To:
Medical Staff, Advanced Practice Providers, Nursing Leadership

From:
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Chemistry Analyzer Upgrade

The Department of Pathology and Laboratory Medicine is pleased to announce the upcoming implementation of the Roche Cobas chemistry platform at Dayton Children's Hospital.
This investment replaces aging chemistry analyzers with a modern platform that improves long-term reliability, standardizes chemistry testing across our laboratory network, and supports enhanced pediatric reference intervals.

Over the past several months, our laboratory team has partnered with physician leadership, Roche Diagnostics, Information Services, and clinical stakeholders to complete extensive validation studies in accordance with CLIA, CAP, and CLSI requirements. These efforts ensure the new platform provides accurate, reliable, and clinically appropriate patient results while positioning our laboratory for future growth.

Key Takeaways
Beginning on the go-live date:

- Continue interpreting laboratory results within the clinical context of your patient.
- **Always use the reference interval displayed on the laboratory report.**
- Some analytes may demonstrate numerical differences because of changes in analytical methodology.
- Exercise caution when comparing results between legacy analyzer and new analyzer.
- Laboratory leadership is available to assist with interpretation or implementation questions

What This Means for Patient Care

Most laboratory testing will continue to be interpreted exactly as it is today.
However, because different analyzer manufacturers use different analytical methods and calibration systems, some laboratory values may change following implementation.

Providers should anticipate:

- Updated pediatric reference intervals
- Changes to selected critical value thresholds
- Systematic differences for selected analytes
- Improved standardization across laboratory locations
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These changes are expected and *do not represent changes in patient physiology or laboratory quality.*

Provider Recommendations

Beginning on the implementation date, providers should:

- Use the reference interval displayed with each laboratory result.
- Consider the analyzer transition when comparing current results with historical laboratory values.
- Exercise additional clinical judgment when monitoring patients receiving:
    - Therapeutic drug monitoring
    - Oncology treatment
    - Renally adjusted medications
    - Endocrine replacement therapy
    - Transplant management
- Contact the Laboratory with questions regarding interpretation or implementation.

What Is Not Changing

The following will remain unchanged:

- Laboratory quality standards
- Specimen collection procedures
- Laboratory turnaround time expectations
- Critical result notification process
- Laboratory accreditation and regulatory compliance

Who can I contact with questions?

Questions regarding clinical interpretation:
Todd Boyd, DO, MT(ASCP)
Medical Director, Department of Pathology and Laboratory Medicine

Questions regarding implementation or laboratory operations:
Jennifer Nichols, MBA
Director, Clinical Laboratory

Closing

This project represents many months of planning, validation, and collaboration across the Laboratory, Pathology, Information Services, Nursing, and our clinical partners.

We appreciate your continued partnership and support throughout this transition. The implementation of the Roche Cobas chemistry platform strengthens our ability to provide accurate, reliable, and standardized laboratory testing while continuing to deliver the highest quality care to the patients and families we serve.

Respectfully,
Todd and Jen

Clinical Reference Guide

The following information is provided to assist providers in interpreting laboratory results following implementation of the Roche Cobas chemistry platform.

Why Some Results May Change

Laboratory instruments from different manufacturers often use different analytical methods, calibration materials, reagents, and detection technologies.
Although each method is validated and produces clinically accurate results, small systematic differences between methods are expected for selected analytes.
These differences have been evaluated extensively during laboratory validation and are consistent with published literature.

Analytes Requiring Additional Clinical Consideration

Most chemistry analytes correlate extremely well between analyzer platforms.
Providers should be aware that the following tests may demonstrate expected method-related differences.

<u>Renal Function</u>

- Creatinine- Systematic differences may occur between analytical methods.
  When monitoring patients longitudinally (such as those with chronic kidney disease or receiving nephrotoxic medications), interpret trends with awareness of the platform transition.

  If clinically appropriate, consider establishing a new baseline following implementation.

<u>Liver Function</u>
Providers may observe analytical differences involving:

- AST
- ALT
- Alkaline phosphatase
- LDH
- Total bilirubin
- Direct bilirubin

Interpretation should continue to incorporate the patient's overall clinical presentation.

<u>Pancreatic Enzymes</u>
Differences may occur for:

- Lipase
- Amylase

These differences are method-related and were evaluated during laboratory validation.

<u>Protein Studies</u>
Analytical differences may occur with:

- Albumin
- Total protein

Reference intervals displayed on the laboratory report should guide interpretation.

Therapeutic Drug Monitoring

Some therapeutic drug assays and immunoassays may demonstrate manufacturer-dependent differences because different antibodies and calibration materials are used.
Continue using the therapeutic ranges reported with each assay.

Pediatric Reference Intervals

Updated pediatric reference intervals have been implemented with the Roche Cobas platform. These intervals better reflect pediatric physiology and were verified as part of the implementation process.

Providers should always interpret laboratory results using the reference interval displayed on the patient report rather than relying on previously memorized reference ranges.

Critical Values

Selected critical value thresholds have been reviewed as part of implementation.
The process for notification of critical results remains unchanged.

References

Detailed assay methodology, validation data, and supporting scientific literature are available upon request and are summarized in the Medical Director's technical review document.

Frequently Asked Questions

Why does today's result differ from one obtained several months ago?
Small differences may reflect expected analytical variation between analyzer platforms rather than a change in the patient's clinical condition.

Should abnormal results be repeated?
Routine repeat testing is generally unnecessary solely because of analyzer conversion. Clinical judgment should continue to guide patient management.

Can I compare results before and after implementation?
Yes. However, exercise additional caution when trending analytes known to demonstrate method-related differences.

Are the new analyzers more accurate?
The Roche Cobas platform meets or exceeds current CLIA, CAP, CLSI, and manufacturer performance specifications and represents a significant modernization of the Dayton Children's chemistry laboratory.