

Update Summary		
New Test Activation	3/25/2025	BZNCP - "Brazil Nut IgE Component Panel"
New Test Activation	3/25/2025	BZNRP - "Brazil Nut IgE with Reflex to Component Panel"
New Test Activation	3/25/2025	DIPHU - "Diphenhydramine, Urine"
New Test Activation	3/25/2025	IAH5C - "Influenza A (H5) Virus RNA, Qual Real-Time PCR, Conjunctiva"
New Test Activation	3/25/2025	IAH5R - "Influenza A (H5) Virus RNA, Qual Real-time PCR, Respiratory"
Update Existing Test	3/11/2025	A1AP - "Alpha-1 Antitrypsin Phenotype"
Update Existing Test	3/24/2025	AGDEL - "Alpha-globin Gene Del or Dup"
Update Existing Test	3/4/2025	BCAF - "Blood Culture, Acid-Fast Bacillus (AFB)"
Update Existing Test	2/21/2025	CD08C - "Clin Urine Drug Abuse Scrn 8C w/Confirm"
Update Existing Test	2/21/2025	CD10C - "Clin Urine Drug Abuse Scrn 10C w/Confirm"
Update Existing Test	2/21/2025	CT10C - "Clin Urine Drug Abuse Scrn 10C w/Confirm"
Update Existing Test	3/24/2025	FAMED - "Familial Medit Fever Mutation"
Update Existing Test	3/24/2025	GAUCH - "Gaucher Disease, Mutation Analysis"
Update Existing Test	2/21/2025	MECO7 - "Drug Abuse Screen, Meconium 7"
Update Existing Test	3/17/2025	MGENR - "Mycoplasma genitalium, rRNA, TMA"
Update Existing Test	2/21/2025	MMA01 - "Methylmalonic Acid"
Update Existing Test	3/17/2025	MUPCR - "SureSwab(R), Mycoplasma/Ureaplasma Panel, PCR"
Update Existing Test	2/21/2025	PN03C - "Drug Screen, Pain Management Panel"
Update Existing Test	3/4/2025	SBG - "Sex Hormone Binding Globulin"
Update Existing Test	3/25/2025	SOMAT - "Somatostatin"
Update Existing Test	2/21/2025	UCAMP - "Clin Urine Amphetamine Confirm"
Update Existing Test	2/21/2025	UCATE - "Catecholamines, Fractionated, Urine - 24 hour"
Update Existing Test	2/21/2025	UCATR - "Catecholamines, Urine, Random"
Update Existing Test	2/21/2025	UCBEN - "Clin Urine Benzodiazepine Confirm"
Update Existing Test	2/21/2025	UCBUP - "Clin Urine Buprenorphine Confirm"
Update Existing Test	2/21/2025	UCOPT - "Clin Urine Opiate Confirm"
Update Existing Test	2/21/2025	UCTHC - "Clin Urine THC Confirm"
Update Existing Test	2/21/2025	UDS01 - "Drug Screen, Urine Comprehensive"
Update Existing Test	2/21/2025	UETG3 - "EtG Screen w/ EtG/EtS Confirmation"
Update Existing Test	2/21/2025	UMET - "Metanephries, Fractionated, Urine, 24 hour"
Update Existing Test	2/21/2025	UMETR - "Metanephries,Urine Random"
Update Existing Test	2/21/2025	UVMA - "Vanillylmandelic Acid, Urine, 24 hr"
Update Existing Test	2/21/2025	UVMAR - "Vanillylmandelic Acid, Urine, Random"
Update Existing Test	3/24/2025	VONWI - "von Willebrand Disease Gene Sequencing"

Inactivate Test With Replacement	3/25/2025	CHROA - "Chromogranin A" replaced by CGA - "Chromogranin A"
Inactivate Test With Replacement	3/25/2025	NMOFC - "NMO/AQP4-IgG FACS, CSF" replaced by NMOCS - "NMO/AQP4 FACS, CSF"
Inactivate Test With Replacement	3/25/2025	NMOFS - "NMO/AQP4-IgG FACS, Serum" replaced by NMOSE - "NMO AQP4 FACS, S"

New Test Activation

Effective Date	3/25/2025
Name	Brazil Nut IgE Component Panel
Code	BZNCP
CPT Code(s)	86008
Notes	New York DOH Approval Status: Yes

Specimen Requirements

Specimen Required	<p><i>Collect:</i> Serum separator tube (SST)</p> <p><i>Specimen Preparation:</i> Centrifuge, separate serum and send 2.0 mL serum in a screw capped plastic vial.</p> <p><i>Minimum Volume:</i> 0.5 mL</p> <p><i>Transport Temperature:</i> Refrigerated</p>
Alternate Specimen	<p>Plasma: EDTA, Heparin (sodium or lithium)</p> <p>Serum: Red top</p>
Stability	<p>Room temperature: Undetermined</p> <p>Refrigerated: 7 days</p> <p>Frozen: Undetermined</p>

Performing Information

Methodology	Fluorescent Enzyme Immunoassay
Reference Range	See report
Performed Days	Monday - Friday
Turnaround Time	1 - 4 days
Performing Laboratory	Warde Medical Laboratory

Interface Information

Legacy Code	BZNCP		
Interface Order Code	3000396		
Result Code	Name	LOINC Code	AOE/Prompt
3000397	r Ber e 1 (f354)		No
3000398	r Ber e 1 Class		No
3069000	Allergy Interpretation		No



LABORATORY REPORT

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

EXAMPLE, REPORT W
WX0000003827 M 07/08/1968 56 Y

Allergy Testing - Panels

Collected: 02/05/2025 15:08 Received: 02/05/2025 15:08

Test Name	Result	Flag	Ref-Ranges	Units	Site
Brazil Nut IgE Component Panel					
r Ber e 1 (f354)	<0.10		<0.10	kU/L	WMRL
r Ber e 1 Class	CLASS 0				WMRL
Allergy Interpretation	See Below				WMRL

CLASS	kU/L	Level of Allergen Specific IgE Antibody
0	<0.10	Undetectable
0/1	0.10 - 0.34	Very Low Level
1	0.35 - 0.69	Low Level
2	0.70 - 3.49	Moderate Level
3	3.50 - 17.4	High Level
4	17.5 - 49.9	Very High Level
5	50.0 - 100.0	Very High Level
6	>100.0	Very High Level

Reported Date: 02/05/2025 15:08 BZNCP

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

H005000021
WX0000003827

Printed D&T: 02/05/25 15:08

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002516

Kajal V. Sitwala, MD, PhD - Medical Director

Form: MM RL1

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New Test Activation

Effective Date	3/25/2025
Name	Brazil Nut IgE with Reflex to Component Panel
Code	BZNRP
CPT Code(s)	86003, plus 86008 if reflex to component
Notes	New York DOH Approval Status: Yes

Specimen Requirements

Specimen Required	<i>Collect:</i> Serum separator tube (SST) <i>Specimen Preparation:</i> Centrifuge, separate serum and send 2.0 mL serum in a screw capped plastic vial. <i>Minimum Volume:</i> 0.5 mL <i>Transport Temperature:</i> Refrigerated
Alternate Specimen	Plasma: EDTA, Heparin (sodium or lithium) Serum: Red top
Stability	Room temperature: Undetermined Refrigerated: 7 days Frozen: Undetermined

Performing Information

Methodology	Fluorescent Enzyme Immunoassay
Reference Range	See report
Performed Days	Monday - Friday
Turnaround Time	1 - 4 days
Performing Laboratory	Warde Medical Laboratory

Interface Information

Legacy Code	BZNRP		
Interface Order Code	3000399		
Result Code	Name	LOINC Code	AOE/Prompt
3062213	Brazil Nut, IgE	6050-9	No
3062216	Brazil Nut Class	6934-4	No
3000401	r Ber e 1 (f354)		No
3000402	r Ber e 1 Class		No
3069000	Allergy Interpretation		No



LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Allergy Testing - Panels

Collected: 02/05/2025 15:09 Received: 02/05/2025 15:09

Test Name	Result	Flag	Ref-Ranges	Units	Site
Brazil Nut IgE with Reflex to Components					
Brazil Nut, IgE	<0.10		<0.10	kU/L	WMRL
Brazil Nut Class	CLASS 0				WMRL
r Ber e 1 (f354)	.TNP				WMRL
r Ber e 1 Class	.TNP				WMRL
Allergy Interpretation	See Below				WMRL

CLASS	kU/L	Level of Allergen Specific IgE Antibody
-----	-----	-----
0	<0.10	Undetectable
0/1	0.10 - 0.34	Very Low Level
1	0.35 - 0.69	Low Level
2	0.70 - 3.49	Moderate Level
3	3.50 - 17.4	High Level
4	17.5 - 49.9	Very High Level
5	50.0 - 100.0	Very High Level
6	>100.0	Very High Level

Reported Date: 02/05/2025 15:09 BZNRP

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

H005000022
WX0000003826

Printed D&T: 02/05/25 15:09

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002353

Kajal V. Sitwala, MD, PhD - Medical Director

Form: MM RL1

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New Test Activation			
Effective Date	3/25/2025		
Name	Diphenhydramine, Urine		
Code	DIPHU		
CPT Code(s)	80375		
Notes	New York DOH Approval Status: Yes		
Specimen Requirements			
Specimen Required	Collect: Random Urine Specimen Preparation: Send 1.0 mL urine in a preservative-free screw capped plastic urine container. Minimum Volume: 0.4 mL Transport Temperature: Refrigerated		
Rejection Criteria	Specimens collected with preservatives		
Stability	Room Temperature: 30 days Refrigerated: 30 days Frozen: 2 years		
Performing Information			
Methodology	High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS)		
Reference Range	See report		
Performed Days	Varies		
Turnaround Time	5 - 7 days		
Performing Laboratory	NMS Labs		
Interface Information			
Legacy Code	DIPHU		
Interface Order Code	3300372		
Result Code	Name	LOINC Code	AOE/Prompt
3300372	Diphenhydramine, Urine		No



LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W

WX0000003826 F 12/05/1988 36 Y

Referral Testing

Collected: 02/05/2025 15:11

Received: 02/05/2025 15:11

<u>Test Name</u>	<u>Result</u>	<u>Flag</u>	<u>Ref-Ranges</u>	<u>Units</u>	<u>Site</u>
Diphenhydramine, Urine	1000			ng/mL	NMRL

Reporting Limit: 50 ng/mL

Synonym(s): Benadryl(R); Nytol; Unisom; Ingredient of Benylin and Panadol

Concentrations of diphenhydramine between 100-3500 ng/mL were found in urine during the first 24 hours of ingestion of 100 mg of the drug.

Analysis by High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS)

This test was developed and its performance characteristics determined by NMS Labs. It has not been cleared or approved by the US Food and Drug Administration.

Digital data review may have taken place remotely by qualified NMS staff utilizing a secure VPN connection for some or all of the reported results. This is in accordance with and follows CLIA regulations.

Testing performed at NMS Labs, Inc.
200 Welsh Road
Horsham, PA 19044-2208
CLIA 39D0197898

Reported Date: 02/05/2025 15:12 DIPHU

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

H005000024
WX0000003826

Printed D&T: 02/05/25 15:12

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002353

Kajal V. Sitwala, MD, PhD - Medical Director

Form: MM RL1

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New Test Activation

Effective Date	3/25/2025
Name	Influenza A (H5) Virus RNA, Qual Real-Time PCR, Conjunctiva
Code	IAH5C
CPT Code(s)	87502
Notes	New York DOH Approval Status: No

Specimen Requirements

Specimen Required	<p><i>Collect:</i> Conjunctiva swab</p> <p><i>Specimen Preparation:</i> Send a conjunctiva swab in a VCM (green cap), or equivalent Universal Transport Media (UTM) tube.</p> <p><i>Minimum Volume:</i> 1 swab</p> <p><i>Transport Temperature:</i> Refrigerated (cold packs)</p>
Rejection Criteria	Tubes containing guanidinium isothiocyanate (GITC), Calcium alginate swabs, Cotton swabs with wooden shaft, Amies liquid or gel transport used for bacterial cultures, Tubes with clot activator, Glass tubes, Snap-cap tubes, 3D printed swabs
Stability	<p>Room temperature: 48 hours</p> <p>Refrigerated: 14 days</p> <p>Frozen: 30 days</p>

Performing Information

Methodology	Real-Time Polymerase Chain Reaction (PCR)
Reference Range	<p>Influenza A Not detected</p> <p>Influenza H5 Not detected</p>
Performed Days	Sunday - Saturday
Turnaround Time	5 - 6 days
Performing Laboratory	Quest

Interface Information

Legacy Code	IAH5C		
Interface Order Code	3401046		
Result Code	Name	LOINC Code	AOE/Prompt
3401029	Screened for Flu A/B?		Yes
3401031	Employed in Farming?		Yes
3401032	Symptomatic?	95419-8	Yes
3401033	Date of symptom onset?	65222-2	Yes
3401042	Specimen Type?	31208-2	Yes
3401036	Pregnant?	82810-3	Yes
3401037	Race?	32624-9	Yes
3401038	Ethnicity?	42784-9	Yes
3401043	Influenza A	88193-8	No
3401044	Influenza H5	38272-1	No



LABORATORY REPORT

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

EXAMPLE, REPORT W
WX0000003827 M 07/08/1968 56 Y

Referral Testing

Collected: 02/18/2025 14:40

Received: 02/18/2025 14:40

Test Name	Result	Flag	Ref-Ranges	Units	Site
Influenza A (H5) Virus RNA, Qual Real-Time PCR, Conjunctiva					
Screened for Flu A/B?	Yes				QCRL
Employed in Farming?	No				QCRL
Symptomatic?	No				QCRL
Date of symptom onset?	2/10/2025				QCRL
Specimen Type?	Swab				QCRL
Pregnant?	No				QCRL
Race?	Unknown				QCRL
Ethnicity?	Unknown				QCRL
Influenza A	NOT DETECTED				QCRL
Influenza H5	NOT DETECTED				QCRL

Influenza A virus was not detected in this specimen.

Results are valid due to detection of RNase P, indicating sufficient patient sampling. This test does not detect Influenza B or other respiratory viruses. Consider additional testing if clinically indicated.

REFERENCE RANGE: NOT DETECTED

This test is an Immediate Response test and can only be ordered by a licensed healthcare professional (for prescription use only). This test has not been reviewed or authorized by FDA. It was developed and its analytical performance characteristics determined by Quest Diagnostics pursuant to CLIA regulations for clinical purposes.

For additional information, please refer to:
<https://www.questdiagnostics.com/healthcare-professionals/clinical-education-center/faq/faq315>
(This link is being provided for informational/educational purposes only.)

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

Reported Date: 02/18/2025 14:40 IAH5C

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

H018000008
WX0000003827
Printed D&T: 02/18/25 14:41

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002516

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

Effective Date	3/25/2025
Name	Influenza A (H5) Virus RNA, Qual Real-time PCR, Respiratory
Code	IAH5R
CPT Code(s)	87502
Notes	New York DOH Approval Status: No

Specimen Requirements

Specimen Required	<p><i>Collect:</i> Nasopharyngeal, anterior nares, or oropharyngeal swab</p> <p><i>Specimen Preparation:</i> Send a nasopharyngeal, anterior nares, or oropharyngeal swab in a VCM (green cap), or equivalent Universal Transport Media (UTM) tube.</p> <p><i>Minimum Volume:</i> 1 swab or 1.0 mL</p> <p><i>Transport Temperature:</i> Refrigerated (cold packs)</p>
Alternate Specimen	1 mL bronchial alveolar lavage (BAL)/wash collected in a sterile leak-proof container
Rejection Criteria	Tubes containing guanidinium isothiocyanate (GITC), Calcium alginate swabs, Cotton swabs with wooden shaft, Amies liquid or gel transport used for bacterial cultures, Tubes with clot activator, Glass tubes, Snap-cap tubes, 3D printed swabs
Stability	<p>Room temperature: 48 hours</p> <p>Refrigerated: 14 days</p> <p>Frozen: 30 days</p>

Performing Information

Methodology	Real-Time Polymerase Chain Reaction (PCR)
Reference Range	<p>Influenza A Not detected</p> <p>Influenza H5 Not detected</p>
Performed Days	Sunday - Saturday
Turnaround Time	5 - 6 days
Performing Laboratory	Quest

Interface Information

Legacy Code	IAH5R		
Interface Order Code	3401028		
Result Code	Name	LOINC Code	AOE/Prompt
3401029	Screened for Flu A/B?		Yes
3401031	Employed in Farming?		Yes
3401032	Symptomatic?	95419-8	Yes
3401033	Date of symptom onset?	65222-2	Yes
3401034	Specimen Type?	31208-2	Yes
3401036	Pregnant?	82810-3	Yes
3401037	Race?	32624-9	Yes
3401038	Ethnicity?	42784-9	Yes
3401039	Influenza A	92142-9	No
3401041	Influenza H5	38272-1	No



LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

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

Referral Testing

Collected: 02/18/2025 14:44 Received: 02/18/2025 14:44

Test Name	Result	Flag	Ref-Ranges	Units	Site
Influenza A (H5) Virus RNA, Qual Real-Time PCR, Respiratory					
Screened for Flu A/B?	Yes				QCRL
Employed in Farming?	Yes				QCRL
Symptomatic?	Yes				QCRL
Date of symptom onset?	2/15/2025				QCRL
Specimen Type?	Swab				QCRL
Pregnant?	No				QCRL
Race?	Unknown				QCRL
Ethnicity?	Unknown				QCRL
Influenza A	DETECTED	AB			QCRL
Influenza H5	DETECTED	AB			QCRL

Influenza A(H5) virus was detected.

Refer to the CDC for current patient management guidance at:
<https://www.cdc.gov/bird-flu/hcp/clinicians-evaluating-patients>

REFERENCE RANGE: NOT DETECTED

This test is an Immediate Response test and can only be ordered by a licensed healthcare professional (for prescription use only). This test has not been reviewed or authorized by FDA. It was developed and its analytical performance characteristics determined by Quest Diagnostics pursuant to CLIA regulations for clinical purposes.

For additional information, please refer to:
<https://www.questdiagnostics.com/healthcare-professionals/clinical-education-center/faq/faq315>
(This link is being provided for informational/educational purposes only.)

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

Reported Date: 02/18/2025 14:45 IAH5R

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

H018000009
WX0000003826

Printed D&T: 02/18/25 14:45

Ordered By: KAJAL SITWALA, MD, PHD
WX000000000002353

Kajal V. Sitwala, MD, PhD - Medical Director

Form: MM RL1

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Update Existing Test

Effective Date	3/11/2025
Name	Alpha-1 Antitrypsin Phenotype
Code	A1AP
Interface Order Code	3000360
Legacy Code	ALPHA1P
Notes	Update to LOINC code.

Required Testing Changes

Result Code	Name	LOINC Code	AOE/Prompt
3000380	Alpha-1 Antitrypsin	1825-9	No
3000385	Phenotype	6770-2	No
3000390	Interpretation	32769-2	No

Update Existing Test

Effective Date	3/24/2025
Name	Alpha-globin Gene Del or Dup
Code	AGDEL
Interface Order Code	3426420
Legacy Code	AGDELDUP
Notes	Update to CPT codes, New York approval, specimen requirements, rejection criteria, stability, reference range, and turnaround time.

Required Testing Changes

CPT Code(s)	81269, add 88235 if testing is performed on amniotic fluid or chorionic villi at additional charge
New York Approval	New York DOH Approval Status: Yes
Specimen Required	<p>Patient Preparation: This test requires a physician attestation form that patient consent has been received if the ordering medical facility is located in AK, DE, FL, GA, IA, MA, MN, NV, NJ, NY OR, SD or VT or test is performed in MA.</p> <p>Specimen Preparation: Send 5.0 mL whole blood in a screw capped plastic vial.</p> <p>Minimum Volume: Whole Blood: 3.0 mL, Amniotic fluid: 10.0 mL, Chorionic villi: 10.0 mg</p>
Rejection Criteria	Sample received frozen, Sample received refrigerated, Plasma
Stability	<p>Whole Blood: Room temperature: 30 days Refrigerated: 30 days Frozen: 30 days</p> <p>Amniotic fluid, chorionic villi, cultured cells: Room temperature: 48 hours Refrigerated: Unacceptable Frozen: Unacceptable</p>
Reference Range	See report
Turnaround Time	16 - 23 days

Update Existing Test

Effective Date	3/4/2025
Name	Blood Culture, Acid-Fast Bacillus (AFB)
Code	BCAF
Interface Order Code	3618400
Legacy Code	BACF
Notes	Update to alternate specimen.

Required Testing Changes

Alternate Specimen	Bone marrow: 5 mL Bactec® Myco/F Lytic bottle or 7 mL Yellow (SPS) tube Whole blood: 7 mL Yellow (SPS) tube
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Update Existing Test

Effective Date	2/21/2025
Name	Clin Urine Drug Abuse Scrn 8C w/Confirm
Code	CD08C
Interface Order Code	1845210
Legacy Code	CD08C
Notes	Update to turnaround time.

Required Testing Changes

Turnaround Time	2 - 5 days
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Update Existing Test

Effective Date	2/21/2025
Name	Clin Urine Drug Abuse Scrn 10C w/Confirm
Code	CD10C
Interface Order Code	1845250
Legacy Code	CD10C
Notes	Update to turnaround time.

Required Testing Changes

Turnaround Time	2 - 5 days
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Update Existing Test

Effective Date	2/21/2025
Name	Clin Urine Drug Abuse Scrn 10C w/Confirm
Code	CT10C
Interface Order Code	1836740
Legacy Code	UDC10C
Notes	Update to turnaround time.

Required Testing Changes

Turnaround Time	2 - 5 days
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Update Existing Test

Effective Date	3/24/2025
Name	Familial Medit Fever Mutation
Code	FAMED
Interface Order Code	3721060
Legacy Code	FAMMEDGSP
Notes	Update to CPT codes, specimen requirements, alternate specimen, rejection criteria, and stability.

Required Testing Changes

CPT Code(s)	81402, add 88235 if testing is performed on amniotic fluid or chorionic villi at additional charge
Specimen Required	<p><i>Collect:</i> Lavender EDTA</p> <p><i>Specimen Preparation:</i> Send 5.0 mL whole blood in a screw capped plastic vial.</p> <p><i>Minimum Volume:</i> Whole blood: 3.0 mL; Amniotic Fluid: 10.0 mL; Chorionic Villi: 10.0 mg;</p> <p><i>Cultured cells:</i> 75% confluent</p> <p><i>Transport Temperature:</i> Room temperature</p>
Alternate Specimen	Whole blood: Yellow ACD, amniotic fluid, chorionic villi in a sterile leak-proof container, cultured cells collected in each of two sterile T-25 flask.
Rejection Criteria	Refrigerated specimens, frozen specimens
Stability	<p>Whole blood:</p> <p>Room temperature: 8 days</p> <p>Refrigerated: 8 days</p> <p>Frozen: Unacceptable</p> <p>Amniotic Fluid, Cultured cells, Chorionic villi:</p> <p>Room temperature: 48 hours</p> <p>Refrigerated: Unacceptable</p> <p>Frozen: Unacceptable</p>

Update Existing Test

Effective Date	3/24/2025
Name	Gaucher Disease, Mutation Analysis
Code	GAUCH
Interface Order Code	3515000
Legacy Code	GAUCHER
Notes	Update to CPT codes, specimen requirements, alternate specimen, stability, and methodology.
Required Testing Changes	
CPT Code(s)	81251, add 88235 if testing is performed on amniotic fluid or chorionic villi at additional charge
Specimen Required	<p>Specimen Information: The following germline genetic tests from Quest require physician attestation that patient consent has been received if ordering medical facility is located in AK, DE, FL, GA, IA, MA, MN, NV, NJ, NY, OR, SD or VT or test is performed in MA.</p> <p>Specimen Preparation: Send 4.0 mL whole blood in a screw capped plastic vial.</p> <p>Minimum Volume: Whole blood and Bone marrow: 3.0 mL, Amniotic fluid: 10.0 mL, Cultured cells: 75% confluent filled with culture media, Chorionic villi: 10.0 mg</p>
Alternate Specimen	<p>Whole Blood: ACD yellow top tube, royal blue top, sodium or lithium heparin green tube.</p> <p>Amniotic fluid collected in a sterile plastic leak-proof container, chorionic villi collected in a sterile tube filled with sterile culture media, cultured cells in each of two sterile T-25 flask.</p>
Stability	<p>Whole blood or bone marrow: Room temperature: 8 days Refrigerated: 8 days Frozen: Unacceptable</p> <p>Amniotic fluid, cultured cells, chorionic villi: Room temperature: 48 hours Refrigerated: Unacceptable Frozen: Unacceptable</p>
Methodology	Polymerase Chain Reaction (PCR), Next Generation Sequencing

Update Existing Test

Effective Date	2/21/2025
Name	Drug Abuse Screen, Meconium 7
Code	MECO7
Interface Order Code	1841040
Legacy Code	MEC7A
Notes	Update to turnaround time.
Required Testing Changes	
Turnaround Time	2 - 6 days

Update Existing Test

Effective Date	3/17/2025
Name	Mycoplasma genitalium, rRNA, TMA
Code	MGENR
Interface Order Code	3400808
Legacy Code	MGENR
Notes	Update to rejection criteria.

Required Testing Changes

Rejection Criteria	<p>Transport tube with 2 swabs</p> <p>Transport tubes with non-aptima® swabs</p> <p>Swab transport tubes with no swab</p> <p>Swab submitted in non-Aptima® transport containers</p> <p>Urine sample where fluid level is not between the black fill lines</p> <p>Urine submitted in non-Aptima® transport containers</p> <p>Patients less than 15 years of age</p>
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Update Existing Test

Effective Date	2/21/2025
Name	Methylmalonic Acid
Code	MMA01
Interface Order Code	1013000
Legacy Code	MMA
Notes	Update to turnaround time.

Required Testing Changes

Turnaround Time	2 - 4 days
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Update Existing Test

Effective Date	3/17/2025
Name	SureSwab(R), Mycoplasma/Ureaplasma Panel, PCR
Code	MUPCR
Interface Order Code	3400019
Legacy Code	MUPCR
Notes	Update to specimen requirements and rejection criteria.

Required Testing Changes

Specimen Required	<p>Specimen Preparation: Vaginal Swab: Follow instructions in the Aptima® Swab Specimen Collection kit or Multitest Collection kit.</p> <p>Urine: Male urine collected in an Aptima® Urine Specimen Transport tube. Collect a first-catch urine in a urine cup (preservative free). Transfer 2.0 mL of urine to an Aptima® Urine Specimen Transport tube within 24 hours of collection and before being assayed. Fluid levels should be between the black lines on the tube label.</p> <p>Male Urethral swab: Follow instructions in the Aptima® Unisex Swab Specimen Collection kit.</p> <p>Transport Temperature: Room temperature</p>
Rejection Criteria	Urine from a female patient, transport tubes with 2 swabs, transport tubes with non-Aptima® swabs, transport tubes with no swab, swab in non-Aptima® transport tube, urine submitted in non-Aptima® transport containers, urine samples where the fluid level is not between the black lines, patients less than 15 years of age.

Update Existing Test

Effective Date	2/21/2025
Name	Drug Screen, Pain Management Panel
Code	PN03C
Interface Order Code	1845280
Legacy Code	PN03C
Notes	Update to turnaround time.

Required Testing Changes

Turnaround Time	2 - 6 days
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Update Existing Test

Effective Date	3/4/2025
Name	Sex Hormone Binding Globulin
Code	SBG
Interface Order Code	3000391
Legacy Code	SBG
Notes	Update to New York approval and reference range.

Required Testing Changes

New York Approval	New York DOH Approval Status: Yes
Reference Range	<p>Female:</p> <p>20-46 years of age, non pregnant 18-136 nmol/L</p> <p>47-91 years of age, post menopausal 17-125 nmol/L</p> <p>Reference ranges are not available for females under the age of 20 years or over the age of 91 years.</p> <p>Male:</p> <p>>=20 years of age 13-90 nmol/L</p> <p>Reference ranges are not available for males under the age of 20 years.</p>

Update Existing Test

Effective Date	3/25/2025
Name	Somatostatin
Code	SOMAT
Interface Order Code	3420920
Legacy Code	SOMATQ
Notes	Update to specimen requirements.

Required Testing Changes

Specimen Required	<p>Collect: Lavender EDTA</p> <p>Specimen Preparation: Draw in a pre-chilled lavender top tube. Separate and freeze immediately. DO NOT THAW.</p> <p>Minimum Volume: 0.6 mL</p> <p>Transport Temperature: Frozen</p>
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Update Existing Test

Effective Date	2/21/2025
Name	Clin Urine Amphetamine Confirm
Code	UCAMP
Interface Order Code	1846150
Legacy Code	UCAMP
Notes	Update to turnaround time.

Required Testing Changes

Turnaround Time	2 - 5 days
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Update Existing Test

Effective Date	2/21/2025
Name	Catecholamines, Fractionated, Urine - 24 hour
Code	UCATE
Interface Order Code	1006955
Legacy Code	UCATE
Notes	Update to performed days and turnaround time.
Required Testing Changes	
Performed Days	Monday, Wednesday, Friday
Turnaround Time	2 - 5 days

Update Existing Test

Effective Date	2/21/2025
Name	Catecholamines, Urine, Random
Code	UCATR
Interface Order Code	1013200
Legacy Code	UCATR
Notes	Update to performed days and turnaround time.
Required Testing Changes	
Performed Days	Monday, Wednesday, Friday
Turnaround Time	2 - 5 days

Update Existing Test

Effective Date	2/21/2025
Name	Clin Urine Benzodiazepine Confirm
Code	UCBEN
Interface Order Code	1846800
Legacy Code	UCBEN
Notes	Update to turnaround time.
Required Testing Changes	
Turnaround Time	2 - 5 days

Update Existing Test

Effective Date	2/21/2025
Name	Clin Urine Buprenorphine Confirm
Code	UCBUP
Interface Order Code	1846300
Legacy Code	UCBUP
Notes	Update to turnaround time.
Required Testing Changes	
Turnaround Time	2 - 5 days

Update Existing Test

Effective Date	2/21/2025
Name	Clin Urine Opiate Confirm
Code	UCOPT
Interface Order Code	1847600
Legacy Code	UCOPT
Notes	Update to turnaround time.

Required Testing Changes

Turnaround Time	2 - 4 days
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Update Existing Test

Effective Date	2/21/2025
Name	Clin Urine THC Confirm
Code	UCTHC
Interface Order Code	1848100
Legacy Code	UCTHC
Notes	Update to turnaround time.

Required Testing Changes

Turnaround Time	2 - 5 days
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Update Existing Test

Effective Date	2/21/2025
Name	Drug Screen, Urine Comprehensive
Code	UDS01
Interface Order Code	1820000
Legacy Code	UDS
Notes	Update to turnaround time.

Required Testing Changes

Turnaround Time	2 - 6 days
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Update Existing Test

Effective Date	2/21/2025
Name	EtG Screen w/ EtG/EtS Confirmation
Code	UETG3
Interface Order Code	1825390
Legacy Code	UETG3
Notes	Update to performed days.

Required Testing Changes

Performed Days	Monday, Wednesday, Friday
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Update Existing Test	
Effective Date	2/21/2025
Name	Metanephrines, Fractionated, Urine, 24 hour
Code	UMET
Interface Order Code	1007094
Legacy Code	UMET
Notes	Update to performed days and turnaround time.
Required Testing Changes	
Performed Days	Monday, Wednesday, Friday.
Turnaround Time	2 - 5 days

Update Existing Test	
Effective Date	2/21/2025
Name	Metanephrines,Urine Random
Code	UMETR
Interface Order Code	1013300
Legacy Code	UMETR
Notes	Update to performed days and turnaround time.
Required Testing Changes	
Performed Days	Monday, Wednesday, Friday
Turnaround Time	2 - 5 days

Update Existing Test	
Effective Date	2/21/2025
Name	Vanillylmandelic Acid, Urine, 24 hr
Code	UVMA
Interface Order Code	1007138
Legacy Code	UVMA
Notes	Update to performed days and turnaround time.
Required Testing Changes	
Performed Days	Monday, Wednesday, Friday
Turnaround Time	2 - 5 days

Update Existing Test

Effective Date	2/21/2025
Name	Vanillylmandelic Acid, Urine, Random
Code	UVMAR
Interface Order Code	1013400
Legacy Code	UVMAR
Notes	Update to performed days and turnaround time.

Required Testing Changes

Performed Days	Monday, Wednesday, Friday
Turnaround Time	2 - 5 days

Update Existing Test

Effective Date	3/24/2025
Name	von Willebrand Disease Gene Sequencing
Code	VONWI
Interface Order Code	3400356
Legacy Code	VONWI
Notes	Update to CPT codes, specimen requirements, alternate specimen, rejection criteria, stability, performed days, and turnaround time.

Required Testing Changes

CPT Code(s)	81408, add 88235 if testing is performed on amniotic fluid or chorionic villi at additional charge
Specimen Required	Specimen Information: The following germline genetic tests from Quest require physician attestation that patient consent has been received if ordering medical facility is located in AK, DE, FL, GA, IA, MA, MN, NV, NJ, NY, OR, SD or VT or test is performed in MA. Minimum Volume: Whole blood: 3.0 mL, Amniotic fluid: 10.0 mL, Chorionic villi: 10.0 mg, Cultured cells: 75% confluent
Alternate Specimen	Yellow top (ACD), sodium heparin royal blue top, Sodium heparin green top, amniotic fluid, chorionic villi collected in a sterile leak-proof container, cultured cells collected in each of two sterile T-25 flasks.
Rejection Criteria	Plasma, Refrigerated specimens, Frozen specimens
Stability	Whole blood: Room temperature: 14 days Refrigerated: 14 days Frozen: Unacceptable Amniotic fluid, cultures cells, chorionic villi: Room temperature: 48 hours Refrigerated: Unacceptable Frozen: Unacceptable
Performed Days	Varies
Turnaround Time	30 - 44 days

Inactivate Test With Replacement

Effective Date 3/25/2025

Inactivated Test

Name Chromogranin A

Code CHROA

Legacy Code CHROMAQ

Interface Order Code 3420100

Replacement Test

Name Chromogranin A

Code CGA

CPT Code(s) 86316

Notes New York DOH Approval Status: Yes

Specimen Requirements

Specimen Required

Collect: Red top

Specimen Preparation: Centrifuge, separate and send 1.0 mL serum in a screw capped plastic vial.

Minimum Volume: 0.5 mL

Transport Temperature: Frozen

Alternate Specimen Serum separator tube (SST)

Rejection Criteria Plasma, whole blood

Stability

Room temperature: 48 hours

Refrigerated: 3 days

Frozen: 3 months

Performing Information

Methodology Immunofluorescence assay

Reference Range 0 - 187 ng/mL

Performed Days Tuesday, Friday

Turnaround Time 2 - 6 days

Performing Laboratory Warde Medical Laboratory

Interface Information

Legacy Code CGA

Interface Order Code 3000392

Result Code

Name

LOINC Code

AOE/Prompt

3000393

Chromogranin A

No



LABORATORY REPORT

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

EXAMPLE, REPORT W
WX0000003827 M 07/08/1968 56 Y

Molecular

Collected: 02/05/2025 15:10 Received: 02/05/2025 15:10

<u>Test Name</u>	<u>Result</u>	<u>Flag</u>	<u>Ref-Ranges</u>	<u>Units</u>	<u>Site</u>
Chromogranin A					
Chromogranin A	100		0-187	ng/mL	WMRL

This test is performed using the BRAHMS CGA II Kryptor kit. Results obtained with different methods or kits cannot be used interchangeably. Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease and should be evaluated in combination with clinical symptoms, diagnostic evidence, and/or other laboratory parameters. The change of CGA concentration over time provides diagnostic information whether a tumor progression has occurred.

An increase of CgA serum concentrations of more than 50% to a value of greater than 100ng/mL between consecutive monitoring visits defines a positive test result, representing a higher probability that a tumor progression has occurred.

A change of CgA serum concentrations of equal or less than 50% increase between monitoring visits or to a value of 100 ng/mL or less defines a negative test result, representing a lower probability that a tumor progression has occurred. Nontumor related elevations of Chromogranin A can be observed in gastrointestinal, cardiovascular, and renal disorders, cancers other than neuroendocrine tumors, as well as with proton pump inhibitor (PPI) therapy. It is recommended to stop PPI treatment for at least 14 days prior to testing.

Reported Date: 02/05/2025 15:11 CGA

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

H005000023
WX0000003827

Printed D&T: 02/05/25 15:11

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002516

Kajal V. Sitwala, MD, PhD - Medical Director

Form: MM RL1

PAGE 1 OF 1

Inactivate Test With Replacement

Effective Date 3/25/2025

Inactivated Test

Name NMO/AQP4-IgG FACS, CSF

Code NMOFC

Legacy Code NMOFC

Interface Order Code 3805580

Replacement Test

Name NMO/AQP4 FACS, CSF

Code NMOCS

CPT Code(s) 86053, plus 86053 if reflexed to titer, at additional cost

Notes New York DOH Approval Status: Yes

Specimen Requirements

Specimen Required

Collect: Cerebrospinal fluid (CSF)

Specimen Preparation: Send 3.0 mL CSF in a screw capped plastic vial. Include relevant clinical information and physician name.

Minimum Volume: 2.0 mL

Transport Temperature: Refrigerated

Stability

Room temperature: 72 hours

Refrigerated: 28 days

Frozen: 28 days

Performing Information

Methodology Fluorescence-Activated Cell Sorting Assay (FACS)

Reference Range Negative

Performed Days Monday, Tuesday, Thursday

Turnaround Time 4 - 6 days

Performing Laboratory Mayo Clinic Laboratories

Interface Information

Legacy Code NMOCS

Interface Order Code 3800398

Result Code	Name	LOINC Code	AOE/Prompt
3800399	NMO/AQP4-IgG FACS, CSF	46718-3	No
3800401	NMO/AQP4 FACS Titer, CSF		No



LABORATORY REPORT

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

EXAMPLE, REPORT W
WX0000003827 M 07/08/1968 56 Y

Referral Testing

Collected: 02/18/2025 14:46 Received: 02/18/2025 14:46

<u>Test Name</u>	<u>Result</u>	<u>Flag</u>	<u>Ref-Ranges</u>	<u>Units</u>	<u>Site</u>
NMO/AQP4 FACS, CSF					
NMO/AQP4-IgG FACS, CSF	Negative		Negative		MMRL

Aquaporin-4 antibody testing is more sensitive in serum than in spinal fluid. Recommend serum testing now if not completed, and repeating in 6 months if clinical suspicion is high. Negative result can occur in the setting of immunosuppression.

-----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 Main Campus
200 First Street SW, Rochester, MN 55905
Lab Director: Nikola A. Baumann Ph.D.; CLIA# 24D0404292

NMO/AQP4 FACS Titer, CSF .TNP MMRL

Reported Date: 02/18/2025 14:46 NMOCS

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

H01800010
WX0000003827

Printed D&T: 02/18/25 14:47

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002516

Kajal V. Sitwala, MD, PhD - Medical Director

Form: MM RL1

PAGE 1 OF 1

Inactivate Test With Replacement

Effective Date 3/25/2025

Inactivated Test

Name NMO/AQP4-IgG FACS, Serum

Code NMOFS

Legacy Code NMOFS

Interface Order Code 3805560

Replacement Test

Name NMO AQP4 FACS, S

Code NMOSE

CPT Code(s) 86053, plus 86053 if reflexed to titer, at additional 86053, plus 86053 if reflexed to titer, at additional cost.

Notes New York DOH Approval Status: Yes

Specimen Requirements

Specimen Required
Collect: Red top
Specimen Preparation: Centrifuge, remove serum from cells and send 3.0 mL serum in a screw capped plastic vial.
Minimum Volume: 2.0 mL
Transport Temperature: Refrigerated

Alternate Specimen Serum: Serum separator tube

Stability
Room temperature: 72 hours
Refrigerated: 28 days
Frozen: 28 days

Performing Information

Methodology Fluorescence-Activated Cell Sorting Assay (FACS)

Reference Range Negative

Performed Days Monday, Tuesday, Thursday

Turnaround Time 5 - 8 days

Performing Laboratory Mayo Clinic Laboratories

Interface Information

Legacy Code NMOSE

Interface Order Code 3800394

Result Code	Name	LOINC Code	AOE/Prompt
3800396	NMO/AQP4 FACS, S	43638-6	No
3800397	NMO/AQP4 FACS Titer, S	86241-7	No



LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W

WX0000003826 F 12/05/1988 36 Y

Referral Testing

Collected: 02/18/2025 14:47

Received: 02/18/2025 14:47

Test Name	Result	Flag	Ref-Ranges	Units	Site
NMO AQP4 FACS, S					
NMO/AQP4 FACS, S	Reactive	AB	Negative		MMRL

Screen Reactive, see confirmatory test results.

-----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 Main Campus
200 First Street SW, Rochester, MN 55905
Lab Director: Nikola A. Baumann Ph.D.; CLIA# 24D0404292

NMO/AQP4 FACS Titer, S	Positive 1:10	H	<1:5	titer	MMRL
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This autoantibody supports the diagnosis of neuromyelitis optica or a neuromyelitis optica spectrum disorder. Neurological accompaniments include optic neuritis, myelitis and encephalitis. Seropositivity predicts high risk for relapse.

-----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 Main Campus
200 First Street SW, Rochester, MN 55905
Lab Director: Nikola A. Baumann Ph.D.; CLIA# 24D0404292

Reported Date: 02/18/2025 14:47 NMOSE

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

H018000011
WX0000003826
Printed D&T: 02/18/25 14:48

Ordered By: KAJAL SITWALA, MD, PHD
WX000000000002353

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1
PAGE 1 OF 1