

May 3, 2009

**Methodology Change Notice: Introducing a new, more sensitive Luteinizing Hormone (LH) Assay – Esoterix LH assay will now be performed utilizing sensitive Electrochemiluminescent (ECL) Technology**

**Test Titles:** Luteinizing Hormone (LH)

**Esoterix Test Code:** 500234

**CPT Code:** 83002

**Effective Date:** March 9, 2009

**Explanation of change:** The methodology change for Luteinizing Hormone to Electrochemiluminescent (ECL) Technology provides greater sensitivity.

Serum LH is an important test for children and patients with gonadal issues, especially related to developmental and pubertal issues including precocious and delayed puberty. Levels in children are often below the lower limit of detection of automated assays.

LH by ECL technology offers enhanced sensitivity, using less serum compared to the predicate method, ICMA. The ECL method has a lower limit of quantitation (LLOQ) of 0.005 mIU/mL, compared with the predicate assay method LLOQ of 0.02 mIU/mL. The reference ranges were verified and correlated with the previous ICMA methodology, and have remained the same with the ECL method.

Please refer to the attached chart for preferred sample requirements for the new methodology. For additional information, please call us at (800) 444-9111. We value you as a customer, and thank you for choosing Esoterix.

