Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Update Summary		
New Test Activation	8/6/2024	AFPL3 - "Alpha-Fetoprotein (AFP) and AFP-L3"
New Test Activation	8/6/2024	DCP - "Des-gamma-carboxy Prothrombin"
New Test Activation	8/6/2024	UALAR - "Aminolevulinic Acid (ALA), Random Urine"
New Test Activation	8/6/2024	UMERR - "Mercury, Random Urine"
New Test Activation	8/6/2024	UPBR - "Lead, Random Urine"
Update Existing Test	8/6/2024	AHA - "Histone Antibody, IgG"
Update Existing Test	8/6/2024	ALDR - "Aldosterone/Direct Renin Ratio"
Update Existing Test	8/6/2024	AMIOD - "Amiodarone (Cordarone)"
Update Existing Test	8/6/2024	APCAB - "Gastric Parietal Cell Antibody"
Update Existing Test	9/9/2024	BRIVA - "Brivaracetam, Serum/Plasma"
Update Existing Test	8/6/2024	CD48 - "CD4/CD8"
Update Existing Test	8/12/2024	CYIEL - "Cyclospora and Isospora Examination"
Update Existing Test	8/6/2024	DISAC - "Disaccharidases"
Update Existing Test	8/12/2024	FELES - "Fecal Leukocyte Stain"
Update Existing Test	8/6/2024	G6PD - "G6PD"
Update Existing Test	8/19/2024	HMGCR - "HMGCR Antibody IgG"
Update Existing Test	8/19/2024	HSPNE - "Hypersensitivity Pneumonitis Extended"
Update Existing Test	8/6/2024	INHNA - "INHIBIN-A"
Update Existing Test	7/29/2024	KIDST - "Kidney Stone Diagnostic Prof"
Update Existing Test	8/12/2024	MOTRQ - "Motor Neuropathy Compl Ab Pnl"
Update Existing Test	8/6/2024	NORTI - "Nortriptyline"
Update Existing Test	8/12/2024	OPCPS - "Ova and Parasites, Conc. And Perm Smear"
Update Existing Test	8/6/2024	PN14S - "Pneumococcal Antibody Panel (14 Serotype)"
Update Existing Test	8/6/2024	TBNK - "Immunodeficiency Screening"
Update Existing Test	9/9/2024	TIGAB - "Tiagabine (Gabatril), Serum/Plasma"
Update Existing Test	8/6/2024	UALAA - "Aminolevulinic Acid (ALA) Urine"
Update Existing Test	8/6/2024	UCATE - "Catecholamines, Fractionated, Urine - 24 hour"
Update Existing Test	8/6/2024	UCATR - "Catecholamines, Urine, Random"
Update Existing Test	8/6/2024	UCI24 - " Citrate, Urine, 24hr"
Update Existing Test	8/6/2024	UCITR - "Citrate, Urine, Random"
Update Existing Test	8/6/2024	UMERA - "Mercury Urine"
Update Existing Test	8/6/2024	UMET - "Metanephrines, Fractionated, Urine, 24 hour"
Update Existing Test	8/6/2024	UMETR - "Metanephrines,Urine Random"
Update Existing Test	8/6/2024	UMYO - "Myoglobin, Urine"
Update Existing Test	8/6/2024	UPBA - "Lead, Urine"
Inactivate Test With Replacement	8/19/2024	5FL - "5-Fluorocytosine" replaced by FLUC - "5-Flucytosine, Serum"

Inactivate Test With Replacement	8/19/2024	DPYD3 - "Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants" replaced by DPYDV - "Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants"
Inactivate Test With Replacement	8/27/2024	FOBIA - "Occult Blood, Fecal by Immunoassay" replaced by OBFIT - "Fecal Immunochemical Test for Occult Blood"
Inactivate Test With Replacement	8/27/2024	HCVGG - "HCV Genotyping Panel" replaced by HCVRG - "HCV RNA, QN, Real Time PCR Reflex to Genotype LiPA"
Inactivate Test With Replacement	8/27/2024	HCVGO - "HCV Genotype" replaced by HCVGT - "Hepatitis C Viral RNA, Genotype, LiPA"
Inactivate Test With Replacement	8/19/2024	UGT1G - "UGT1A1 Genotyping" replaced by UGT1A - "UGT1A1 Genotyping"
Inactivate Test With Replacement	8/6/2024	VIP - "Vasoactive Intestinal Polypeptide (VIP), Plasma" replaced by VIPP - "Vasoactive Intestinal Polypeptide (VIP)"
Inactivate Test Without Replacement	8/19/2024	BACTL - "Bactericidal Levels"
Inactivate Test Without Replacement	8/27/2024	RF324 - "Hops IgE"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

New Test Activation

Effective Date	8/6/2024
Name	Alpha-Fetoprotein (AFP) and AFP-L3
Code	AFPL3
CPT Code(s)	82107
Notes	New York DOH Approval Status: Yes

Specimen Requirements

Specimen Required	*Collect:* Red top *Specimen Preparation:* Centrifuge, separate and send 1.5 mL serum in a screw capped plastic vial. *Minimum Volume:* 0.5 mL *Transport Temperature:* Refrigerated
Alternate Specimen	Serum separator tube (SST)
Rejection Criteria	Hemolysis, lipemia
Stability	Room Temperature: 72 hours Refrigerated: 5 days Frozen: 2 years

Performing Information

Methodology	Liquid-Phase Binding Assay System
Reference Range	AFP 1.6-4.5 ng/mL AFP-L3 0.5-9.9 %
Performed Days	Tuesday, Friday
Turnaround Time	3 - 5 days
Performing Laboratory	Quest SJC

Interface Information

Legacy Code	AFPL3
Interface Order Code	3400962

Result Code	Name	LOINC Code	AOE/Prompt
3400963	AFP	1834-1	No
3400964	AFP-L3	42332-7	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: 07/16/2024 12:01 Received: 07/16/2024 12:01

Test Name	Result	Flag	Ref-Ranges	Units	Site
Alpha-Fetoprotein (AFP) and AFP-L3					
AFP	3.4		1.6-4.5	ng/mL	QCRL
AFP-L3	4.5		0.5-9.9	%	QCRL

The micro-total analysis system (uTASWako) employs microchip capillary electrophoresis to quantitatively measure AFP and AFP-L3% by immunochemical techniques. The assay principle involves DNA-coupled antibodies and dye labeled antibodies, which react with proteins in liquid phase within the microchannels. Both analytes are quantified using laser-induced fluorescence. Instrument and associated reagents are supplied by Wako Diagnostics Richmond, VA, USA.

Patients with elevated AFP-L3% values (>=10%) have been shown to have an increased risk of developing hepatocellular carcinoma (HCC). In a selected group of patients, the risk of developing HCC was 48.8% with an elevated AFP-L3% and was 7.0% with a negative AFP-L3% result.

Limitations of Procedure:

1. The AFP-L3% value is not calculated when the AFP-L3 concentration is below 0.3 ng/mL. In such cases the AFP-L3% result field will indicate 'NO VALUE DETERMINED' 2. Heterophilic antibodies in human serum can react with the immunoglobulins included in the assay components causing interference with in vitro immunoassays. Samples from patients routinely exposed to animals or animal serum products can demonstrate this type of interference and can potentially cause an anomalous result. The Wako uTAS System has been formulated to minimize the risk of the interference; however, potential interactions between rare sera and ingredients can occur. 3. For diagnostic purposes, the results obtained from this assay should always be used and interpreted in conjunction with clinical examination, patient medical history, and other findings. 4. Pregnancy can cause high values of AFP-L3% and AFP is not interpretable in pregnant females. 5. AFP producing tumors other than HCC can show high values of AFP-L3% and AFP. 6. Samples from patients having acute hepatitis and fulminant hepatitis can show high values of AFP-L3% and AFP. 7. It is recommended that this assay be used in conjunction with imaging studies for clinical diagnosis. 8. Liver diseases caused by other etiologies such as alcoholic liver disease, hemachromatosis, Wilson's disease, autoimmune hepatitis and steatohepatisis have not been studied with the assay. 9. The assay is linear for AFP concentration of 0.3 to 1000 ng/mL. 10. Values obtained with different assay methods or kits cannot be used interchangeably.
Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 07/16/2024 12:01 Received: 07/16/2024 12:01

Test Name	Result	Flag	Ref-Ranges	Units	Site

Reported Date: 07/16/2024 12:01 AFPL3

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

G316000286
WX0000003826
Printed D&T: 07/16/24 12:02

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002353

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

New Test Activation

Effective Date	8/6/2024
Name	Des-gamma-carboxy Prothrombin
Code	DCP
CPT Code(s)	83951
Notes	New York DOH Approval Status: Yes

Specimen Requirements

Specimen Required	*Collect:* Serum separator tube (SST) *Specimen Preparation:* Allow specimen to clot completely at room temperature. Separate serum from cells within 2 hours of collection and send 1.0 mL serum in a screw capped plastic vial. *Minimum Volume:* 0.5 mL *Transport Temperature:* Refrigerated
Alternate Specimen	Serum: Red top
Rejection Criteria	Plasma
Stability	Room Temperature: 8 hours Refrigerated: 7 days Frozen: 21 days (avoid repeated freeze/thaw cycles)

Performing Information

Methodology	Quantitative Liquid Chromatography/Immunoassay
Reference Range	0.0 - 7.4 ng/mL
Performed Days	Monday, Thursday
Turnaround Time	3 – 7 days
Performing Laboratory	ARUP Reference Laboratory

Interface Information

Legacy Code	DCP
Interface Order Code	3600406

Result Code	Name	LOINC Code	AOE/Prompt
3600406	Des-gamma-carboxy Prothrombin	34444-0	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 46 Y

Referral Testing

Collected: 07/16/2024 14:30 Received: 07/16/2024 14:30

Test Name	Result	Flag	Ref-Ranges	Units	Site
Des-gamma-carboxy Prothrombin	6.3		0.0-7.4	ng/mL	ARRL

INTERPRETIVE INFORMATION: Des-gamma-carboxy Prothrombin

The uTASWako method is used. Results obtained with different assay methods or kits cannot be used interchangeably. The des-gamma-carboxy prothrombin (DCP) assay is intended as a risk assessment for the development of hepatocellular carcinoma in patients with chronic liver diseases. Elevated DCP values have been shown to be associated with an increased risk for developing hepatocellular carcinoma. Patients with elevated serum DCP should be more intensely evaluated for evidence of hepatocellular carcinoma. Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.

Medication containing vitamin K preparations may cause a negative bias of the DCP values.
Medication containing vitamin K antagonist or antibiotic may cause a positive bias of the DCP values.
Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Jonathan R. Genzen, MD, PhD
CLIA Number: 46D0523979

Reported Date: 07/16/2024 14:30 DCP

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

G316000287
WX0000003827
Printed D&T: 07/16/24 14:31

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002365

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

New Test Activation

Effective Date	8/6/2024
Name	Aminolevulinic Acid (ALA), Random Urine
Code	UALAR
CPT Code(s)	82135
Notes	New York DOH Approval Status: Yes

Specimen Requirements

Specimen Required	*Patient Preparation:* Refrain from alcohol consumption 24 hours prior to collection. *Collect:* Random urine *Specimen Preparation:* Send 4.0 mL urine aliquot in a screw capped plastic vial. *Minimum Volume:* 1.2 mL *Transport Temperature:* Refrigerated
Rejection Criteria	Body fluids other than urine.
Stability	Room Temperature: Unacceptable Refrigerated: 4 days Frozen: 30 days

Performing Information

Methodology	Quantitative Ion Exchange Chromatography/Spectrophotometry
Reference Range	Aminolevulinic Acid - per volume 0-35 µmol/L ALA, Random Urine - ratio to CRT See report
Performed Days	Monday, Wednesday, Friday
Turnaround Time	3 - 6 days
Performing Laboratory	ARUP Reference Laboratory

Interface Information

Legacy Code	UALAR
Interface Order Code	3600401

Result Code	Name	LOINC Code	AOE/Prompt
3600402	Creatinine, Urine - per volume	2161-8	No
3600403	Aminolevulinic Acid - per volume	34284-0	No
3600404	ALA, Random Urine ratio to CRT	39782-8	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: 06/24/2024 14:08 Received: 06/24/2024 14:08

Test Name	Result	Flag	Ref-Ranges	Units	Site
Aminolevulinic Acid (ALA), Random Urine					
Creatinine, Urine - per volume	112			mg/dL	ARRL
Aminolevulinic Acid - per volume	34		0-35	umol/L	ARRL
ALA, Random Urine ratio to CRT	<5.0			mg/gCR	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: 06/24/2024 14:08 UALAR

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

G224000002
WX0000003826
Printed D&T: 06/24/24 14:08

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002353

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

New Test Activation

Effective Date	8/6/2024
Name	Mercury, Random Urine
Code	UMERR
CPT Code(s)	83825
Notes	New York DOH Approval Status: Yes

Specimen Requirements

Specimen Required	*Patient Preparation:* Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician), and avoid shellfish and seafood for 48 to 72 hours. High concentrations of iodine may interfere with elemental testing. Collection of urine specimens from patients receiving iodinated or gadolinium-based contrast media should be avoided for a minimum of 72 hours post-exposure. Collection from patients with impaired kidney function should be avoided for a minimum of 14 days post-contrast media exposure. *Collect:* Random urine *Specimen Preparation:* Mix well and send 8.0 mL urine in a blue-capped ARUP metal-free screw capped plastic vial. Please contact laboratory for metal-free screw capped plastic vials. Specimens in other containers will be rejected. *Minimum Volume:* 1.0 mL *Transport Temperature:* Refrigerated
Rejection Criteria	Urine collected within 72 hours after administration of iodinated or gadolinium-based contrast media. Acid preserved urine. Specimens contaminated with blood or fecal material. Specimens transported in non-trace element free transport tube.
Stability	Room Temperature: 7 days Refrigerated: 14 days Frozen: 1 year

Performing Information

Methodology	Quantitative Inductively Coupled Plasma-Mass Spectrometry
Reference Range	Mercury, Urine - per volume 0.0-5.0 µg/L Mercury, Urine - ratio to CRT 0.0-20.0 µg/gCRT
Performed Days	Sunday - Saturday
Turnaround Time	3 - 7 days
Performing Laboratory	ARUP Reference Laboratory

Interface Information

Legacy Code	UMERR
Interface Order Code	3600396

Result Code	Name	LOINC Code	AOE/Prompt
3600397	Creatinine, Urine - per volume	2161-8	No
3600398	Mercury, Urine - per volume	5689-5	No
3600399	Mercury, Urine - ratio to CRT	13465-0	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 06/24/2024 14:14 Received: 06/24/2024 14:14

Test Name	Result	Flag	Ref-Ranges	Units	Site
Mercury, Random Urine					
Creatinine, Urine - per volume	75			mg/dL	ARRL
Mercury, Urine - per volume	<2.5		0.0-5.0	ug/L	ARRL

INTERPRETIVE INFORMATION: Mercury, Urine

Urinary mercury levels predominantly reflect acute or chronic elemental or inorganic mercury exposure. Urine concentrations in unexposed individuals are typically less than 10 ug/L. 24 hour urine concentrations of 30 to 100 ug/L may be associated with subclinical neuropsychiatric symptoms and tremors. Concentrations greater than 100 ug/L can be associated with overt neuropsychiatric disturbances and tremors. Urine mercury levels may be useful in monitoring chelation therapy.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Mercury, Urine - ratio to CRT	Not Applicable		0.0-20.0	ug/g CRT	ARRL

Unable to accurately calculate the creatinine normalized result due to a low per volume result.
Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Jonathan R. Genzen, MD, PhD
CLIA Number: 46D0523979

Reported Date: 06/24/2024 14:14 UMERR

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

G224000003
WX0000003826
Printed D&T: 06/24/24 14:15

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002353

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

New Test Activation

Effective Date	8/6/2024
Name	Lead, Random Urine
Code	UPBR
CPT Code(s)	83655
Notes	New York DOH Approval Status: Yes

Specimen Requirements

Specimen Required	*Patient Preparation:* Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). High concentrations of iodine may interfere with elemental testing. Collection of urine specimens from patients receiving iodinated or gadolinium-based contrast media should be avoided for a minimum of 72 hours post-exposure. Collection from patients with impaired kidney function should be avoided for a minimum of 14 days post-contrast media exposure. *Collect:* Random urine *Specimen Preparation:* Mix well and send 8.0 mL urine in a blue-capped ARUP metal-free screw capped plastic vial. Please contact laboratory for metal-free screw capped plastic vials. Specimens in other containers will be rejected. *Minimum Volume:* 1.0 mL *Transport Temperature:* Refrigerated
Rejection Criteria	Urine collected within 72 hours after administration of iodinated or gadolinium-based contrast media.
Stability	Room Temperature: 7 days Refrigerated: 14 days Frozen: 1 year

Performing Information

Methodology	Quantitative Inductively Coupled Plasma-Mass Spectrometry
Reference Range	Lead, Urine - per volume 0.0-5.0 µg/L Lead, Urine - ratio to CRT 0.0-5.0 µg/gCRT
Performed Days	Sunday - Saturday
Turnaround Time	3 - 7 days
Performing Laboratory	ARUP Reference Laboratory

Interface Information

Legacy Code	UPBR
Interface Order Code	3600391

Result Code	Name	LOINC Code	AOE/Prompt
3600392	Creatinine, Urine - per volume	2161-8	No
3600393	Lead, Urine - per volume	5676-2	No
3600394	Lead, Urine - ratio to CRT	13466-8	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: 06/24/2024 14:17 Received: 06/24/2024 14:17

Test Name	Result	Flag	Ref-Ranges	Units	Site
Lead, Random Urine					
Creatinine, Urine - per volume	34			mg/dL	ARRL
Lead, Urine - per volume	**27.4**	**H**	0.0-5.0	ug/L	ARRL

INTERPRETIVE INFORMATION: Lead, Urine

Quantification of urine excretion rates before or after chelation therapy has been used as an indicator of lead exposure. Urinary excretion of >125 mg of lead per 24 hours is usually associated with related evidence of lead toxicity.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Lead, Urine - ratio to CRT	**80.6**	**H**	0.0-5.0	ug/g CRT	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: 06/24/2024 14:17 UPBR

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

G224000004
WX0000003826
Printed D&T: 06/24/24 14:17

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002353

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Update Existing Test	
Effective Date	8/6/2024
Name	Histone Antibody, IgG
Code	AHA
Interface Order Code	3671850
Legacy Code	AHA
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	*Collect*: Serum separator tube (SST) *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*: Frozen**

Update Existing Test	
Effective Date	8/6/2024
Name	Aldosterone/Direct Renin Ratio
Code	ALDR
Interface Order Code	1003990
Legacy Code	ALDR
Notes	Update to New York approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: No**

Update Existing Test	
Effective Date	8/6/2024
Name	Amiodarone (Cordarone)
Code	AMIOD
Interface Order Code	1756000
Legacy Code	AMIO
Notes	Update to New York approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: No**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Update Existing Test	
Effective Date	8/6/2024
Name	Gastric Parietal Cell Antibody
Code	APCAB
Interface Order Code	3007760
Legacy Code	APCAB
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	*Collect*: Serum separator tubes (SST) *Specimen Preparation*: Centrifuge, separate serum from cells and send 1.0 mL serum refrigerated in a screw capped plastic vial. *Minimum Volume*: 0.5 mL ***Transport Temperature*: Frozen**

Update Existing Test	
Effective Date	9/9/2024
Name	Brivaracetam, Serum/Plasma
Code	BRIVA
Interface Order Code	3300332
Legacy Code	BRIVA
Notes	Update to specimen requirements and rejection criteria.
Required Testing Changes	
Specimen Required	*Collect:* Red top *Specimen Preparation:* Centrifuge, separate serum from cells **as soon as possible** and send 1.0 mL serum in a screw capped plastic vial. *Minimum Volume:* 0.2 mL *Transport Temperature:* Refrigerated
Rejection Criteria	Serum separator tube (SST), **Polymer gel separator tube (PST)**

Update Existing Test	
Effective Date	8/6/2024
Name	CD4/CD8
Code	CD48
Interface Order Code	3080150
Legacy Code	CD4/CD8
Notes	Update to New York approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: No**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Update Existing Test	
Effective Date	8/12/2024
Name	Cyclospora and Isospora Examination
Code	CYIEL
Interface Order Code	3400672
Legacy Code	CYIEL
Notes	Update to specimen requirements and turnaround time.
Required Testing Changes	
Specimen Required	*Collect:* Stool in Total-Fix® ***Specimen Preparation:*** **Place 10.0 g or 10.0 mL in a Total-Fix® vial within 30 minutes of collection. Fill to the line on the transport vial.** *Minimum Volume:* 5.0 g or 5.0 mL *Transport Temperature:* Room temperature
Turnaround Time	**3 - 5 days**

Update Existing Test	
Effective Date	8/6/2024
Name	Disaccharidases
Code	DISAC
Interface Order Code	3724460
Legacy Code	DISAC
Notes	Update to New York approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: Yes**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Update Existing Test	
Effective Date	8/12/2024
Name	Fecal Leukocyte Stain
Code	FELES
Interface Order Code	3700496
Legacy Code	FELES
Notes	Update to specimen requirements, alternate specimen, and rejection criteria.
Required Testing Changes	
Specimen Required	*Patient Preparation:* Patients should refrain from ingesting barium for 7 days before specimen collection. *Collect:* Stool in Total-Fix® transport vial. *Specimen Preparation:* Place 10.0 g or 10.0 mL stool **or fecal pus** in a Total-Fix® transport vial and send room temperature. Stool must be collected in a clean dry container and must not be contaminated with urine or water. Add stool to bring the liquid to the "fill to here" line and mix contents until homogeneous. *Minimum Volume:* 5.0 g or 5.0 mL *Transport Temperature:* Room temperature
Alternate Specimen	Stool in Zn-PVA **Fecal pus in Zn-PVA**
Rejection Criteria	**Unpreserved stools; stools preserved in transport media other than Total-Fix or Zn-PVA**

Update Existing Test	
Effective Date	8/6/2024
Name	G6PD
Code	G6PD
Interface Order Code	1004700
Legacy Code	G6PDQNT
Notes	Update to New York approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: No**

Update Existing Test	
Effective Date	8/19/2024
Name	HMGCR Antibody IgG
Code	HMGCR
Interface Order Code	3600035
Legacy Code	HMGCR
Notes	Update to specimen requirements and rejection criteria.
Required Testing Changes	
Specimen Required	*Collect:* Serum separator tube (SST) ***Specimen Preparation:*** **Centrifuge, separate serum from cells within 2 hours of collection and send 0.5 mL serum in a screw capped plastic vial.** ***Minimum Volume:*** **0.3 mL** *Transport Temperature:* Refrigerated
Rejection Criteria	**Contaminated, heat-inactivated, clots, fibrin, gross red blood cells, severely lipemic, severely hemolyzed, or severely lipemic specimens.**

Update Existing Test	
Effective Date	8/19/2024
Name	Hypersensitivity Pneumonitis Extended
Code	HSPNE
Interface Order Code	3600089
Legacy Code	HSPNE
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	*Collect:* Serum separator tube (SST) *Specimen Preparation:* Centrifuge, separate serum from cells within 2 hours and send two 2.5 mL aliquots in screw capped plastic vials. ***Minimum Volume:*** **1.6 mL total, 0.8 mL in two aliquots** *Transport Temperature:* Refrigerated

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Update Existing Test	
Effective Date	8/6/2024
Name	INHIBIN-A
Code	INHNA
Interface Order Code	3000893
Legacy Code	INHNA
Notes	Update to specimen requirements 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:* 0.6 mL *Transport Temperature:* Refrigerated **New York Transport Temperature: Frozen**
Stability	Room temperature: 7 days Refrigerated: 7 days Frozen: 60 days **New York Stability:** **Room Temperature: Unacceptable** **Refrigerated: 48 hours** **Frozen: Undetermined**

Update Existing Test	
Effective Date	7/29/2024
Name	Kidney Stone Diagnostic Prof
Code	KIDST
Interface Order Code	3717400
Legacy Code	KIDSTDX
Notes	Update to New York approval and performing laboratory.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: No**
Performing Laboratory	Quest SJC

Update Existing Test	
Effective Date	8/12/2024
Name	Motor Neuropathy Compl Ab Pnl
Code	MOTRQ
Interface Order Code	3425200
Legacy Code	MOTORQ
Notes	Update to rejection criteria.
Required Testing Changes	
Rejection Criteria	**Gross hemolysis; grossly lipemic; grossly icteric, plasma**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Update Existing Test	
Effective Date	8/6/2024
Name	Nortriptyline
Code	NORTI
Interface Order Code	1750325
Legacy Code	NORT
Notes	Update to reference range.
Required Testing Changes	
Reference Range	**Therapeutic range: 10 - 35 ng/mL** Toxic: >500 ng/mL

Update Existing Test	
Effective Date	8/12/2024
Name	Ova and Parasites, Conc. And Perm Smear
Code	OPCPS
Interface Order Code	3400652
Legacy Code	OPCPS
Notes	Update to alternate specimen and rejection criteria.
Required Testing Changes	
Alternate Specimen	**Stool preserved in 10% formalin and polyvinyl alcohol transport vials.** Urine: Send 25.0 mL urine in sterile screw capped container. Note: Urine maybe submitted unpreserved for exam for Schistosoma. Collect at mid-day. Peak egg secretion occurs between noon and 3 pm. DO NOT SUBMIT FIRST MORNING SPECIMEN. In patients with hematuria, eggs may be found in last voided portion of urine specimens. **Sputum or BAL:** Send 10.0 mL sputum **or BAL** in a sterile screw capped container or with 10% formalin. Specimen should be a deep expectorated sputum preferably collected in early morning. 24-hour sputum collection is also acceptable.
Rejection Criteria	Unpreserved stool; specimens containing barium; **stool preserved in medium other than those listed as acceptable; preserved urine, liver abscess or aspirate.**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Update Existing Test

Effective Date	8/6/2024
Name	Pneumococcal Antibody Panel (14 Serotype)
Code	PN14S
Interface Order Code	3300348
Legacy Code	PN14S
Notes	Update to LOINC codes.

Required Testing Changes

Result Code	Name	LOINC Code	AOE/Prompt
3300349	Pneumo Ab Type 1	85955-3	No
3300351	Pneumo Ab Type 3	86081-7	No
3300352	Pneumo Ab Type 4	86108-8	No
3300353	Pneumo Ab Type 5	86129-4	No
3300354	Pneumo Ab Type 8	86148-4	No
3300356	Pneumo Ab Type 9 (9N)	**86166-6**	No
3300357	Pneumo Ab Type 12 (12F)	85974-4	No
3300358	Pneumo Ab Type 14	85992-6	No
3300359	Pneumo Ab Type 19 (19F)	86021-3	No
3300361	Pneumo Ab Type 23 (23F)	86061-9	No
3300362	Pneumo Ab Type 26 (6B)	40905-2	No
3300363	Pneumo Ab Type 51 (7F)	40911-0	No
3300364	Pneumo Ab Type 56 (18C)	40913-6	No
3300366	Pneumo Ab Type 68 (9V)	**40926-8**	No

Update Existing Test

Effective Date	8/6/2024
Name	Immunodeficiency Screening
Code	TBNK
Interface Order Code	3080090
Legacy Code	IPFLOW
Notes	Update to New York approval.

Required Testing Changes

New York Approval	**New York DOH Approval Status: No**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Update Existing Test	
Effective Date	9/9/2024
Name	Tiagabine (Gabatril), Serum/Plasma
Code	TIGAB
Interface Order Code	3510500
Legacy Code	TIAGABINE
Notes	Update to specimen requirements and rejection criteria.
Required Testing Changes	
Specimen Required	*Collect:* Red top *Specimen Preparation:* Centrifuge, separate serum from cells **as soon as possible** and send 1.0 mL serum in a screw capped plastic vial. Draw sample prior to dosing (trough). *Minimum Volume:* 0.4 mL *Transport Temperature:* Refrigerated
Rejection Criteria	**Serum separator tube (SST), Polymer gel separator tube (PST)**

Update Existing Test	
Effective Date	8/6/2024
Name	Aminolevulinic Acid (ALA) Urine
Code	UALAA
Interface Order Code	3684615
Legacy Code	UALAARP
Notes	Update to alternate specimen.
Required Testing Changes	
Alternate Specimen	**No alternate specimen listing.**

Update Existing Test	
Effective Date	8/6/2024
Name	Catecholamines, Fractionated, Urine - 24 hour
Code	UCATE
Interface Order Code	1006955
Legacy Code	UCATE
Notes	Update to New York approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: No**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Update Existing Test	
Effective Date	8/6/2024
Name	Catecholamines, Urine, Random
Code	UCATR
Interface Order Code	1013200
Legacy Code	UCATR
Notes	Update to New York approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: No**

Update Existing Test	
Effective Date	8/6/2024
Name	Citrate, Urine, 24hr
Code	UCI24
Interface Order Code	1005020
Legacy Code	UCIT24
Notes	Update to New York approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: No**

Update Existing Test	
Effective Date	8/6/2024
Name	Citrate, Urine, Random
Code	UCITR
Interface Order Code	1005150
Legacy Code	UCITR
Notes	Update to New York approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: No**

Update Existing Test	
Effective Date	8/6/2024
Name	Mercury Urine
Code	UMERA
Interface Order Code	3671570
Legacy Code	UMERARP
Notes	Update to alternate specimen.
Required Testing Changes	
Alternate Specimen	**No alternate specimen listing.**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Update Existing Test	
Effective Date	8/6/2024
Name	Metanephrines, Fractionated, Urine, 24 hour
Code	UMET
Interface Order Code	1007094
Legacy Code	UMET
Notes	Update to New York approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: No**

Update Existing Test	
Effective Date	8/6/2024
Name	Metanephrines,Urine Random
Code	UMETR
Interface Order Code	1013300
Legacy Code	UMETR
Notes	Update to New York approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: No**

Update Existing Test	
Effective Date	8/6/2024
Name	Myoglobin, Urine
Code	UMYO
Interface Order Code	1005050
Legacy Code	UMYO
Notes	Update to New York approval.
Required Testing Changes	
New York Approval	**New York DOH Approval Status: No**

Update Existing Test	
Effective Date	8/6/2024
Name	Lead, Urine
Code	UPBA
Interface Order Code	3685350
Legacy Code	ULEADAR
Notes	Update to alternate specimen.
Required Testing Changes	
Alternate Specimen	**No alternate specimen listing.**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Inactivate Test With Replacement			
Effective Date	8/19/2024		
Inactivated Test			
Name	5-Fluorocytosine		
Code	5FL		
Legacy Code	5FL		
Interface Order Code	3502845		
Replacement Test			
Name	5-Flucytosine, Serum		
Code	FLUC		
CPT Code(s)	80299		
Notes	New York DOH Approval Status: Yes		
Specimen Requirements			
Specimen Required	*Patient Preparation:* Serum for a peak level should be collected 1 to 2 hours after oral dose or 30 minutes after intravenous infusion. Trough specimens should be collected immediately prior to next scheduled dose. *Collect:* Red top *Specimen Preparation:* Centrifuge, separate cells from serum within 2 hours of collection and send 0.5 mL serum refrigerated in a screw capped plastic vial. *Minimum Volume:* 0.3 mL *Transport Temperature:* Refrigerated		
Alternate Specimen	Serum separator tube (SST)		
Rejection Criteria	Plasma, whole blood, urine		
Stability	Room Temperature: 28 days Refrigerated: 28 days Frozen: 28 days		
Performing Information			
Methodology	Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)		
Reference Range	Therapeutic concentration: Peak >25.0 mcg/mL (difficult infections may require higher concentrations) Toxic concentration: Peak >100.0 mcg/mL		
Performed Days	Tuesday, Thursday		
Turnaround Time	5 - 10 days		
Performing Laboratory	Mayo Clinic Laboratories		
Interface Information			
Legacy Code	FLUC		
Interface Order Code	3800384		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt**
3800384	5-Flucytosine, Serum	3639-2	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 46 Y

Referral Testing

Collected: 07/16/2024 14:37 Received: 07/16/2024 14:37

Test Name	Result	Flag	Ref-Ranges	Units	Site
5-Flucytosine, Serum	50.0			mcg/mL	MMRL

```
-------------------REFERENCE VALUE--------------------------
>25.0 (Peak), >100.0 (Toxic)

------------------ADDITIONAL INFORMATION-------------------
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.

Test Performed by:
Mayo Clinic Laboratories - Rochester Superior Drive
3050 Superior Drive NW, Rochester, MN 55905
Lab Director: Nikola A. Baumann Ph.D.; CLIA# 24D1040592
```

Reported Date: 07/16/2024 14:37 FLUC

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

G316000289
WX0000003827
Printed D&T: 07/16/24 14:37

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002516

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Inactivate Test With Replacement			
Effective Date	8/19/2024		
Inactivated Test			
Name	Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants		
Code	DPYD3		
Legacy Code	DPYD3		
Interface Order Code	3600323		
Replacement Test			
Name	Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants		
Code	DPYDV		
CPT Code(s)	81232		
Specimen Requirements			
Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Send 3.0 mL whole blood. *Minimum Volume:* 1.0 mL *Transport Temperature:* Refrigerated		
Alternate Specimen	Whole blood: Yellow ACD A or B		
Rejection Criteria	Plasma or serum, heparinized specimens. Frozen specimens in glass collection tubes.		
Stability	Room temperature: 72 hours Refrigerated: 7 days Frozen: 30 days		
Performing Information			
Methodology	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring		
Reference Range	See report		
Performed Days	Varies		
Turnaround Time	7 - 12 days		
Performing Laboratory	ARUP Reference Laboratory		
Interface Information			
Legacy Code	DPYDV		
Interface Order Code	3600414		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt**
3600416	DPYD Specimen	31208-2	No
3600417	DPYD Genotype	45284-7	No
3600418	DPYD Phenotype	104284-5	No
3600419	DPYD Interpretation	79719-1	No
3600421	EER Dihydropyrimidine Dehydrogenase	11526-1	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 46 Y

Referral Testing

Collected: 07/16/2024 14:35 Received: 07/16/2024 14:35

Test Name	Result	Flag	Ref-Ranges	Units	Site
Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants					
DPYD Specimen	Whole Blood				ARRL
DPYD Genotype	*1/*1				ARRL
DPYD Phenotype	Normal				ARRL
DPYD Interpretation	See Note				ARRL

This result has been reviewed and approved by Philip Bernard, M.D.
BACKGROUND INFORMATION: Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants
CHARACTERISTICS: 5-Fluorouracil (5-FU) is the most frequently used chemotherapeutic drug for the treatment of many types of cancer, particularly colorectal adenocarcinoma. Grade III-IV drug toxicity attributed to 5-FU occurs in approximately 16 percent of patients, and may include hematologic, gastrointestinal, and dermatologic complications. In some cases, this toxicity can cause death. When 5-FU is metabolized in the body, approximately 80 percent is catabolized by the dihydropyrimidine dehydrogenase (DPD) enzyme. Variants in the DPYD gene can lead to reduced 5-FU catabolism, resulting in the aforementioned toxicity complications.
INHERITANCE: Autosomal codominant.
CAUSE: DPYD gene mutations.
DPYD Variants Tested:
Non-functional alleles and toxicity risk:
*13 (rs55886062, c.1679T>G) - Increased risk
*2A (rs3918290, c.1905+1G>A) - Increased risk
Decreased function allele and toxicity risk:
c.2846A>T (rs67376798) - Increased risk
A result of *1 indicates no variants detected and is predictive of functional alleles and normal enzymatic activity.
CLINICAL SENSITIVITY: Estimated at 31 percent for the DPYD variants analyzed.
METHODOLOGY: Polymerase chain reaction (PCR) and fluorescence monitoring.
ANALYTICAL SENSITIVITY and SPECIFICITY: 99 percent.
LIMITATIONS: Only the targeted DPYD variants will be detected by this panel. Diagnostic errors can occur due to rare sequence variations. 5-FU drug metabolism, efficacy and risk for toxicity may be affected by genetic and non-genetic factors that are not evaluated by this test. Genotyping does not replace the need for therapeutic drug monitoring or clinical observation.

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 46 Y

Referral Testing

Collected: 07/16/2024 14:35 Received: 07/16/2024 14:35

Test Name	Result	Flag	Ref-Ranges	Units	Site

Please note the information contained in this report does not contain medication recommendations, and should not be interpreted as recommending any specific medications. Any dosage adjustments or other changes to medications should be evaluated in consultation with a medical provider.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

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

EER Dihydropyrimidine Dehydrogenase	See Note				ARRL

Authorized individuals can access the ARUP Enhanced Report using the following link:

https://c11-erpt.aruplab.com/?t=062406aA32Z6Hc232
Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Jonathan R. Genzen, MD, PhD
CLIA Number: 46D0523979

Reported Date: 07/16/2024 14:35 DPYDV

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Inactivate Test With Replacement			
Effective Date	8/27/2024		
Inactivated Test			
Name	Occult Blood, Fecal by Immunoassay		
Code	FOBIA		
Legacy Code	FOBIA		
Interface Order Code	3681320		
Replacement Test			
Name	Fecal Immunochemical Test for Occult Blood		
Code	OBFIT		
CPT Code(s)	82274		
Notes	New York DOH Approval Status: Yes		
Specimen Requirements			
Specimen Required	*Collect*: Stool in OC-Auto Sampling Bottle *Specimen Preparation*: Send stool collected in an OC-Auto Sampling Bottle. Dip sampling bottle transfer wand into stool collection and place back into the OC-Auto sampling bottle. Stool must be transferred to sampling bottle within 4 hours of collection. *Transport Temperature*: Refrigerated		
Rejection Criteria	Unpreserved stool		
Stability	Room Temperature: 15 days Refrigerated: 30 days Frozen: Unacceptable		
Performing Information			
Methodology	Qualitative Immunoassay		
Reference Range	Not Detected		
Performed Days	Monday - Friday		
Turnaround Time	2 - 3 days		
Performing Laboratory	Warde Medical Laboratory		
Interface Information			
Legacy Code	OBFIT		
Interface Order Code	3000894		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt**
3000896	Fecal Occult Blood	29771-3	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Molecular

Collected: 07/18/2024 07:47 Received: 07/18/2024 07:47

Test Name	Result	Flag	Ref-Ranges	Units	Site
Fecal Immunochemical Test for Occult Blood					
Fecal Occult Blood	**DETECTED**	**AB**			WMRL

No single cutoff provides superior colorectal cancer detection rates. The test manufacturer recommends the use of a 100 ng/mL cutoff that produces a specificity of approximately 95 percent for the detection of lower gastrointestinal bleeding. This test does not detect upper gastrointestinal bleeding.

Reported Date: 07/18/2024 07:47 OBFIT

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

G318000000
WX0000003826
Printed D&T: 07/18/24 07:47

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002353

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Inactivate Test With Replacement	
Effective Date	8/27/2024
Inactivated Test	
Name	HCV Genotyping Panel
Code	HCVGG
Legacy Code	HCVGP
Interface Order Code	3016130
Replacement Test	
Name	HCV RNA, QN, Real Time PCR Reflex to Genotype LiPA
Code	HCVRG
CPT Code(s)	87522, plus 87902 if reflexed to Genotype, at an additional charge.
Notes	New York DOH Approval Status: Yes
Specimen Requirements	
Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Centrifuge and separate plasma from cells within 24 hours of collection by centrifugation at 800-1600 X G for 20 minutes at room temperature. Send 3.0 mL plasma in a screw capped polypropylene plastic vial. *Minimum Volume:* 1.5 mL *Transport Temperature:* Refrigerated
Alternate Specimen	Plasma: Potassium EDTA (white top), Plasma preparation tube (PPT) 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
Stability	Room Temperature: 72 hours Refrigerated: 14 days Frozen: 42 days
Performing Information	
Methodology	Real-Time Polymerase Chain Reaction (PCR)
Reference Range	HCV RNA, QN, Real-Time PCR Not detected (IU/mL) HCV RNA, QN, Real-Time PCR Not detected (Log IU/mL)
Performed Days	Monday - Saturday
Turnaround Time	4 - 6 days
Performing Laboratory	Quest SJC
Interface Information	
Legacy Code	HCVRG
Interface Order Code	3400966

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, LiPA	32286-7	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 46 Y

Referral Testing

Collected: 07/16/2024 14:44 Received: 07/16/2024 14:44

Test Name	Result	Flag	Ref-Ranges	Units	Site
HCV RNA, QN, Real Time PCR Reflex to Genotype LiPA					
HCV RNA, QN, Real Time PCR	**355**	**H**		IU/mL	QCRL
HCV RNA, QN, Real Time PCR	**2.55**	**H**		Log IU/mL	QCRL

```
REFERENCE RANGE:
          NOT DETECTED  IU/mL
          NOT DETECTED  Log IU/mL

For additional information, please refer to
http://education.questdiagnostics.com/faq/FAQ22v1
(This link is being provided for informational/
educational purposes only.)

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
```

HCV RNA Genotype, LiPA	DETECTED	QCRL

```
The method used in this test is RT-PCR and reverse
hybridization (Line Probe) of the 5' UTR and core
region of the HCV genome.

The analytical performance characteristics of this
assay have been determined by Quest Diagnostics. The
modifications have not been cleared or approved by
the FDA. 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/HCVGenotyping
(This link id being provided for informational/
educational purposes only.)

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
```

Reported Date: 07/16/2024 14:44 HCVRG

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

G316000291
WX0000003827
Printed D&T: 07/16/24 14:44

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002516

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Inactivate Test With Replacement			
Effective Date	8/27/2024		
Inactivated Test			
Name	HCV Genotype		
Code	HCVGO		
Legacy Code	HCVGO		
Interface Order Code	3016200		
Replacement Test			
Name	Hepatitis C Viral RNA, Genotype, LiPA		
Code	HCVGT		
CPT Code(s)	87902		
Notes	New York DOH Approval Status: Yes		
Specimen Requirements			
Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Centrifuge and separate plasma from cells within 24 hours of collection by centrifugation at 800-1600 X G for 20 minutes at room temperature. Send 2.0 mL plasma in a screw capped polypropylene plastic vial. *Minimum Volume:* 0.6 mL *Transport Temperature:* Refrigerated		
Alternate Specimen	Plasma: Potassium EDTA (white top), Plasma preparation tube (PPT) Serum: Red top or Serum separator tube (SST)		
Rejection Criteria	Unspun PPT tubes, Unspun serum separator tube (SST), Unspun red top tube (no gel), Received room temperature, Heparinized samples		
Stability	Room Temperature: 72 hours Refrigerated: 14 days Frozen: 42 days		
Performing Information			
Methodology	Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) - Sequencing		
Reference Range	See report		
Performed Days	Sunday - Saturday		
Turnaround Time	4 – 7 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code	HCVGT		
Interface Order Code	3400971		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt**
3400971	Hepatitis C Viral RNA, Genotype, LiPA	32286-7	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 46 Y

Referral Testing

Collected: 07/16/2024 14:39 Received: 07/16/2024 14:39

Test Name	Result	Flag	Ref-Ranges	Units	Site
Hepatitis C Viral RNA, Genotype, LiPA	1a				QCRL

The method used in this test is RT-PCR and reverse hybridization (Line Probe) of the 5' UTR and core region of the HCV genome.

The analytical performance characteristics of this assay have been determined by Quest Diagnostics. The modifications have not been cleared or approved by the FDA. 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/HCVGenotyping (This link id being provided for informational/ educational purposes only.)

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway

Reported Date: 07/16/2024 14:39 HCVGT

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

G316000290
WX0000003827
Printed D&T: 07/16/24 14:39

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002516

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Inactivate Test With Replacement			
Effective Date	8/19/2024		
Inactivated Test			
Name	UGT1A1 Genotyping		
Code	UGT1G		
Legacy Code	UGT1A1GA		
Interface Order Code	3620140		
Replacement Test			
Name	UGT1A1 Genotyping		
Code	UGT1A		
CPT Code(s)	81350		
Specimen Requirements			
Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Send 3.0 mL whole blood. *Minimum Volume:* 1.0 mL *Transport Temperature:* Refrigerated		
Alternate Specimen	Yellow ACD A		
Rejection Criteria	Frozen specimens		
Stability	Room temperature: 7 days Refrigerated: 1 month Frozen: Unacceptable		
Performing Information			
Methodology	Polymerase Chain Reaction/Fragment analysis		
Reference Range	See report		
Performed Days	Varies		
Turnaround Time	4 - 9 days		
Performing Laboratory	ARUP Reference Laboratory		
Interface Information			
Legacy Code	UGT1A		
Interface Order Code	3600407		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt**
3600408	UGT1A1 Genotyping Specimen	66746-9	Yes
3600409	UGT1A1 Genotyping Allele 1	51951-2	No
3600411	UGT1A1 Genotyping Allele 2	51952-0	No
3600412	UGT1A1 Genotyping Interpretation	34509-0	No
3600413	EER UGT1A1	11526-1	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 46 Y

Referral Testing

Collected: 07/16/2024 14:56 Received: 07/16/2024 14:56

Test Name	Result	Flag	Ref-Ranges	Units	Site
UGT1A1 Genotyping					
UGT1A1 Genotyping Specimen	Whole Blood				ARRL
UGT1A1 Genotyping Allele 1	(TA)6 or *1				ARRL
UGT1A1 Genotyping Allele 2	**(TA)5 or *36**	**AB**			ARRL
UGT1A1 Genotyping Interpretation	See Note				ARRL

Indications for ordering:
- Determine sensitivity to irinotecan or related compounds.
- Confirm a diagnosis of Gilbert syndrome.

Heterozygous UTG1A1 (TA)6/(TA)5: One copy of *1 (TA)6 and one copy of *36 (TA)5 were detected. Clinical data is limited for the impact of the (TA)5 allele; however, enzyme levels are predicted to be normal and predicts a normal metabolizer status. Although not characterized clinically, this genotype is not expected to contribute to Gilbert's syndrome (benign familial hyperbilirubinemia).

This result has been reviewed and approved by Makenzie Fulmer, Ph.D.
BACKGROUND INFORMATION: UDP Glucuronosyltransferase 1A1 (UGT1A1) Genotyping
CHARACTERISTICS: UGT1A1 is responsible for the clearance of drugs (e.g., irinotecan) and endobiotic compounds (e.g., bilirubin). Irinotecan's major active and toxic metabolite (SN-38) is inactivated by the UGT1A1 enzyme and then eliminated via the bile. UGT1A1 gene mutations cause accumulation of SN-38, which may lead to irinotecan-related toxicities (neutropenia, diarrhea).
CAUSE: Variations in TA repeat number in the TATAAA element of the 5'UGT1A1-promoter affects transcription efficiency. The common number of repeats is six [(TA)6, *1 allele], while seven repeats [(TA)7, *28 allele] is associated with reduced transcription activity. Homozygosity for the (TA)7 allele is also associated with Gilbert syndrome (benign familial hyperbilirubinemia).
ALLELES TESTED: *36 allele, (TA)5; *1 allele, (TA)6; *28 allele, (TA)7 and *37 allele, (TA)8.
CLINICAL SENSITIVITY/SPECIFICITY: Risk of irinotecan toxicity by genotype (Br J Cancer. 2004; 91:678-82).
6/6 (*1/*1): diarrhea 17 percent; neutropenia 15 percent
6/7 (*1/*28): diarrhea 33 percent; neutropenia 27 percent
7/7 (*28/*28): diarrhea 70 percent; neutropenia 40 percent

Warde Medical Laboratory

LABORATORY REPORT

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EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 46 Y

Referral Testing

Collected: 07/16/2024 14:56 Received: 07/16/2024 14:56

Test Name	Result	Flag	Ref-Ranges	Units	Site

ALLELIC FREQUENCY:
*1(TA)6: Whites 0.61, Asians 0.84, African Americans 0.47
*28(TA)7: Whites 0.39, Asians 0.16, African Americans 0.43

METHODOLOGY: Polymerase chain reaction followed by size analysis using capillary electrophoresis.
ANALYTICAL SENSITIVITY AND SPECIFICITY: Greater than 99 percent.
LIMITATIONS: Variations in the UGT1A1 gene, other than those targeted, will not be detected. Clinical significance of the rare *36, (TA)5 and *37, (TA)8 alleles in predicting irinotecan toxicities is not well established. Genetic and non-genetic factors other than UGT1A1, may contribute to irinotecan toxicity and efficacy. Diagnostic errors can occur due to rare sequence variations.

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.

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

EER UGT1A1	See Note				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: 07/16/2024 14:56 UGT1A

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

G316000292
WX0000003827
Printed D&T: 07/16/24 14:56

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002516

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Inactivate Test With Replacement

Effective Date	8/6/2024

Inactivated Test

Name	Vasoactive Intestinal Polypeptide (VIP), Plasma
Code	VIP
Legacy Code	VIPAR
Interface Order Code	3687500

Replacement Test

Name	Vasoactive Intestinal Polypeptide (VIP)
Code	VIPP
CPT Code(s)	84586
Notes	New York DOH Approval Status: No

Specimen Requirements

Specimen Required	*Patient Preparation:* Patient should be fasting 10-12 hours prior to collection of specimen. Patient should not be on any antacid medication or medications that affect intestinal motility for at least 48 hours prior to collection. *Collect:* Lavender EDTA *Specimen Preparation:* Centrifuge, separate plasma from cells as soon as possible and send 10 mL plasma in a screw capped plastic vial. *Minimum Volume:* 1.0 mL *Transport Temperature:* Frozen
Alternate Specimen	Plasma collected in a G.I. Preservative tube
Rejection Criteria	Gross hemolysis, Grossly lipemic
Stability	EDTA Plasma: Room Temperature: Unacceptable Refrigerated: 24 hours Frozen: 6 months G.I. Plasma: Room Temperature: Unacceptable Refrigerated: 7 days Frozen: 6 months

Performing Information

Methodology	Direct Enzyme Immunoassay/Enzyme Linked Immunosorbent Assay
Reference Range	Up to 36 pg/mL
Performed Days	Monday - Friday
Turnaround Time	5 - 7 days
Performing Laboratory	Quest SJC

Interface Information

Legacy Code	VIPP
Interface Order Code	3400961

Result Code	Name	LOINC Code	AOE/Prompt
3400961	Vasoactive Intestinal Polypeptide (VIP)		No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 46 Y

Referral Testing

Collected: 07/16/2024 14:58 Received: 07/16/2024 14:58

Test Name	Result	Flag	Ref-Ranges	Units	Site
Vasoactive Intestinal Polypeptide (VIP)	12		UP TO 36	pg/mL	QCRL

This test was developed and it's performance characteristics
determined by Inter Science Institute. It has not been cleared or
approved by the US Food and Drug Administration. The FDA has
determined that such clearance or approval is not necessary.
Test Performed at:
Inter Science Institute
944 West Hyde Park Blvd

Reported Date: 07/16/2024 14:58 VIPP

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

G316000293
WX0000003827
Printed D&T: 07/16/24 14:58

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002516

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2024

Inactivate Test Without Replacement	
Effective Date	8/19/2024
Name	Bactericidal Levels
Code	BACTL
Legacy Code	BL
Interface Code	3500522
Notes	Test discontinued.

Inactivate Test Without Replacement	
Effective Date	8/27/2024
Name	Hops IgE
Code	RF324
Legacy Code	RARF324
Interface Code	3062520
Notes	Test discontinued.