Laboratory Services Newsletter

SUMMER 2020

COVID-19 TESTING

SARS-CoV-2 IgG Testing

Nationwide Children's Laboratory Services is offering in-house qualitative antibody (IgG) testing for SARS-CoV-2 by chemiluminescent immunoassay. SARS-CoV-2 IgG testing is available for serum and plasma (EDTA) samples.

Debbie Miller - Laboratory Services

Antibody testing should not be used to diagnose acute infection.
This test detects human SARS-CoV-2 IgG antibodies that are generated as part of the adaptive immune response to the nucleocapsid protein of the SARS-CoV-2 virus. A positive result indicates that antibodies to SARS-CoV-2 were detected, and the individual has potentially been exposed to COVID-19 and should be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Positive results will be reported to the CDC and/or local and state public health authorities. A negative result does not rule out COVID-19 and should not be used as the sole basis for treatment, patient management decisions, or to rule out active infection. Molecular testing is recommended for diagnosis of active infection. This test is available in the United States through the FDA under an Emergency Use Authorization (EUA). Fact sheets for patients and health-care providers are available on the NCH Laboratory Guide to Services.

SARS-CoV-2 IgG Antibodies by Chemiluminescence	
Test Code	SARIGG
Specimen Types & Volume	Blood collection, Serum (Red/Gold) or Plasma (EDTA-purple, LiHep-green) 1.0 mL minimum
Transport / Stability	Transport whole blood to lab immediately or separate serum/plasma from cells within 2 hours • Serum/plasma may be stored at room temp for up to 2 days • Serum/plasma may be store refrigerated for 7 days
Performed / Turnaround Time	Daily, Monday through Friday
Comments	This is a qualitative test Positive results reported to ODH

COVID-19 continued

COVID–19 TESTING

SARS-CoV-2 IgG – Frequently Asked questions (FAQ)

1. **Should I send for serology testing in a patient in whom I suspect active COVID-19?**
   No. A PCR test should be used to diagnose active infection.
2. **What is the difference between SARS-CoV-2 PCR and serology (or antibody) testing?**
   PCR tests – also called molecular tests, nucleic-acid amplification tests, or NAAT tests – detect the presence of viral RNA and are used to detect active infection with SARS-CoV-2. Serology tests – also called antibody tests – detect the antibodies produced by the body in response to infection with SARS-CoV-2. As serology tests identify the body's immune response and not the virus itself, serology tests are not used to diagnose an acute infection. Serology tests are intended to detect recent or prior infection only.
3. **What type of serology test does Nationwide Children's Laboratory Services offer?**
   Nationwide Children's Laboratory Services performs the Abbott SARS-CoV-2 IgG Chemiluminescent Immunoassay which detects IgG antibodies to SARS-CoV-2 nucleocapsid protein.
4. **What is the sensitivity and specificity of this serology test?**
   According to the FDA EUA Authorized Serology Test Performance web-page, the sensitivity and specificity (95% CI) of this assay is 100% (95.8-100) and 99.6 (99.0-99.9), respectively. This assay is unlikely to cross-react with other human coronaviruses, though cross-reactivity cannot be completely ruled out. Results should be interpreted with caution particularly in immunocompromised patients as detectable levels of antibodies may not be produced, or antibody response may be delayed.
5. **How are results reported?**
   Results are reported as either SARS-CoV-2 IgG POSITIVE (Index (S/C) ≥ 1.4) or SARS-CoV-2 IgG NEGATIVE (Index (S/C < 1.4).
6. **What is the turn-around-time for serology results?**
   The test is performed daily Monday through Friday. Specimens received prior to 9:00 a.m. will be run the same day. Specimens received after 9:00 a.m. will be run the next business day.
7. **What are the indications for serologic testing for SARS-CoV-2?**
   Outside of public health and research settings, serologic testing for SARS-CoV-2 should be limited to patients in whom infection is suspected to have occurred > 10-14 days ago AND knowledge of this immune response to recent or prior infection will impact clinical care. An example of a scenario where serology testing might be useful is in determining timing of initiating immunosuppressant therapy to a patient with COVID-19 diagnosed several weeks prior.
8. **How do I interpret a positive SARS-CoV-2 IgG result?**
   A positive SARS-CoV-2 IgG in most cases represents recent or prior infection but results should be interpreted with clinical and epidemiological findings. At this time, it is not known whether the presence of antibodies confers protection against repeat infection. The duration of antibody response is also not known at this time.
9. **How do I interpret a negative SARS-CoV-2 IgG result?**
   The absence of detectable IgG may represent either that the patient has not been infected with SARS-CoV-2 or that the patient has been infected, but has not developed.

COVID-19 continued

COVID–19 TESTING

Respiratory Infection Array: Addition of SARS-CoV-2

There may be times when it is important to perform a more comprehensive and sensitive test for respiratory pathogens in the outpatient setting. The Respiratory Infection Array is an amplified nucleic acid test that detects 17 viruses or viral subtypes and 4 bacterial targets.

The Respiratory Infection Array (FARVPP) Panel now includes **SARS-CoV-2** (COVID 19). In addition, the individual influenza A subtypes and coronaviruses will appear in the report.

Test Name	Respiratory Infection Array
Test Code	FARVPP
Sample Type	NP swab in viral transport media (use collection kit provided)
Stability	Room temperature - 4 hours. Refrigerated - 3 days
Turnaround Time	Inpatients and ED/UC patients will be prioritized and reported within 2 hours. All other patients will be reported within 8 hours of specimen receipt. Significant increases in test volumes could cause extended turnaround time.

Viral Targets	
• Adenovirus	• Parainfluenza Virus 1- 4
• Coronavirus: 229E, HKU1, NL63, OC43	• Respiratory Syncytial Virus (RSV)
• Human Metapneumovirus	• Rhinovirus/Enterovirus
• Influenza A: H1, H1 2009, H3	• SARS-CoV-2
• Influenza B	

Bacterial Targets
• *Bordetella parapertussis*
• *Bordetella pertussis*
• *Chlamydophila pneumoniae*
• *Mycoplasma pneumoniae*

For more information about SARS-COV-2 IgG, Respiratory Infection Array (FARVPP) and SARS-CoV-2 testing, please contact Nationwide Children's Laboratory Services at (800) 934-6575.

INFORMATION TO KNOW

Summer Time

With warm weather in full swing, stool parasites and microbes are often prevalent with spoiled food, swimming pools, lakes and ponds. Laboratory Services offers multiplex molecular testing for gastrointestinal (GI) pathogens. The spectrum of pathogens that cause GI infections is quite broad and typically requires an assortment of classical detection methods (fecal examination, bacterial culture, and PCR testing) to identify the causative agent. Many of these classical methods suffer from variable specificity and sensitivity, and are often poorly utilized due to a lack of understanding of each method's intended use. Molecular testing is more sensitive and faster than conventional methods for detection of gastrointestinal pathogens.

The Gastrointestinal Infection Array tests for common gastrointestinal pathogens including 11 bacteria, 5 viruses, and 4 protozoa that cause infectious diarrhea. The GI Array is designed as a screening test for gastrointestinal infections where a rapid comprehensive answer is desired. It is meant to be ordered in place of conventional testing such as routine stool culture, ova and parasite examinations, and antigen testing.

For optimal GI Array testing, stool specimens should be collected in a Cary-Blair collection container with media, and transported to a Nationwide Children's Laboratory Service Center within 24 hours at room temperature or 72 hours refrigerated. Testing is performed 24/7 with a turn-around time estimated at 8 hours of receipt.

Warm Weather Reminder

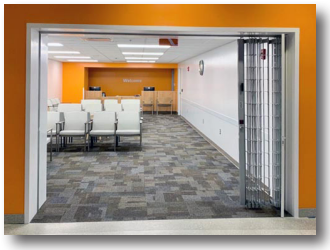
Now that summer is here, it is important that samples placed in a lockbox prior to transport to the laboratory be maintained at the appropriate temperature.

If refrigerated samples are stored in the lockbox, then a refrigerated cold pack should be placed in the lockbox to maintain the samples at the **refrigerated temperature**. The **cold pack should not be frozen**, since you do not want refrigerated whole blood samples to freeze.

Many laboratory tests performed require adequate refrigeration of specimens. By following this lockbox practice, you will help insure the integrity of the samples and ultimately obtain reliable laboratory results.

Nationwide Children's Orange Lab (Outpatient Lab) on Main Campus has Moved

The Orange Laboratory has moved from the lower level to the first floor level of the Outpatient Care Center at 555 South 18th Street. The entrance is located on the Orange Path next to the Orange Pharmacy across from Clementine's Cafe. Unlike the half wall pods in the previous space, the new lab has private phlebotomy draw rooms that provide a quiet space for patients and families. The larger first floor waiting area is convenient, and easy to access for patients and families (*see picture at left).*



The new Orange Lab waiting area viewed from the Orange Path

The Orange Lab is open from 8 a.m. to 7 p.m. Monday through Friday and 8:30 a.m. to 3:30 p.m. on Saturdays. *(Due to the pandemic, please visit NationwideChildrens.org/locations/laboratory-services for current hours of operation.)*

The Orange Parking garage, adjacent to the Outpatient Care Center, provides convenient parking for patients and families.

INFORMATION TO KNOW

Urine Test Requisition Reminders

As a reminder, the source of the urine sample is critical information for testing and must be included on the order requisition.

Failure to provide a urine source on the requisition may lead to a delay in testing or rejection of the sample. **Please note that "random" or "contaminated" urine collections are not appropriate for culture or urinalysis reflex to culture.**

Urine Source Option	Urine Specimen Type Guide
Clean catch	Clean catch
Bagged	Bagged
Indwelling Tube	Indwelling Catheter: • Foley • Suprapubic Tube • Mitrofanoff • Nephrostomy • Transurethral

Test Requisition Reminders

Make it a habit to review the printed requisition to make sure the Patient, Insurance, and Specimen Information is correct before sending a specimen to the laboratory. Missing patient or billing information for specimen registration often results in a phone call to your office staff requesting the missing information.

Clarification of terms in the Billing Information section of the Laboratory Service's requisition are as follows:

- **Guarantor** is the name legal guardian or parent of the patient (the child cannot be the guarantor)
- **Subscriber** is the person that is the carrier of the insurance for the patient

Are You Submitting a Bacterial or Viral Culture?

To receive the most reliable result on your patient, please provide an accurate specimen description on the test requisition for every bacterial and viral culture which includes:

Exact type of culture examples	AND	Exact body site or source examples
• Wound, Abscess	+	• Greater left toe
• Urine	+	• Straight catheter
• Dermatophyte	+	• Nail

ICD-10 Impacts the Diagnosis Information

As a reminder, we require accurate ICD-10 codes to aid with billing and other functions associated with laboratory testing. Everyone who is covered by the Health Insurance Portability and Accountability Act must transition to ICD-10 coding. If claims are not filed with ICD-10 codes they will be rejected and not be paid. With the correct ICD-10 code, the bill will likely be paid without unnecessary delays. This will reduce re-work for your billing office and make for a better patient experience. If you are using ChildLink, ICD-10 codes will automatically be available for selection. If you are still using manual test requisitions, the ICD-10 code will need to be included on the test requisition. If you do not know the ICD-10 code please write the diagnosis.

INFORMATION TO KNOW

How to Screen for Sexually Transmitted Diseases in Adolescents

Chlamydia trachomatis and *Neisseria gonorrhea*

Chlamydia and gonorrhea are the most common reportable infections in the US, and rates are increasing.[1] Infections may be asymptomatic, or may lead to cervicitis, PID, chronic pelvic pain, ectopic pregnancy, and tubal infertility. Males may experience urethritis, epididymitis, and rectal infections.

Specimens:

- Vaginal swabs are preferred for females, with higher sensitivity than urine.[2, 3]
  These may be clinician-collected or self-collected, using the appropriate collection kit supplied by the manufacturer.
- First catch urine is appropriate for screening asymptomatic females, and for all testing in males.
- Urethral and endocervical specimens are also acceptable, using the appropriate collection kit.
- Pharyngeal/rectal specimens may be sent for adolescents who engage in receptive oral/anal intercourse, using the Viral Transport Media collection kit (NCH), or the appropriate collection kit.

First-Catch Urine Collection
At least one hour since last void
Females should NOT clean perineum prior to voiding
Collect first 10-15 ml of urine stream into sterile specimen cup; remainder of void into toilet
May be left at room temperature for 24 hours

Tests:

- Nucleic acid amplification tests (NAAT) are the gold standard. NCH laboratory services uses Hologic's Aptima Combo 2® assay, ordered as "Chlamydia and GC by amplified detection".

Trichomonas vaginalis (TV)

T. vaginalis infection is a common cause of vaginal discharge, though it may be asymptomatic. Trichomoniasis is associated with adverse pregnancy outcomes and an increased risk of HIV transmission. Screening of asymptomatic women at increased risk is therefore permissible. Screening asymptomatic males is not advised, but testing may be considered in males with persistent urethritis symptoms.

Specimens:

- Vaginal swab (clinician-collected)
- First-catch urine (FDA-approved for females; validated at NCH for use in males)
- May send a single specimen for testing for gonorrhea, chlamydia, and trichomonas

Tests:

- NAATs are the gold standard. NCH laboratory services uses Hologic's Aptima® T. vaginalis assay, ordered as "Trichomonas vaginalis amplified probe" or "Chlamydia/GC/Trichomonas amplified probe panel".
- Visualization of motile trichomonads on microscopic evaluation of a vaginal specimen provides immediate results but has low sensitivity.
- The BD Affirm vaginal panel, used for diagnosis of vaginal candidiasis and bacterial vaginosis, has very low sensitivity for diagnosing trichomoniasis.

Continued on next page

INFORMATION TO KNOW

How to Screen for Sexually Transmitted Diseases in Adolescents *continued*

Human Immunodeficiency Virus (HIV)

It is estimated that over 50,000 adolescents and young adults in the US have HIV, but only about half are aware of their infection.[4] AAP recommends screening all adolescents at least once by 16-18 years-old. Sexually active adolescents should be tested sooner.[2] Testing should be considered routine and does not require written consent. Patients have a right to "opt out" of testing.

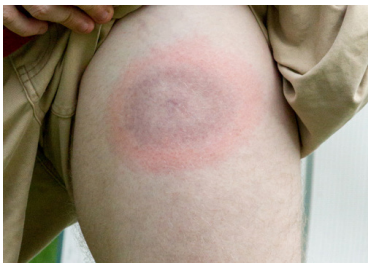
Specimens and Testing:

- HIV 1 and HIV 2 Ag/Ab Screen (venipuncture)

Resources:

1) 2018 CDC STDs in Adolescents and Young Adults-https://www.cdc.gov/std/stats18/adolescents.htm. 2) AAP Policy Statement: Screening for nonviral STI in adolescents and young adults. Pediatrics 2014;134:e302 3) CDC. Sexually Transmitted Diseases Treatment Guidelines, 2015. MMWR Recomm Rep 2015; 64(No. RR-3). 4) CDC HIV and Youth- https://www.cdc.gov/hiv/group/age/youth/index.html.

Testing for Lyme Disease at Nationwide Children's Hospital



Lyme serology should be conducted if the epidemiology as well as signs and symptoms are consistent with possible Lyme disease.

An enzyme-linked fluorescent immunoassay (ELFA) screens for antibodies to the Borrelia burgdorferi complex. The assay detects total antibody (IgG and IgM) to Borrelia burgdorferi complex in human serum and is intended for use as an aid in diagnosis of Lyme disease.

Testing is not intended or indicated as a screening procedure for the general population, and it should be done only when exposure history or symptoms suggest Lyme disease.

- **Negative Results**
  Negative results do not rule out a diagnosis of Lyme disease. Patients in early stages of infection may not produce detectable levels of antibody. Antibiotic therapy in early stages may prevent antibody production from reaching diagnostic levels. Patients with clinical history or symptoms or both suggestive of Lyme disease but with negative results should be retested in 4-6 weeks. A single positive result only indicates prior infection.
- **Positive Results**
  Positive results must be interpreted with caution. Clinical symptoms, epidemiological information and other laboratory test results must all be considered. Following CDC recommendations, Western Blot testing is performed to confirm all positive ELFA results.
- **Confirmation by Western Blot**
  This method is used to confirm positive total antibody screens. The Western Blot method identifies the proteins of the bacteria to which the antibody response is directed, both IgM and IgG. This test should only be used to confirm positives, and it should not be ordered as a stand-alone diagnostic test.

For more information regarding test availability or specimen requirements for STI and Lyme Disease testing, please call (800) 934-6575 or visit NationwideChildrens.org/Lab.

NATIONWIDE CHILDREN'S

When your child needs a hospital, everything matters.℠

Nationwide Children's Hospital
700 Children's Drive
Columbus, Ohio 43205-2664

How can Nationwide Children's Laboratory Services help your practice?

- Pediatric pathologist consults on lab results
- Wide acceptance of insurance plans
- Pediatric reference ranges
- Services to enhance the laboratory process in your practice
- Interface compatibility with provider EMR systems

If you would like to become a client or learn more information about Nationwide Children's Laboratory Services, contact us at (800) 934-6575 or visit our website at NationwideChildrens.org/Lab.

Would you like to receive the Nationwide Children's Laboratory Services Newsletter electronically? Please e-mail us at LaboratoryServices@NationwideChildrens.org and let us know!