

In This Issue

Billing and Compliance

- Additional plans following Medicare Medical Necessity guidelines

Coagulation

- Protein C activity changes

Microbiology

- Clostridium difficile toxin PCR

Referral Testing

- Multiple new orderable tests
- Calculi, urinary
- GQ1b antibody, IgG
- Lamellar body count
- Neuropathy profile IV
- Neuropathy profile V
- Platelet associated immunoglobulins
- Poliovirus immune status
- Thyroid stimulating immunoglobulin

Supplies

- Storage of 24 hour urine jugs with preservative

Website

- New website up and running!

Phone

612-863-4678
800-281-4379

Fax

612-863-4067

BILLING AND COMPLIANCE

Additional plans following Medicare Medical Necessity guidelines

In addition to the Humana Gold MR, Medica Advantage MR, Medica Dual Solutions MSHO, Medica Prime Solutions MR, UCARE Medicare Complete, UCARE Medicare Plans MR (including UCARE for Seniors and UCARE Medicare Advantage plans), medical necessity guidelines are now also in effect for Allina Health Aetna MR and BCBS Medicare replacement plans.

Going forward, waivers will need to be collected on the patients that have these plans for any testing that does not meet medical necessity requirements. A list that includes the affected tests as well as a waiver, can be found on the medical necessity tab of the [Lab billing](#) page of our website.

COAGULATION

Protein C activity changes

On January 7, 2020, Allina Health Laboratory changed from a clotting assay to a Chromogenic assay methodology for the performance of the Protein C activity (5756/85303.0).

Due to the change in methodology, the following changes to the reference range also went into effect:

	Previous	New
Reference range	70-140%	70-150%

MICROBIOLOGY

Clostridium difficile toxin PCR

On January 14, 2020 Allina Health Laboratory instituted a multi-step algorithm for testing and reporting *C. difficile* results. Positive *C. difficile* toxin PCR tests reflex to additional testing, at an additional charge, to confirm that the patient has existing *C. difficile* disease as opposed to being colonized or a carrier.

The PCR test detects the gene encoding for *C. difficile* toxin but does not indicate whether the toxins are actively being produced. The reflexed EIA (enzyme immunoassay) test will detect GDH antigen, indicating the presence of the organism. In addition, it will detect the presence of the Toxin A/B.


By using a testing algorithm that utilizes PCR as the first layer of testing, the lab is able to screen out most of the negative samples. If a sample is PCR positive, it is reflexed to a less sensitive EIA test to screen out possible carriers. A positive EIA with antigen and toxin detected are considered a true *C. difficile* infection.

Note:


Questions regarding interpretation of this algorithm should be directed to Infection Prevention or an Infectious Disease practitioner. The lab cannot interpret patient specific result for this algorithm.

The testing results will be accompanied by an interpretation and comment when indicated:

Positive for toxigenic *C. difficile*

12/12/2019 1427	
ID STOOL	
CTA INTERPRETATION	Positive for to... !
C. DIFFICILE GDH A...	Positive
C. DIFFICILE TOXIN...	Positive
CLOSTRIDIUM DIFFIC...	


Negative for toxigenic *C. difficile*

12/12/2019 1427	
ID STOOL	
CTA INTERPRETATION	Negative for to...
C. DIFFICILE GDH A...	Negative
C. DIFFICILE TOXIN...	Negative
CLOSTRIDIUM DIFFIC...	

Suggests no Active C. difficile disease


Comment:

C. difficile present but toxin was not detected. This could be a non-toxigenic strain, a carrier state, or toxin level too low for detection. The result should be used in conjunction with clinical history when deciding on additional testing and/or possible therapy. Consider ID consultation.

ID STOOL	
CTA INTERPRETATION	Suggests no ac... * !
C. DIFFICILE GDH A...	Positive
C. DIFFICILE TOXIN...	Negative
CLOSTRIDIUM DIFFIC...	

Invalid

Comment: Invalid result. Consider recollection if clinical suspicion of infection still exists.

ID STOOL	
CTA INTERPRETATION	Invalid * !
C. DIFFICILE GDH A...	
C. DIFFICILE TOXIN...	
CLOSTRIDIUM DIFFIC...	

Printed report

CLOST DIFFICILE TOXIN P (Final result)

ID:	19CL-347M0001	Collected:	12/13/2019 1117
Source:	Stool	Verified On:	12/13/2019 1216
Resulting Lab:	ANWLCR		
Component		Value	Ref. Interval
CLOSTRIDIUM DIFFICILE PCR		Positive	
Positive C. difficile PCR results reflexed to EIA testing for confirmation.			
PRESUMPTIVE NAP1 STRAIN		Negative	
Comments: The NAP1 (027 or BI) strain is a hypervirulent strain. Detection may be useful for epidemiological purposes.			

Toxin Activity (Final result)

ID:	19CL-347M0001	Collected:	12/13/2019 1117
Source:	Stool	Verified On:	12/13/2019 1216
Resulting Lab:	ANWLCR		
Component		Value	Ref. Interval
CTA INTERPRETATION		Suggests no active C. difficile disease (A)	Negative for toxigenic C. difficile
C. difficile present but toxin was not detected. This could be a non-toxigenic strain, a carrier state, or toxin level too low for detection. The result should be used in conjunction with clinical history when deciding on additional testing and/or possible therapy. Consider ID consultation.			
C. DIFFICILE GDH ANTIGEN EIA		Positive	
C. DIFFICILE TOXIN A & B EIA		Negative	

CPT Code for EIA testing: 87324 and 87449

REFERRAL TESTING

Multiple new orderable tests

Multiple tests referred to LabCorp, that previously required the use of the Miscellaneous test order (994/LAB994/MSO), are now orderable with unique test order codes.

Test name	Test #	Excellian order	Abbreviation
Apha-galactoside A	14229	LAB14229	ALPHAGALA
Bullous pemphigoid 180 antibody	14222	LAB14222	BP180&230
Clobazam, serum or plasma	14235	LAB14235	CLOBAZAM
C-telopeptide	14230	LAB14230	CTELOPEP
Cystatin C	14224	LAB14224	CYSTATINC
Eslicarbazepine metabolite	14234	LAB14234	ESLICARBAZMET
GQ1b antibody, IgG	14236	LAB14236	GQ1bIGG
Hepatitis E virus, IgM	14239	LAB14239	HEPEIGM
JC virus Ab titer, quantitative	14238	LAB14238	JCVANQNT
Lactate dehydrogenase, CSF/synovial	14223	LAB14223	LSCSFSYN
MAG IgM autoantibodies	14225	LAB14225	MAGIGM
Magnesium, urine	14221	LAB14221	MGU
Mango, IgE	14233	LAB14233	MANGOIGE
Myositis panel III	14241	LAB14241	MYOSITIS
Perampanel, serum/plasma	14240	LAB14240	PERAMPANEL
Phospholipase A2 receptor autoantibodies, IgG	14330	LAB14330	PLA2R
Striational antibodies	14228	LAB14228	STRIATEDABS
Trout, IgE	14232	LAB14232	TROUTEIGE

Calculi, urinary

Effective January 27, 2020, LabCorp will transition the calculi testing from their Burlington laboratory to their Litholink specialty testing facility in Itasca, Illinois.

Details

	Current	NEW
Test name	Calculi, urinary	Stone analysis
Performing lab	LabCorp Burlington (120790)	LabCorp Litholink (910180)
Specimen	Urinary calculi	Calculi (urinary, biliary or salivary)
Days set up	Mo – Sa	Daily
Expected TAT	4 – 10 days	3 – 8 days
Method	Polarized light microscopy supported by infrared spectroscopy and chemical testing	Infrared spectroscopy
CPT	82360	82365

There will be no fee changes as a result of these testing changes.

GQ1b antibody, IgG

LabCorp has shared that due to reagent procurement issues, they are currently unable to perform the GQ1b antibody, IgG assay (14236/LAB14236). The suggested alternative test is the Ganglioside GQ1b antibody (IgG), EIA, which LabCorp will forward to Quest Diagnostics, San Juan Capistrano (34144) for analysis.

Test name:	Ganglioside GQ1b antibody (IgG), EIA
Test number:	994/LAB994
Patient preparation:	Overnight fasting prior to specimen collection is preferred
Specimen type:	1 mL serum—gold SST
Processing instructions:	Spin separate and freeze
Transport container:	LabCorp screw-capped purple frozen plastic transport tube
Transport/stability:	Frozen (preferred) - 21 days
Performing lab:	Quest Diagnostics - San Juan Capistrano (34144) via LabCorp (MISC); R-NX
Expected TAT:	5 – 10 days
Reference range:	< 1:100
CPT codes:	83520

Lamellar body count

Effective immediately, the Lamellar body count assay (994/LAB 994 MSO), referred to LabCorp, has been made obsolete and is no longer available.

Per ACOG guidelines, amniotic fluid testing for fetal lung maturity is no longer recommended. Because of this recommendation, the assay has been discontinued at local and national laboratories.

Neuropathy profile IV

LabCorp has shared that due to reagent procurement issues, they are currently unable to perform the Neuropathy profile IV (994/LAB994) assay.

The suggested alternative test is the Motor neuropathy panel, which LabCorp will forward to ARUP (34144) for analysis. Test ordering and specimen details are as included below.

Test name:	Motor neuropathy panel
Test number:	994/LAB994
Abbreviation:	MSO
Test includes:	Albumin, Alpha 1 globulin, Alpha 2 globulin, Beta globulin, Gamma, Immunofixation, Immunoglobulin A, Immunoglobulin G, Immunoglobulin M, Total protein, Asialo-GM1 Abs-IgG/IgM, GM1 Abs-IgG/IgM, GD1a Abs-IgG/IgM, GD1b Abs-IgG/IgM, GQ1b Abs-IgG/IgM, SGPG Ab-IgM, MAG Ab-IgM ELISA
Specimen type:	Serum
Volume:	4 mL (minimum 2 mL)
Collection container	Gold SST
Processing instructions:	Separate from cells within 2 hours of collection, and freeze
Transport container:	Screw-cap polypropylene frozen transport vial/tube - 4mL (LabCorp)
Transport/stability:	Frozen (preferred) – 1 month
	Refrigerated – 1 week
Performing lab:	ARUP (0051225) via LabCorp (009985); R-NX
Days set up:	Su - Sa
Expected TAT:	8 days
CPT codes:	82784x3, 83516x7, 84155, 84165 and 86334

Neuropathy profile V

LabCorp has shared that due to reagent procurement issues, they are currently unable to perform the Neuropathy profile V (13656/LAB13656) assay.

The suggested alternative test is the Motor neuropathy panel, which LabCorp will forward to ARUP (34144) for analysis. Test ordering and specimen details are as included below.

Test name:	Motor neuropathy panel
Test number:	994/LAB994
Abbreviation:	MSO
Test includes:	Albumin, Alpha 1 globulin, Alpha 2 globulin, Beta globulin, Gamma, Immunofixation, Immunoglobulin A, Immunoglobulin G, Immunoglobulin M, Total protein, Asialo-GM1 Abs-IgG/IgM, GM1 Abs-IgG/IgM, GD1a Abs-IgG/IgM, GD1b Abs-IgG/IgM, GQ1b Abs-IgG/IgM, SGPG Ab-IgM, MAG Ab-IgM ELISA
Specimen type:	Serum
Volume:	4 mL (minimum 2 mL)
Collection container	Gold SST
Processing instructions:	Separate from cells within 2 hours of collection, and freeze
Transport container:	Screw-cap polypropylene frozen transport vial/tube - 4mL (LabCorp)
Transport/stability:	Frozen (preferred) – 1 month Refrigerated – 1 week
Performing lab:	ARUP (0051225) via LabCorp (009985); R-NX
Days set up:	Su - Sa
Expected TAT:	8 days
CPT codes:	82784x3, 83516x7, 84155, 84165 and 86334

Platelet associated immunoglobulins

Effective immediately, the Platelet associated immunoglobulins assay (2199), used to detect platelet-specific autoantibodies, and referred to the American Red Cross (ARC), is no longer available.

Allina Health Laboratory has received communication from the ARC sharing that, because the manufacturer is no longer offering reagents for their Platelet associated immunoglobulins assay within the US, effective immediately, they are no longer offering this test.

The suggested alternative test is the [Platelet autoantibody profile, whole blood](#), referred to LabCorp.

Platelet autoantibody profile, whole blood-994

Test info	Specimen	Performance	Clinical and Interpretive info	Billing
Test name:	Platelet autoantibody profile, whole blood			
Test number:	994			
Excellian order number:	LAB994			
Abbreviation:	MSO			
Alternate names:	Direct platelet antibodies Platelet-associated immunoglobulin			

Poliovirus immune status

LabCorp has shared communications indicating that the Poliovirus Immune Status profile assay (13588/LAB13588) has been made non-orderable.

Due to the World Health Organization (WHO) announcement of eradication of Poliovirus Type 3, the Poliovirus immune status assay, referred to LabCorp, is no longer offered.

No replacement test is available.

Thyroid stimulating immunoglobulin

LabCorp has announced a transport and stability change for the Thyroid stimulating immunoglobulin assay (13399/LAB13399) which will go into effect on January 20, 2020.

Details

Current	New
Frozen (preferred) – 12 months Refrigerated – 7 days Ambient – 24 hours	Ambient (preferred) – 14 days Refrigerated – 14 days Frozen – 14 days <i>Freeze/thaw cycle: stable x3</i>

WEBSITE

New website up and running!

We would like to take this opportunity to remind all of our clients that in December of 2019, the new Allina Health Laboratory website went live.

We have a new url, which is allinahealth.org/allinahealthlaboratory. Please make sure to update any bookmarks or shortcuts that you may have saved. If you have questions or concern about our site, contact your account representative for assistance.

**Thank you for choosing Allina Health Laboratory -
we appreciate your business!**