

Intermountain Health hospitals and Central Laboratory transition to New Chemistry Analyzers

Beginning in November 2023, Intermountain Health Laboratory Services began phasing out Abbott chemistry instrumentation and introducing Roche chemistry analyzers across the Canyons and Desert Regions. This change is occurring on a phased schedule, grouping facilities that share a geographic area. The rollout will be completed in 2025.

A small number of Chemistry tests will be significantly affected (see below). Most reference ranges will be unchanged, but some will have small changes. Reference ranges will continue to be provided with test results.

If STAT chemistry testing is sent to a local hospital lab and routine chemistry testing is completed at the Central Lab, you may have a period of time where you receive test results from both Abbott and Roche instrumentation.

Why make this change now?

Many of Intermountain's chemistry analyzers have reached end-of-life, and our contract with the current vendor is soon to expire. Changing to these new analyzers will align Intermountain to more widely adopted automated chemistry analyzers, providing increased lab efficiencies and more current testing options.

What tests will be impacted?

Parallel testing and validations are being directed by laboratory PhD-level clinical chemists. Some chemistry test reference ranges will update with the transition, but new ranges will be included in all results. All specimen type changes except BNP can be implemented immediately.

Testing directly impacted by this change includes the following:

- Troponin I will be replaced with high sensitivity Troponin T (hsTnT) Use of the hsTnT test for acute coronary syndrome evaluation is significantly different than Troponin I, with different units and markedly different reference ranges. The specimen type will change to a mint top tube (lithium heparin plasma separator) only. Serum will no longer be acceptable.
- **B-Type Natriuretic Peptide (BNP)** will be replaced by **N Terminal proBNP (NTproBNP)** – Reference range change.
- Hepatitis A IgG will be replaced by Hepatitis A Antibody Total (IgG and IgM) preferred specimen is gold (SST) or green (PST).
- Ammonia acceptable specimen type is transitioning to lavender (EDTA) on ice ONLY.
- Serum Drug Screen Preferred specimen type is serum from a red top (NO GEL).
- Acetaminophen Preferred specimen type is serum from a red top (NO GEL).

- Vancomycin Preferred specimen type is serum from a red top (NO GEL).
- **HbA1C-** Changing from an enzymatic to immunoassay method. This change is a move toward higher sensitivity and lesser specificity. The change will not affect all patients but may measure hemoglobin %A1C higher by up to 0.2 or even 0.5 for some patients. The reference range based on the ADA guidelines for interpretation of results, will continue to used.
- **Rubella IgG** will be replaced by Rubella IgG (RUBGR). The cut off for Roche Non-Reactive vs Reactive results is 10 IU/ml. Preferred specimen type is serum (red or gold SST) or green PST.
- **Reference ranges** Reference ranges or interpretive ranges will change for alkaline phosphatase, C-reactive protein, cortisol, creatine kinase, estradiol, ethanol, hCG, luteinizing hormone, parathyroid hormone, procalcitonin, prolactin, PSA, rubella IgG, free T4, TSH, total T4, and urine drug screens.

Will availability of results be impacted?

This transition should not affect a patient's ability to view their own results through the Intermountain Health portal. Chemistry reference ranges, though different, are published with all results and may differ from previous test ranges.

- Faxed Results: test descriptions may differ; chemistry reference ranges will be different.
- Web portal: some test codes and descriptions will change, reference ranges will update.
- Interfaced Clients: test compendium updates are required (see below summary table).

| Old Test | New Test | CPT | Price | Specimen Type |
|----------|----------|-----------|-----------|-------------------------|
| BNPEP | BNPPRO | No change | No change | No change |
| HAVG | HAVTR | No change | No change | Gold SST or Green PST |
| RUBG | RUBGR | No change | No change | Serum (red or Gold SST, |
| | | | _ | Green PST |

What is the proposed schedule?

| Site Utah Valley Spanish Fork Orem Layton McKay Dee Central Lab/IMED Primary Children's Salt Lake Clinic Primary Children's – Lehi LDSH Riverton Alta View | Tentative Go-Live Date Live 11-14-23 Live 11-15-23 Live 11-15-23 Live 12-5-23 January 22, 2024 February 5, 2024 February 5, 2024 February 12, 2024 June 2024* June 2024* |
|--|---|
| | |

| St. George | September 2024* | | |
|---|-----------------|--|--|
| Hurricane ED | September 2024* | | |
| Cedar City | November 2024* | | |
| Sevier | November 2024* | | |
| American Fork | December 2024* | | |
| Saratoga Springs ED | December 2024* | | |
| Park City | February 2025* | | |
| Heber Valley | February 2025* | | |
| Garfield | March 2025* | | |
| Sanpete | March 2025* | | |
| Delta | April 2025* | | |
| Fillmore | April 2025* | | |
| * Current projections; timeline may move earlier or later | | | |
| Biotin Interference | - | | |

Some Roche assays may be subject to interference from dietary biotin.

What is Biotin?

Biotin (vitamin B7) is involved in producing energy from carbohydrates, fats, and amino acid. The daily recommended allowance for biotin is 0.03 mg, but some dietary supplements contain far great amounts (5-20 mg or more. In certain conditions, mega-doses of biotin may prescribed.

How does biotin affect laboratory results performed using Roche assays?

Certain immunoassays use biotin-streptavidin technology that may be subject to interference from high concentrations of biotin in patients' specimens. High biotin in a patient sample can potentially cause falsely elevated cortisol, digoxin, estradiol, free T4, and progesterone and falsely decreased LH and PTH.In addition, mega-doses of biotin (>300 mg/day) may cause falsely decreased FSH, hepatitis B surface antigen, quantitative hCG, NT-proBNP, procalcitonin, PSA, hsTnT, and TSH.

Patients may be unaware that they are taking high doses of biotin; therefore, it is important for clinicians to obtain an accurate list of supplements or medications. This information should then be provided to the laboratory when investigating unexpected patient results to assess potential effects on laboratory results.

Roche recommendation for those taking high dose biotin

Roche recommends that patients wait at least 8 hours before undergoing laboratory testing after consuming biotin doses of 5 mg or more.

Other Resources:

NIH Biotin fact sheet for consumers: <u>https://ods.od.nih.gov/factsheets/Biotin-Consumer/</u> Full FDA statement:

https://public4.pagefreezer.com/content/FDA/16-06-2022T13:39/https://www.fda.gov/medical-devices/safety-communications/update-fdawarns-biotin-may-interfere-lab-tests-fda-safety-communication

Questions?

Please contact your Outreach Liaison or Client Services at 801-507-2110.

Additional Resources can be found on Intermountain Laboratory Services Test Menu

- <u>Change to High Sensitivity Troponin Testing</u>
- Suspected Acute Coronary Syndrome (ACS) ED and Inpatient
- Abbott to Roche Was-Is List
- <u>Changes in HbA1C Methodology</u>
- Pediatric Thyroid Reference Intervals Update