Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2023

Update Summary		
Update Existing Test	1/1/2024	ACHBL - "Acetylcholine Receptor Blocking Antibody"
Update Existing Test	1/1/2024	ACHMD - "Acetylcholine Receptor Modulating Antibodies"
Update Existing Test	1/1/2024	ACHRB - "Acetylcholine Receptor Binding Antibody"
Update Existing Test	11/28/2023	AHPR - "Acute Hepatitis Panel"
Update Existing Test	12/19/2023	B2T - "Beta-2 Transferrin, Body Fluid"
Update Existing Test	12/11/2023	BABDN - "Babesia microti DNA, Real-Time PCR"
Update Existing Test	12/19/2023	FOSMQ - "Osmolality, Feces"
Update Existing Test	11/28/2023	FPSA - "Prostate Specific Antigen, Free"
Update Existing Test	11/28/2023	HAAB - "Hepatitis A Antibody, Total"
Update Existing Test	11/28/2023	HAM - "Hepatitis A Antibody, IgM"
Update Existing Test	11/28/2023	HBCAB - "Hepatitis B Core Antibody, Total"
Update Existing Test	11/28/2023	HBCM - "Hepatitis B Core Antibody, IgM"
Update Existing Test	11/28/2023	HBSAB - "Hepatitis B Surface Antibody"
Update Existing Test	11/28/2023	HBSAG - "Hepatitis B Surface Antigen"
Update Existing Test	11/28/2023	HBVSC - "Hepatitis B Screening Panel"
Update Existing Test	11/28/2023	HCVR - "Hepatitis C Antibody, Diagnostic, with reflex to PCR"
Update Existing Test	11/28/2023	HCVSR - "Hepatitis C Antibody, Screening, with reflex to PCR"
Update Existing Test	12/12/2023	HIVA - "HIV Ag/Ab 5th Gen (Diag)"
Update Existing Test	12/12/2023	HIVD - "HIV-D"
Update Existing Test	1/1/2024	MGP1 - "Myasthenia Gravis Panel 1"
Update Existing Test	1/1/2024	MGP2 - "Myasthenia Gravis Panel 2"
Update Existing Test	1/1/2024	MGP3 - "Myasthenia Gravis Panel 3"
Update Existing Test	11/28/2023	PSADX - "Prostate Specific Ag, Diagnostic"
Update Existing Test	11/28/2023	PSASN - "Prostate Specific Ag, Screen"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2023

Update Existing Test	
Effective Date	1/1/2024
Name	Acetylcholine Receptor Blocking Antibody
Code	ACHBL
Interface Order Code	3708430
Legacy Code	ACHRBLKSP
Notes	Update to CPT Code.
Required Testing Changes	
CPT Code(s)	**86042**

Update Existing Test	
Effective Date	1/1/2024
Name	Acetylcholine Receptor Modulating Antibodies
Code	ACHMD
Interface Order Code	3680030
Legacy Code	ACHMODARP
Notes	Update to CPT Code.
Required Testing Changes	
CPT Code(s)	**86043**

Update Existing Test	
Effective Date	1/1/2024
Name	Acetylcholine Receptor Binding Antibody
Code	ACHRB
Interface Order Code	3700050
Legacy Code	ACHRBIND
Notes	Update to CPT Code.
Required Testing Changes	
CPT Code(s)	**86041**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2023

Update Existing Test	
Effective Date	11/28/2023
Name	Acute Hepatitis Panel
Code	AHPR
Interface Order Code	3001485
Legacy Code	AHPR
Notes	Update to Specimen stability, Specimen information, NY approval *New York DOH Approval Status:* **Yes**
Required Testing Changes	
Specimen Required	*Patient Preparation:* **Performance of the HCV assay has not been established with cord blood or neonatal specimens.** *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:* Refrigerated
Stability	Room temperature: Unacceptable Refrigerated: 5 days Frozen (-20°C): **Undetermined**

Update Existing Test	
Effective Date	12/19/2023
Name	Beta 2 Transferrin
Code	B2T
Interface Order Code	1002990
Legacy Code	B2T
Notes	Update to specimen preparation, transport temperature, stability, rejection criteria, test name
Required Testing Changes	
Name	Beta-2 Transferrin, Body Fluid
Specimen Required	*Collect:* Nasal, eye or ear fluid *Specimen Preparation:* Send 0.5 mL nasal, eye or ear fluid in a screw capped plastic vial. **Specimens contaminated with salivary fluid degrade the beta-2 transferrin. These specimens should be frozen immediately following collection and should be kept frozen until testing is performed.** *Minimum Volume:* 0.2 mL *Transport Temperature:* **Room temperature**
Rejection Criteria	**Specimens collected with additives, specimens collected with a culture swab.**
Stability	Room temperature: **15 days** Refrigerated: **15 days** Frozen: **60 days**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2023

Update Existing Test	
Effective Date	12/11/2023
Name	Babesia microti DNA, Real-Time PCR
Code	BABDN
Interface Order Code	3428200
Legacy Code	BABDN
Notes	Update to Alternate Specimen: Whole blood: ACD is no longer acceptable. Update to Minimum Volume.
Required Testing Changes	
Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Send 1.0 mL whole blood refrigerated in a screw capped plastic vial. *Transport Temperature:* Refrigerated ***Minimum Volume:* 0.5 mL**
Alternate Specimen	**Tick - live or in 70% ethanol submitted in a sterile plastic screw-capped container.**

Update Existing Test	
Effective Date	12/19/2023
Name	Osmolality, Feces
Code	FOSMQ
Interface Order Code	3424520
Legacy Code	FOSMQ
Notes	Updates to specimen preparation, alternate specimen collection duration times, stability.
Required Testing Changes	
Specimen Required	*Collect:* Liquid stool *Specimen Preparation:* **Send 1.0 mL watery, liquid stool in a screw capped plastic container.** *Minimum Volume:* 0.2 mL *Transport Temperature:* Refrigerated
Alternate Specimen	**24-hour, 48- hour, or 72-hour liquid stool collection**
Stability	Room temperature: Unacceptable Refrigerated: **48 hours** Frozen: **60 days**

Update Existing Test	
Effective Date	11/28/2023
Name	Prostate Specific Antigen, Free
Code	FPSA
Interface Order Code	1012090
Legacy Code	FPSA
Notes	Update to reference range message.
Required Testing Changes	
Reference Range	**See Example Report**

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 45 Y

Immunochemistry

Collected: 11/24/2023 08:49 Received: 11/24/2023 08:49

Test Name	Result	Flag	Ref-Ranges	Units	Site
Prostate Specific Antigen, Total and Free					
Prostate Specific Antigen	3.0		<=4.0	ng/mL	WMRL

The intended use for this assay is measurement of serum PSA in conjunction with digital rectal examination as an aid in the detection of prostate cancer in men aged 50 years or older. There is also a second indication for this assay, which is serial measurement of PSA to aid in the prognosis and management of patients with prostate cancer; as such, specimens from patients under the age of 50 are not rejected by the laboratory. Interpretation of results, and use of provided reference range (established for the indication of prostate cancer detection in men 50 and older), should take intended uses into consideration.

Free PSA	0.50			ng/mL	WMRL
Percent Free PSA	17			%	WMRL

The % free PSA should be used to evaluate patients that have total PSA values between 2.0 and 10.0 ng/mL. For patients whose total PSA value falls below 2.0 ng/mL or above 10 ng/mL, the risk of prostate cancer is determined on the basis of total PSA alone and a Free PSA will not be calculated.

For total PSA levels between 4.0 and 10.0 ng/mL, a percent free PSA <25% indicates increased risk of prostate cancer; the lower the percentage, the greater the risk. For total PSA levels between 2.0 and 3.9 ng/mL, a percent free PSA <18% indicates increased risk of prostate cancer; the lower the percentage, the greater the risk. However, although the probability is low, cancer may be present even when the free PSA percentage is >25% (or >18% of the total PSA values between 2.0 and 3.9 ng/mL).

This test was performed using the Beckman Coulter method, calibrated to the original Hybritech Tandem-R assay. PSA values obtained with other assay methods or kits cannot be used interchangeably with results obtained by the Beckman Tandem-R method.

Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.

Reported Date: 11/24/2023 08:52 FPSA

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

F524000000
WX0000003827
Printed D&T: 11/24/23 08:52

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002365

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2023

Update Existing Test	
Effective Date	11/28/2023
Name	Hepatitis A Antibody, Total
Code	HAAB
Interface Order Code	3000710
Legacy Code	HAAB
Notes	Update to Specimen stability, NY approval New York DOH Approval Status: **Yes**
Required Testing Changes	
Stability	Room temperature: 12 hours Refrigerated: **7 days** Frozen: 1 year

Update Existing Test	
Effective Date	11/28/2023
Name	Hepatitis A Antibody, IgM
Code	HAM
Interface Order Code	3010010
Legacy Code	HAM
Notes	Update to New York approval. New York DOH Approval Status: **Yes**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2023

Update Existing Test	
Effective Date	11/28/2023
Name	Hepatitis B Core Antibody, Total
Code	HBCAB
Interface Order Code	3000680
Legacy Code	HBCAB
Notes	Update to Patient preparation, alternate specimen, rejection criteria, stability, reference range
Required Testing Changes	
Specimen Required	*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 1.0 mL serum in a screw capped plastic vial. *Minimum Volume:* 0.5 mL *Transport Temperature:* Refrigerated
Alternate Specimen	Serum: Red top Plasma: Lavender EDTA, **lithium heparin, sodium heparin**
Rejection Criteria	**Grossly hemolyzed or grossly lipemic specimens, Plasma separator tube (PST)**
Stability	Room temperature: **3 days** Refrigerated: **7 days** Frozen: **12 months**
Reference Range	Negative **See Website: Resource/Interpretation Guide and Forms/Viral Serology Testing Guide**

Update Existing Test	
Effective Date	11/28/2023
Name	Hepatitis B Core Antibody, IgM
Code	HBCM
Interface Order Code	3010200
Legacy Code	HBCM
Notes	Updates to Patient preparation and Reference range, New York approval. New York DOH Approval Status: **Yes**
Required Testing Changes	
Specimen Required	*Patient Preparation:* **Performance of the HBCM assay has not been established with cord blood or neonatal specimens.** *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
Reference Range	Negative **See Website: Resource/Interpretation Guide and Forms/Viral Serology Testing Guide**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2023

Update Existing Test	
Effective Date	11/28/2023
Name	Hepatitis B Surface Antibody
Code	HBSAB
Interface Order Code	3001640
Legacy Code	HBSAB
Notes	Update to Alternate specimen, reference range.
Required Testing Changes	
Alternate Specimen	Serum: Red top Plasma: Lavender EDTA, **lithium heparin, sodium heparin**
Reference Range	Qualitative: Not Immune: Negative Immune: Positive Quantitative: Not Immune: <10 mIU/mL Immune: ≥10 mIU/mL **See Website: Resource/Interpretation Guide and Forms/Viral Serology Testing Guide**

Update Existing Test	
Effective Date	11/28/2023
Name	Hepatitis B Surface Antigen
Code	HBSAG
Interface Order Code	3000660
Legacy Code	HBSAG
Notes	Update to Reference Range
Required Testing Changes	
Reference Range	Negative **See Website: Resource/Interpretation Guide and Forms/Viral Serology Testing Guide**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2023

Update Existing Test	
Effective Date	11/28/2023
Name	Hepatitis B Screening Panel
Code	HBVSC
Interface Order Code	3000530
Legacy Code	HBVSC
Notes	Update to patient preparation, alternate specimen, rejection criteria, stability, reference range and New York approval New York DOH Approval Status: **Yes**
Required Testing Changes	
Specimen Required	*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
Alternate Specimen	Serum: Red top Plasma: Lavender EDTA, **lithium heparin, sodium heparin**
Stability	Room temperature: Undetermined Refrigerated: **7 days** Frozen: Undetermined
Reference Range	HBSAG: Negative HBCAB: Negative HBSAB: Qualitative: Not Immune: Negative Immune: Positive Quantitative: Not Immune: <10 mIU/mL Immune: ≥10 mIU/mL **See Website: Resource/Interpretation Guide and Forms/Viral Serology Testing Guide**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2023

Update Existing Test	
Effective Date	11/28/2023
Name	Hepatitis C Antibody, Diagnostic, with reflex to PCR
Code	HCVR
Interface Order Code	3001440
Legacy Code	HCVR
Notes	Update to patient preparation, alternate specimen
Required Testing Changes	
Specimen Required	*Patient Preparation:* **Performance of the HCV assay has not been established with cord blood or neonatal specimens.** *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
Alternate Specimen	**Red top, lavender EDTA plasma, lithium heparin, sodium heparin may be substituted for the serum specimen**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2023

Update Existing Test	
Effective Date	11/28/2023
Name	Hepatitis C Antibody, Screening, with reflex to PCR
Code	HCVSR
Interface Order Code	3001452
Legacy Code	HCVSR
Notes	Update to Patient preparation, alternate specimen, rejection criteria, New York approval. **New York DOH Approval Status: Yes**
Required Testing Changes	
Specimen Required	*Patient Preparation:* **Performance of the HCV assay has not been established with cord blood or neonatal specimens.** *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
Alternate Specimen	**HCV Antibody: red top, lavender EDTA (follow Plasma collection guide for PCR), lithium heparin, sodium heparin** **HCV PCR: Serum: red top** ***PCR and antibody testing cannot be done on shared specimens. Separate tubes must be clearly labeled for antibody and PCR specimens.**
Rejection Criteria	**HCV Antibody: gross hemolysis, gross lipemia** **HCV PCR: gross hemolysis, gross lipemia, heparin plasma, gel-based plasma separation tubes, specimens subjected to repeat freeze thaw cycles, shared specimens**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2023

Update Existing Test

Effective Date	12/12/2023
Name	HIV Ag/Ab 5th Gen (Diag)
Code	HIVA
Interface Order Code	3010685
Legacy Code	HIV1/2/A
Notes	Update to LOINC codes.

Required Testing Changes

Result Code	Name	LOINC Code	AOE/Prompt[2]
3010690	HIV 1/2 Ag/Ab Diagnostic 5th Generation	**56888-1**	No
3010920	HIV-1 Ab Differentiation	**7917-8**	No
3010930	HIV-2 Ab Differentiation	**7919-4**	No

Update Existing Test

Effective Date	12/12/2023
Name	HIV-D
Code	HIVD
Interface Order Code	3010900
Legacy Code	HIV1/2D
Notes	Update to LOINC codes.

Required Testing Changes

Result Code	Name	LOINC Code	AOE/Prompt[2]
3010920	HIV-1 Ab Differentiation	**7917-8**	No
3010930	HIV-2 Ab Differentiation	**7919-4**	No

Update Existing Test

Effective Date	1/1/2024
Name	Myasthenia Gravis Panel 1
Code	MGP1
Interface Order Code	3432650
Legacy Code	MGP1
Notes	Update to CPT Code(s).

Required Testing Changes

CPT Code(s)	**86041, 86255 with reflex to 86256, at additional cost**

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2023

Update Existing Test	
Effective Date	1/1/2024
Name	Myasthenia Gravis Panel 2
Code	MGP2
Interface Order Code	3432700
Legacy Code	MGP2
Notes	Update to CPT Code(s)
Required Testing Changes	
CPT Code(s)	**86041, 86042, 86043**

Update Existing Test	
Effective Date	1/1/2024
Name	Myasthenia Gravis Panel 3
Code	MGP3
Interface Order Code	3400432
Legacy Code	MGP3
Notes	Update to CPT Code(s).
Required Testing Changes	
CPT Code(s)	**86041, 86042, 86043, 86255, plus 86256 if reflexed, at an additional cost.**

Update Existing Test	
Effective Date	11/28/2023
Name	Prostate Specific Ag, Diagnostic
Code	PSADX
Interface Order Code	1011270
Legacy Code	PSA DIAG
Notes	Update to reference range message.
Required Testing Changes	
Reference Range	**See Example Report**

Update Existing Test	
Effective Date	11/28/2023
Name	Prostate Specific Ag, Screen
Code	PSASN
Interface Order Code	1011275
Legacy Code	PSA SCRN
Notes	Update to reference range message.
Required Testing Changes	
Reference Range	**See Example Report**

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 45 Y

Chemistry

Collected: 11/24/2023 08:55 Received: 11/24/2023 08:55

Test Name	Result	Flag	Ref-Ranges	Units	Site
Prostatic Specific Antigen (PSA), Diagnostic					
Prostate Specific Ag, Diagnostic	2.5		<=4.0	ng/mL	WMRL

After radical prostatectomy, the reference interval is less than 0.1 ng/mL if there is no residual disease. In healthy males without prostatectomy, the reference interval is 4.0 or less. The lower limit of detection is 0.1 ng/mL.

The intended use for this assay is measurement of serum PSA in conjunction with digital rectal examination as an aid in the detection of prostate cancer in men aged 50 years or older. There is also a second indication for this assay, which is serial measurement of PSA to aid in the prognosis and management of patients with prostate cancer; as such, specimens from patients under the age of 50 are not rejected by the laboratory. Interpretation of results, and use of provided reference range (established for the indication of prostate cancer detection in men 50 and older), should take intended uses into consideration.

This test was performed using the Beckman Coulter method, calibrated to the original Hybritech Tandem-R assay. PSA values obtained with other assay methods or kits cannot be used interchangeably with results obtained by the Beckman Tandem-R method.

Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.

Reported Date: 11/24/2023 08:56 PSADX

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

F524000001
WX0000003827
Printed D&T: 11/24/23 08:56

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002365

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

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 45 Y

Chemistry

Collected: 11/24/2023 08:57 Received: 11/24/2023 08:57

Test Name	Result	Flag	Ref-Ranges	Units	Site
Prostatic Specific Antigen (PSA), Screen					
Prostate Specific Ag, Screen	3.2		<=4.0	ng/mL	WMRL

The intended use for this assay is measurement of serum PSA in conjunction with digital rectal examination as an aid in the detection of prostate cancer in men aged 50 years or older. There is also a second indication for this assay, which is serial measurement of PSA to aid in the prognosis and management of patients with prostate cancer; as such, specimens from patients under the age of 50 are not rejected by the laboratory. Interpretation of results, and use of provided reference range (established for the indication of prostate cancer detection in men 50 and older), should take intended uses into consideration.

This test was performed using the Beckman Coulter method, calibrated to the original Hybritech Tandem-R assay. PSA values obtained with other assay methods or kits cannot be used interchangeably with results obtained by the Beckman Tandem-R method.

Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.

Reported Date: 11/24/2023 08:57 PSASN

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

F524000002
WX0000003827
Printed D&T: 11/24/23 08:57

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002365

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