



Change in Instrumentation: Immunochemistry Assays to Roche COBAS® Electrochemiluminescent (eCLIA) Methodology

Offering our clients state-of-the-art testing is part of CPL's ongoing commitment to excellence.

Effective March 4, 2019, Clinical Pathology Laboratories (CPL) will change current immunochemistry instrumentation and reagents to Roche COBAS® Electrochemiluminescent (eCLIA) methodology for the following assays:

- Adrenocorticotrophic hormone (ACTH)
- C-peptide
- Dehydroepiandrosterone sulfate (DHEA-S)
- Human growth hormone (HGH)
- Insulin-like growth factor 1 (IGF-1)
- Insulin-like growth factor binding protein 3 (IGF-BP3)
- Intact parathyroid hormone (iPTH)

The Roche assays provide improved precision and sensitivity, partially due to high-specificity biotin-streptavidin interactions in the immunoassay.¹ As a result of this change all related reference ranges, specimen requirements, analytic measuring ranges and interferences were reviewed. The reference ranges for all analytes are modified in the validation process, with gender and age-stratification applied as appropriate. For certain assays, previously supplied Tanner charts are not currently available; instead, providers may reference granular gender- and age-stratified normal ranges. The Tanner charts may be reestablished for specific analytes with literature review and after accumulation of population data and analysis.

The reference interval changes have been distributed to the interfaced laboratory users group in a separate communication. If you or your practice requires a chart of the reference intervals across gender or age, please contact your CPL Account Representative.

Laboratory reports will be appended with a notice of the change in reference range and method as a part of this transition. As always, please review your laboratory results in the context of the provided reference interval and flagging.

Please contact your CPL Account Representative should you have any questions regarding this change.

¹ Assays may be susceptible to interference by high doses (e.g. >5 mg/day) of biotin. Patients should avoid high dose biotin supplements for at least 8 hours prior to phlebotomy.

Thank you for supporting Clinical Pathology Laboratories