

January 31, 2010

Endocrinology Service Update: Method Change

Test Title: 1,25-Dihydroxy Vitamin D

Test Code: 500342 (no change)

CPT Code: 82652 (no change)

Effective Date: March 8, 2010

Explanation of change: The new methodology for 1,25-Dihydroxy Vitamin D will be HPLC with Tandem Mass Spectrometry.

Serum 1,25-Dihydroxy Vitamin D is the physiologically active form of vitamin D. Although 25-Hydroxy Vitamin D is the best test of vitamin D status, 1,25-Dihydroxy Vitamin D may be tested in patients with suspected renal abnormalities, those with metabolic disorders or cancers affecting metabolism, or those receiving calcitriol (1,25-Dihydroxy Vitamin D) as a treatment.

HPLC with tandem mass spectrometry offers enhanced specificity, accuracy, and precision, compared to the predicate method, radio-receptor assay after column chromatography. HPLC with tandem mass spectrometry will also offer results for fractionated 1,25-Dihydroxy Vitamin D-2, 1,25-Dihydroxy Vitamin D-3, and total 1,25-Dihydroxy Vitamin D using less specimen volume. There will be no change in reference ranges. The new methodology provides results that are highly correlated to the predicate method.

Please refer to the attached chart for updated 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.

Description	Predicate Method	New Method
Assay Method	1,25-Dihydroxy Vitamin D, Radio-Receptor Assay after Column Chromatography	1,25-Dihydroxy Vitamin D, HPLC with Tandem Mass Spectrometry
Reference Range	<p>NEWBORNS 0 – 30 Days</p> <p>INFANTS AND CHILDREN 31 Days – 17 Years</p> <p>ADULTS > 18 Years</p>	<p>Range (pg/mL)</p> <p><10 - 72</p> <p>15 - 90</p> <p>21 - 65</p>
LLOQ (sensitivity)	10 pg/mL	10 pg/mL
Assay Set frequency	Monday and Thursday (2 days per week)	Tues, Thurs, Sat (3 days per week)
Preferred Sample Requirement	3 mL serum	2 mL serum or plasma
Pediatric Minimum Sample Requirement	1 mL serum (note: this volume does not allow for repeat analysis)	0.8 mL serum or plasma (note: this volume does not allow for repeat analysis)