

April 1, 2008

Implementation Notice: Method Change

Test Title: Cortisol, Salivary

Test Code: 500094

Effective Date: May 19, 2008

Explanation of change: The new methodology is HPLC with Tandem Mass Spectrometry.

Salivary cortisol is an important screening tool for Cushing’s syndrome. HPLC with Tandem Mass Spectrometry offers enhanced accuracy and precision with a 5-fold improvement in analytical sensitivity (LLOQ). Cortisol levels are low in saliva, especially in samples collected at midnight. The improved sensitivity and selectivity increased accuracy in these key samples. New reference range data was collected to improve the clinical utility of the new test methodology.

CPT codes remain the same. Please contact your Esoterix representative if you have any additional questions regarding this methodology change.

Description	Predicate Method	New Method
Assay Method	Salivary Cortisol, RIA	Salivary Cortisol, HPLC with Tandem Mass Spectrometry
Reference Range Salivary Cortisol (ug/dL)	Pubertal children 8:00 AM 0.17 – 1.2 4:00 PM 0.11 – 0.33 11:00 PM <0.05 – 0.19 Adults 8:00 AM 0.18 – 0.95 4:00 PM 0.10 – 0.28 11:00 PM 0.05 – 0.17	Children and Adults 8:00 AM 0.025 – 0.600 4:00 PM 0.010 – 0.200 Midnight <0.01 – 0.090
LLOQ (sensitivity)	0.05 ug/dL	0.01 ug/dL
Assay Set frequency	Monday, Wednesday, Friday	Monday, Wednesday, Friday