Warde Medical Laboratory

TEST DIRECTORY UPDATE

NOVEMBER 2025

Update Summary		
New Test Activation	11/18/2025	B27M - "HLA-B27 Identification by PCR"
Update Existing Test	11/4/2025	COADP - "Complete Atopic Dermatitis Panel"
Update Existing Test	11/4/2025	HMGCR - "HMGCR Antibody IgG"
Update Existing Test	11/4/2025	OBFIT - "Fecal Immunochemical Test for Occult Blood"
Update Existing Test	11/4/2025	PHBF - "pH, Body Fluid"
Update Existing Test	11/4/2025	RUBEM - "Measles (Rubeola) IgM Antibody"
Update Existing Test	11/4/2025	TMSI - "Microsatellite Instability, Tumor"
Update Existing Test	12/1/2025	UPHEP - "Phenol Exposure, Urine"
Inactivate Test With Replacement	11/4/2025	GRAN - "Granulocyte Antibodies, Serum" replaced by GRANS - "Granulocyte Antibody Screen, Serum"
Inactivate Test Without Replacement	11/4/2025	MUMPM - "Mumps Virus Antibody IgM"
Inactivate Test Without Replacement	11/3/2025	UBSP - "Bath Salts Panel (Qualitative), Urine"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

NOVEMBER 2025

New Test Activation

Effective Date	11/18/2025
Name	HLA-B27 Identification by PCR
Code	B27M
CPT Code(s)	81374
Notes	New York DOH Approval Status: No

Specimen Requirements

Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Draw blood in a lavender EDTA. Send 4.0 mL whole blood. *Minimum Volume*: 0.5 mL *Transport Temperature*: Refrigerated
Alternate Specimen	Whole blood: ACD A
Rejection Criteria	Serum, plasma, heparinized whole blood, tissue
Stability	Room temperature: 3 days Refrigerated: 7 days Frozen: 30 days

Performing Information

Methodology	Polymerase Chain Reaction (PCR)
Reference Range	See report
Performed Days	Monday, Thursday
Turnaround Time	3 - 5 days
Performing Laboratory	Warde Medical Laboratory

Interface Information

Legacy Code	B27M
Interface Order Code	3000462

Result Code	Name	LOINC Code	AOE/Prompt
3000463	HLA-B27 Allele		No

Warde Medical Laboratory

LABORATORY REPORT

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

EXAMPLE, REPORT
WX0000000237 F 12/05/1988 36 Y

Molecular

Collected: 10/14/2025 10:29 Received: 10/14/2025 10:29

Test Name	Result	Flag	Ref-Ranges	Units	Site

HLA-B27 Identification by PCR

HLA-B27 Allele	**DETECTED**	**AB**	WMRL

BACKGROUND: Presence of the HLA-B27 allele is strongly associated with ankylosing spondylitis (AS), Reiter syndrome, anterior uveitis, psoriatic arthritis, and inflammatory bowel disease.

PREVALENCE: The HLA-B27 allele can be found in 8% of Caucasians but varies regionally. The allele frequency is 25% in Northern Scandinavia, 2-8% in Southern Europe, North Africa and China, and <0.5% in Japanese.

INCIDENCE: >90% of patients with AS are HLA-B27 positive compared to 5-10% of the general population.

PENETRANCE: 2-8% of individuals with at least one copy of the HLA-B27 allele will develop AS.

METHODOLOGY: Polymerase chain reaction (PCR) and melt curve analysis (MCA).

ASSAY PERFORMANCE: >95% clinical sensitivity. >99% clinical specificity. LOD >1 ng gDNA. No cross-reactivity with any other HLA-B alleles has been observed.

LIMITATIONS: The primers are expected to miss the following HLA-B27 allele subtypes: B*27:04:03, B*27:07:01, B*27:07:02, B*27:07:03, B*27:07:04, B*27:102, B*27:11, B*27:125, B*27:14, B*27:19, B*27:20, B*27:21, B*27:24, B*27:30, B*27:32, B*27:33, B*27:34, B*27:36, B*27:43, B*27:70, B*27:81, B*27:90:01, B*27:90:02.

This test was developed and its performance characteristics determined by Warde Medical Laboratory. 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.

Reported Date: 10/14/2025 10:29 B27M

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

E214000002
WX0000000237
Printed D&T: 10/14/25 10:29

Ordered By: CLIENT CLIENT
WX00000000000336

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

NOVEMBER 2025

Update Existing Test	
Effective Date	11/4/2025
Name	Complete Atopic Dermatitis Panel
Code	COADP
Interface Order Code	3300367
Legacy Code	COADP
Notes	Update to turnaround time.
Required Testing Changes	
Turnaround Time	**12 - 14 days**

Update Existing Test	
Effective Date	11/4/2025
Name	HMGCR Antibody IgG
Code	HMGCR
Interface Order Code	3600035
Legacy Code	HMGCR
Notes	Update to CPT code, stability, methodology, reference range, performed days, and turnaround time.
Required Testing Changes	
CPT Code(s)	**82397**
Stability	Room temperature: 48 hours Refrigerated: 14 days **Frozen: 30 days (avoid repeated freeze/thaw cycles)**
Methodology	**Semi-quantitative Chemiluminescent Immunoassay (CLIA)**
Reference Range	**Less than 20.0**
Performed Days	**Monday, Wednesday, Friday**
Turnaround Time	**3 - 7 days**

Update Existing Test	
Effective Date	11/4/2025
Name	Fecal Immunochemical Test for Occult Blood
Code	OBFIT
Interface Order Code	3000894
Legacy Code	OBFIT
Notes	Update to rejection criteria and stability.
Required Testing Changes	
Rejection Criteria	Unpreserved stool; **Specimens received >15 days from date of collection**
Stability	Room temperature: 15 days **Refrigerated: 15 days** Frozen: Unacceptable

Warde Medical Laboratory

TEST DIRECTORY UPDATE

NOVEMBER 2025

Update Existing Test	
Effective Date	11/4/2025
Name	pH, Body Fluid
Code	PHBF
Interface Order Code	3619600
Legacy Code	PHBF
Notes	Update to specimen requirements.
Required Testing Changes	
Specimen Required	*Collect:* Body fluid *Specimen Preparation:* Send 5.0 mL of well-mixed body fluid in a **sterile** screw capped plastic vial. Indicate specimen source. *Minimum Volume:* 1.0 mL *Transport Temperature:* Refrigerated

Update Existing Test	
Effective Date	11/4/2025
Name	Measles (Rubeola) IgM Antibody
Code	RUBEM
Interface Order Code	3685580
Legacy Code	RUBEMAR
Notes	Update to specimen requirements, rejection criteria, stability, methodology, and reference range.
Required Testing Changes	
Specimen Required	*Collect:* Serum Separator Tube (SST) ***Specimen Preparation:*** Centrifuge, separate serum from cells within 2 hours, and send 0.5 mL serum in a screw capped plastic vial. **Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Mark specimens plainly as "acute" or "convalescent".** ***Minimum volume:*** **0.3 mL** *Transport Temperature:* Refrigerated
Rejection Criteria	**Bacterially contaminated, heat-inactivated, hemolyzed, icteric, lipemic, or turbid specimens.**
Stability	**Room temperature: 48 hours** Refrigerated: 14 days **Frozen: 30 days (avoid repeated freeze/thaw cycles)**
Methodology	**Semi-quantitative Indirect Fluorescent Antibody (IFA)**
Reference Range	**Less than 1:10**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

NOVEMBER 2025

Update Existing Test	
Effective Date	11/4/2025
Name	Microsatellite Instability, Tumor
Code	TMSI
Interface Order Code	3800241
Legacy Code	TMSI
Notes	Update to specimen requirements, alternate specimen, stability, and performed days.
Required Testing Changes	
Specimen Required	***Patient Preparation:*** **Pathology report must accompany specimen in order for testing to be performed. This assay requires at least 40% tumor nuclei for endometrial specimens and at least 20% tumor nuclei for colorectal specimens.** ***Collect:*** **Tissue block** ***Specimen Preparation:*** **Send a formalin-fixed paraffin embedded tissue block, (non-decalcified), with approximately 72 mm(2) area of tumor.** ***Minimum Volume:*** **18 mm(2) area of tumor** *Transport Temperature:* Room temperature
Alternate Specimen	**Tissue slide: 1 Slide stained with hematoxylin and eosin and 10 Unstained, nonbaked slides with 5-micron thick sections of the tumor tissue.** **Note: The total amount of required tumor nuclei can be obtained by scraping up to 10 slides from the same block. Unused unstained slides will not be returned.**
Stability	**Room temperature: Indefinitely** Refrigerated: Unacceptable Frozen: Unacceptable
Performed Days	**Varies**

Update Existing Test	
Effective Date	12/1/2025
Name	Phenol Exposure, Urine
Code	UPHEP
Interface Order Code	3301475
Legacy Code	UPHEP
Notes	Update to CPT code and methodology.
Required Testing Changes	
CPT Code(s)	**82570**
Methodology	**Colorimetry**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

NOVEMBER 2025

Inactivate Test With Replacement			
Effective Date	11/4/2025		
Inactivated Test			
Name	Granulocyte Antibodies, Serum		
Code	GRAN		
Legacy Code[1]	GRANABM		
Interface Order Code	3801950		
Replacement Test			
Name	Granulocyte Antibody Screen, Serum		
Code	GRANS		
CPT Code(s)	86021 x2		
Notes	New York DOH Approval Status: Yes		
Specimen Requirements			
Specimen Required	*Patient Preparation:* Only a specimen collected before a transfusion reaction is acceptable. *Collect:* Red top *Specimen Preparation:* Centrifuge, separate and send 1.5 mL serum refrigerated in a screw capped plastic vial. *Minimum Volume:* 0.3 mL *Transport Temperature:* Refrigerated		
Rejection Criteria	Serum separator tube (SST), gross hemolysis		
Stability	Room temperature: 7 days Refrigerated: 30 days Frozen: 1 year		
Performing Information			
Methodology	Flow Cytometry/Agglutination		
Reference Range	Negative		
Performed Days	Tuesday, Thursday		
Turnaround Time	9 - 17 days		
Performing Laboratory	Mayo Clinic Laboratories		
Interface Information			
Legacy Code	GRANS		
Interface Order Code	3800422		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt**
3800423	GIFT/GAT Interpretation	105288-5	No
3800424	GIFT Result	105286-9	No
3800426	GAT Result	105287-7	No

Warde Medical Laboratory

LABORATORY REPORT

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

EXAMPLE, REPORT
WX0000000237 F 12/05/1988 36 Y

Referral Testing

Collected: 10/16/2025 11:10 Received: 10/16/2025 11:10

Test Name	Result	Flag	Ref-Ranges	Units	Site

Granulocyte Antibody Screen, Serum

GIFT/GAT Interpretation	SEE BELOW				MMRL

RESULT: No granulocyte antibody reactivity was detected.

GIFT Result	Negative				MMRL

----------ADDITIONAL INFORMATION----------
Method: Flow Cytometry

GAT Result	Negative				MMRL

----------ADDITIONAL INFORMATION----------
Method: Agglutination Test

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.

CLIA: 24D0404292 CLIA Lab Director: NIKOLA BAUMANN,Ph.D.

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: 10/16/2025 11:13 GRANS

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

E216000001
WX0000000237
Printed D&T: 10/16/25 11:14

Ordered By: CLIENT CLIENT
WX00000000000511

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

NOVEMBER 2025

Inactivate Test Without Replacement	
Effective Date	11/4/2025
Name	Mumps Virus Antibody IgM
Code	MUMPM
Legacy Code	MUMPSMARP
Interface Code	3620660
Notes	Test discontinued.

Inactivate Test Without Replacement	
Effective Date	11/3/2025
Name	Bath Salts Panel (Qualitative), Urine
Code	UBSP
Legacy Code	UBSP
Interface Code	3300132
Notes	Test discontinued.