

Update Summary		
<b>New Test Activation</b>	2/11/2025	<a href="#">QHV6P - "HHV-6 A and B DNA Quant PCR, P"</a>
<b>Update Existing Test</b>	2/10/2025	<a href="#">ABLKD - " ABL Kinase Domain Mutation"</a>
<b>Update Existing Test</b>	2/4/2025	<a href="#">AERI - "Aerobic Organism ID"</a>
<b>Update Existing Test</b>	2/4/2025	<a href="#">ALZE - "ADmark (R) Phospho-Tau/Total-Tau A Beta42 CSF"</a>
<b>Update Existing Test</b>	2/4/2025	<a href="#">C5F - "C5 Complement, Functional"</a>
<b>Update Existing Test</b>	2/4/2025	<a href="#">C6 - "C6 Complement, Functional, Serum"</a>
<b>Update Existing Test</b>	2/4/2025	<a href="#">C7FX - "C7 Complement, Functional, Serum"</a>
<b>Update Existing Test</b>	2/4/2025	<a href="#">C8FX - "C8 Complement, Functional, Serum"</a>
<b>Update Existing Test</b>	2/4/2025	<a href="#">C9FX - "C9 Complement, Functional, Serum"</a>
<b>Update Existing Test</b>	2/4/2025	<a href="#">CSFPD - "14-3-3 Protein, CSF (Prion Disease)"</a>
<b>Update Existing Test</b>	2/4/2025	<a href="#">IL28B - "Interleukin 28B (IL28B) Variant (rs12979860), Varies"</a>
<b>Update Existing Test</b>	2/4/2025	<a href="#">MICBO - "MIC Panel, Anaerobic"</a>
<b>Update Existing Test</b>	2/4/2025	<a href="#">MIFC - "Antimicrobial Susceptibility Fungi"</a>
<b>Update Existing Test</b>	2/4/2025	<a href="#">PN14S - "Pneumococcal Antibody Panel (14 Serotype)"</a>
<b>Update Existing Test</b>	2/4/2025	<a href="#">PN23M - "Strep pneumoniae IgG Abs, 23 Serotypes, Ser"</a>
<b>Update Existing Test</b>	2/4/2025	<a href="#">PNP - "Pneumocystis jirovecii, Qualitative Real-Time PCR"</a>
<b>Inactivate Test With Replacement</b>	2/11/2025	<a href="#">CTX - "Collagen Type 1, C-Telopeptide (CTx)"</a> replaced by <a href="#">BCTX - "Collagen Type 1, C-Telopeptide (CTx)"</a>
<b>Inactivate Test With Replacement</b>	2/11/2025	<a href="#">SHBG - "Sex Hormone Binding Globulin"</a> replaced by <a href="#">SBG - "Sex Hormone Binding Globulin"</a>
<b>Inactivate Test With Replacement</b>	2/24/2025	<a href="#">SPABM - "Susceptability Panel, Anaerobic Bacteria, MIC (Gradient)"</a> replaced by <a href="#">APABM - "Antimicrobial Susceptibility Panel, Anaerobic Bacteria, MIC"</a>
<b>Inactivate Test With Replacement</b>	2/11/2025	<a href="#">STRAT - "Stratify JCV Ab (w/Index) w/Ref to Inhib Assay"</a> replaced by <a href="#">STRAB - "Stratify JCV Ab (w/Index) w/Ref to Inhib Assay"</a>

New Test Activation			
<b>Effective Date</b>	2/11/2025		
<b>Name</b>	HHV-6 A and B DNA Quant PCR, P		
<b>Code</b>	QHV6P		
<b>CPT Code(s)</b>	87533		
<b>Notes</b>	New York DOH Approval Status: Yes		
Specimen Requirements			
<b>Specimen Required</b>	<i>Collect:</i> Lavender EDTA <i>Specimen Preparation:</i> Centrifuge, separate plasma from cells and send 1.0 mL plasma in a screw capped plastic vial. <i>Minimum Volume:</i> 0.3 mL <i>Transport Temperature:</i> Refrigerated		
<b>Rejection Criteria</b>	Gross hemolysis, gross lipemia, Heparin		
<b>Stability</b>	Room temperature: 24 hours Refrigerated: 7 days Frozen: 7 days		
Performing Information			
<b>Methodology</b>	Real-Time Polymerase Chain Reaction (PCR)		
<b>Reference Range</b>	Undetected		
<b>Performed Days</b>	Monday - Friday		
<b>Turnaround Time</b>	6 - 8 days		
<b>Performing Laboratory</b>	Mayo Clinic Laboratories		
Interface Information			
<b>Legacy Code</b>	QHV6P		
<b>Interface Order Code</b>	3800391		
Result Code	Name	LOINC Code	AOE/Prompt
3800392	HHV6 A DNA Detect/Quant, P	49392-4	No
3800393	HHV6 B DNA Detect/Quant, P	49392-4	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: 01/10/2025 13:34 Received: 01/10/2025 13:34

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Contains two rows for HHV-6 A and B DNA Quant PCR, P tests, both showing Undetected results.

Result in log copies/mL is Undetected.

Result in log copies/mL is Undetected.

-----ADDITIONAL INFORMATION-----

The quantification range of this assay is 500 to 5,000,000 copies/mL (2.70 log to 6.70 log copies/mL). 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: 01/10/2025 13:35 QHV6P

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

Update Existing Test			
Effective Date	2/10/2025		
Name	ABL Kinase Domain Mutation in CML, Cell-based		
Code	ABLKD		
Interface Order Code	3400350		
Legacy Code	ABLKD		
Notes	Change to test and result component name.		
Required Testing Changes			
Name	ABL Kinase Domain Mutation		
Result Code	Name	LOINC Code	AOE/Prompt
3400351	ABL Mutation	55135-8	No
3400352	ABL Possible Mutations	55135-8	No

Update Existing Test			
Effective Date	2/4/2025		
Name	Aerobic Organism ID		
Code	AERI		
Interface Order Code	3515260		
Legacy Code	AERIDARP		
Notes	Update to CPT code.		
Required Testing Changes			
CPT Code(s)	CPT code and price for identification may vary based upon method.		

Update Existing Test			
Effective Date	2/4/2025		
Name	ADmark (R) Phospho-Tau/Total-Tau A Beta42 CSF		
Code	ALZE		
Interface Order Code	3429300		
Legacy Code	ALZE		
Notes	Update to CPT codes.		
Required Testing Changes			
CPT Code(s)	84393, 82234, 84394		

Update Existing Test	
Effective Date	2/4/2025
Name	C5 Complement, Functional
Code	C5F
Interface Order Code	3804760
Legacy Code	C5FM
Notes	Update to specimen requirements and alternate specimen.
Required Testing Changes	
Specimen Required	<p><i>Patient Preparation:</i> Fasting prior to draw preferred  <b>Collect: Serum Separator Tube (SST)</b>  <i>Specimen Preparation:</i> Place tube on wet ice immediately after collection. Centrifuge, separate serum from clot and send 1.0 mL serum frozen in a screw capped plastic vial.  <i>Minimum Volume:</i> 0.5 mL  <i>Transport Temperature:</i> Frozen</p>
Alternate Specimen	Red top

Update Existing Test	
Effective Date	2/4/2025
Name	C6 Complement, Functional, Serum
Code	C6
Interface Order Code	3501000
Legacy Code	C6
Notes	Update to specimen requirements and alternate specimen.
Required Testing Changes	
Specimen Required	<p><i>Patient Preparation:</i> Fasting prior to draw preferred  <b>Collect: Serum Separator Tube (SST)</b>  <i>Specimen Preparation:</i> Place tube on wet ice immediately after collection. Centrifuge, separate serum from clot and send 1.0 mL serum frozen in a screw capped plastic vial.  <i>Minimum Volume:</i> 0.5 mL  <i>Transport Temperature:</i> Frozen</p>
Alternate Specimen	Red top

## Update Existing Test

<b>Effective Date</b>	2/4/2025
<b>Name</b>	C7 Complement, Functional, Serum
<b>Code</b>	C7FX
<b>Interface Order Code</b>	3800334
<b>Legacy Code</b>	C7FX
<b>Notes</b>	Update to specimen requirements and alternate specimen.

## Required Testing Changes

<b>Specimen Required</b>	<p><i>Patient Preparation:</i> Fasting prior to draw preferred  <b>Collect: Serum Separator Tube (SST)</b>  <i>Specimen Preparation:</i> Place tube on wet ice immediately after collection. Centrifuge, separate serum from clot and send 1.0 mL serum frozen in a screw capped plastic vial.  <i>Minimum Volume:</i> 0.5 mL  <i>Transport Temperature:</i> Frozen</p>
<b>Alternate Specimen</b>	<b>Red top</b>

## Update Existing Test

<b>Effective Date</b>	2/4/2025
<b>Name</b>	C8 Complement, Functional, Serum
<b>Code</b>	C8FX
<b>Interface Order Code</b>	3800336
<b>Legacy Code</b>	C8FX
<b>Notes</b>	Update to specimen requirements and alternate specimen.

## Required Testing Changes

<b>Specimen Required</b>	<p><i>Patient Preparation:</i> Fasting prior to draw preferred  <b>Collect: Serum Separator Tube (SST)</b>  <i>Specimen Preparation:</i> Place tube on wet ice immediately after collection. Centrifuge, separate serum from clot and send 1.0 mL serum frozen in a screw capped plastic vial. CRITICAL FROZEN.  <i>Minimum Volume:</i> 0.5 mL  <i>Transport Temperature:</i> CRITICAL FROZEN</p>
<b>Alternate Specimen</b>	<b>Red top</b>

Update Existing Test	
Effective Date	2/4/2025
Name	C9 Complement, Functional, Serum
Code	C9FX
Interface Order Code	3800337
Legacy Code	C9FX
Notes	Update to specimen requirements and alternate specimen.
Required Testing Changes	
Specimen Required	<p><i>Patient Preparation:</i> Fasting prior to draw preferred  <b>Collect: Serum Separator Tube (SST)</b>  <i>Specimen Preparation:</i> Place tube on wet ice immediately after collection. Centrifuge, separate serum from clot and send 1.0 mL serum in a screw capped plastic vial. CRITICAL FROZEN.  <i>Minimum Volume:</i> 0.5 mL  <i>Transport Temperature:</i> CRITICAL FROZEN</p>
Alternate Specimen	Red top

Update Existing Test	
Effective Date	2/4/2025
Name	14-3-3 Protein, CSF (Prion Disease)
Code	CSFPD
Interface Order Code	3700116
Legacy Code	CSFPD
Notes	Update to CPT codes.
Required Testing Changes	
CPT Code(s)	83520, 84394, 0035U

Update Existing Test	
Effective Date	2/4/2025
Name	Interleukin 28B (IL28B) Variant (rs12979860), Varies
Code	IL28B
Interface Order Code	3514950
Legacy Code	IL28BP
Notes	Update to specimen requirements and stability.
Required Testing Changes	
Specimen Required	<p><b>Patient Preparation:</b> If using saliva sample, patient should not eat, drink, smoke, or chew gum for 30 minutes prior to collection. <b>A previous bone marrow transplant from an allogenic donor will interfere with testing.</b></p> <p><b>Specimen Preparation:</b> Invert tube several times to mix blood and send 3.0 mL whole blood in original collection tube. <b>Do not aliquot.</b></p> <p><b>Minimum Volume:</b>  <b>Whole blood: 3.0 mL</b>            Saliva: 1 swab  <b>Extracted DNA: 100 mcl at a concentration of 75 ng/mcl</b>  <i>Transport Temperature:</i> Room temperature</p>
Stability	<p><b>Whole blood:</b>            Room temperature: 4 days            Refrigerated: 4 days            Frozen: 4 days</p> <p><b>Saliva:</b>            Room temperature: 30 days            Refrigerated: 30 days            Frozen: Unacceptable</p> <p><b>Extracted DNA:</b>            Room temperature: 1 year            Refrigerated: 1 year            Frozen: 1 year</p>

Update Existing Test	
Effective Date	2/4/2025
Name	MIC Panel, Anaerobic
Code	MICBO
Interface Order Code	3505020
Legacy Code	MIC BIO PN
Notes	Update to CPT code.
Required Testing Changes	
CPT Code(s)	CPT codes for susceptibility vary based on method.



<b>Update Existing Test</b>	
Effective Date	2/4/2025
Name	Antimicrobial Susceptibility Fungi
Code	MICF
Interface Order Code	3514770
Legacy Code	MICF
Notes	Update to CPT code.
<b>Required Testing Changes</b>	
CPT Code(s)	CPT codes for susceptibility vary based on method.

<b>Update Existing Test</b>	
Effective Date	2/4/2025
Name	Pneumococcal Antibody Panel (14 Serotype)
Code	PN14S
Interface Order Code	3300348
Legacy Code	PN14S
Notes	Update to CPT code.
<b>Required Testing Changes</b>	
CPT Code(s)	86581

<b>Update Existing Test</b>	
Effective Date	2/4/2025
Name	Strep pneumoniae IgG Abs, 23 Serotypes, Ser
Code	PN23M
Interface Order Code	3800302
Legacy Code	PN23M
Notes	Update to CPT code.
<b>Required Testing Changes</b>	
CPT Code(s)	86581

<b>Update Existing Test</b>	
Effective Date	2/4/2025
Name	Pneumocystis jirovecii, Qualitative Real-Time PCR
Code	PNP
Interface Order Code	3426380
Legacy Code	PNEUMOPCR
Notes	Update to CPT code.
<b>Required Testing Changes</b>	
CPT Code(s)	87594



<b>Turnaround Time</b>	1 - 4 days		
<b>Performing Laboratory</b>	Warde Medical Laboratory		
<b>Interface Information</b>			
<b>Legacy Code</b>	BCTX		
<b>Interface Order Code</b>	3000907		
<b>Result Code</b>	<b>Name</b>	<b>LOINC Code</b>	<b>AOE/Prompt</b>
3000907	Collagen Type 1, C-Telopeptide (CTx)	41171-0	No



# LABORATORY REPORT

Example Client, XYZ123  
1234 Warde Road  
Ann Arbor MI 48108

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

## Immunochemistry

Collected: 01/15/2025 08:18 Received: 01/15/2025 08:18

<u>Test Name</u>	<u>Result</u>	<u>Flag</u>	<u>Ref-Ranges</u>	<u>Units</u>	<u>Site</u>
Collagen Type 1, C-Telopeptide (CTx)	458			pg/mL	WMRL

Reference Range for Females  
 Premenopausal 121-747 pg/mL  
 Postmenopausal 189-1003 pg/mL

The assay and reference ranges were updated by the manufacturer, with new methodology effective February 11, 2025. Providers should consider this when comparing measurements before and after February 11, 2025 in the same patient.

**Reported Date:** 01/15/2025 08:18 BCTX

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

G915000000 Ordered By: KAJAL SITWALA, MD, PHD  
WX0000003826 WX00000000002353  
Printed D&T: 01/15/25 08:18

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

Inactivate Test With Replacement			
<b>Effective Date</b>	2/11/2025		
Inactivated Test			
<b>Name</b>	Sex Hormone Binding Globulin		
<b>Code</b>	SHBG		
<b>Legacy Code</b>	SHBG		
<b>Interface Order Code</b>	1013500		
Replacement Test			
<b>Name</b>	Sex Hormone Binding Globulin		
<b>Code</b>	SBG		
<b>CPT Code(s)</b>	84270		
<b>Notes</b>	New York DOH Approval Status: No		
Specimen Requirements			
<b>Specimen Required</b>	<i>Collect:</i> Red top <i>Specimen Preparation:</i> Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial. <i>Minimum Volume:</i> 0.5 mL <i>Transport Temperature:</i> Refrigerated		
<b>Alternate Specimen</b>	Serum separator tube (SST)		
<b>Rejection Criteria</b>	Plasma, hemolysis, lipemia, and exceed stability.		
<b>Stability</b>	Room temperature: 8 hours Refrigerated: 7 days Frozen: 2 months		
Performing Information			
<b>Methodology</b>	Chemiluminescence		
<b>Reference Range</b>	Female: 20-46 years of age, non pregnant      18-136      nmol/L 47-91 years of age, post menopausal    17-125      nmol/L Reference ranges are not available for females under the age of 20 years or over the age of 91 years.  Male: ≥20 years of age                              13-90      nmol/L Reference ranges are not available for males under the age of 20 years.		
<b>Performed Days</b>	Monday - Friday		
<b>Turnaround Time</b>	1 - 4 days		
<b>Performing Laboratory</b>	Warde Medical Laboratory		
Interface Information			
<b>Legacy Code</b>	SBG		
<b>Interface Order Code</b>	3000391		
<b>Result Code</b>	<b>Name</b>	<b>LOINC Code</b>	<b>AOE/Prompt</b>
3000391	Sex Hormone Binding Globulin	13967-5	No



# LABORATORY REPORT

Example Client, XYZ123  
1234 Warde Road  
Ann Arbor MI 48108

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

## Immunochemistry

Collected: 01/15/2025 08:19 Received: 01/15/2025 08:19

<u>Test Name</u>	<u>Result</u>	<u>Flag</u>	<u>Ref-Ranges</u>	<u>Units</u>	<u>Site</u>
Sex Hormone Binding Globulin	50			nmol/L	WMRL

Female:

20-46 years of age, non pregnant 18-136 nmol/L

47-91 years of age, post menopausal 17-125 nmol/L

Reference ranges are not available for females under the age of 20 years or over the age of 91 years.

**Reported Date:** 01/15/2025 08:20 SBG

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

G91500001  
WX0000003826

Ordered By: KAJAL SITWALA, MD, PHD  
WX00000000002353

Printed D&T: 01/15/25 08:20

Kajal V. Sitwala, MD, PhD - Medical Director

Form: MM RL1

PAGE 1 OF 1

Inactivate Test With Replacement			
<b>Effective Date</b>	2/24/2025		
Inactivated Test			
<b>Name</b>	Susceptability Panel, Anaerobic Bacteria, MIC (Gradient)		
<b>Code</b>	SPABM		
<b>Legacy Code</b>	SPABM		
<b>Interface Order Code</b>	3400094		
Replacement Test			
<b>Name</b>	Antimicrobial Susceptibility Panel, Anaerobic Bacteria, MIC		
<b>Code</b>	APABM		
<b>CPT Code(s)</b>	87181 per antibiotic tested		
<b>Notes</b>	New York DOH Approval Status: Yes		
Specimen Requirements			
<b>Specimen Required</b>	<p><i>Collect:</i> Pure culture  <i>Specimen Preparation:</i> Send pure culture of anaerobic isolate refrigerated. Collect specimens using an Amies gel transport swab, Amies liquid elution swab (Eswab) or equivalent. Number of antibiotics tested is dependent on organism ID.  <i>Transport Temperature:</i> Refrigerated</p>		
<b>Rejection Criteria</b>	Isolate in Thioglycollate broth, aerobic slant, plate or swab, frozen isolates (unless $\leq 70^{\circ}\text{C}$ in glycerol broth)		
<b>Stability</b>	<p>Room temperature: Determined by viability            Refrigerated: Determined by viability            Frozen: Unacceptable</p>		
Performing Information			
<b>Methodology</b>	Gradient Diffusion		
<b>Reference Range</b>	See report		
<b>Performed Days</b>	Sunday - Saturday		
<b>Turnaround Time</b>	6 - 7 days		
<b>Performing Laboratory</b>	Quest		
Interface Information			
<b>Legacy Code</b>	APABM		
<b>Interface Order Code</b>	3400982		
Result Code	Name	LOINC Code	AOE/Prompt
3400981	Source		Yes
3400134	Organism	42803-7	Yes
3400148	Ampicillin/Sulbactam	18865-6	No
3400149	Clindamycin	193-3	No
3400156	Imipenem	279-0	No
3400157	Meropenem	6652-2	No
3400158	Metronidazole	327-7	No
3400159	Penicillin	6932-8	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: 01/10/2025 13:28 Received: 01/10/2025 13:28

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Contains data for Antimicrobial Susceptibility Panel, Anaerobic Bacteria, MIC including Source (SWAB), Organism (FUSOBACTERIUM NUCLEATUM), and various antibiotic MIC values.

MIC values are expressed in mcg/mL

S=Susceptible, I=Intermediate, R=Resistant

All breakpoints are based on FDA or CLSI guidelines. Only the MIC value is reported when FDA or CLSI guideline is not available.

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway

Reported Date: 01/10/2025 13:30 APABM

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

G91000004
WX0000003827

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002516

Printed D&T: 01/10/25 13:30

Kajal V. Sitwala, MD, PhD - Medical Director

Form: MM RL1

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Inactivate Test With Replacement			
<b>Effective Date</b>	2/11/2025		
Inactivated Test			
<b>Name</b>	Stratify JCV Ab (w/Index) w/Ref to Inhib Assay		
<b>Code</b>	STRAT		
<b>Legacy Code</b>	STRAT		
<b>Interface Order Code</b>	3400812		
Replacement Test			
<b>Name</b>	Stratify JCV Ab (w/Index) w/Ref to Inhib Assay		
<b>Code</b>	STRAB		
<b>CPT Code(s)</b>	86711		
<b>Notes</b>	New York DOH Approval Status: Yes		
Specimen Requirements			
<b>Specimen Required</b>	<i>Collect:</i> Serum Separator Tube (SST) <i>Specimen Preparation:</i> Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial. <i>Minimum Volume:</i> 0.5 mL <i>Transport Temperature:</i> Refrigerated		
<b>Alternate Specimen</b>	Plasma: Lavender EDTA		
<b>Rejection Criteria</b>	Gross hemolysis, Grossly lipemic, Grossly icteric		
<b>Stability</b>	Room temperature: 7 days Refrigerated: 14 days Frozen: 90 days		
Performing Information			
<b>Methodology</b>	Immunoassay		
<b>Reference Range</b>	Negative		
<b>Performed Days</b>	Monday - Saturday		
<b>Turnaround Time</b>	4 - 8 days		
<b>Performing Laboratory</b>	Quest		
Interface Information			
<b>Legacy Code</b>	STRAB		
<b>Interface Order Code</b>	3400974		
Result Code	Name	LOINC Code	AOE/Prompt
3400976	Natalizumab Therapy?		Yes
3400813	Index Value	100977-8	No
3400814	JCV Antibody	70173-0	No
3400828	Stratify JCV Antibody Inhibition Assay	70173-0	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: 01/10/2025 13:36 Received: 01/10/2025 13:36

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: Stratify JCV Ab (w/Index) w/Ref to Inhib Assay. Row 2: Natalizumab Therapy? Yes. Row 3: Index Value 0.15. Row 4: JCV Antibody NEGATIVE.

Index interpretive criteria:
<0.20 negative
0.20-0.40 indeterminate
>0.40 positive

INTERPRETATION
Negative: Antibodies to JCV not detected.

Indeterminate: Low level reactivity detected, see
Inhibition Assay result below for the final
antibody result.

Positive: Antibodies to JC virus (JCV) detected
indicating the patient has been exposed to JCV at
an undetermined time.

The STRATIFY JCV(R) DxSelect(TM) Antibody Test is
an enzyme-linked immunosorbent assay (ELISA)
designed to detect JCV antibodies to help identify
individuals who have been exposed to the virus.
Samples with low level reactivity in the detection
assay are retested in a confirmation (inhibition)
assay to confirm presence or absence of JCV-specific
antibodies.

Retrospective analyses of post marketing data from
various sources, including observational studies and
spontaneous reports obtained worldwide, suggest that
the risk of developing PML may be associated with
relative levels of serum anti-JCV antibody as measured
by anti-JCV antibody index.(1)

(1) TYSABRI(natalizumab)US Prescribing Information
Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD

Stratify JCV Antibody Inhibition Assay

QCRL

Reported Date: 01/10/2025 13:36 STRAB

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

G91000007
WX0000003827
Printed D&T: 01/10/25 13:37

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002516

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1
PAGE 1 OF 2



## LABORATORY REPORT

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

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

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

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

G91000007  
WX0000003827

Ordered By: KAJAL SITWALA, MD, PHD  
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