room temperature: 8 hours Refrigerated: 48 hours Frozen: **Undetermined**

Update Existing Test	
Effective Date	5/7/2024
Name	Pneumocystis jirovecii, Quan, Real-Time PCR
Code	PNJRP
Interface Order Code	3400816
Legacy Code	PNJRP
Notes	Update to LOINC code.

Required Testing Changes

Result Code	Name	LOINC Code	AOE/Prompt
3400817	Source	31208-2	Yes
3400818	P. jirovecii DNA, QN PCR	49441-9	No
3400819	P. jirovecii DNA, QN PCR	**100693-1**	No

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Sirolimus (Rapamycin)
Code	SIROL
Interface Order Code	1800500
Legacy Code	SIROL
Notes	Update to specimen requirements, stability and reference range.
Required Testing Changes	
Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Send 1.0 mL whole blood. ***Minimum Volume:* 0.5 mL** *Transport Temperature:* Refrigerated
Stability	Room temperature: 24 hours **Refrigerated: 7 days** **Frozen: 14 days**
Reference Range	4 - 12 ng/mL Toxic Level: >25 ng/mL K**idney Transplant (with cyclosporine)** **Post Transplant: NA** **Trough Level: 4.0 - 12.0 ng/mL** **Kidney Transplant** **Post Transplant:** **After cyclosporine withdrawal:** **<12 months Trough Level: 16.0 - 24.0 ng/mL** **>12 month Trough Level: 12.0 - 20.0 ng/mL**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Smooth Muscle (F-actin) IgG Ab
Code	SMAB
Interface Order Code	3002250
Legacy Code	SMAB
Notes	Update to rejection criteria and specimen stability.
Required Testing Changes	
Rejection Criteria	Grossly hemolyzed, **heat-treated, microbially contaminated** or lipemic specimens, plasma
Stability	Room temperature: 8 hours Refrigerated: 48 hours **Frozen: Undetermined**

Update Existing Test	
Effective Date	5/7/2024
Name	Methadone, Serum, Qualitative
Code	SMTH1
Interface Order Code	1800340
Legacy Code	METHSER
Notes	Update to alternate specimen and stability.
Required Testing Changes	
Alternate Specimen	**No alternate listing.**
Stability	Room temperature: 48 hours **Refrigerated: 7 days** Frozen: 14 days

Update Existing Test	
Effective Date	5/7/2024
Name	Total Glutathione in Whole Blood
Code	TGIWB
Interface Order Code	3400636
Legacy Code	TGIWB
Notes	Update to specimen requirements and rejection criteria.
Required Testing Changes	
Specimen Required	***Collect:*** **Yellow ACD B** ***Specimen Preparation:*** **Send 1 full tube whole blood collected in an ACD solution B (yellow-top) tube.** ***Minimum volume:*** **6.0 mL** *Transport Temperature:* Refrigerated
Rejection Criteria	Hemolyzed samples. Samples oversaturated with ACD solution, **Yellow ACD A**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Topiramate (Topamax)
Code	TOPIR
Interface Order Code	1752050
Legacy Code	TOPIR
Notes	Update to specimen requirements and alternate specimen.
Required Testing Changes	
Specimen Required	*Collect:* Red top *Specimen Preparation:* Centrifuge, separate serum from cells within 6 hours and send 1.0 mL serum in a screw capped plastic vial. ***Minimum Volume:* 0.5 mL** *Transport Temperature:* Refrigerated
Alternate Specimen	**No alternate specimen listing.**

Update Existing Test	
Effective Date	5/7/2024
Name	Amphetamine, Urine, Clinical, GC/MS Confirmation (Quantitative)
Code	UCAMP
Interface Order Code	1846150
Legacy Code	UCAMP
Notes	Update to test name and methodology.
Required Testing Changes	
Name	**Amphetamine, Urine, Clinical, LC/MS-MS Confirmation (Quantitative)**
Methodology	**Liquid Chromatography/Tandem Mass Spectrometry**

Update Existing Test	
Effective Date	5/7/2024
Name	Barbiturate, Urine, Clinical, GC/MS Confirmation (Quantitative)
Code	UCBAR
Interface Order Code	1846500
Legacy Code	UCBAR
Notes	Update to reference range and New York approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: No**
Reference Range	Decision level: 40 ng/mL **Phenobarbital: 200 ng/mL**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Clin Urine Benzodiazepine Confirm
Code	UCBEN
Interface Order Code	1846800
Legacy Code	UCBEN
Notes	Updates to clinical information and test name.
Required Testing Changes	
Name	**Benzodiazepine, Urine, Clinical, LC/MS/MS, Confirmation (Quantitative)**
Clinical Information	**Alprazolam confirmed as alpha hydroxy alprazolam.** **Clonazepam confirmed as 7-amino clonazepam.** **Flurazapam confirmed as 2-hydroxy ethyl flurazepam.**

Update Existing Test	
Effective Date	5/7/2024
Name	Cocaine, Urine Clinical GC/MS Confirmation (Quantitative)
Code	UCCOC
Interface Order Code	1847100
Legacy Code	UCCOC
Notes	Update to test name and methodology.
Required Testing Changes	
Name	**Cocaine, Urine, Clinical, LC/MS-MS Confirmation (Quantitative)**
Methodology	**Liquid Chromatography/Tandem Mass Spectrometry**

Update Existing Test	
Effective Date	5/7/2024
Name	Ethanol, Urine Clinical Confirmation (Qualitative)
Code	UCETH
Interface Order Code	1847200
Legacy Code	UCETH
Notes	Update to test name, specimen stability, and New York approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: No**
Name	**Ethanol, Urine, Clinical, Confirmation (Qualitative)**
Stability	Room temperature: 48 hours **Refrigerated: 7 days** Frozen: 30 days

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Methadone, Urine Clinical GC/MS Confirmation (Quantitative)
Code	UCMTH
Interface Order Code	1847300
Legacy Code	UCMTH
Notes	Update to test name and methodology.
Required Testing Changes	
Name	**Methadone, Urine, Clinical, LC/MS-MS Confirmation (Quantitative)**
Methodology	**Liquid Chromatography/Tandem Mass Spectrometry**

Update Existing Test	
Effective Date	5/7/2024
Name	Opiate, Urine Clinical GC/MS Confirmation (Quantitative)
Code	UCOPT
Interface Order Code	1847600
Legacy Code	UCOPT
Notes	Update to test name and performed days.
Required Testing Changes	
Name	**Opiate, Urine, Clinical, LC/MS-MS Confirmation (Quantitative)**
Performed Days	**Monday-Friday**

Update Existing Test	
Effective Date	5/7/2024
Name	Phencyclidine, Urine Clinical GC/MS Confirmation (Quantitative)
Code	UCPCP
Interface Order Code	1847920
Legacy Code	UCPCP
Notes	Update to test name, specimen requirements, and methodology.
Required Testing Changes	
Name	**Phencyclidine, Urine, Clinical, LC/MS-MS Confirmation (Quantitative)**
Specimen Required	*Collect*: Random urine *Specimen Preparation*: **Send 10.0 mL urine in a screw capped plastic urine container.** *Minimum Volume*: **3.0 mL** *Transport Temperature*: Refrigerated
Methodology	**Liquid Chromatography/Tandem Mass Spectrometry**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Propoxyphene, Urine Clinical GC/MS Confirmation (Quantitative)
Code	UCPRP
Interface Order Code	1847840
Legacy Code	UCPRP
Notes	Update to test name.
Required Testing Changes	
Name	**Propoxyphene, Urine, Clinical, GC/MS Confirmation (Quantitative)**

Update Existing Test	
Effective Date	5/7/2024
Name	THC, Urine, Clinical, GC/MS Confirmation (Quantitative)
Code	UCTHC
Interface Order Code	1848100
Legacy Code	UCTHC
Notes	Update to performed days and New York approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: No**
Performed Days	**Monday-Friday**

Update Existing Test	
Effective Date	5/7/2024
Name	6-Acetylmorphine, Clinical, Quantitative
Code	UMAC1
Interface Order Code	1836900
Legacy Code	UMAMCL
Notes	Update to test name and specimen requirements.
Required Testing Changes	
Name	**6-Acetylmorphine, Urine, Clinical, Quantitative**
Specimen Required	*Collect*: Random urine *Specimen Preparation*: Send 20.0 mL urine in a screw capped plastic urine container. *Minimum Volume*: **11.0 mL** *Transport Temperature*: Refrigerated

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Varicella IgG/IgM Antibodies
Code	VARGM
Interface Order Code	3017440
Legacy Code	VARGM
Notes	Update to specimen stability and performed days.
Required Testing Changes	
Stability	Room temperature: 8 hours Refrigerated: 48 hours **Frozen: Undetermined**
Performed Days	**Monday-Friday**

Update Existing Test	
Effective Date	5/7/2024
Name	Varicella Zoster IgM Antibody
Code	VARM
Interface Order Code	3017400
Legacy Code	VARM
Notes	Update to specimen stability and performed days.
Required Testing Changes	
Stability	Room temperature: 8 hours Refrigerated: 48 hours **Frozen: Undetermined**
Performed Days	**Sunday, Thursday**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Update Existing Test	
Effective Date	5/7/2024
Name	Volatiles Screen
Code	VOLAT
Interface Order Code	1755005
Legacy Code	VOLATIL
Notes	Update to specimen requirements and stability.
Required Testing Changes	
Specimen Required	*Collect:* Gray sodium flouride. Do not remove cap from collection container. *Specimen Preparation:* Send 1.0 mL whole blood in original tube. Do not open. ***Minimum Volume:* 2.0 mL** *Transport Temperature:* Refrigerated
Stability	Whole Blood: Room temperature: 48 hours Refrigerated: 7 days **Frozen: Unacceptable** Plasma, Urine, Serum: Room temperature: 48 hours Refrigerated: 7 days **Frozen: 30 days**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Inactivate Test With Replacement			
Effective Date	5/20/2024		
Inactivated Test			
Name	Trypanosoma cruzi (Chagas' Disease) Ab, IgG		
Code	CHAG		
Legacy Code	CHAG		
Interface Order Code	3500730		
Replacement Test			
Name	Trypanosoma cruzi Ab, Total w/ Ref to Confirmation		
Code	TRCAB		
CPT Code(s)	86753		
Specimen Requirements			
Specimen Required	*Collect:* Serum separator tube (SST) *Specimen Preparation:* Centrifuge, separate serum from cells and send 0.5 mL serum in a screw capped plastic vial. *Minimum Volume:* 0.2 mL *Transport Temperature:* Room temperature		
Rejection Criteria	Grossly hemolyzed, grossly icteric, grossly lipemic, bacterially contaminated specimens.		
Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days		
Performing Information			
Methodology	Immunoassay (IA)		
Reference Range	See report		
Performed Days	Sunday, Thursday		
Turnaround Time	3 - 7 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code	TRCAB		
Interface Order Code	3400918		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt**
3400919	T. cruzi Ab, Total	57320-4	No
3400921	T. cruzi Ab, Confirmation		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: 04/16/2024 14:52 Received: 04/16/2024 14:52

Test Name	Result	Flag	Ref-Ranges	Units	Site
Trypanosoma cruzi Ab, Total w/ Ref to Conf					
T. cruzi Ab, Total	**REACTIVE**	**AB**			QCRL

REFERENCE RANGE: NONREACTIVE

The enzyme immunoassay for T. cruzi (Chagas disease) total antibodies is sensitive and specific for acute or chronic American trypanosomiasis. However, cross-reactivity may be observed in patients with leishmaniasis. Specimens with an indeterminate or reactive total antibody result are tested using a confirmatory T. cruzi IgG lateral flow assay that uses different antigens as per CDC recommendations. A positive confirmatory assay result supports the diagnosis of Chagas disease, whereas a negative confirmatory assay result suggests the total antibody result was falsely indeterminate/reactive.

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway

T. cruzi Ab, Confirmation	**POSITIVE**	**AB**	QCRL

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway

Reported Date: 04/16/2024 14:53 TRCAB

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

G016000013
WX0000003827
Printed D&T: 04/16/24 14:53

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002365

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

Inactivate Test With Replacement

Effective Date	5/28/2024

Inactivated Test

Name	Estrone
Code	E1Q
Legacy Code	E1Q
Interface Order Code	3400039

Replacement Test

Name	Estrone, LC/MS/MS
Code	EONE
CPT Code(s)	82679

Specimen Requirements

Specimen Required	*Collect:* Red top *Specimen Preparation:* Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial. *Minimum Volume:* 0.5 mL *Transport Temperature:* Refrigerated
Rejection Criteria	Serum separator tube (SST), gross hemolysis, gross lipemia, plasma
Stability	Room temperature: 8 hours Refrigerated: 7 days Frozen: 30 days

Performing Information

Methodology	Liquid Chromatography/Tandem Mass Spectrometry
Reference Range	Estrone pg/mL Early Follicular <150 Late Follicuular 100-250 Luteal <200 Post-menopausal 3-32 ESTRONE (EONE) MALE FEMALE 7-9 years <7 <20 10-12 year <11 1-40 13-15 years 1-30 8-105 16-17 years 1-32 4-133 18+ 9-36 message ages for <18 yrs. MALE pg/mL FEMALE pg/mL Tanner Stage I <7 <27 Tanner Stage II <11 1-39 Tanner Stage III 1-31 8-117 Tanner Stage IV-V 2-30 4-109
Performed Days	Monday, Thursday
Turnaround Time	2 - 6 days
Performing Laboratory	Warde Medical Laboratory

Interface Information

Legacy Code	EONE		
Interface Order Code	3000892		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt**
3000892	Estrone, LC/MS/MS		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

Immunochemistry

Collected: 04/11/2024 08:14 Received: 04/11/2024 08:14

Test Name	Result	Flag	Ref-Ranges	Units	Site
Estrone, LC/MS/MS	50			pg/mL	WMRL

Early Follicular	<150
Late Follicular	100-250
Luteal	<200
Post-menopausal	3-32

This test was developed and its performance characteristics determined by Warde Medical Laboratory in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration. This test is used for patient testing purposes. It should not be regarded as investigational or for research.

Reported Date: 04/11/2024 08:14 EONE

Performing Site:
WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108

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

G011000000
WX0000003826
Printed D&T: 04/11/24 08:15

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002353

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

Inactivate Test With Replacement			
Effective Date	5/20/2024		
Inactivated Test			
Name	IDH1 and IDH2 Mutation Analysis FFPE Tissue		
Code	IDHMF		
Legacy Code[1]	IDHMF		
Interface Order Code	3600097		
Replacement Test			
Name	IDH1 and IDH2 Mutation Detection		
Code	IDHMD		
CPT Code(s)	81120, 81121		
Specimen Requirements			
Specimen Required	*Collect:* Tumor tissue *Specimen Preparation:* Send formalin-fixed, paraffin embedded tissue. Send tissue block or 8 unstained 5-micron slides. Protect form excessive heat. Tissue block will be returned after testing. Please include pathology report. *Minimum Volume:* 5 slides *Transport Temperature:* Room temperature		
Rejection Criteria	Fixative other than 10 percent neutral buffered formalin, decalcified specimens (except in EDTA), less than 20 percent tumor		
Stability	Tissue Block: Room Temperature: Indefinitely Refrigerated: Indefinitely Frozen: Unacceptable		
Performing Information			
Methodology	Massively Parallel Sequencing		
Reference Range	See report		
Performed Days	Varies		
Turnaround Time	12-17 days		
Performing Laboratory	ARUP Reference Laboratory		
Interface Information			
Legacy Code	IDHMD		
Interface Order Code	3600387		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt**
3600388	IDH1-IDH2 Int	35474-6	No
3600389	Block ID	57723-9	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: 04/16/2024 13:53 Received: 04/16/2024 13:53

Test Name	Result	Flag	Ref-Ranges	Units	Site

IDH1 and IDH2 Mutation Detection

IDH1-IDH2 Int	Detected				ARRL

IDH1 and IDH2 Mutation Detection

A mutation in IDH1 was detected: c.395G>A, p.Arg132His (NM_005896.3).

This result has been reviewed and approved by Rakhi Jattani, Sequencing Analyst.
BACKGROUND INFORMATION: IDH1 and IDH2 Mutation Detection

CHARACTERISTICS: This assay is an amplicon enrichment-based massively parallel sequencing assay targeting hotspot variants in genes critical for the diagnostic, prognostic, and therapeutic assessment of various solid tumors. The amplicon primer pool is designed to interrogate variants within a limited set of highly clinically relevant gene loci for the identification of actionable somatic variants in FFPE tissue from solid tumors.

GENES TESTED: IDH1 (NM_005896) exon 4 and IDH2 (NM_002168) exon 4 are evaluated to detect hotspot variants. Targeted regions include chr2:209113083-209113124, chr15:90631809-90631869, and chr15:90631901-90631989.

METHODOLOGY: Genomic DNA was isolated from a microscopically-guided dissection of FFPE tumor tissue and then enriched for the targeted regions of the tested genes. The variant status of the targeted genes was determined by massively parallel sequencing. The hg19 (GRCh37) reference sequence was used as a reference for identifying genetic variants. Clinically significant single nucleotide variants and variants of uncertain significance within the preferred transcripts are reported. Other types of variants may be reported with a disclaimer, if detected.

LIMITATIONS: This test will not detect variants in areas outside the targeted genomic regions or below the limit of detection. More information about the targeted regions of this test is included in the Additional Technical Information available in the Laboratory Test Directory. Copy number alterations (losses or amplifications), translocations, microsatellite instability, tumor mutational burden, deep intronic variants, and insertions/deletions will not be detected. Since this is a

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 04/16/2024 13:53 Received: 04/16/2024 13:53

Test Name	Result	Flag	Ref-Ranges	Units	Site

DNA-based assay, RNA variants will not be detected. This test evaluates for variants in tumor tissue only and cannot distinguish between somatic and germline variants. Therefore, if a hereditary/familial cancer is of clinical concern, additional clinical evaluation and genetic counseling should be considered prior to additional testing. In some cases, variants may not be identified due to technical limitations related to the presence of known pseudogenes, GC-rich regions, repetitive or homologous regions, low mappability regions, and/or variants located in regions overlapping amplicon primers. Tissue samples yielding between 1ng and 5ng total DNA input may yield suboptimal results and will be accepted for testing with a client-approved disclaimer. Benign or likely benign variants in the preferred transcript are not reported. Variant allele frequency (VAF) is not reported. Additional evaluation should be considered for complete genetic analysis, including detection of variants outside of the hotspot regions of IDH1 or IDH2, variants within other genes, gene methylation, translocations, or gene rearrangements, if clinically indicated.

LIMIT OF DETECTION (LOD): The LOD for this assay is 10 percent VAF. For variants near the assay LOD, positive percent agreement (PPA) was found to be greater than 90 percent.

ANALYTICAL ACCURACY/SENSITIVITY (PPA): The PPA estimate for the relevant variant class (with 95 percent credibility region) is listed below. Genes included on this test are a subset of a larger methods-based validation from which the PPA values are derived.
Single nucleotide variants (SNVs): 98.4 percent (95.1-99.7 percent)

CLINICAL DISCLAIMER: Results of this test must always be interpreted within the context of clinical findings and other relevant data and should not be used alone for a diagnosis of malignancy, determination of prognosis, or recommendation of therapy. This test is not intended to detect minimal residual disease.

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.

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: 04/16/2024 13:53 Received: 04/16/2024 13:53

Test Name	Result	Flag	Ref-Ranges	Units	Site
Block ID	TEST12345				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: 04/16/2024 13:54 IDHMD

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

G016000010
WX0000003827
Printed D&T: 04/16/24 13:54

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002354

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

Inactivate Test With Replacement			
Effective Date	5/14/2024		
Inactivated Test			
Name	Collagen Cross Linked N Telopeptide (NTX), 24H U w/Creat		
Code	NTELO		
Legacy Code	NTELO		
Interface Order Code	3700491		
Replacement Test			
Name	Collagen Cross Linked N Telopeptide (NTx), 24H U		
Code	NTELU		
CPT Code(s)	82523, 82570		
Specimen Requirements			
Specimen Required	*Collect:* 24 hour urine *Specimen Preparation:* Discard first morning urine void. Collect urine voids for the next 24 hour period. The last sample collection should be the first morning specimen voided the following morning at the same time as the previous mornings first voiding. Mix well and send 2.0 mL urine frozen in a screw capped plastic urine container. Record total volume on test requisition and specimen label. *Minimum Volume:* 1.0 mL *Transport Temperature:* Frozen		
Stability	Room temperature: 72 hours Refrigerated: 5 days Frozen: 30 days		
Performing Information			
Methodology	Chemiluminescence		
Reference Range	See report		
Performed Days	Tuesday, Thursday, Saturday		
Turnaround Time	4 - 7 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code	NTELU		
Interface Order Code	3400922		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt**
3400923	Total Volume	3167-4	Yes
3400924	N-Telopeptide (NTx), 24h U	21216-7	No
3400926	Creatinine, 24-Hour Urine	2162-6	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: 04/11/2024 08:15 Received: 04/11/2024 08:15

Test Name	Result	Flag	Ref-Ranges	Units	Site
Collagen Cross Linked N Telopeptide (NTx), 24H U					
Total Volume	1800				QCRL
N-Telopeptide (NTx), 24h U	45		5-88		QCRL
UNITS OF MEASURE: nM BCE/mM creat					
Creatinine, 24-Hour Urine	1.30		0.50-2.15	g/24 h	QCRL

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway

Reported Date: 04/11/2024 08:17 NTELU

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

G011000001
WX0000003827
Printed D&T: 04/11/24 08:18

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002365

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

MAY 2024

Inactivate Test Without Replacement	
Effective Date	5/20/2024
Name	IDH1 and IDH2 Mutation Analysis, exon 4
Code	IDHMA
Legacy Code	IDHMA
Interface Code	3600099