Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2025

Update Summary		
New Test Activation	8/26/2025	EGFRA - "EGFR Mut. w/r to NSCLC, ALK 2p23 Rearrangement, FISH"
Update Existing Test	8/26/2025	AHPR - "Acute Hepatitis Panel"
Update Existing Test	8/26/2025	HAAB - "Hepatitis A Antibody, Total"
Update Existing Test	8/26/2025	HAM - "Hepatitis A Antibody, IgM"
Update Existing Test	8/26/2025	HBCAB - "Hepatitis B Core Antibody, Total"
Update Existing Test	8/26/2025	HBCM - "Hepatitis B Core Antibody, IgM"
Update Existing Test	8/26/2025	HBSAB - "Hepatitis B Surface Antibody"
Update Existing Test	8/26/2025	HBSAG - "Hepatitis B Surface Antigen"
Update Existing Test	8/26/2025	HBVSC - "Hepatitis B Screening Panel"
Update Existing Test	8/26/2025	HCVR - "Hepatitis C Antibody, Diagnostic, with reflex to PCR"
Update Existing Test	8/26/2025	HCVSR - "Hepatitis C Antibody, Screening, with reflex to PCR"
Update Existing Test	8/25/2025	IGD - "IgD, Serum"
Update Existing Test	8/5/2025	IOD24 - "Iodine, 24 Hr, U"
Update Existing Test	8/5/2025	IODCU - "Iodine/Creatinine Ratio, Random, Urine"
Inactivate Test With Replacement	8/4/2025	ALZE - "ADmark (R) Phospho-Tau/Total Tau A Beta42 CSF" replaced by ALZEC - "Admark Alzheimer's Evaluation, CSF"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2025

New Test Activation

Effective Date	8/26/2025
Name	EGFR Mut. w/r to NSCLC, ALK 2p23 Rearrangement, FISH
Code	EGFRA
CPT Code(s)	81325
Notes	New York DOH Approval Status: Yes

Specimen Requirements

Specimen Required	*Collect:* Lung tissue biopsy, formalin-fixed paraffin-embedded block **or** charged/+slides from formalin-fixed paraffin embedded tissue. *Specimen Preparation:* Formalin fixed paraffin embedded tissue block sent at room temperature. *Minimum Volume:* 5 unstained charged (+) slides *Transport Temperature:* Room temperature
Alternate Specimen	Slide: 8 (5 minimum) unstained charged (+) slides.
Rejection Criteria	Fresh tissue, non-fixed tissue, frozen tissue
Stability	Room temperature: 5 years Refrigerated: 5 years Frozen: Unacceptable

Performing Information

Methodology	Next Generation Sequencing, Fluorescence in situ Hybridization (FISH)
Reference Range	EGFR Mutation: Not detected FISH, ALK 2p23 Rearrangement: See report
Performed Days	Sunday - Saturday
Turnaround Time	7 - 9 days
Performing Laboratory	Quest

Interface Information

Legacy Code	EGFRA
Interface Order Code	3401056

Result Code	Name	LOINC Code	AOE/Prompt
3401057	Source	31208-2	Yes
3401058	Block/Specimen ID:		Yes
3401059	Clinical Indication:	55752-0	Yes
3401061	Referring Physician:	46608-6	Yes
3401062	Referring Physician Phone:	81230-5	Yes
3401063	Client/Phone#:		Yes
3401064	Client Accession #:		Yes
3401066	Patient ID:	56794-1	Yes
3401067	EGFR Mutation Analysis	21665-5	No
3401068	FISH, ALK 2p23, Lung Cancer	78205-2	No

Warde Medical Laboratory

LABORATORY REPORT

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

EXAMPLE, REPORT W
WX0000003827 M 07/08/1968 57 Y

Referral Testing

Collected: 07/17/2025 08:39 Received: 07/17/2025 08:39

Test Name	Result	Flag	Ref-Ranges	Units	Site
EGFR Mut. w/r to NSCLC, ALK 2p23 Rearrangement, FISH					
Source	Lung				QCRL
Block/Specimen ID:	9657				QCRL
EGFR Mutation Analysis	**DETECTED**	**AB**			QCRL

Reference Range:
NOT DETECTED

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

FISH, ALK 2p23, Lung Cancer — SEE NOTE — QCRL

Specimen Type: Paraffin Embedded Tumor Tissue

Clinical Indication: FISH study for oncology

Method : FISH
Total Cells : 50
Images Captured : 2

RESULT :

nuc ish(5'ALKx1-4,3'ALKx2-5)(5'ALK sep
3'ALKx1)(23/50)/(ALKx3)(8/50)

INTERPRETATION :

POSITIVE FISH RESULT FOR REARRANGEMENT OF ALK GENE

This fluorescence in-situ hybridization (FISH) analysis, using break-apart probes specific for ALK gene (2p23; Abbott Molecular), exhibited an abnormal pattern of hybridization consistent with an ALK rearrangement in 46% of interphase cells. In addition, 16% of interphase cells showed 3 copies of ALK region. The rest of the cells showed a normal hybridization pattern.

Overexpression of the ALK kinase, through a rearrangement producing a variety of different fusion proteins, is seen in a variety of

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EXAMPLE, REPORT W
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Test Name	Result	Flag	Ref-Ranges	Units	Site

neoplasms, including anaplastic large cell lymphoma (most commonly NPM1-ALK), non-small cell lung carcinoma (ELM4-ALK), and inflammatory myofibroblastic tumors (partners genes include TPM3, TPM4, and CLTC, among others). While the significance of copy number gain or amplification of the ALK region is not clear.

This result should be considered in combination with other clinical and/or laboratory data. Please expect the result of any other concurrent test in a separate report.

This fluorescence in situ hybridization (FISH) test was performed using a break-apart probe specific for the ALK gene (2p23; Abbott Molecular). According to the manufacturer's directional insert, the cutoff value for ALK rearrangement is 15% of interphase cells in paraffin-embedded specimens.

The analytical performance characteristics of this assay have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano, CA. 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.

Guang Li, PhD, FACMG
Electronic Signature:05/21/2025
Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

Reported Date: 07/17/2025 08:39 EGFRA

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2025

Update Existing Test	
Effective Date	8/26/2025
Name	Acute Hepatitis Panel
Code	AHPR
Interface Order Code	3001485
Legacy Code	AHPR
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	***Specimen Information:*** **Assay performance has not been established for immunocompromised, immunosuppressed, cord blood or pediatrics less than 18 months of age. High biotin concentration (for example, from dietary supplements) can adversely affect results.** *Collect:* Serum separator tube (SST), Lavender EDTA - Both specimens required. *Specimen Preparation:* Centrifuge, separate serum from cells and send 4.0 mL serum and 3.0 mL plasma in screw capped plastic vials. Serum should be labeled with AHP label and plasma with HCVFR label. *Minimum Volume:* SST: 2.0 mL serum EDTA: 2.5 mL plasma *Transport Temperature:* Serum separator tube (SST): Refrigerated Plasma EDTA: Frozen

Update Existing Test	
Effective Date	8/26/2025
Name	Hepatitis A Antibody, Total
Code	HAAB
Interface Order Code	3000710
Legacy Code	HAAB
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	***Specimen Information:*** **Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients.** *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:* 0.3 mL *Transport Temperature:* Refrigerated

Update Existing Test	
Effective Date	8/26/2025
Name	Hepatitis A Antibody, IgM
Code	HAM
Interface Order Code	3010010
Legacy Code	HAM
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	***Specimen Information:*** **Assay performance characteristics have not been established for immunocompromised, immunosuppressed, cord blood or pediatrics less than 2 years of age.** *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:* 0.4 mL *Transport Temperature:* Refrigerated

Update Existing Test	
Effective Date	8/26/2025
Name	Hepatitis B Core Antibody, Total
Code	HBCAB
Interface Order Code	3000680
Legacy Code	HBCAB
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	***Specimen Information:*** **This assay is not for use in pediatrics under the age of 2 years or for the screening of donors for blood or blood products.** *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:* Refrigerated

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2025

Update Existing Test	
Effective Date	8/26/2025
Name	Hepatitis B Core Antibody, IgM
Code	HBCM
Interface Order Code	3010200
Legacy Code	HBCM
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	***Specimen Information:*** **Assay performance characteristics have not been established for immunocompromised, immunosuppressed, cord blood or pediatrics less than 2 years of age.** *Collect:* Serum separator tube (SST) *Specimen Preparation:* Centrifuge, separate serum from cells and send 1.0 mL serum in screw capped plastic vial. *Minimum Volume:* 0.4 mL *Transport Temperature:* Refrigerated

Update Existing Test	
Effective Date	8/26/2025
Name	Hepatitis B Surface Antibody
Code	HBSAB
Interface Order Code	3001640
Legacy Code	HBSAB
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	***Specimen Information:*** **Assay performance characteristics have not been established for pregnant women, or for populations of immunocompromised or immunosuppressed patients. This assay is not intended for use in screening blood or plasma donors.** *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:* Refrigerated

Update Existing Test	
Effective Date	8/26/2025
Name	Hepatitis B Surface Antigen
Code	HBSAG
Interface Order Code	3000660
Legacy Code	HBSAG
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	**Specimen Information: High biotin concentration (for example, from dietary supplements) can adversely affect results.** *Collect:* Serum separator tube (SST) *Specimen Preparation:* Centrifuge, separate serum from cells and send 2.0 mL serum in a screw capped plastic vial. *Minimum Volume:* 1.5 mL *Transport Temperature:* Refrigerated

Update Existing Test	
Effective Date	8/26/2025
Name	Hepatitis B Screening Panel
Code	HBVSC
Interface Order Code	3000530
Legacy Code	HBVSC
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	***Specimen Information:*** **Assay performance characteristics have not been established for pregnant women, pediatrics under the age of 2 years, or for populations of immunocompromised or immunosuppressed patients. This assay is not intended for use in screening blood or plasma donors. High biotin concentration (for example, from dietary supplements) can adversely affect results.** *Patient Preparation:* Not for use in pediatrics under the age of 2 years. *Collect:* Serum separator tube (SST) *Specimen Preparation:* Centrifuge, separate serum from cells and send 2.0 mL serum in a screw capped plastic vial. *Minimum volume:* 1.5 mL *Transport Temperature:* Refrigerated

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2025

Update Existing Test	
Effective Date	8/26/2025
Name	Hepatitis C Antibody, Diagnostic, with reflex to PCR
Code	HCVR
Interface Order Code	3001440
Legacy Code	HCVR
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	***Specimen Information:*** **Assay performance has not been established for immunocompromised, immunosuppressed, cord blood or pediatrics less than 18 months of age.** *Collect:* HCV Antibody Screen: Serum Separator Tube (SST) HCV PCR: Lavender EDTA *Both specimens required. *Specimen Preparation:* HCV Antibody Screen (Label: HCAB) - Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial. HCV PCR Plasma (Label: HCVFR): Centrifuge, separate plasma from cells within 6 hours of collection. Send 3.0 mL plasma in screw capped plastic vial. *PCR and antibody testing cannot be done on shared specimens. Separate tubes must be clearly labeled for antibody and PCR specimens. *Minimum Volume:* HCV antibody: 0.5 mL HCV PCR: 2.5 mL *Transport Temperature:* Serum: Refrigerated Plasma: Frozen

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2025

Update Existing Test	
Effective Date	8/26/2025
Name	Hepatitis C Antibody, Screening, with reflex to PCR
Code	HCVSR
Interface Order Code	3001452
Legacy Code	HCVSR
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	***Specimen Information:*** **Assay performance has not been established for immunocompromised, immunosuppressed, cord blood or pediatrics less than 18 months of age.** *Collect:* HCV Antibody Screen: Serum Separator Tube (SST) HCV PCR: Lavender EDTA *Both specimens required. *Specimen Preparation:* HCV Antibody Screen (Label: HCAB) - Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial. HCV PCR Plasma (Label: HCVFR): Centrifuge, separate plasma from cells within 6 hours of collection. Send 3.0 mL plasma in screw capped plastic vial. *PCR and antibody testing cannot be done on shared specimens. Separate tubes must be clearly labeled for antibody and PCR specimens. *Minimum Volume:* HCV antibody: 0.5 mL HCV PCR: 2.5 mL *Transport Temperature:* Serum: Refrigerated Plasma: Frozen

Update Existing Test	
Effective Date	8/25/2025
Name	IgD, Serum
Code	IGD
Interface Order Code	3420620
Legacy Code	IGDQ
Notes	Update to rejection criteria, performed days, and turnaround time.
Required Testing Changes	
Rejection Criteria	**Moderately and grossly lipemic, grossly icteric.**
Performed Days	**Tuesday, Thursday, Saturday**
Turnaround Time	**3 - 5 days**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2025

Update Existing Test	
Effective Date	8/5/2025
Name	Iodine, 24 Hr, U
Code	IOD24
Interface Order Code	3800232
Legacy Code	IOD24
Notes	Update to stability
Required Testing Changes	
Stability	**Room temperature: 28 days** **Refrigerated: 28 days** **Frozen: 28 days**

Update Existing Test	
Effective Date	8/5/2025
Name	Iodine/Creatinine Ratio, Random, Urine
Code	IODCU
Interface Order Code	3800238
Legacy Code	IODCU
Notes	Update to stability.
Required Testing Changes	
Stability	**Room temperature: 28 days** **Refrigerated: 14 days** **Frozen: 28 days**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

AUGUST 2025

Inactivate Test With Replacement

Effective Date	8/4/2025

Inactivated Test

Name	ADmark (R) Phospho-Tau/Total Tau A Beta42 CSF
Code	ALZE
Legacy Code	ALZE
Interface Order Code	3429300

Replacement Test

Name	Admark Alzheimer's Evaluation, CSF
Code	ALZEC
CPT Code(s)	84393, 82234, 84394
Notes	New York DOH Approval Status: Yes

Specimen Requirements

Specimen Required	*Collect:* Cerebrospinal fluid (CSF) *Specimen Preparation:* Send 1.0 mL Cerebrospinal fluid (CSF) in a screw capped polypropylene vial. Note: Perform lumbar puncture (LP) before noon using gravity drip collection method. Do not use the first 2.0 mL of CSF for testing. *Minimum Volume:* 0.7 mL *Transport Temperature:* Refrigerated
Rejection Criteria	Gross hemolysis
Stability	Room Temperature: 5 days Refrigerated: 14 days Frozen: 56 days

Performing Information

Methodology	Electrochemiluminescence		
Reference Range	Beta-Amyloid (1-42), CSF	Not Established	pg/mL
	tTau, CSF	Not Established	pg/mL
	pTau181, CSF	Not Established	pg/mL
	Ttau/Abeta-42 Ratio	< or = 0.28	
	pTau181/Abeta-42 Ratio	< or = 0.023	
Performed Days	Monday, Wednesday, Friday, Saturday		
Turnaround Time	4 - 6 days		
Performing Laboratory	Quest		

Interface Information

Legacy Code	ALZEC
Interface Order Code	3401103

Result Code	Name	LOINC Code	AOE/Prompt
3401104	Summary Interpretation		No
3401106	Beta-Amyloid (1-42), CSF		No
3401107	tTau, CSF	30160-6	No
3401108	pTau181, CSF	72260-3	No
3401109	tTau/Abeta42 Ratio	41027-4	No
3401111	tTau/Abeta42 Interpretation		No

3401112	pTau181/Abeta42 Ratio	97102-8	No
3401113	pTau181/Abeta42 Interpretation		No
3401114	Comments	8251-1	No

Warde Medical Laboratory

LABORATORY REPORT

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

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 36 Y

Referral Testing

Collected: 07/17/2025 08:35 Received: 07/17/2025 08:35

Test Name	Result	Flag	Ref-Ranges	Units	Site
Admark Alzheimer's Evaluation, CSF					
Summary Interpretation	Negative		Negative		QCRL
Test Performed at: Quest Diagnostics Nichols Institute 33608 Ortega Highway San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA					
Beta-Amyloid (1-42), CSF	440.0			pg/mL	QCRL
Reference Range: Not established Test Performed at: Quest Diagnostics Nichols Institute 33608 Ortega Highway San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA					
tTau, CSF	100.0			pg/mL	QCRL
Reference Range: Not established Test Performed at: Quest Diagnostics Nichols Institute 33608 Ortega Highway San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA					
pTau181, CSF	10.0			pg/mL	QCRL
Reference Range: Not established Test Performed at: Quest Diagnostics Nichols Institute 33608 Ortega Highway San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA					
tTau/Abeta42 Ratio	0.23				QCRL
Reference Range: < OR = 0.28					
tTau/Abeta42 Interpretation	SEE NOTE				QCRL
A negative result consistent with a negative amyloid PET scan result. tTau/Abeta42 ratio result is used as an adjunct to other clinical diagnostic evaluations. Test Performed at: Quest Diagnostics Nichols Institute					

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
WX0000003826 F 12/05/1988 36 Y

Referral Testing

Collected: 07/17/2025 08:35 Received: 07/17/2025 08:35

Test Name	Result	Flag	Ref-Ranges	Units	Site
33608 Ortega Highway San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA					
pTau181/Abeta42 Ratio	0.023				QCRL
Reference Range: < OR = 0.023					
pTau181/Abeta42 Interpretation	SEE NOTE				QCRL
A negative result consistent with a negative amyloid PET scan result. pTau181/Abeta42 ratio results is used as an adjunct to other clinical diagnostic evaluations.					
Comments	SEE NOTE				QCRL
Tests performed by Roche Diagnostics Electrochemiluminescence Immunoassay (ECLIA). Values obtained with different assay methods or kits cannot be used interchangeably. Healthcare providers with questions regarding these results, please contact Quest Diagnostics at 1-800-642-4657. Test Performed at: Quest Diagnostics Nichols Institute 33608 Ortega Highway San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA					

Reported Date: 07/17/2025 08:39 ALZEC

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

H517000001
WX0000003826
Printed D&T: 07/17/25 08:39

Ordered By: CLIENT CLIENT
WX00000000002823

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