The Development and Validation of Specific Ligand Binding Methods for the Determination of Parathyroid Hormone (1-34) and (1-84) in Human Plasma for Pharmacokinetic Sample Analysis

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**METHODS:**

- **PTH (1-84):** Unknown samples and calibration samples prepared in human plasma treated with an antibody against the C-terminal portion of PTH (1-84) attached to a solid substrate to remove endogenous PTH (1-84) and to label the analyte. The same antibody was used to label the analyte in the final assay. The same antibody was used to label the analyte in the final assay. No significant interference for PTH (1-84) was observed in any of the 10 human plasma (EDTA) lots that were fortified near the concentration of the high QC (1500 pg/mL) sample.

- **PTH (1-34):** Unknown samples and calibration samples in human plasma were pre-treated with an antibody against the C-terminal portion of PTH (1-34) attached to a solid substrate to remove PTH (1-34). The pre-treated samples and calibration samples were pipetted into microwell plates coated with the appropriate capture antibody. The wells were washed to remove unbound labeled antibody and any native labeled antibody that had cross-reacted with endogenous PTH (1-34). When preparing controls and calibrators in plasma, methods for antibody cross-reactivity with endogenous PTH (1-34).

**CONCLUSIONS:**

The validated methods allow for rapid, selective, accurate and reproducible quantitation of PTH (1-84) and PTH (1-34) in human plasma samples for pharmacokinetic evaluation.

**REFERENCES:**

- **Inter-batch precision of PTH (1-84) quality control samples between 10.0 and 2000 pg/mL, was less than 11.6% C.V. Inter-batch accuracy (% bias of the same quality control samples was between -1.3 and +8.0% (Table 1), Inter-batch precision (CVo) of PTH (1-34) quality control samples between 5.00 and 150 pg/mL.