

New Chemistry Platforms at Akron Children's Hospital

Our department of Pathology and Laboratory Medicine has upgraded its chemistry and immunochemistry testing platforms, resulting in several improvements, as well as changes.

By consolidating our testing instruments to Roche platforms for chemistry and immunochemistry, we are bringing more tests in-house due to the increased capacity. These platform changes will also:

- Reduce sample volume required to run the tests
- Improve turnaround time through automation
- Improve consistency and quality by measuring common issues that may interfere with results, namely hemolysis, lipemia and icterus
- Allow our lab staff to process twice as many tests per hour

The Akron lab implemented the new platforms on Jan. 25, while Mahoning Valley is expected to upgrade their systems in the coming months.

Testing now in-house on the Akron campus includes:

- Cortisol
- Estradiol
- Folate
- Hepatitis A Antibodies (IgM)
- Hepatitis B Core Antibodies (IgM)
- Hepatitis B Surface Antibody Total
- Hepatitis B Surface Antibody (Qualitative)
- Hepatitis B Surface Antigen (Qualitative)
- Hepatitis C Antibody
- HIV 1 & 2
- Insulin-Like Growth Factor 1
- Insulin-Like Growth Factor-Binding Protein 3
- Pro-BNP
- Vitamin B-12

While the process for ordering lab tests remains the same, there are a few changes as a result of the new chemistry platforms on our Akron campus, which will impact your practice:

- All chemistry urine testing is now orderable as either a random or 24-hour collection.
- Miscellaneous fluids are no longer a general order. Instead, specific tests are orderable for commonly collected fluid types. This list of tests was determined in collaboration with other hospital departments including Surgery, Nephrology and Hematology/Oncology:
 - **Pleural Fluid:** Amylase, Glucose, Lactate Dehydrogenase, Lipase, Total Protein, Triglyceride
 - **Peritoneal Dialysate:** BUN, Creatinine, Glucose
- Oxycodone has been removed from the drugs of abuse panel because a reagent was not available on the Roche platform at the time of planning. If oxycodone testing is required, a miscellaneous test can be ordered that will be sent to the Summa Health Toxicology Laboratory. A reagent has since become available, so we will investigate the need to reimplement this as an in-house test at a later date.
- Some tests now have a significant change in reference range values with these new platforms (see charts that follow).



If you have questions, please call:

Shannon Niziolek, Centralized Core Lab manager,
at 330-543-8467 or 330-543-8419

akronchildrens.org



Tests with Significant Results Shift

Test Name	Magnitude of Change	Reference Interval Comparison	
		Previous Reference Ranges:	New Reference Ranges:
<p>Ferritin</p> <p>Note: Samples collected in Mahoning Valley will be transported to Akron campus for testing.</p>	<p>Major change in reference range values. Transferred from correlation studies.</p> <p>27.3% bias from current reference range.</p>	<p>0 - 30 days (male): 36 - 381 ng/mL 0 - 30 days (female): 36 - 483 ng/mL</p> <p>31 days - 6 months (male): 36 - 391 ng/mL 31 days - 6 months (female): 36 - 329 ng/mL</p> <p>7 months - 14 years: 12 - 113 ng/mL</p> <p>15 y - 18 y (male): 18 - 380 ng/mL 15 y - 18 y (female): 12 - 156 ng/mL</p> <p>19+ years (male): 22 - 322 ng/mL 19+ years (female): 10 - 291 ng/mL</p>	<p>0 - 30 days (male) = 55 - 492 ng/mL 0 - 30 days (female) = 55 - 621 ng/mL</p> <p>31 days - 6 months (male) = 55 - 505 ng/mL 31 days - 6 months (female) = 55 - 426 ng/mL</p> <p>7 months - 14 years = 25 - 153 ng/mL</p> <p>15 y - 18 y (male) = 32 - 491 ng/mL 15 y - 18 y (female) = 25 - 207 ng/mL</p> <p>19+ years (male) = 37 - 417 ng/mL 19+ years (female) = 22 - 378 ng/mL</p>
<p>Folate</p> <p>Note: Samples collected in Mahoning Valley will be transported to Akron campus for testing.</p>	<p>Major change in reference range values. Transferred from Cleveland Clinic Akron General based on data obtained from correlation studies.</p> <p>Bias % not applicable.</p>	<p>> or = 4.0 mcg/L</p>	<p>> or = 4.8 ng/mL</p>
<p>Prolactin</p> <p>Note: Samples collected in Mahoning Valley will be transported to Akron campus for testing.</p>	<p>Major change in reference range values. Pediatric ranges adopted from CALIPER and adult ranges adopted from Roche IFU.</p> <p>Removal of non-pregnant, pregnant, postmenopausal comments. To append following comment to all results: Women (Not pregnant): 4.8 - 23.3 ng/mL</p>	<p>FEMALE Non-pregnant: 2.8 - 29.2 ng/mL Pregnant: 9.7 - 208.5 ng/mL Postmenopausal: 1.8 - 20.3 ng/mL</p> <p>MALE 2.1 - 17.7 ng/mL</p>	<p>0 days - <1 month: 1.1 - 470 ng/mL 1 month - <1 year: 5.2 - 60.0 ng/mL 1 year - <19 years: 3.0 - 25.0 ng/mL > or = 19 years: 4.0 - 15.2 ng/mL</p> <p>FEMALE > or = 19 years: 4.8 - 23.3 ng/mL</p>
<p>TSH</p>	<p>Major changes in reference range values/age ranges. Adopted from Mayo Clinic.</p> <p>Mahoning Valley will implement and adopt reference ranges in the second phase of implementation.</p> <p>Bias % not applicable.</p>	<p>0.35 - 5.50 μIU/mL</p>	<p>3 decimal places: 0 - 5 days: 0.700 - 15.200 μIU/mL 6 days - 2 months: 0.700 - 11.000 μIU/mL 3 - 11 months: 0.700 - 8.400 μIU/mL 1 - 5 years: 0.700 - 6.000 μIU/mL 6 - 10 years: 0.600 - 4.800 μIU/mL 11 - 19 years: 0.500 - 4.300 μIU/mL > or = 20 years: 0.300 - 4.200 μIU/mL</p>
<p>Insulin</p> <p>Note: Samples collected in Mahoning Valley will be transported to Akron campus for testing.</p>	<p>Major changes in reference range values/ ranges. Adopted reference range values from correlation studies.</p> <p>27.9% bias from current reference range.</p>	<p>Post 4 - 12 hour Fast: 0 - 8 years: 0 - 13 μIU/mL > 8 years: 0 - 17 μIU/mL 2-hour Post Meal: 7.6 - 26 μIU/mL 2-hour Post Glucose Testing: 15 - 53 μIU/mL</p>	<p>Post 4 - 12 hour Fast: 0 - 8 years: 0 - 17 μIU/mL > 8 years: 0 - 22 μIU/mL 2-hour Post Meal: 10 - 33 μIU/mL 2-hour Post Glucose Testing: 19 - 66 μIU/mL</p>

Test Name	Magnitude of Change	Reference Interval Comparison	
		Previous Reference Ranges:	New Reference Ranges:
Acetaminophen	<p>Major changes in reference range values / ranges. Adopted reference range values from correlation studies.</p> <p>Change will be adopted at Akron and Mahoning Valley campuses.</p> <p>AMR less than value changed due to Roche IFU.</p> <p>24.9% bias from current reference range.</p>	<p>Therapeutic = 10 - 25 µg/mL</p> <p>Toxic: > 200 µg/mL</p>	<p>Therapeutic: 8 - 19 µg/mL</p> <p>Toxic: > 149 µg/mL</p> <p>Major change in AMR. Previous result as < 10.0 µg/mL, now changed to < 5.0 µg/mL with Roche platforms.</p>
ALT	<p>Major changes in reference range values / ranges. Adopted reference range values from correlation studies.</p> <p>Change will be adopted at Akron and Mahoning Valley campuses.</p> <p>14.8% bias from current reference range.</p>	<p>Female: ≤ 31 IU/L</p> <p>Male: ≤ 41 IU/L</p>	<p>Female: ≤ 34 IU/L</p> <p>Male: ≤ 46 IU/L</p>
Gentamicin	<p>Major changes in reference range values / ranges. Adopted reference range values from correlation studies.</p> <p>Change will be adopted at Akron and Mahoning Valley campuses.</p> <p>Change to verbiage of ranges. Previous ranges were for peak and trough levels. New ranges are peak, trough and random. Established ranges were adjusted and values were transferred from correlation studies.</p> <p>37.9% bias from current reference range.</p> <p>Testing to be brought in-house at Mahoning Valley campus when new platforms go live.</p>	<p>THERAPEUTIC</p> <p>Peak: 4.0 - 10.0 µg/mL</p> <p>Trough: < 2.0 µg/mL</p>	<p>Random: ≤ 6.6 µg/mL</p> <p>Trough: < 1.3 µg/mL</p> <p>Peak: 2.4 - 5.5 µg/mL</p>
LDH	<p>Major changes in reference range values / ranges. Adopted current range utilized at Mahoning Valley campus due to close relationship between Roche Integra and Roche Cobas Pro platforms.</p> <p>Mahoning Valley to retain ranges with go live of Roche c501 platforms.</p> <p>24.5% bias from current reference range.</p>	<p>MALE</p> <p>0 - 5 years: 140 - 304 IU/L</p> <p>6 - 10 years: 155 - 290 IU/L</p> <p>11 - 15 years: 115 - 257 IU/L</p> <p>16 years +: 98 - 192 IU/L</p> <p>FEMALE</p> <p>0 - 5 years: 142 - 297 IU/L</p> <p>6 - 10 years: : 142 - 261 IU/L</p> <p>11 - 15 years : 122 - 234 IU/L</p> <p>16 years +: 98 - 192 IU/L</p>	<p>MALE</p> <p>0 - 5 years: 171 - 371 IU/L</p> <p>6 - 10 years: 189 - 354 IU/L</p> <p>11 - 15 years: 140 - 314 IU/L</p> <p>16 years +: 120 - 234 IU/L</p> <p>FEMALE</p> <p>0 - 5 years: 173 - 362 IU/L</p> <p>6 - 10 years: 173 - 318 IU/L</p> <p>11 - 15 years: 149 - 285 IU/L</p> <p>16 years +: 120 - 234 IU/L</p>
Lipase	<p>Major changes in reference range values / ranges. Adopted reference range values from correlation studies.</p> <p>Change will be adopted at Akron and Mahoning Valley campuses.</p> <p>23.7% bias from current reference range.</p>	<p>16 - 63 IU/L</p>	<p>13 - 95 IU/L</p>

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Tests with Significant Results Shift

Test Name	Magnitude of Change	Reference Interval Comparison	
		Previous Reference Ranges:	New Reference Ranges:
<p>Tobramycin</p> <p>Note: Samples collected in Mahoning Valley will be transported to Akron campus for testing.</p>	<p>Major changes in reference range values/ ranges. Adopted reference range values from correlation studies.</p> <p>Change to verbiage of ranges. Previous ranges were for peak and trough levels. New ranges are peak, trough and random. Established ranges were adjusted and values were transferred from correlation studies.</p> <p>19.1% bias from current reference range.</p>	<p>THERAPEUTIC</p> <p>Peak: 4.0 - 8.0 µg/mL</p> <p>Trough: < 2.0 µg/mL</p>	<p>Random: ≤ 9.0 µg/mL</p> <p>Trough: < 2.0 µg/mL</p> <p>Peak: 3.0 - 6.0 µg/mL</p>
<p>IgE</p> <p>Note: Samples collected in Mahoning Valley will be transported to Akron campus for testing.</p>	<p>Major change in reference range values. Transferred from correlation studies.</p> <p>14.8% bias from current reference range.</p>	<p>AGE</p> <p>Neonates (0 - 28 days): 0 - 2 IU/mL</p> <p>Infants (29 days - 365 days): 0 - 15 IU/mL</p> <p>Children (1 - 5 years): 0 - 60 IU/mL</p> <p>Children (6 - 9 years): 0 - 90 IU/mL</p> <p>Children (10 - 15 years): 0 - 200 IU/mL</p> <p>Adults (16+ years): 0 - 100 IU/mL</p>	<p>AGE</p> <p>Neonates (0 - 28 days): 0 - 24 IU/mL</p> <p>Infants (29 days - 365 days): 0 - 37 IU/mL</p> <p>Children (1 - 5 years): 0 - 83 IU/mL</p> <p>Children (6 - 9 years): 0 - 113 IU/mL</p> <p>Children (10 - 15 years): 0 - 225 IU/mL</p> <p>Adults (16+ years): 0 - 123 IU/mL</p>
<p>IGF-1</p> <p>Note: Samples collected in Mahoning Valley will be transported to Akron campus for testing.</p>	<p>Testing previously sent to Mayo Clinic. No change to reference ranges, as continuing to utilize Mayo Clinic ranges.</p>	<p>Comment to be appended to all results:</p> <p>TANNER STAGES REFERENCE RANGES</p> <p>MALES</p> <p>Stage I: 81 - 255 ng/mL</p> <p>Stage II: 106 - 432 ng/mL</p> <p>Stage III: 245 - 511 ng/mL</p> <p>Stage IV: 223 - 578 ng/mL</p> <p>Stage V: 227 - 518 ng/mL</p>	<p>FEMALES</p> <p>Stage I: 86 - 323 ng/mL</p> <p>Stage II: 118 - 451 ng/mL</p> <p>Stage III: 258 - 529 ng/mL</p> <p>Stage IV: 224 - 586 ng/mL</p> <p>Stage V: 188 - 512 ng/mL</p>
<p>IGFBP-3</p> <p>Note: Samples collected in Mahoning Valley will be transported to Akron campus for testing.</p>	<p>Major change in reference range values.</p> <p>24.7% bias was observed between previous and current results.</p>	<p>Adopting reference intervals from Roche per Roche IGFBP-3 IFU (2020-05 version). Ranges were selected from 2.5% and 97.5% values.</p> <p>Ranges are not in document due to vast size. Please see contact section if more information is required.</p>	
<p>Uric Acid</p>	<p>No change in reference intervals at Akron campus.</p> <p>Mahoning Valley campus will adopt Beckman Coulter DxC 600 age-related ranges upon implementation of the c501 platform.</p>	<p>Reference Ranges currently utilized at Mahoning Valley campus:</p> <p>Male: 3.4 - 7.0 mg/dL</p> <p>Female: 2.4 - 5.7 mg/dL</p>	<p>Reference Ranges that will remain at Akron campus and Mahoning Valley will adopt:</p> <p>0 - 9 yrs: 1.9 - 5.4 mg/dL</p> <p>10 - 17 yrs: 3.5 - 7.3 mg/dL</p> <p>Adult Male (18+ yrs): 4.8 - 8.7 mg/dL</p> <p>Adult Female (18+ yrs): 2.6 - 8.0 mg/dL</p>

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