Laboratory Services Newsletter WINTER 2019

Required Information for Lead Level Testing

December 14th, 2018 you may have received a fax that we are taking action to provide the required information for lead level testing to the Ohio Department of Health. Any child who is tested for lead levels and resides in the state of Ohio, the Ohio Revised Code 3701-30-05 states and the Ohio Department (ODH) of Health requires the following demographic information to be provided to ODH:

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

All specimens received after December 14th that do not have all of the required demographic information will not be tested until it is provided. If demographics are missing Nationwide Children's Hospital Laboratory Services will attempt to reach out to you. If all information cannot be collect in a timely manner testing will not be performed. By the end of the year, you will receive a requisition specifically for lead testing to aid in collecting the required demographics. If you have filter paper lead kits with the old requisition, please dispose of them.

FAQ

- Does this apply to other testing performed by Nationwide Children's Hospital? No, our normal requisition will suffice unless otherwise specified in the Guide to Services
- Does this change affect patients residing outside the state of Ohio? Yes, other states require similar information.
- What should I do with samples that have already been collected but not sent? Please collect all the required information listed above before sending.
- What happens if testing cannot be performed? A report will be issued stating the testing could not be performed. The patient will not be charged.
- Can I order lead testing on a common requisition form? No, going forward all lead level orders should be on a lead specific requisition.
- We order through an interface, do I need to fill out the requisition? We are requesting that you fill out the requisition; this is the best way for both of us to make sure we have all of the required information and that we can perform testing.
- Will we ever be able to order through the interface without a paper requisition? We are working very hard to make all required information mandatory in the interfaces. Stay tuned!
- Will any process improvements be made to streamline this process? Absolutely, we are working to make this process as easy as possible for everyone. Please share any feedback you have with your account representative.

We appreciate all of your help in providing the required information to the Ohio Department of Health.

For more information about the lead level testing changes, please contact Nationwide Children's Laboratory Services at (800) 934-6575 or visit Nationwidechildrens.org/Lab.

INFORMATION TO KNOW

Check Your Lab Supplies' Expiration Dates!

As we begin a new year, we would like to take the opportunity to remind you to always check the expiration dates of your collection containers prior to collecting samples. Such containers include blood collection tubes, blood culture media, swabs, blood spot filter paper cards and all transport media (e.g., O&P, and Cary Blair media, viral M4 media, ThinPrep and Protocol 10% formalin media). It is good practice to incorporate "Supply Expiration Date" checks into your monthly checklist to avoid sample rejections, time taken to recollect the specimen, and delay of treatment.

Cold Weather Specimen Storage Reminder

Now that winter has arrived, it is important that samples placed in a lockbox outdoors prior to transport to the laboratory be maintained at the appropriate temperature. If refrigerated samples are stored in the lockbox, a non-frozen cold pack stored at room temperature should be placed in the lockbox to prevent the samples from freezing while left outside during the winter The cold pack **should not be frozen**, since you do not want refrigerated whole blood samples to freeze.

Many laboratory tests performed at Nationwide Children's Laboratory Services 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.

Reminder: ChildLink Access for Employees No Longer in Practice

For security purposes, it is important to notify Laboratory Services at (800) 934-6575, as soon as an employee with ChildLink access (Laboratory Services online access center for tests) leaves your practice. Calling us as soon as possible ensures that previous employees are deactivated from ChildLink in a timely manner. Also, your Laboratory Services Account Representative would like to hear from you when new physicians or practitioners join your staff or if you have moved location(s). Having the most current information about your office demographics and practitioners, ensures prompt turnaround time of patient's lab reports.

Signature Requirements for Clinical Laboratory Test Requisitions

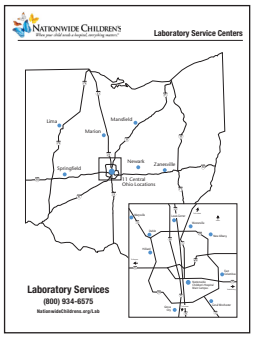
As a reminder, test requisitions for clinical laboratory testing must include an authorized provider's signature. Stamped signatures, printed signatures, printed signatures with the RN or other staff's initials next to it are not considered authorized signatures. Test requisitions received without an authorized provider's signature will be treated as a verbal order and a request will be sent to the ordering provider requesting a signature. This requirement does not apply to the ChildLink electronic test orders when the authorized provider logs onto the ChildLink system and places the order.

Both CMS (Centers for Medicare and Medicaid) and CLIA '88 require validation that the clinical laboratory tests are ordered by an authorized individual. Test requisition requirements are referenced in CLIA 493.1241 Standard: test requisition and CMS CodeMap® Compliance Briefing: 7/1/2010. For further clarification regarding signature requirements for clinical test requisitions, please contact Client Services at (800) 934-6575.

Looking for Printable Maps of Our Ohio Locations?

Laboratory Services offers three easy ways for your office to obtain maps with contact information and hours of operation for all of the Laboratory Service Centers located in Ohio.

1. Contact your Account Representative.
2. Call Client Services at (800) 934-6575.



TEST UPDATES

HIV-1 RNA Quantitative by RT-PCR Change

In October, 2018, methodology for the quantitation of **HIV-1** using real time PCR was changed to transcription-mediated amplification (TMA). The new methodology will lower the reporting cut off from <40 copies/mL to <30 copies/mL (<1.47 log10 copies/mL).

Changes in Reference Ranges

Last November Nationwide Children's Laboratory Services began using revised reference ranges for Serum/Plasma **Creatinine** (CREA), **Ristocetin Cofactor** (RCOF) and **Sedimentation Rate** (SED). These reference ranges were updated to better reflect the patient population we serve.

- **Creatinine Reference Range**

Serum/Plasma Creatinine Reference Ranges				
New Ranges			**Old Ranges**	
Age	Female	Male	Age	Female / Male
0 – 14d	0.3 – 0.9	0.3 – 0.9	0 – 11m	0.1 – 0.3
15d – 2y	0.15 – 0.4	0.15 – 0.4	1y	0.1 – 0.5
2 – 5y	0.2 – 0.4	0.2 – 0.4	2y – 7y	0.1 – 0.6
5 – 12y	0.3 – 0.6	0.3 – 0.6	8y – 10y	0.2 – 0.7
12 – 15y	0.5 – 0.8	0.6 – 0.8	11y – 12y	0.2 – 0.8
15 – 19y	0.5 – 0.8	0.6 – 1.0	13y – 17y	0.4 – 1.1
>19y	0.5 – 1.0	0.5 – 1.2	≥18y	0.5 – 1.2

- **Ristocetin Co-factor Reference Range**

Ristocetin Cofactor Reference Range			
New Range		**Old Range**	
Age	Female / Male	Age	Female / Male
All ages	40% – 200%	All ages	46% – 146%

- **Sedimentation Rate Reference Range**

Sedimentation Rate Reference Ranges					
New Ranges			**Old Ranges**		
Age	Female	Male	Age	Female	Male
0 – 13y	<13 mm/hour	<13 mm/hour	0 – 13y	0 – 13 mm/hour	0 – 13 mm/hour
14 – 50y	<20 mm/hour	<15 mm/hour	14 – 50y	0 – 20 mm/hour	0 – 15 mm/hour
>50y	<30 mm/hour	<20 mm/hour	>50y	0 – 30 mm/hour	0 – 20 mm/hour

TEST UPDATES

Cystatin-C Assay Re-standardization

Starting Tuesday, January 8th, Nationwide Children's Laboratory Services will introduce a re-standardized **Cystatin-C** (CYSTC) assay. The new assay has been standardized based on international reference material which includes a new reference range and reportable range.

Cystatin-C Reference Ranges			
Old Ranges		**New Ranges**	
Age	Female/Male	Age	Female/Male
0 – 3m	0.8 – 2.3 mg/L	0 – 3m	0.9 – 2.8 mg/L
4 – 11m	0.7 – 1.5 mg/L	4 – 11m	0.8 – 1.8 mg/L
1 – 17y	0.5 – 1.3 mg/L	1 – 17y	0.5 – 1.6 mg/L
≥ 18y	0.5 – 1.0 mg/L	≥ 18y	0.5 – 1.2 mg/L

Cystatin-C Reportable Ranges	
Old Reportable Range	**New Reportable Range**
<0.5 - >7.3 mg/L	<0.4 - >9.4 mg/L

New Testing – *Aspergillus fumigatus* by PCR

In December 2018, the NCH Microbiology Laboratory started molecular testing for ***Aspergillus fumigatus*** using polymerase chain reaction method. This test has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

- The testing is performed on Tissue and BAL samples.
- PCR testing for Aspergillus fumigatus should be ordered in addition to culture but not as a replacement for fungal culture.

Ordering Information:

***Aspergillus fumigatus* PCR**	
Test Code	AFUPCR
Specimen Types & Volume	Tissue, 2mm BAL, 0.5mL
Transport/Stability	Tissue: Room temperature – 1 hr Refrigerated – 6 hrs Frozen – indefinite BAL: Room temperature – 8 hrs Refrigerated – 4 days Frozen – indefinite
Performed	Dayshift, Monday through Friday
Turnaround time	4 days

TEST UPDATES

Fragile X Repeat Analysis with Reflex to Methylation Analysis

In December, 2018, the NCH Institute for Genomic Medicine (IGM) Clinical Laboratory will start offering a new test called **Fragile X Repeat Analysis with Reflex to Methylation**. This test was previously sent out to the OSU Molecular Pathology Laboratory, but will now be performed by the NCH IGM Clinical Laboratory. There is no change in the test methodology.

This test detects the number of trinucleotide CGG repeats in the 5'-untranslated region (UTR) of the *FMR1* gene. Disorders associated with the *FMR1* CGG repeat expansion include X-linked fragile X syndrome, fragile X-associated tremor/ataxia syndrome (FXTAS), and *FMR1*-related primary ovarian insufficiency (POI). The American College of Medical Genetics and Genomics (ACMG) defines a normal repeat length as less than or equal to 44 CGG repeats, an intermediate/gray zone as 45-54 repeats, a premutation category as 55-200 repeats, and a full mutation as over 200 repeats. More than 99% of patients with fragile X syndrome have aberrant *FMR1* methylation caused by CGG repeat expansion (typically >200 repeats).

If patient is undergoing diagnostic testing, reflex to methylation will occur if the patient has a premutation or full mutation allele. If patient is undergoing carrier testing, reflex to methylation will occur if patient has a full mutation allele.

Result Information:
The test results will now appear as do all other internal genomic test reports in Epic. There will be a link to open a PDF file of the full report.

Ordering Information:

Fragile X Repeat Analysis with Reflex to Methylation Analysis	
Test Code	FRAGX
Specimen Types & Volume	Peripheral blood (4-8 mL in EDTA tube, 3 mL minimum)
Transport/Stability	Transport at room temperature within 24 hours or refrigerated within 72 hours after collection
Turnaround Time	2 weeks
Comments	• Submission of the informed consent form is recommended, but not required. • Test is orderable in the NCH EPIC system. To search for this test, enter "Genetics" in Meds & Orders search field, click on the "Facility List (F6)" tab, select "CYTOGENETICS/MOLECULAR GENETICS ORDERS" (do not choose the STAT order set), and click Accept. This will display list of genetic tests including "FRAGILE X REPEAT ANALYSIS WITH REFLEX TO METHYLATION". Leave the checkbox checked for "GENETICS SPECIMEN LABEL." • Please obtain insurance preauthorization for both CPT codes: 81243 and 81244. CPT code 81244 will only be used if reflex to methylation is performed.

For more information about these test updates, please contact Nationwide Children's Laboratory Client Services at (614) 722-5477 or (800) 934-6575.

NATIONWIDE CHILDREN'S

When your child needs a hospital, everything matters.℠

Nationwide Children's Hospital
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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!