Laboratory Services Newsletter SUMMER 2021

SEXUALLY TRANSMITTED DISEASES ON THE RISE

An All-Time High

The newly released 2019 STD Surveillance Report from the CDC states that sexually transmitted diseases reached an all-time high for the sixth year in a row.

The report found:

- 2.5 million reported cases of chlamydia, gonorrhea, and syphilis; the three most reported STDs in 2019[1].
- Young people aged 15–24 years make up 61% of chlamydia cases, and 42% of gonorrhea cases[1].
- A nearly 30% increase in these reportable STDs between 2015 and 2019[1].

"STDs will not wait for the pandemic to end, so we must rise to the challenge now," Raul A. Romaguera, DMD, MPH Acting Deputy Director of NCHHSTP said. "These new data should create a sense of urgency and mobilize the resources needed, so that future reports can tell a different story."[1]

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.

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.

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.

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. AAP recommends screening all adolescents at least once by 16-18 years-old.

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INFORMATION TO KNOW

Human Immunodeficiency Virus (HIV) *(STDs on the Rise - continued from page 1)*

Sexually active adolescents should be tested sooner. Testing should be considered routine and does not require written consent. Patients have a right to "opt out" of testing. **Testing:** HIV 1 and HIV 2 Ag/Ab Screen (venipuncture)

Resources: 1) Reported STDs Reach All-time High for 6th Consecutive Year- https://www.cdc.gov/media/releases/2021/p0413-stds.html.

Outdoor Temperatures and Lockbox Specimen Storage

It is imparative that samples placed in a lockbox outdoors prior to transport to the laboratory be maintained at the appropriate temperature especially those days and evenings when outside temperatures dip below freezing, or soar during the day.

Outside temperature is above 46°F:
If refrigerated samples are stored in your lockbox, then one or two **refrigerated cold packs** should be placed in the lockbox to maintain the samples at the refrigerated temperature until the courier picks them up. The **gel pack should not be frozen**, since you do not want refrigerated whole blood samples to freeze.
Note: Please be aware of your lockbox if it is sitting in the sun, or on concrete/asphalt walkways. The internal temperature of the lockbox may be warmer than the outside temperature.

Outside temperature is below 40°F:
If refrigerated samples are stored in your lockbox, a **room temperature gel pack** should be placed in the lockbox to prevent the samples from freezing while left outside. The **gel 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.

New Pregnancy Loss Brochure: Testing Options Available to Help Find Out the Cause

Pregnancy loss can be very difficult. Nationwide Children's Hospital Laboratory Services offers genetic and pathology tests to help find out why your patient's loss happened. These results may provide you significant information that can help you assist your patients' plans for future pregnancies.

Our new brochure, available to healthcare providers and labor and delivery units, is a comprehensive educational brochure designed for your patients that have experienced a pregnancy loss. Knowing how difficult this time can be, but also needing to take into consideration time with these delicate tissues and the ability to test, this brochure helps to explain options available to your patients. It's topics include: Genetic tests for pregnancy loss, Chromosome analysis, Microarray analysis, when more tests are needed, pathology tests, test results, costs and tissue leftover from testing. It is offered complementary to our valued clients.

New Products of Conception (POC) and Fetal Tissue Procedure Manuals

Our newest version of our POC and Fetal Tissue Procedure manual is also now available with procedure updates, and a NEW Autopsy policy taking effect May 1, 2021.

For questions regarding lockbox storage temperatures, how to receive your updated POC and Fetal Tissue Procedure manual, or would like Pregnancy Loss Brochures, please contact your account representative, or call Laboratory Client Services at (800) 934-6575.

INFORMATION TO KNOW

BLOOD COLLECTION CONCERNS

The Hazards of Uncapping Evacuated (Vacutainer®) Blood Collection Tubes

Did you know uncapping an evacuated tube could compromise testing, delay results, or cause a recollection? Providers commonly order hematology studies (CBC, ESR) paired with clinical chemistry testing (CMTP). Recently, while running testing on a patient who had the three tests above ordered, we discovered the rubber caps/stoppers had been removed from the tubes during the collection process, and switched. The EDTA tube had on a green top instead of a purple top, and the Lithium Heparin tube had a purple top instead of a green top. The switch caused the wrong sample type to go to Hematology and Clinical Chemistry respectively. While this might seem insignificant, it is very significant.

Had these issues not been discovered prior to the release of test results, very aberrant or erroneous test results could have reached the patient. **Test results are directly and many times significantly impacted by the collection procedure**.

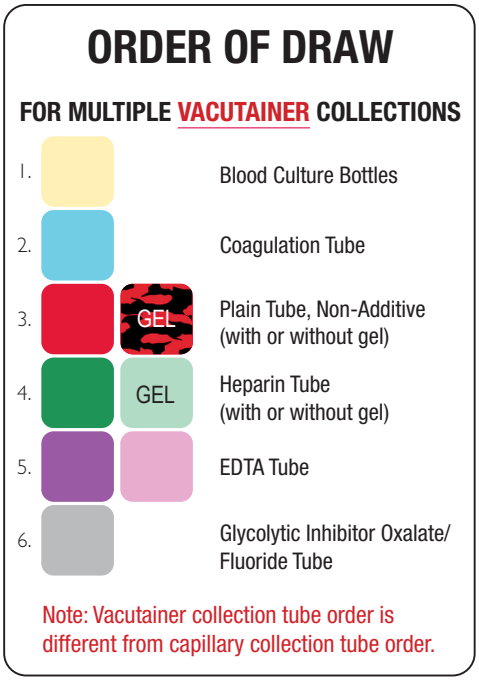
Please do not uncap evacuated tubes to fill them:

- As the manufacturer and the FDA have not validated them when used in that manner.
- The vacuum in the sealed tube controls the fill volume and will help prevent over or under filling. This is of particular importance with the sodium citrate, blue top tubes used in coagulation studies.
- Our own internal test validation studies are performed from factory-sealed (evacuated) tubes.
- Test reference ranges are often established based on venous blood collected directly into the evacuated tubes without exposure to ambient air.
- Collection tubes' caps or stoppers are also more likely to come loose once removed, causing specimen spills and potential blood exposure to health care staff.

Order of Vacutainer® Tube Collection Q & A

Q: What would cause a patient's plasma potassium to be measured as >14 mmol/L and their plasma calcium to be measured as <1 mg/dL?

A: The problem described above regarding tube caps that have been switched, or if a purple-top EDTA evacuated tube was filled prior to a lithium heparin green-top tube when using the multisample or transfer device. The EDTA anticoagulant is "carried over" or contaminates the lithium heparin tube via the needle that punctures their caps. The EDTA anticoagulant is actually a salt containing dipotassium EDTA which causes the potassium to be significantly increased. EDTA is a strong chelater ("grabber") of calcium, which also severely decreases the calcium in the sample. We recently saw this on a patient's Chemistry panel and confirmed with the collector that the EDTA tube was filled first "because the CBC is high priority for our patients." While the intention was certainly good, current phlebotomy standards recommend the green-top heparinized tube be filled first, then the EDTA tube when using the multisample adapter/transfer device, to avoid such a problem.



INFORMATION TO KNOW

Laboratory Testing Turnaround Time

Our clinical laboratory, like most, monitors how quickly we are reporting much of our patients' testing. This is usually referred to as "turnaround time". Most laboratories measure this as the time between specimen receipt in the laboratory to the time when test results are released to our information system(s). This performance is shared with our testing personnel, sometimes summarized daily (for high volume STAT testing), weekly, or monthly. While average, median and standard deviation are usually included, we may also monitor such things as the percentage of Emergency Department patient WBC differentials released in less than 30 minutes. That can be a more meaningful measure of our performance.

Why not monitor or measure from specimen collection time to test reporting time? Because in many labs, including ours, the collection and delivery processes are not under the control of the laboratory for most testing, and they are subject to a lot of variation. It's important to remember that collection, handling and delivery time of a specimen *may exceed the actual time it takes us to perform the analysis and reporting of your patient's test results.*

Turnaround time targets or goals can be found in the Laboratory Guide to Services under each test's listing. These targets are for a "routine" priority orders (not STAT) and can be influenced by instrument/analyzer downtime (sometimes scheduled instrument service; sometimes unexpected), supply shortages, and occasionally, unexpected increases or surges in patient testing volumes. This happened recently when significant snowfall kept patients from reporting for COVID-related collection appointments, and then had to "shift" their appointments to the next day. Some testing may also require a Pathologist's review or consultation, which can add to the actual test reporting time and this is often stated in the Laboratory Guide to Services.

In addition, quality and turnaround time in clinical laboratories cannot be understood by merely focusing on the analytical aspects only; there is a need to put attention on pre-analytical and post-analytical aspects of laboratory testing to improve overall quality of laboratory diagnosis. In the six month study, *Test requisition form- A check point in pre-analytical phase for laboratory errors,* published in Asian Pac. J. Health Sci., 2017; 4(2):175-182, authors P Toshniwal, S Toshniwal, J Jasani, and R M Shah evaluate the contribution of incompletely filled test requisition form in pre-analytical phase (which begins from the clinicians test order request including the examination, requisition, preparation of the patient, collection of the primary sample and transportation to and within the laboratory and ending when the analytical examination begins) and how this error could be minimized in the pre-analytical phase so to improve the quality and turnaround time of total testing process.

Incomplete or incorrect test requisition forms are the major sources of pre-analytical error that affects the quality of total testing process and influence patient safety and outcomes. Errors taking place in the pre-analytical phase almost account between 60 to 70% than the other phase's errors in the total testing process and potenial extended turnaround times.

Details of incomplete and incorrect test requisition form observed at Nationwide Children's Laboratory Services:

- Incomplete or wrong name of patient
- No date of birth of patient
- Gender not mentioned
- Incorrect or no ICD-10 code
- No date/time of collection
- No specimen colletors name
- No/incorrectly filled billing information
- Test checked/mentioned incorrectly
- Test mentioned in short forms
- Test not checked/mentioned
- Type of specimen not defined
- Priority of test not marked
- Ordering provider name not mentioned
- No physician's signature

Make it a practice to review the printed requisition to make sure the Patient, Insurance, and Specimen Information is complete and correct before sending a specimen to the laboratory. Missing patient information often results in a phone call to your office staff requesting the missing information which could delay turnaround time and treatment.

INFORMATION TO KNOW

Lead and Hemoglobin Screening by Finger Stick

With provider offices currently scheduling school physicals for the 2021 – 2022 school year, Nationwide Children's Laboratory Services would like to help you by providing a blood lead and hemoglobin* screening test using a filter card. Both tests ordered together only requires three circles filled with blood on the filter card. Collecting these tests on the same card reduces patient distress, provides a quick collection, gains a higher patient compliance, and is very easy to transport.

Collection using the Lead and Hemoglobin Filter Card has these benefits:

- **Improves patient compliance**
- **Simple finger stick collection method**
- **Specimens can be mailed to our laboratory**
- **Quick turn-around time is usually 2 to 3 days upon receipt in the lab**
- **A terrific value-added service for your practice**

**This assay is considered a screening test. The results may vary from a whole blood CBC due to different methodologies. Laboratory Services recommends follow-up testing be performed, if clinically warranted, using a non-filter card test.*

Required Information for Lead Level Testing

As a reminder, the Ohio Revised Code 3701-30-05 states that the Ohio Department (ODH) of Health requires the following demographic information to be provided to ODH on any child who is tested for lead levels and resides in the state of Ohio:

- Child's full legal name
- Child's street and mailing address, including the city, state, and zip code
- Child's date of birth, sex, race and ethnicity
- Child's parent's or guardian's name
- Telephone number, with area code, where the parent or guardian can be reached
- Physician's or healthcare provider's first name, last name, address, telephone number, and national provider identifier, if applicable.

If demographics are missing, Laboratory Services will attempt to reach out to you. If all information cannot be collect in a timely manner testing will not be performed. We will accept patient demographic sheets providing all information required is complete.

Helping Hand™ Stool Collection Guidelines with Stool Collection Chart

Laboratory Services would like to inform you of a patient tool, Helping Hand™ Stool Collection Guidelines with Stool Collection Chart, that would help guide your patients/parents on how to properly collect stool samples from their infant, toddler, or older child. Also included is information on specimen drop-off locations for their collection as well as a stool collection chart, that has been recently updated. The Stool Collection Chart lists specific stool collections based on test; noting the type of collection container with picture, detailed collection instructions, storage temperatures and stability times.

To obtain blood filter cards for lead and hemoglobin screening, Helping Hand™ Stool Collection Guidelines with chart, or the Stool Collection Chart only, please call Laboratory Client Services at (800) 934-6575 or your account representative.

TEST UPDATES

National Supply Shortages Affected Testing Due to COVID-19

In January, supply orders were being restricted by manufacturers requiring the laboratory to temporarily suspend testing stool for Gastrointestinal Infection by multiplex PCR, as well as urine screening for sexually transmitted infections using the Aptima transport kits, unisex swabs, and other laboratory testing supplies used for *Chlamydia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis* testing. We are happy to announce that Nationwide Children's Hospital Laboratory has resumed GI Array (GIIA) and sexually transmitted infection testing, under previous guidelines as outlined in the Lab Guide to Services.

Test Reference Range Updates

In the first quarter of 2021, our normal chemistry, endocrine, and complete blood counts (CBC) and white blood cell differentials (WBC) reference ranges were adjusted based on internal studies of our patient population and literature review.

Chemistry Tests:

- Arterial pH
- Carbon Dioxide
- Carboxyhemoglobin
- Creatine Kinase
- Ionized Calcium
- Potassium
- Pre-dose Gentamicin
- Total Protein
- Venus Oxygen Saturation
- Point of Care Testing, Venous PO_2 – ABL Blood Gas Instument

Endocrinology Tests:

- 17-OH-pregnenolone
- Cortisol by LC MS (Liquid Chromatography/Mass Spectrometry)
- Dehydroepiandrosterone
- Progesterone

Additionally, test names within the Congenital Adrenal Hyperplasia Profile (CAH Profile 6) were updated to better identify the tests included in the profile.

Hematology Highlights:

- Absolute values will be reported on all differential parameters
- Promyelocyte, myelocyte, and metamylocyte absolute values will be reported together as absolute immature granulocytes.
- Band and segmented neutrophils will be reported together as absolute neutrophils.
- Reticulocytes will have reduced number of age groups; from 22 to 3.

Documents containing both the previous and new normal reference ranges can be found on the Nationwide Children's Laboratory Services web page, Laboratory Services News and Publications – Testing Updates. https://www.nationwidechildrens.org/specialties/laboratory-services/for-providers/laboratory-services-news-publications

If you have any questions about the above test updates, please contact Laboratory Services at (800) 934-6575.

INFORMATION TO KNOW

Nationwide Children's Laboratory Service Centers

Central Ohio Locations:

Canal Winchester
***Close To Home*℠ Center with Urgent Care**

7901 Diley Road, Suite 150
Canal Winchester, Ohio 43110
P: (614) 355-9050 F: (614) 355- 9051
M – F: 8:30 a.m. – 10 p.m.
Sat: 9 a.m. – 8 p.m. / Sun: noon – 8 p.m.
ECG services available

Dublin
***Close To Home*℠ Center with Urgent Care**

7450 Hospital Drive
Dublin, Ohio 43016
P: (614) 355-7000 F: (614) 355-7010
M - F: 8:30 a.m. – 10 p.m.
Sat: 9 a.m. – 8 p.m. / Sun: noon – 8 p.m.
ECG services available

East Columbus
***Close To Home*℠ Center with Urgent Care**

6435 East Broad Street
Columbus, Ohio 43213
P: (614) 355-8100 F: (614) 355-8110
M – F: 8:30 a.m. – 10 p.m.
Sat: 9 a.m. – 8 p.m. / Sun: noon – 8 p.m.
ECG services available

Grove City
Laboratory Service Center

2047 Stringtown Road
Grove City, Ohio 43123
P: (614) 355-9390 F: (614) 355-9392
M – F: 9 a.m. – 5 p.m.

Hilliard
***Close To Home*℠ Center with Urgent Care**

4363 All Season's Drive
Hilliard, Ohio 43026
P: (614) 355-5900 F: (614) 355-5930
M – F: 8:30 a.m. – 10 p.m.
Sat: 9 a.m. – 8 p.m. / Sun: noon – 8 p.m.
ECG services available

Lewis Center
***Close To Home*℠ Center with Emergency Department**

7853 Pacer Drive
Delaware, Ohio 43015
P: (614) 355-7900 F: (614) 355-7910
Sun. – Sat: 8 a.m. – 8 p.m.
ECG services available

Marysville
***Close To Home*℠ Center with Urgent Care**

100 Colemans Crossing Boulevard
Marysville, Ohio 43040
P: (937) 578-7600 F: (937) 578-7610
M – F: 8:30 a.m. – 10 p.m.
Sat: 9 a.m. – 9 p.m. / Sun: 9 a.m. – 9 p.m.
ECG services available

Nationwide Children's Hospital
Outpatient Lab - Orange

555 S. 18th Street – First Floor
Columbus, Ohio 43205
P: (614) 722-5428 F: (614) 722-5479
M – F: 8 a.m. – 7 p.m.
Sat: 8:30 a.m. – 3:30 p.m.

Nationwide Children's Hospital
Livingston Ambulatory Center
Outpatient Lab - Yellow

380 Butterfly Gardens Drive
Columbus, Ohio 43215
P: (614) 355-7142 F: (614) 355-7120
M – F: 8 a.m. – 5 p.m.

Westerville
***Close To Home*℠ Center with Urgent Care**

433 N. Cleveland Avenue
Westerville, Ohio 43082
P: (614) 355-8300 F: (614) 355-8310
M – F: 8:30 a.m. – 10 p.m.
Sat: 9 a.m. – 8 p.m. / Sun: noon – 8 p.m.
ECG services available

Other Ohio Locations:

Lima
Laboratory Service Center

830 West High Street, Suite 375
(830 Professional Building is located off of W. North Street)
Lima, Ohio 45801
P: (419) 221-3177 F: (419) 221-3178
M – F: 8:30 a.m. – 5:30 p.m.

Mansfield
***Close To Home*℠ Center**

536 S. Trimble Road
Mansfield, OH 44906
P: (419) 528-1351 F: (419) 528-3235
M - F: 8:30 a.m. – 5 p.m.
ECG services available by appointment

Marion
***Close To Home*℠ Center**

1069 Delaware Avenue, Suite 205C
Marion, Ohio 43302
P: (740) 387-7777 F: (740) 387-3848
M – F: 8:30 a.m. – 12:30 p.m. &
1 p.m. – 5 p.m.

Newark
***Close To Home*℠ Center**

75 S. Terrace Avenue
Newark, Ohio 43055
P: (740) 522-3221 F: (740) 522-3066
M – F: 8:30 a.m. – 6 p.m.
ECG services available

Springfield
***Close To Home*℠ Center**
(Ohio Pediatric Care Alliance)

1644 N. Limestone Street
Springfield, OH 45503
P: (937) 342-1182 F: (937) 342-1480
M – F: 8:30 a.m. – 8 p.m.
Sat: 8:30 a.m. – 2 p.m.

Zanesville
Laboratory Service Center

1166 Military Road, Suite 2B
Zanesville, Ohio 43701
P: (740) 588-0237 F: (740) 588-0240
M – F: 9 a.m. – 12:30 p.m. &
1 p.m. – 5:30 p.m.
Sat: 9 a.m. – 1 p.m.
Note: There are NO Saturday hours from Memorial Day to Labor Day. *Due to COVID-19, please call to confirm Saturday hours.
ECG services available by appointment

To obtain pads of Laboratory Service Center location maps, please call Client Services at (800) 934-6575, or visit NationwideChildrens.org/Lab and click on "For Physicians" or "For Patients" > click on "Laboratory Service Centers" in the gray box on the right side of the web page > click on the "Laboratory Services Map" link that is located on the right side of the page and print.

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/Specialties/Laboratory-Services.

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!