

May 31, 2009

Methodology Change Notice: Glucagon

Test Title: Glucagon, Plasma

Esoterix Test Code: 500204

CPT Code: 82943 (no change)

Effective Date: July 1, 2009

Explanation of change: Esoterix has identified its alternate source for reagents replacing the previous, discontinued, reagents. Validation of the assay using the new reagents has been completed, and the data indicates a difference in reference ranges. The new reference range will be 40 – 130 pg/mL.

Glucagon is an important test to diagnose glucagonomas, a syndrome that includes diabetes and glucagon-producing tumors and frequently a characteristic skin rash. (Endotext.org 2009)

Please refer to the attached chart for the changes in reference range. 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	Glucagon, Plasma (Double Antibody Radio immunoassay)	Glucagon, Plasma (Radio immunoassay)
Reference Range Glucagon (pg/mL)	Children and Adults (fasting): 50 – 150 pg/mL	40 – 130 pg/mL
Assay Set frequency	Thursday (1x per week)	Thursday (1x per week)
Preferred Sample Requirement	1.0 mL EDTA plasma (lavender top), Frozen	1.0 mL EDTA plasma with Trasylol®, Frozen
Pediatric Minimum Sample Requirement	0.3 mL (note: minimum volume does not permit repeat analysis)	0.5 mL (note: minimum volume does not permit repeat analysis)