



Intact-PTH ELISA



- Secure differentiation of primary hyperparathyroidism from other causes of hypercalcaemia
- Reliable detection of intact parathyroid hormone – also in dialysis patients
- Automated processing possible

Technical data

Coating	Polyclonal anti-C-terminal PTH antibody
Calibration	Quantitative, in picograms per millilitre (pg/ml), 6 calibrators between 8 and 500 pg/ml (depending on the lot)
Sample dilution	Serum or plasma; 50 µl undiluted
Reagents	Ready for use, with the exception of the wash buffer (10 x), calibrators (lyophilised)
Testablauf	180 min/30 min/15 min, room temperature, fully automatable; microplate shaker required 400 U/min
Measurement	450 nm, reference wavelength between 620 nm and 650 nm
Test kit format	96 break-off wells; kit includes all necessary reagents
Order number	EQ 6421-9601

Clinical significance

Parathyroid hormone (PTH) is a peptide hormone consisting of 84 amino acids, which is synthesised in the parathyroid glands. Besides 1,25-dihydroxy vitamin D₃, PTH is the second most important hormonal regulator of the calcium and phosphate balance because it increases the blood calcium level and decreases the phosphate level.

A low calcium level in the blood signals the parathyroid glands to release PTH. Via the blood stream PTH enters predominantly the bones, where it activates the osteoclasts. This leads to the resorption of bone tissue and the release of calcium and phosphate. At the same time PTH promotes the reabsorption of calcium in the kidneys and inhibits renal phosphate resorption. In turn, a high concentration of calcium in the blood inhibits the release of PTH.

The determination of intact PTH is carried out in suspected disorders of the calcium and bone metabolism and for differentiation of primary hyperparathyroidism from other causes of hypercalcaemia.

Diagnostic application

The biological half-life period of PTH is very short. After only a few minutes the peptide hormone breaks down into fragments of different length, including an N-terminal, C-terminal and a middle fragment. Determination of intact PTH, also in the biologically active form of the hormone, allows direct measurement of the secretory activity in the parathyroid glands. The EUROIMMUN Intact PTH ELISA reliably detects intact PTH.



Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation using 3 samples. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on triplicate determinations performed in ten different runs. The inter-lot CVs are based on duplicate determinations repeated in 3 different runs with 3 different lots.

Intra-assay precision, n = 20			Inter-assay precision, n = 10 × 3			Inter-lot precision, n = 3 × 3 × 2		
Sample	Mean value (pg/ml)	CV (%)	Sample	Mean value (pg/ml)	CV (%)	Sample	Mean value (pg/ml)	CV (%)
1	5	9.5	1	7	11.0	1	7	11.4
2	42	2.9	2	41	10.8	2	37	8.2
3	325	2.2	3	309	9.5	3	283	7.1

Linearity

The linearity was determined by diluting 3 serum samples (140 to 330 pg/ml) to a final dilution of 1 : 16 with calibrator 1. The mean concordance with respect to the expected value was 93.4% (71 to 110%), with a mean correlation coefficient of $r = 0.998$.

Sample	Dilution	Measured value (pg/ml)	Expected value (pg/ml)	Mean concordance (%)
1	native	330	330	100
	1:2	181	165	110
	1:4	76	83	92
	1:8	38	41	93
	1:16	17	21	81
2	native	253	253	100
	1:2	120	127	95
	1:4	60	63	95
	1:8	27	32	84
	1:16	11	16	71
3	native	140	140	100
	1:2	72	70	103
	1:4	36	35	101
	1:8	16	18	90
	1:16	8	9	85

Expected values

- For EDTA plasma: EDTA plasma samples from 30 healthy blood donors (15 women and 15 men) from 17 to 62 years of age were analysed using the EUROIMMUN Intact-PTH ELISA. 95% of the measured PTH concentrations were between 10.9 and 54.8 pg/ml.
- For serum: Plasma samples from 67 healthy blood donors (28 women, 39 men) from 18 to 69 years of age were analysed using the EUROIMMUN Intact-PTH ELISA. 95% of the measured PTH concentrations were between 3.1 and 40.0 pg/ml.

Method comparison

The EUROIMMUN Intact-PTH ELISA was compared to a commercially available method from another manufacturer (Roche Intact PTH ECLIA). The correlation was as follows:
 $\text{EUROIMMUN} = 1.068 \times (\text{Roche}) - 5.6 \text{ pg/ml}$; $n = 42$; $R^2 = 0.985$.

