

June 5, 2010

Endocrinology Service Update: Reference Range Update

Test Title: Pregnenolone by HPLC-MS/MS

Test Code: 500258

CPT Code: 84140 (no change)

Effective Date: July 12, 2010

Explanation of change: The Pubertal and Adults reference ranges for Pregnenolone by HPLC-MS/MS will be changed from a previous numeric range of <20 to 150 ng/dL to a value of <151 ng/dL.

In an effort to make Pregnenolone reference ranges consistent with the assay's current lower limit of quantitation, Esoterix will be updating the reference range for male and female Pubertal and Adults. This range will be updated to reflect a less than value instead of the previous numerical range. There is no change in the assay performance, lower limit of quantitation, methodology, specimen requirements, or pricing.

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

Description	Predicate Reference Range	New Reference Range
<p>Reference Range Pregnenolone, HPLC-MS/MS</p> <p>Reporting units of ng/dL</p>	<p>Gender Range (ng/dL)</p> <p>Newborn: Premature (26 - 28w) Day 4: 260 – 2104</p> <p>Premature (34 - 36w) Day 4: 203 – 1024</p> <p>Neonates (1 - 7d): 150 - 2000</p> <p>Male & Female (<3 mo): Neonates (1 -7d): 150 - 2000</p> <p>Levels decrease after birth and are within the prepubertal range of 20 - 140 by 3 months.</p> <p>Prepubertal Male (<10 yrs): 20 - 140</p> <p>Prepubertal Female (<9 yrs): 20 - 140</p> <p>Male & Female (Pubertal and Adults): <20 - 150</p>	<p>Gender Range (ng/dL)</p> <p>Newborn: Premature (26 - 28w) Day 4: 260 – 2104</p> <p>Premature (34 - 36w) Day 4: 203 – 1024</p> <p>Neonates (1 - 7d): 150 - 2000</p> <p>Male & Female (<3 mo): Neonates (1 -7d): 150 - 2000</p> <p>Levels decrease after birth and are within the prepubertal range of 20 - 140 by 3 months.</p> <p>Prepubertal Male (<10 yrs): 20 - 140</p> <p>Prepubertal Female (<9 yrs): 20 - 140</p> <p>Male & Female (Pubertal and Adults): <151</p>