Warde Medical Laboratory

TEST DIRECTORY UPDATE

OCTOBER 2024

Update Summary

Update Existing Test	10/22/2024	VB7 - "Biotin (Vitamin B7)"
Inactivate Test With Replacement	10/8/2024	CSFPR - "14-3-3 Protein, CSF (Prion Disease)" replaced by CSFPD - "14-3-3 Protein, CSF (Prion Disease)"
Inactivate Test With Replacement	11/12/2024	ZPP - "Zinc Protoporphyrin" replaced by ZPPWB - "Zinc Protoporphyrin (ZPP), Whole Blood"
Inactivate Test Without Replacement	10/21/2024	CYSUP - "Cytology, SurePathLiquid-Based Pap Test and HPV"
Inactivate Test Without Replacement	10/21/2024	HIVBL - "Human Immunodeficiency Virus 1 (HIV-1) Qualitative by NAAT"
Inactivate Test Without Replacement	10/1/2024	MBMET - "Methyl Bromide Metabolite, Serum/Plasma"
Inactivate Test Without Replacement	10/1/2024	RSVAB - "RSV Antibody"
Inactivate Test Without Replacement	10/21/2024	SPPAP - "Cytology, SurePath Liquid-Based Pap Test"

Update Existing Test

Effective Date	10/22/2024
Name	Biotin (Vitamin B7)
Code	VB7
Interface Order Code	3721040
Legacy Code	VB7SP
Notes	Update to stability.

Required Testing Changes

Stability	Room temperature: Unacceptable **Refrigerated: 7 days** Frozen: 14 days

Warde Medical Laboratory

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OCTOBER 2024

Inactivate Test With Replacement			
Effective Date	10/8/2024		
Inactivated Test			
Name	14-3-3 Protein, CSF (Prion Disease)		
Code	CSFPR		
Legacy Code	CSFPR		
Interface Order Code	3700101		
Replacement Test			
Name	14-3-3 Protein, CSF (Prion Disease)		
Code	CSFPD		
CPT Code(s)	83520 x2, 0035U		
Notes	New York DOH Approval Status: Yes		
Specimen Requirements			
Specimen Required	*Patient Preparation*: The patient must be 12 years of age or older. *Collect*: Cerebrospinal fluid (CSF) *Specimen Preparation*: Collect CSF - do not send the first 2.0 mL of CSF flow from tap. Send 2.0 mL CSF frozen immediately after collection, in a sterile screw capped plastic vial. Please call client service for a form. The ordering physician name and phone number are required by the National Prion Lab. *Minimum Volume*: 1.0 mL *Transport Temperature*: CRITICAL FROZEN		
Alternate Specimen	CSF collected in a SARSTEDT Polypropylene (PP), low binding sterile collection tube. CSF collected in a Sarstedt CSF false-bottom tube.		
Rejection Criteria	Bloody and insufficient sample quantity. Samples that are colored or contain blood cannot be performed for RT-QuIC and 14-3-3 GAMMA.		
Stability	Room temperature: Unacceptable Refrigerated: Unacceptable Frozen: Indefinitely		
Performing Information			
Methodology	Qualitative Enzyme-Linked Immunosorbent Assay		
Reference Range	RT-QuIC (CSF): No Change T-tau protein (CSF): No Change 14-3-3 GAMMA (CSF): 173 - 1999 AU/mL Likelihood of prion disease: No Change		
Performed Days	Varies		
Turnaround Time	7 - 9 days		
Performing Laboratory	Quest Valencia		
Interface Information			
Legacy Code	CSFPD		
Interface Order Code	3700116		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt**
3700102	Likelihood of prion dis		No
3700104	T-tau protein (CSF)		No
3700105	14-3-3 GAMMA (CSF)	31989-7	No

3700103	RT-QuIC (CSF)*		No
3700117	Specimen Condition		No
3700118	Reviewed and Approved by:		No

Inactivate Test With Replacement

Effective Date	11/12/2024

Inactivated Test

Name	Zinc Protoporphyrin
Code	ZPP
Legacy Code	ZPP
Interface Order Code	1001550

Replacement Test

Name	Zinc Protoporphyrin (ZPP), Whole Blood
Code	ZPPWB
CPT Code(s)	84202
Notes	New York DOH Approval Status: Yes

Specimen Requirements

Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Send 3.0 mL whole blood in the original collection tube. *Minimum Volume:* 0.2 mL *Transport Temperature:* Refrigerated
Alternate Specimen	Whole Blood: Royal blue (K2EDTA), Royal blue (NaHep), Tan (K2EDTA), Pink (K2EDTA).
Rejection Criteria	Hemolyzed, clotted or frozen samples
Stability	Room temperature: 30 hours Refrigerated: 5 weeks Frozen: Unacceptable

Performing Information

Methodology	Quantitative Hematofluorometry
Reference Range	0-69 µmol ZPP/ mol Hem
Performed Days	Monday - Friday
Turnaround Time	3 - 6 days
Performing Laboratory	ARUP Reference Laboratory

Interface Information

Legacy Code	ZPPWB
Interface Order Code	3600422

Result Code	Name	LOINC Code	AOE/Prompt
3600422	Zinc Protoporphyrin (ZPP), Whole Blood	29763-0	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: 09/24/2024 14:28 Received: 09/24/2024 14:28

Test Name	Result	Flag	Ref-Ranges	Units	Site
14-3-3 Protein, CSF (Prion Disease)					
Likelihood of prion dis	<1.0			%	QDRL

Comment: These tests, together or alone, must not be used to exclude prion disease. A definitive diagnosis of prion disease can only be given after thorough examination of autopsy brain tissue.

The NPDPSC is able to offer a no-cost autopsy for this patient. Autopsy can help to delineate whether prion disease is sporadic, acquired or genetic in etiology. NPDPSC staff (phone 216-368-0587) are available to work with healthcare providers and the patient's family to plan an autopsy, if desired.

T-tau protein (CSF)++	**2482**	**H**	0-1149	pg/mL	QDRL
14-3-3 GAMMA (CSF)++	**14253**	**H**	173-1999	AU/mL	QDRL

T-tau protein and 14-3-3 GAMMA are indirect markers of neurodegenerative disease

RT-QuIC (CSF)*	NEGATIVE		NEGATIVE		QDRL

RT-QuIC identifies the disease-causing agent

Specimen Condition	Clear				QDRL
Reviewed and Approved by:	Name, PhD				QDRL

Disclaimer: This test was developed and its performance characteristics determined by the National Prion Disease Pathology and Surveillance Center Clinical Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. These assays should be used in conjunction with other clinical, pathological and laboratory findings. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform clinical laboratory testing.

TEST PERFORMED AT:
NATL PRION DISEASE PATH
W RESERVE UNIV 2085 ADELBERT RD RM 418 CLEVELAND, OH 44106-4907

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

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: 09/24/2024 14:28 Received: 09/24/2024 14:28

Test Name	Result	Flag	Ref-Ranges	Units	Site

Reported Date: 09/24/2024 14:33 CSFPD

Performing Site:
QDRL: QUEST DIAGNOSTICS REFERENCE LAB VALENCIA 27027 Tourney Road Valencia CA 91355

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

G524000002
WX0000003827
Printed D&T: 09/24/24 14:33

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002516

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

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: 09/17/2024 10:33 Received: 09/17/2024 10:33

Test Name	Result	Flag	Ref-Ranges	Units	Site
Zinc Protoporphyrin (ZPP), Whole Blood	32		0-69	umolZPP/molHem	ARRL

INTERPRETIVE INFORMATION: Zinc Protoporphyrin (ZPP) WholeBld Ratio
This test was performed on the ProtoFluor Z system manufactured by Helena Laboratories. The result is not comparable to results obtained from extraction-based methods or from the AVIV ZPP system.

The 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.
Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Jonathan R. Genzen, MD, PhD
CLIA Number: 46D0523979

Reported Date: 09/17/2024 10:33 ZPPWB

Performing Site:
ARRL: ARUP REFERENCE LAB 500 Chipeta Way Salt Lake City UT 841081221

Warde Medical Laboratory

TEST DIRECTORY UPDATE

OCTOBER 2024

Inactivate Test Without Replacement	
Effective Date	10/21/2024
Name	Cytology, SurePathLiquid-Based Pap Test and HPV
Code	CYSUP
Legacy Code	CYSUP
Interface Code	3600037
Notes	Test discontinued.

Inactivate Test Without Replacement	
Effective Date	10/21/2024
Name	Human Immunodeficiency Virus 1 (HIV-1) Qualitative by NAAT
Code	HIVBL
Legacy Code	HIVBL
Interface Code	3600041
Notes	Test discontinued.

Inactivate Test Without Replacement	
Effective Date	10/1/2024
Name	Methyl Bromide Metabolite, Serum/Plasma
Code	MBMET
Legacy Code	MBMET
Interface Code	3600043
Notes	Test discontinued.

Inactivate Test Without Replacement	
Effective Date	10/1/2024
Name	RSV Antibody
Code	RSVAB
Legacy Code	RSVAB
Interface Code	3509740
Notes	Test discontinued. Suggested alternative is a respiratory sample with Warde test RVPCR: Respiratory Syncytial Virus (RSV) PCR.

Inactivate Test Without Replacement	
Effective Date	10/21/2024
Name	Cytology, SurePath Liquid-Based Pap Test
Code	SPPAP
Legacy Code	SPPAP
Interface Code	3662200
Notes	Test discontinued.