



A LabCorp Company

May 10, 2009

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

Test Titles: Follicle Stimulating Hormone (FSH)

Esoterix Test Code: 500192

CPT Code: 83001 (No Change)

Effective Date: May 4, 2009

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

Serum FSH 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.

FSH 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 0.017 mIU/mL, compared with the predicate assay method LLOQ of 0.080 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.

