

COVID-19 Update

May 13: Workforce App Update, Monoclonal Antibody Treatment, and Anti-SARS-CoV-2 Immunoglobulin Testing

Today's issue features the latest update to the NM Workforce app and information regarding changes for monoclonal antibody treatment. It also includes an update on COVID-19 antibody testing.

WORKFORCE APP UPDATE

The latest NM Workforce app update makes accessing COVID-19 vaccine information easier. Once updated, the app will display a new tile: **COVID-19 Vaccination Record**. When selected, the tile will display an electronic copy of your COVID-19 vaccine information that includes:

- Name of vaccine manufacturer
- Lot number
- Date received
- Location received

Make sure to update your **NM Workforce app** to access this new feature.

MONOCLONAL ANTIBODY TREATMENT

The Centers for Disease Control and Prevention (CDC) **identified** early last week that the P.1 variant, which originated in Brazil, is circulating with increasing prevalence in the state of Illinois. Data suggests that bamlanivimab and etesevimab are not active against the P.1 variant. However, the other available authorized monoclonal antibody therapy, casirivimab and imdevimab (REGEN-COV), is expected to retain activity against this variant.

On May 7, the Illinois Department of Public Health, in partnership with the U.S. Food and Drug Administration, issued a Siren Alert with the recommendation that healthcare providers in Illinois only utilize REGEN-COV until further notice. The distribution of bamlanivimab and etesevimab in Illinois has been suspended.

Northwestern Medicine has discontinued the use of bamlanivimab and etesevimab and has implemented REGEN-COV for monoclonal antibody (mAb) treatment against SARS-CoV-2.

What this means for infusion sites

1. Emergency Use Authorization patient and provider fact sheets:

- Discard any bamlanivimab or bamlanivimab/etesevimab mAbs infusion patient and provider fact sheets on hand.
 - Patients must be given the fact sheet for the infusion they are receiving. REGEN-COV patient and provider fact sheets can be found here: [Casirivimab and Imdevimab Injection \(regeneron.com\)](#)
2. Epic order changes:
 - [Ordering the mAbs Order Panel](#) (see tip sheet)
 - [Ordering the mAbs Therapy Plan](#) (see tip sheet)
 3. Changes to infusion time:
 - REGEN-COV infusion is delivered over 20 minutes.
 - Post-infusion observation remains 60 minutes.
 4. IV tubing/filter: No changes.

Please note that next week, Central Region mAbs infusions will transition from Olson 6 to the Streeterville Immediate Care Center. Additional information on timing will be shared once it becomes available.

For more mAbs treatment information and resources, please visit the [Treatment Resources page](#) on Physician Forum and [NMI](#) (login required).

ANTI-SARS-COV-2 IMMUNOGLOBULIN TESTING

With vaccination rates increasing, more questions have arisen regarding the role of serology (antibody) testing for SARS-CoV-2. The CDC discourages antibody testing for assessing immunity post-vaccination. A vaccinated individual may have a negative result even if the vaccine was successful and protective because different serologic tests detect antibodies against different parts of the virus.

Despite several antibody tests on the market, current evidence suggests antibody testing alone is not conclusive for diagnosing current or prior COVID-19 infection, or for predicting a patient's immunity. The duration of antibodies following a COVID-19 infection and the level of antibodies needed to neutralize SARS-CoV-2 following another exposure remain unclear, and additional research is needed.

A positive serology test result suggests that COVID-19 infection occurred at some time in the recent past. A negative test result suggests that there was no recent COVID-19 infection. However, a negative result does not exclude a prior or current infection because antibodies could be present at levels below the level of detection. In general, antibodies become detectable two to three weeks after infection. Also, antibodies may decline over time below detectable levels.

In November 2020, the Northwestern Memorial Hospital Clinical Laboratory began offering anti-SARS-CoV-2 IgG and IgM testing. The assay is designed to detect immunoglobulins specific for the receptor binding domain of the S1 (spike) protein of the virus. Testing for anti-SARS-CoV-2 immunoglobulins is available seven days a week.

Test Name	IgG LAB15000	IgM LAB15030
Test Code	COV2G	COV2M
CPT Code	86769	86769

Turnaround Time	1 hour stat, 4 hours routine
Specimen Requirement	Blood collected in a gold-top Vacutainer® tube

Reporting

Anti-SARS-CoV-2 spike protein IgG	Non-reactive	Equivocal	Reactive
Anti-SARS-CoV-2 spike protein IgG index	≤ 0.80	0.81 – 0.99	≥ 1.00

Result	Non-reactive	Reactive
Anti-SARS-CoV-2 spike protein IgM	≤ 0.99	≥ 1.00

- For equivocal IgG results, a repeat test is recommended one or two weeks later.
- Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary. Results from antibody testing alone should not be used to diagnose or exclude acute SARS-CoV-2 infection.

Clinical Performance

Specificity of Anti-SARS-CoV-2 IgG

Population	Total Samples	# Non-reactive	# Reactive	# Equivocal	Clinical Specificity
Pre-COVID-19	1,400	1,395	3	2	99.8%

Sensitivity of Anti-SARS-CoV-2 IgG

Days Between Positive PCR and Sample Collection	Total Samples	# Non-reactive	# Reactive	# Equivocal	Clinical Specificity
0 – 6	47	14	33	0	70.2%
7 – 14	88	4	84	0	95.5%
> 14	112	1	109	2	99.1%
> 18	58	0	58	0	100%

Specificity of Anti-SARS-CoV-2 IgM

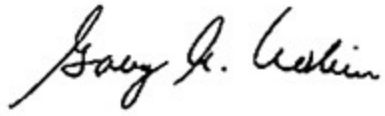
Population	Total Samples	# Non-reactive	# Reactive	Clinical Specificity
Pre-COVID-19	1,400	1,398	2	99.9%

Specificity of Anti-SARS-CoV-2 IgM on Beckman Dxl

Days Between Positive PCR and Sample Collection	Total Samples	# Non-reactive	# Reactive	Clinical Specificity
0 – 7	22	10	12	54.5%
8 – 14	36	3	33	91.7%
15 – 30	115	2	113	98.3%

If you have questions or concerns regarding antibody testing, contact Medical Director of Clinical Chemistry Gregory S. Retzinger, MD, PhD, at gretzing@nm.org or 312.926.2258.

Thank you for your enduring commitment to our *Patients First* mission. Please continue to encourage your patients to get vaccinated.

A handwritten signature in black ink that reads "Gary A. Noskin". The signature is written in a cursive style with a large, prominent initial "G".

Gary A. Noskin, MD
Senior Vice President, Quality
Northwestern Memorial HealthCare
Chief Medical Officer
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