Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2024

Update Summary		
Update Existing Test	12/10/2024	CYIEL - "Cyclospora and Isospora Examination"
Update Existing Test	12/10/2024	EPCSF - "Epilepsy, Autoimm/Paraneo, CSF"
Update Existing Test	12/10/2024	EPSER - "Epilepsy, Autoimm/Paraneo, S"
Inactivate Test With Replacement	12/17/2024	GHBS - "Gamma-Hydroxybutyric Acid Screen, Serum/Plasma" replaced by GHBSP - "Gamma-Hydroxybutyric Acid (GHB) with Reflex to Confirm, Ser"
Inactivate Test With Replacement	12/5/2024	GINPP - "Gastrointestinal Pathogen Panel, PCR, Feces" replaced by GIPPF - "Gastrointestinal Pathogen Panel, PCR, Feces"
Inactivate Test With Replacement	12/17/2024	UGHBS - "Gamma-Hydroxybutyric Acid Screen, Urine" replaced by GHBUR - "Gamma-Hydroxybutyric Acid (GHB) with Reflex to Confirm, Ur"
Inactivate Test Without Replacement	12/9/2024	FINT1 - "Full Integrated Screen Part 1 (With NT)"
Inactivate Test Without Replacement	12/9/2024	FTS1 - "First Trimester Screen"
Inactivate Test Without Replacement	12/17/2024	GHBC - "Gamma-Hydroxylbutyric Acid Confirmation, Serum/Plasma"
Inactivate Test Without Replacement	12/9/2024	INTG1 - "Serum Integrated Screen Part 1 (No NT)"
Inactivate Test Without Replacement	12/9/2024	SEQ1 - "Sequential Screen Part 1"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2024

Update Existing Test	
Effective Date	12/10/2024
Name	Cyclospora and Isospora Examination
Code	CYIEL
Interface Order Code	3400672
Legacy Code	CYIEL
Notes	Update to stability.
Required Testing Changes	
Stability	**Room temperature: 30 days** **Refrigerated: Unacceptable** Frozen: Unacceptable

Update Existing Test	
Effective Date	12/10/2024
Name	Epilepsy, Autoimm/Paraneo, CSF
Code	EPCSF
Interface Order Code	3500037
Legacy Code	EPCSF
Notes	Update to CPT codes.
Required Testing Changes	
CPT Code(s)	86255 x 19, 86341, plus others as appropriate, at additional charges

Update Existing Test	
Effective Date	12/10/2024
Name	Epilepsy, Autoimm/Paraneo, S
Code	EPSER
Interface Order Code	3500038
Legacy Code	EPSER
Notes	Update to CPT codes.
Required Testing Changes	
CPT Code(s)	86255 x 19, 86341, plus others as appropriate, at additional charges

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2024

Inactivate Test With Replacement			
Effective Date	12/17/2024		
Inactivated Test			
Name	Gamma-Hydroxybutyric Acid Screen, Serum/Plasma		
Code	GHBS		
Legacy Code	GHBS		
Interface Order Code	3300800		
Replacement Test			
Name	Gamma-Hydroxybutyric Acid (GHB) with Reflex to Confirm, Ser		
Code	GHBSP		
CPT Code(s)	80307		
Notes	New York DOH Approval Status: Yes		
Specimen Requirements			
Specimen Required	*Collect*: Red top *Specimen Preparation*: Centrifuge, separate serum from cells and send 5.0 mL serum in a screw capped plastic vial. Positive screens will reflex to confirmation. *Minimum Volume*: 2.4 mL *Transport Temperature*: Refrigerated		
Alternate Specimen	Plasma: EDTA		
Rejection Criteria	Serum separator tube (SST), Plasma: sodium citrate or ACD or Plasma separator tube (PST)		
Stability	Room temperature: 30 days Refrigerated: 30 days Frozen: 60 days		
Performing Information			
Methodology	Gas Chromatography/Mass Spectrometry		
Reference Range	See report		
Performed Days	Varies		
Turnaround Time	7 - 12 days		
Performing Laboratory	NMS Labs		
Interface Information			
Legacy Code	GHBSP		
Interface Order Code	3300067		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt**
3300068	GHB Screen, Serum	59681-7	No
3300069	GHB Confirmation, Serum	43194-0	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 35 Y

Referral Testing

Collected: 11/18/2024 08:47 Received: 11/18/2024 08:47

Test Name	Result	Flag	Ref-Ranges	Units	Site
Gamma-Hydroxybutyric Acid w Reflex to Confirm, Ser					
GHB Screen, Serum	See Comment			mcg/mL	NMRL

Reporting Limit: 5.0 mcg/mL
Synonym(s): Gamma-Hydroxybutyrate; GHB
Comment:
Based on this screening result, confirmation testing was performed. Refer to the confirmation test result(s).
Analysis by Gas Chromatography/Mass Spectrometry (GC/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.

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

GHB Confirmation, Serum	900			mcg/mL	NMRL

Reporting Limit: 5.0 mcg/mL
Synonym(s): Gamma-Hydroxybutyrate; GHB
Following an oral dose of 4.5 g, peak plasma concentrations averaged 90 mcg/mL approximately 50 minutes after administration. GHB has a terminal half-life of 0.5 to 1 hour.
The following effects have been generally associated with the corresponding blood concentrations:
>260 mcg/mL: Deep sleep/coma
150-260 mcg/mL: Moderate sleep
52-150 mcg/mL: Light sleep
< 52 mcg/mL: Wakefulness
Responses are variable and may differ even within the same individual.
The value reported for GHB is a total of GHB and its lactone (GBL) in the specimen.
Analysis by Gas Chromatography/Mass Spectrometry (GC/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

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 35 Y

Referral Testing

Collected: 11/18/2024 08:47 Received: 11/18/2024 08:47

Test Name	Result	Flag	Ref-Ranges	Units	Site

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: 11/18/2024 08:48 GHBSP

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2024

Inactivate Test With Replacement	
Effective Date	12/5/2024
Inactivated Test	
Name	Gastrointestinal Pathogen Panel, PCR, Feces
Code	GINPP
Legacy Code	GINPP
Interface Order Code	3800016
Replacement Test	
Name	Gastrointestinal Pathogen Panel, PCR, Feces
Code	GIPPF
CPT Code(s)	87507
Notes	New York DOH Approval Status: Yes
Specimen Requirements	
Specimen Required	*Collect*: Stool *Specimen Preparation*: Place 1.0 g or 5.0 mL of fresh stool Carey Blair media (15 mL of non-nutritive transport medium containing phenol red as a pH indicator) within 2 hours of collection. *Minimum Volume*: 1.0 mL *Transport Temperature*: Room temperature
Alternate Specimen	Para-Pak C and S, Meridian
Rejection Criteria	Unpreserved stool. Specimens containing formalin (SAF, PVA, EcoFix). Endoscopy specimen. Swabs (Cary-Blair, rectal, stool, Gel). Commercial transport media (ETM, AlphaTec, Para-Pak Enteric Plus, C and S Transport Medium, Copan FecalSwab/Eswab
Stability	Room temperature: 4 days Refrigerated: 4 days Frozen: Unacceptable
Performing Information	
Methodology	Multiplex Polymerase Chain Reaction (PCR)
Reference Range	See report
Performed Days	Monday - Sunday
Turnaround Time	3 - 5 days
Performing Laboratory	Mayo Clinic Laboratories
Interface Information	
Legacy Code	GIPPF
Interface Order Code	3800387

Result Code	Name	LOINC Code	AOE/Prompt
3800017	Specimen Source	31208-2	No
3800018	Campylobacter species	82196-7	No
3800019	C. difficile toxin	82197-5	No
3800020	Plesiomonas shigelloides	82198-3	No
3800021	Salmonella species	82199-1	No
3800022	Vibrio species	82200-7	No
3800023	Vibrio cholerae	82201-5	No
3800024	Yersinia species	82202-3	No

3800025	Enteroaggregative e. coli (EAEC)	80349-4	No
3800026	Enteropathogenic E. coli (EPEC)	80348-6	No
3800027	Enterotoxigenic E coli (ETEC)	80351-0	No
3800028	Shiga toxin producing E. coli	82203-1	No
3800029	Escherichia coli O157 serotype	82204-9	No
3800030	Shigella/Enteroinvasive E. coli	80350-2	No
3800031	Cryptosporidium species	82205-6	No
3800032	Cyclospora cayetanensis	82206-4	No
3800033	Entamoeba histolytica	82207-2	No
3800034	Giardia	82208-0	No
3800035	Adenovirus F40/41	82209-8	No
3800036	Astrovirus	82210-6	No
3800037	Norovirus GI/GII	82211-4	No
3800038	Rotavirus	82212-2	No
3800039	Sapovirus	82213-0	No
3800040	Interpretation	59464-8	No
3800389	Vibrio Culture, Stool	6579-7	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 35 Y

Referral Testing

Collected: 11/19/2024 08:52 Received: 11/19/2024 08:52

Test Name	Result	Flag	Ref-Ranges	Units	Site
Gastrointestinal Pathogen Panel, PCR, Feces					
Specimen Source	STOOL				MMRL
Campylobacter speices	Negative		Negative		MMRL
C. difficile toxin	Negative		Negative		MMRL
Plesiomonas shigelloides	Negative		Negative		MMRL
Salmonella species	Negative		Negative		MMRL
Vibrio species	Negative		Negative		MMRL
Vibrio cholerae	Negative		Negative		MMRL
Yersinia species	Negative		Negative		MMRL
Enteroaggregative e. coli (EAEC)	Negative		Negative		MMRL
Enteropathogenic E. coli (EPEC)	Negative		Negative		MMRL
Enterotoxigenic E coli (ETEC)	Negative		Negative		MMRL
Shiga toxin producing E. coli	Negative		Negative		MMRL
Escherichia coli O157 serotype	.				MMRL
Shigella/Enteroinvasive E. coli	Negative		Negative		MMRL
Cryptosporidium species	Negative		Negative		MMRL
Cyclospora cayetanensis	Negative		Negative		MMRL
Entamoeba histoytica	Negative		Negative		MMRL
Giardia	Negative		Negative		MMRL
Adenovirus F40/41	Negative		Negative		MMRL
Astrovirus	Negative		Negative		MMRL
Norovirus GI/GII	Negative		Negative		MMRL
Rotavirus	Negative		Negative		MMRL
Sapovirus	Negative		Negative		MMRL
Interpretation	.				MMRL
Vibrio Culture, Stool	.TNP				MMRL

Reported Date: 11/19/2024 08:52 GIPPF

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

G719000000
WX0000003826
Printed D&T: 11/19/24 08:52

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002353

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
WX0000003826 F 12/05/1988 35 Y

Referral Testing

Collected: 11/19/2024 09:08 Received: 11/19/2024 09:08

Test Name	Result	Flag	Ref-Ranges	Units	Site
Gastrointestinal Pathogen Panel, PCR, Feces					
Specimen Source	STOOL				MMRL
Campylobacter speices	Negative		Negative		MMRL
C. difficile toxin	Negative		Negative		MMRL
Plesiomonas shigelloides	Negative		Negative		MMRL
Salmonella species	Negative		Negative		MMRL
Vibrio species	**Positive**	**AB**	Negative		MMRL

Semi-Urgent Result.

Culture confirmation to follow under test code "VIBC/Vibrio Culture, Stool" due to increased risk of false positive Vibrio results. Cary Blair transport medium may contain non-viable organisms and/or nucleic acids at levels that may be detected by the BIOFIRE GI Panel.

Vibrio cholerae	Negative		Negative		MMRL
Yersinia species	Negative		Negative		MMRL
Enteroaggregative e. coli (EAEC)	Negative		Negative		MMRL
Enteropathogenic E. coli (EPEC)	Negative		Negative		MMRL
Enterotoxigenic E coli (ETEC)	Negative		Negative		MMRL
Shiga toxin producing E. coli	Negative		Negative		MMRL
Escherichia coli O157 serotype	.				MMRL
Shigella/Enteroinvasive E. coli	Negative		Negative		MMRL
Cryptosporidium species	Negative		Negative		MMRL
Cyclospora cayetanensis	Negative		Negative		MMRL
Entamoeba histoytica	Negative		Negative		MMRL
Giardia	Negative		Negative		MMRL
Adenovirus F40/41	Negative		Negative		MMRL
Astrovirus	Negative		Negative		MMRL
Norovirus GI/GII	Negative		Negative		MMRL
Rotavirus	Negative		Negative		MMRL
Sapovirus	Negative		Negative		MMRL

----------ADDITIONAL INFORMATION----------
This assay is performed using the FDA-cleared FilmArray GI Panel (BioFire Diagnostics, Inc.).

Test Performed by:
Mayo Clinic Laboratories - Rochester Main Campus
200 First Street SW, Rochester, MN 55905

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

G719000021
WX0000003826
Printed D&T: 11/19/24 09:08

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002353

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
WX0000003826 F 12/05/1988 35 Y

Referral Testing

Collected: 11/19/2024 09:08 Received: 11/19/2024 09:08

Test Name	Result	Flag	Ref-Ranges	Units	Site
Lab Director: Nikola A. Baumann Ph.D.; CLIA# 24D0404292					
Interpretation	.				MMRL
Vibrio Culture, Stool	**SEE BELOW**	**AB**			MMRL

SOURCE: STOOL
VIBRIO CULTURE, STOOL FINAL
VIBRIO AESTUARIANUS 1+
Semi-Urgent Result.

Culture was performed following a positive PCR result
to attempt to recover an isolate for susceptibility testing.

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: 11/19/2024 09:08 GIPPF

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

G719000021
WX0000003826
Printed D&T: 11/19/24 09:08

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002353

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2024

Inactivate Test With Replacement			
Effective Date	12/17/2024		
Inactivated Test			
Name	Gamma-Hydroxybutyric Acid Screen, Urine		
Code	UGHBS		
Legacy Code	UGHBS		
Interface Order Code	3300840		
Replacement Test			
Name	Gamma-Hydroxybutyric Acid (GHB) with Reflex to Confirm, Ur		
Code	GHBUR		
CPT Code(s)	80307		
Notes	New York DOH Approval Status: Yes		
Specimen Requirements			
Specimen Required	*Collect*: Random urine *Specimen Preparation*: Send 5.0 mL urine refrigerated in a sterile, screw capped plastic urine container. Positive screens will reflex to confirmations. *Minimum Volume*: 2.8 mL *Transport Temperature*: Refrigerated		
Stability	Room temperature: 7 days Refrigerated: 7 days Frozen: 21 days		
Performing Information			
Methodology	Gas Chromatography/Mass Spectrometry		
Reference Range	See report		
Performed Days	Varies		
Turnaround Time	7 - 12 days		
Performing Laboratory	NMS Labs		
Interface Information			
Legacy Code	GHBUR		
Interface Order Code	3300071		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt**
3300072	GHB Screen, Urine	43197-3	No
3300073	GHB Confirmation, Urine	43198-1	No
3300368	Creatinine	2161-8	No
3300369	GHB Confirmation, Creatinine Corrected	47542-6	No
3300371	Specific Gravity	5810-7	No

Warde Medical Laboratory

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: 11/18/2024 08:50 Received: 11/18/2024 08:50

Test Name	Result	Flag	Ref-Ranges	Units	Site
Gamma-Hydroxybutyric Acid w Reflex to Confirm, Ur					
GHB Screen, Urine	See Comment			mcg/mL	NMRL

Reporting Limit: 5.0 mcg/mL
Synonym(s): GHB; Gamma-Hydroxybutyrate
Comment:
Based on this screening result, confirmation testing was performed. Refer to the confirmation test result(s).
Analysis by Gas Chromatography/Mass Spectrometry (GC/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.

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

GHB Confirmation, Urine	400			mcg/mL	NMRL

Reporting Limit: 5.0 mcg/mL
Synonym(s): GHB; Gamma-Hydroxybutyrate
Endogenous GHB levels in healthy adults have been determined to range up to 6.6 mcg/mL.
Sixteen healthy adults given a single oral dose (50 mg/kg) developed urine levels averaging:
168 mcg/mL during the 0 to 3 hour post-dose interval,
157 mcg/mL during the 3 to 6 hour period and
3.8 mcg/mL for the 6 to 12 hour window.
The value reported for GHB is a total of GHB and its lactone (GBL) in the specimen.
Analysis by Gas Chromatography/Mass Spectrometry (GC/MS)

Creatinine	150.0			mg/L	NMRL

Reporting Limit: 100 mg/L
U.S. Population (10th - 90th percentiles, median)
All participants: 335-2370 mg/L, median 1180 (n=22,245)
Males: 495-2540 mg/L, median 1370 (n=10,610)
Females: 273-2170 mg/L, median 994 (n=11,635)
Analysis by Colorimetry (C)

GHB Confirmation, Creatinine Corrected	2600			mg/g Creat	NMRL

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

G718000003
WX0000003827
Printed D&T: 11/18/24 08:52

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002516

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

Warde Medical Laboratory

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: 11/18/2024 08:50 Received: 11/18/2024 08:50

Test Name	Result	Flag	Ref-Ranges	Units	Site
	Reporting Limit: 33 mg/g Creat Endogenous creatinine corrected results did not exceed 10 mg/g among unexposed pregnant females (n=66), non-pregnant females (n=105) and males (n=22) in three peer reviewed studies. Analysis by Gas Chromatography/Mass Spectrometry (GC/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				
Specific Gravity	**600.0**	**H**			NMRL
	Physiologic range: 1.010-1.030. Samples with specific gravity lower than 1.010 are too dilute and should be recollected. Analysis by Refractometer (REF) 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. Testing performed at NMS Labs, Inc. 200 Welsh Road Horsham, PA 19044-2208 CLIA 39D0197898				

Reported Date: 11/18/2024 08:51 GHBUR

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

G718000003
WX0000003827
Printed D&T: 11/18/24 08:52

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002516

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

DECEMBER 2024

Inactivate Test Without Replacement	
Effective Date	12/9/2024
Name	Full Integrated Screen Part 1 (With NT)
Code	FINT1
Legacy Code	FINT1
Interface Code	3000350
Notes	Test discontinued.

Inactivate Test Without Replacement	
Effective Date	12/9/2024
Name	First Trimester Screen
Code	FTS1
Legacy Code	FTS1
Interface Code	3000352
Notes	Test discontinued.

Inactivate Test Without Replacement	
Effective Date	12/17/2024
Name	Gamma-Hydroxylbutyric Acid Confirmation, Serum/Plasma
Code	GHBC
Legacy Code	GHBC
Interface Code	3300820
Notes	Test discontinued. See new Warde test, GHBSP.

Inactivate Test Without Replacement	
Effective Date	12/9/2024
Name	Serum Integrated Screen Part 1 (No NT)
Code	INTG1
Legacy Code	INTG1
Interface Code	3000353
Notes	Test discontinued.

Inactivate Test Without Replacement	
Effective Date	12/9/2024
Name	Sequential Screen Part 1
Code	SEQ1
Legacy Code	SEQ1
Interface Code	3000357
Notes	Test discontinued.