

Intact-PTH ELISA

FDA Cleared

CALCIUM METABOLISM

Quantitative Measurement of Intact-PTH

Intact-PTH: For the Diagnosis of Primary Hyperparathyroidism and Management of Chronic Renal Failure & Renal Bone Disease

Unique

Advanced technology - 2-site affinity-chromatography purified high-affinity polyclonal antibodies. N-Terminal (1-34) specific enzyme conjugate as tag antibody. C-Terminal (39-84) sequence conjugated with biotin as capture antibody. 2-Site Enzyme Labeled Sandwich Assay with streptavidin coated microplate

Accurate

Excellent and extensive patient sample correlation vs. the IRMA Assay

Simple

Single step incubation and one washing step (2-site sandwich assay)

High Sensitivity

0.9 pg/mL analytical sensitivity

Convenient

Same-day Assay - 3 hour incubation for the sandwich assay + ½ hour reaction for the color development



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INTENDED USE

The Biomerica Intact-PTH ELISA is intended for the quantitative determination of Intact-PTH (Parathyroid Hormone) in human serum. The simple 3½ hour ELISA test offers high sensitivity and a simple streptavidin coated microplate assay procedure. The Biomerica immunoassay measures the biologically intact 84 amino acid chain of PTH.

BACKGROUND

PTH (Parathyroid hormone, Parathormone, Parathyrin) is biosynthesized in the parathyroid glands as an 84 amino acid polypeptide. In healthy individuals, regulation of parathyroid hormone secretion normally occurs via a negative feedback action of serum calcium on the parathyroid glands.

The measurement of parathyroid hormone is the most specific way of making the diagnosis of primary hyperparathyroidism. In the presence of hypercalcemia, an elevated level of parathyroid hormone virtually establishes the diagnosis. In over 90% of patients with primary hyperparathyroidism, the parathyroid hormone will be elevated.

When intact PTH level is plotted against serum calcium, the intact PTH concentration for patients with hypercalcemia of malignancy is almost always found to be inappropriately low when interpreted in view of the elevated serum calcium. Unlike C-terminal and mid-region PTH, which typically are grossly elevated in subjects with renal insufficiency, intact PTH assays are less influenced by the declining renal function.

PERFORMANCE

	<u>Assay Time:</u>	<u>Accuracy</u>	<u>Sensitivity</u>
Intact-PTH:	3½ hrs.	Biomerica ELISA = 1.06 - 1.49 pg/mL r = 0.998 N = 309	1.57 pg/mL

ORDERING

<u>Catalog No.</u>	<u>Description</u>
7022	Intact-PTH ELISA kit - Quantitative (96 tests)
7022BU	Intact-PTH Bulk - Unlabeled (minimum quantities required)

 and EN ISO 13485:2003 Compliant, Multi-language inserts available

Bibliography

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6. Kruger, L., Rosenblum, S., Zaazra, J. and Wong, J. Intact PTH is stable in unfrozen EDTA plasma for 48 hours prior to laboratory analysis. Clin. Chem. 41:6: page S47, 1995.



BIOMERICA

17571 Von Karman Avenue • Irvine, CA 92663 USA • Tel (949) 645-2111
Fax (949) 553-1231 • email: bmra@biomerica.com • www.biomerica.com