

## NCH Diagnostic Immunology Program by Dr. Roshini Abraham

In September 2018, Nationwide Children's Hospital started the Diagnostic Immunology Program (DIP) within the Department of Pathology and Laboratory Medicine, which includes the Diagnostic Immunology Laboratory (DIL). The mission of the DIL/DIP is to provide cutting-edge immunological testing and clinical consultative services for the diagnosis and treatment of immunological diseases, including primary immunodeficiencies (PIDs), primary



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immune dysregulatory diseases (PIRDs), collectively referred to as inborn errors of immunity, secondary immunodeficiencies, and other conditions with complex immune dysfunction. In the 15 months since its inception, the DIL has supported several clinical practices and areas at NCH including the Immunodeficiency Clinic within the Division of Allergy/Immunology, Hematology and The Cytopenia Clinic, Bone Marrow Transplantation (BMT), Solid Organ Transplantation, particularly the cardiac and lung transplant programs, Infectious Diseases, Rheumatology, Genomics, Oncology, and Hepatology among others.

The NCH DIL has cellular and molecular immunology sections, and is actively developing and validating a broad array of immunological assays (phenotypic and functional), including esoteric tests not offered in any other clinical diagnostic laboratory in the country. In addition, to clinical test development efforts, DIL has established a biorepository for samples from patients with rare immunological diseases. These samples serve not only as a valuable resource for new clinical test development and validation efforts, but also to advance clinical knowledge and science in the field, by characterization of rare genetic immune disorders, especially those with novel variants and atypical phenotypes. The DIL has one Laboratory Director, two R&D scientists, one Technical Specialist, one Study Coordinator, and two clinical technologists, and continues to grow with expansion of clinical assay development and testing.

The DIL was designated a Jeffrey Modell Foundation for Primary Immunodeficiencies Diagnostic and Research Center in April 2019. In conjunction with the clinical Immunodeficiency program at NCH, the DIL has created a database for continuous capture of primary immunodeficiency/immunology patients seen at NCH. The Laboratory also provides support for newborn screening for severe combined immunodeficiencies (NBS SCID) offered through the Ohio Department of Health through follow-up confirmatory immunological testing. DIL aids the clinical programs within the Comprehensive Transplant Center- Lung Transplant Program/Short Telomere Diseases Group and Allergy/Immunology at the Ohio State University (OSU), and in the aforementioned groups at NCH with diagnostic immunology testing and consultative resources. DIL continues to assist the BMT program through collaboration on a Clinical Practice Guideline (CPG) for assessment of immune reconstitution post-hematopoietic cell transplantation, and NCH participation and commitment to the Primary Immunodeficiency Treatment Consortium (PIDTC).

The DIL is active in the education of fellows and residents and offers a variety of training opportunities in the laboratory for those interested in a career in clinical immunology, in addition, to providing educational information to clinical groups on the diagnostic immunology testing repertoire. DIL has also established clinical and research collaborations with several institutions around the country, which has improved patient diagnosis and management.

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# INFORMATION TO KNOW

## **NCH Diagnostic Immunology Program** *continued*

Another important program that DIL has initiated in the past 15 months is the creation of a healthy adult and pediatric database for the development of reference intervals for interpretation of clinical immunological data. These initiatives have poised DIL to assume a key role within the diagnostic immunology reference laboratory arena in the next few years.

## **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, M6 viral transport 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 is Here! Lockbox 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.

# INFORMATION TO KNOW

## 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 requisitions, the ICD-10 code will need to be entered in the diagnosis code box. If you do not know the ICD-10 code please write the diagnosis.

### Tips from our Health Information Management:

1. Code R50.81- Fever presenting with conditions classified elsewhere cannot be assigned as a first listed diagnosis or an only code. The underlying code or condition should be listed first with the R50.81 listed as second diagnosis.
  - Code R50.9 should be assigned by itself if cause of fever is unknown.
2. If patient's age is 28 days or less with jaundice, code P59.9 should be assigned for neonatal jaundice, unspecified. There is also a neonatal code for jaundice due to breast milk - code P59.3.
3. There are age specific codes for well child checks for newborns code range - codes Z00.110 (< 8days old) and Z00.111 (≥8 days old to 28 days old).

## Biotin Supplementation

According to recent research, biotin supplementation may interfere with certain laboratory tests. The FDA has released a statement regarding possible biotin interference.

Biotin, or vitamin B7, is a water-soluble vitamin that serves as a critical cofactor in many physiological reactions. It is often taken as a supplement and has a recommended daily intake of about 30 mcg/day. Recently, there has been an increase in popularity of hair, nail, and skin supplements, which contain biotin up to 650 times the recommended daily intake. Individuals taking these or other high-dose biotin supplements may have enough biotin in their blood to interfere with certain laboratory assays.

NCH laboratory assays that may be affected by biotin interference are listed below. Biotin could cause a falsely elevated or falsely lowered result, but the interference is usually within +/- 20% of the correct value. NCH laboratory assays that are unaffected by biotin are also listed below.

<b>Tests possibly affected by biotin*</b>	ACTH, anti-thyroperoxidase, C-peptide, DHEAS, ferritin, folic acid, growth hormone, IGFBP3, insulin, and vitamin B12.
<b>Tests NOT affected by biotin*</b>	TSH, fT4, fT3, T4, T3, testosterone, LH, FSH, IGF-1, BNP, troponin, homocysteine, PTH, beta-hCG, cortisol, prolactin, and vitamin D

\*This list is not inclusive; other tests may be affected, particularly those sent out to be tested at another laboratory.

Physicians are encouraged to ask patients about their supplement status, especially of biotin, prenatal, and/or hair, nail, and skin supplements. If on high-dose biotin supplementation, it may be necessary to have patients abstain from their supplements for 8-72 hrs prior to blood collection, depending on the dose of biotin taken. Clinicians should contact the laboratory if test results are not consistent with the clinical picture, especially if the patient is known to have taken biotin supplements.

# INFORMATION TO KNOW

## Nationwide Children's Laboratory Service Centers

We know your patient's schedules can be busy. We make it easier by providing extended weekday hours and weekend times at our various locations throughout the region. Our laboratory services are all within a 15 minute drive from 85 percent of the pediatric population in central Ohio.

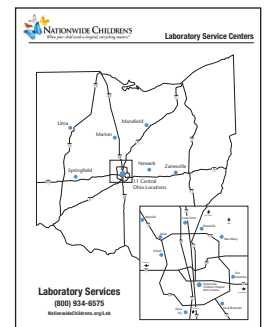
Laboratory Service / CTH Centers	Address	Hours of Operation
*Canal Winchester Close To Home Center	7901 Diley Road, Suite 150, Canal Winchester, Ohio	M – F: 8:30 a.m. – 10 p.m. Sat: 9 a.m. – 8 p.m. & Sun: noon – 8 p.m.
*Dublin Close To Home Center	7450 Hospital Drive, Dublin, Ohio	M – F: 8:30 a.m. – 10 p.m. Sat: 9 a.m. – 8 p.m. & Sun: noon – 8 p.m.
*East Columbus Close To Home Center	6435 East Broad Street, Columbus, Ohio	M – F: 8:30 a.m. – 10 p.m. Sat: 9 a.m. – 8 p.m. & Sun: noon – 8 p.m.
Grove City Laboratory Service Center	2047 Stringtown Road, Grove City, Ohio	M – F: 9 a.m. – 5 p.m.
*Hilliard Close To Home Center	4363 All Season's Drive, Hilliard, Ohio	M – F: 8:30 a.m. – 10 p.m. Sat: 9 a.m. – 8 p.m. & Sun: noon – 8 p.m.
*Lewis Center Close To Home	7853 Pacer Drive, Delaware, Ohio	Sun - Sat: 8 a.m. – 8 p.m.
Lima Laboratory Service Center	830 West High Street, Suite 375, Lima, Ohio	M – F: 8:30 a.m. – 5:30 p.m.
**Mansfield Close To Home Center	680 Park Avenue West, Suite G05, Mansfield, Ohio	M – F: 8:30 a.m. – 5 p.m.
Marion Laboratory Service Center	1069 Delaware Avenue, Suite 205C, Marion, Ohio	M – F: 8:30 a.m. – 12:30 p.m. & 1 p.m. – 5 p.m.
*Marysville Close To Home Center	100 Colemans Crossing Boulevard, Marysville, Ohio	M – F: 8:30 a.m. – 10 p.m. Sat: 9 a.m. – 9 p.m. & Sun: 9 a.m. – 9 p.m.
Nationwide Children's Hospital – Orange Lab	555 S. 18th Street – Lower Level, Columbus, Ohio	M – F: 8 a.m. – 7 p.m. & Sat: 8:30 a.m. – 3:30 p.m.
Nationwide Children's Hospital – Yellow Lab	380 Butterfly Gardens Drive, Columbus, Ohio	M – F: 8 a.m. – 5 p.m.
New Albany - Philip Heit Center for Healthy New Albany	150 W. Main Street, New Albany, Ohio	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	M – F: 8:30 a.m. – 6 p.m. & Sat: 9 a.m. – 1 p.m. Note: There are NO Saturday hours from Memorial Day to Labor Day
Springfield Close To Home Center	1644 N. Limestone Street, Springfield, Ohio	M – F: 8:30 a.m. – 8 p.m. & Sat: 8:30 a.m. – 2 p.m.
*Westerville Close To Home Center	433 N. Cleveland Avenue, Westerville, Ohio	M – F: 8:30 a.m. – 10 p.m. Sat: 9 a.m. – 8 p.m. & Sun: noon – 8 p.m.
**Zanesville Laboratory Service Center	1166 Military Road, Suite 2B, Zanesville, Ohio	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

\*Note - These sites offer walk-in ECG services. \*\*Mansfield and Zanesville ECG services are available by appointment only.

## 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
3. Visit [NationwideChildrens.org/Lab](http://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.



# TEST UPDATES

## New and Updated Diagnostic Immunology Tests Offered

On December 9, 2019, the Diagnostic Immunology Lab began offering two new tests, **Monocyte Subset Quantitation** and **NK Cell Subset Quantitation**. In addition, three current assays will be transitioning to this lab section as shown below. These are the first of many tests to be offered that will be focused on primary immunodeficiency testing, at the direction of Dr. Roshini Abraham.

New Assay: Monocyte Subset Quantitation	
Test Code	MOSQN
Included Tests	CD45+ Monocytes, CD14+ Monocytes, CD14++(Classical Monocytes), CD14+CD16+ (Transitional), CD16++ (Non-Classical Monocytes)

New Assay: NK Cell Subset Quantitation	
Test Code	NKSQN
Included Tests	Abs CD45+/CD14- Lymphs, CD16++CD56+ (Cytotoxic NK cells, mature), CD56++CD16- (Cytokine-producing NK cells)

Assay Updates					
Old Assays			Updated Assays - 12/9/2019		
Test Code	Test Name	Included Tests	Test Code	Test Name	Included Tests
IPB	Peripheral Blood T/B Immunophenotype	CD3 (T-cell), CD4 (CD3+ Helper T-Cell), CD8 (CD3+ Suppressor T-Cell), CD4/CD8 Ratio, CD19 (B-cell), CD56/CD16 (Natural Killer)	TBNK	Lymphocyte Subset (T, B, NK Cells) Quantitation	CD3+, CD4+ and CD8+ T cells, CD19/20+ B cells, CD56/16+ NK cells, CD4:CD8 ratio, CD3+CD4-CD8- DNT cells, CD45+ ALC
TIPB	Peripheral Blood Transplant Immunophenotype	CD3 (T-cell), CD4 (CD3+ Helper T-Cell), CD8 (CD3+ Suppressor T-Cell), CD4/CD8 Ratio, CD19 (B-cell), CD56/CD16 (Natural Killer), CD4/25 (CD3+ Tregs)	TBNKTX	Transplant Lymphocyte Subset (T, B, NK Cells) Quantitation	CD3+, CD4+ and CD8+ T cells, CD19/20+ B cells, CD56/16+ NK cells, CD4:CD8 ratio, CD3+CD4-CD8- DNT cells, CD45+ ALC
RTX	Anti-CD20 Rituximab Monitor	CD19/20% of Lymph, CD19/20 Absolute Count, CD45+	TBCQN	Total B Cell (CD19, CD20) Quantitation	CD19+CD20+, CD45+ ALC

**For more information about the diagnostic immunology tests offered, please contact Nationwide Children's Laboratory Client Services at (614) 722-5477 or (800) 934-6575.**



# TEST UPDATES

## Coming Soon: Urine Culture Consolidation

Early next quarter, Nationwide Children's Hospital Laboratory will be implementing a single urine culture order code, **URNC**. This change is being made to make ordering easier for providers and ensure proper processing of patient's urine samples. **The source of the urine sample is critical to this change and should 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.

Specimen Type Guide	Source Option
Clean Catch	<b>Clean Catch</b>
Bagged	<b>Bagged</b>
Foley/Indwelling catheter: <ul style="list-style-type: none"><li>• Suprapubic tube</li><li>• Mitrofanoff</li><li>• Nephrostomy</li></ul>	<b>Indwelling tube</b>
Open urinary system: <ul style="list-style-type: none"><li>• Vesicostomy</li><li>• Ureterostomy</li></ul>	<b>Open urinary system</b>
Straight catheter or initial placement: <ul style="list-style-type: none"><li>• Mitrofanoff placement</li><li>• Foley placement</li><li>• Transurethral catheter placement</li></ul>	<b>Initial/straight catheter</b>
Percutaneous collection: <ul style="list-style-type: none"><li>• Suprapubic (bladder stick) aspiration</li><li>• Nephrostomy placement</li></ul>	<b>Aspiration</b>
Surgical procedure: <ul style="list-style-type: none"><li>• Cystoscopy</li><li>• Renal aspiration</li><li>• Surgical catheter placement</li></ul>	<b>Surgical/OR collection</b>



# TEST UPDATES

## Allergen Profile Updates

On December 17, 2019, the following modifications were made to the allergen ordering panels. Laboratory Services has worked in collaboration with the Division of Allergy and Immunology to implement these changes to reflect evidence based best practice guidelines. Please see attached for the full menu of available profiles and individual allergens.

- **The following profiles are no longer be offered as a panel of tests. All allergens will remain on the test menu as individually orderable tests:**
  - o Childhood Allergy
  - o Food Allergy
  - o Seafood Allergy
- **NEW Toddler Allergy Profile which recommended for use only in children <3 years of age. The profile includes:**

Cat Dander	Dog Dander	Dust Mite (Mite pteronyssinus)	Total IgE
Cockroach	Dust Mite (Mite farinae)	Mouse Urine	

- **Mouse urine has been added to the Respiratory and Region 5 Allergy Profiles**

### Additional Information:

**Food allergy tests are not diagnostic for food allergy, as they are subject to a 50% false positive rate.** Results are not as simple as “positive” or “negative” and can only be used to determine the likelihood of an allergy being present in the context of the clinical history. There are no clinical indications to order a preselected panel of food allergen tests. If there is concern after a thorough clinical history suggests food allergy, targeted individual food IgE levels may be obtained.

Diagnosing food allergy is more complicated than simply ordering a test.<sup>1</sup> The Choosing Wisely series<sup>2</sup> and professional organizations discourage indiscriminate use of food serum IgE testing and serum IgE panels. Test results are frequently misinterpreted, leading to over diagnosis of food allergy, unnecessary avoidance, increased cost of health care and decreased quality of life. In addition, food allergies may be more likely to develop in infants and young children with atopic dermatitis who are advised to avoid foods they currently tolerate.

### References:

1. What are the pitfalls of food allergy panel testing? Available at: <https://www.aaaai.org/conditions-and-treatments/videos/allergy/food-allergy-testing> . Accessed March 15, 2019.
2. Choosing Wisely. Ten things physicians and patients should question. Available at: <http://www.choosingwisely.org/societies/american-academy-of-allergy-asthma-immunology/> . Accessed March 15, 2019.

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



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- 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](http://NationwideChildrens.org/Lab).**

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