



**STAT-IntraOperative-Intact-PTH Immunoassay Kit  
STAT-IO-I-PTH  
(Parathyroid Hormone)**

3L-IPT-00, rev 04 (04/11)

## Test Instructions

### STAT-IntraOperative-Intact-PTH

Chemiluminescence Immunoassay for the IntraOperative Quantitative Determination of Intact Parathyroid Hormone Levels in Human Serum and EDTA Plasma

**Cat. No: 4K-IPT-00, 48 tests**

For *In Vitro* Diagnostic Use

Store at **2 – 8 °C Upon Receipt**

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## 1. Intended use

The Future Diagnostics STAT-IntraOperative-Intact-PTH (STAT-IO-I-PTH) Immunoassay kit is intended to be used for in vitro quantitative measurement of intact Parathyroid Hormone (PTH) concentrations in human serum and EDTA plasma. This procedure is recommended in intraoperative assay of Intact PTH in human serum and EDTA plasma.

## 2. Summary and explanation of the test

Parathyroid hormone (PTH) is a single chain polypeptide of 84 amino acids (MW 9500 Daltons) and is secreted by the parathyroid glands. The major function of PTH is to regulate optimal ionized calcium levels and is controlled by a direct negative feedback system. Decrease in serum calcium levels stimulates the release of PTH which then acts directly on bone and kidneys: by increasing the rate of calcium ion flow from bone to the extracellular fluid and by increasing renal tubular re-absorption of ionized calcium and renal excretion of phosphate. PTH also stimulates the Vitamin-D metabolism, which promotes the intestinal calcium uptake<sup>1</sup>.

An important characteristic of the intact PTH molecule is the biological half-life of intact PTH which is 3 - 4 minutes, PTH is rapidly metabolized in the liver and kidneys to primarily N-terminal and C-terminal fragments<sup>2,3,4,5</sup>. This short half-life is essential for being able to measure decreasing values of PTH during surgery.

Intact PTH and the N-terminal fragments are biologically active. Ratios of intact hormone to peptide fragments may vary from individual to individual as well as between patients suffering from hypoparathyroidism or chronic renal failure.

Measurement of PTH is an important aid in the diagnosis of calcium metabolism disorders and is of particular value in the differential diagnosis of hypercalcemia, improving the clinical discrimination between patients with hyperparathyroidism, hypoparathyroidism or hypercalcemia of malignancy (HCM)<sup>6,7</sup>.

The STAT-IO-I-PTH assay allows a direct and fast assessment of the parathyroid secretory hormone. Patients undergoing parathyroidectomy show a significant drop of intact PTH levels when the hypersecreting parathyroid tissue has been removed. Decrease of intact PTH levels with a certain percentage, indicates that it may not be necessary to further dissect and localize the remaining normal parathyroid glands. This effect will shorten the operation time considerably<sup>8,9,10,11</sup>. When intact PTH levels in plasma will be elevated persistently, further exploration of the affected parathyroid glands is necessary. Eventually other blood tests and the clinical history of the patient are needed.

The STAT-IO-I-PTH assay offers a quick, reliable and quantitative assurance when all hypersecreting parathyroid tissue has been excised and functions as a possible tool to limit surgical trauma.

## 3. Principle of the test procedure

### Immunometric Assay

The Future Diagnostics STAT-IO-I-PTH kit is a two-site chemiluminescent immunometric assay. The assay utilizes two affinity purified goat polyclonal antibodies against PTH. One anti-PTH antibody (39-84) is coated onto the surface of the micro titer well, the N-terminal anti-PTH antibody (1-34) is labeled with isoluminol and lyophilized in the form of an accsphere and seeded in the wells. The micro titer strip plate is ready to use.

Patient sample, Standards and Controls are introduced into the wells and incubated for 5 minutes on the STAT-Shake. During this time, the intact PTH in the sample, Standards and Controls, is bound and an antibody-antigen-antibody complex is formed. Unbound-labeled antibody is removed by a wash step on the STAT-Wash.

The washed microtiter wells are placed into the STAT-Read, which automatically injects the Activators A1 and A2, initiating the chemiluminescence reaction. The emission of light, expressed in Relative Light Units (RLU), is directly proportional to the concentration of intact PTH in the sample. The observed signals are automatically reduced in the data reduction program of the STAT-Read and the test results of samples and controls are read from the standard curve. A printed report is generated.

## Chemiluminescence

Future Diagnostics utilizes chemiluminescent isoluminol as the label in its chemiluminescence immunoassay kits. Isoluminol emits light when treated with hydrogen peroxide in an alkaline solution. The Activator 1 solution contains sodium hydroxide and Activator 2 solution contains hydrogen peroxide. The STAT-Read automatically injects Activator solutions 1 and 2 into the wells of the antibody coated strip which oxidize the isoluminol. The oxidized product is in an excited state. The subsequent return to the ground state results in the emission of light, which is quantified in 3 seconds and expressed in relative light units (RLU) by the STAT-Read.

## 4. Reagents

### PRECAUTIONS

For *in vitro* diagnostic use



**CAUTION: Handle Serum and Plasma Samples As Potential Biohazardous Material. Handle Samples As If Capable of Transmitting An Infectious Agent.**

All samples should be regarded as potentially contaminated and treated as if they were infectious. These samples should be handled at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Center for Disease Control/National Institutes of Health Manual "Biosafety in Microbiological and Biomedical Laboratories," 1984.

Human serum albumin was used in the manufacturing process of this product. Each donor unit used was tested by FDA-approved methods and found to be non-reactive for hepatitis B surface antigen (HBsAg), HIV antibody, and hepatitis C (HCV) antibody. Because no test method can offer complete assurance that hepatitis B, HIV, HCV or other infectious agents are absent these reagents should be handled at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Center for Disease Control/National Institutes of Health Manual "Biosafety in Microbiological and Biomedical Laboratories," 1984.

**NOTE:** Reagents in this assay contain **sodium azide** as a preservative (0.09%). Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush drains with generous amounts of cold water to prevent azide build-up.

### Activator Solution 1 and 2:

Activator 1 contains 4 % sodium hydroxide (corrosive) and Activator 2 contains 0.12 % hydrogen peroxide (irritating).

#### 4.1 Components in each STAT-IntraOperative-Intact-PTH assay kit

1. **Ready To Use Strip Plate (P1)** (3C-IPT-18)  
1 Microtiter strip plate (48 wells) is coated with affinity purified polyclonal goat anti-PTH (39-84) as capture antibody. The isoluminol labeled affinity purified polyclonal goat anti-PTH (1-34), as tracer antibody, is lyophilized and provided as an accosphere in the well.
2. **PTH Zero Standard (S0)** (3C-IPT-10)  
1 vial labeled 'S0' containing lyophilized PTH-free human serum albumin.
3. **PTH Standards (S1, S2, S3, S4, S5)** (3C-IPT-11 up to and inclusive 3C-IPT-15)  
Each lyophilized vial is labeled 'S1' through 'S5' containing intact PTH in a PTH-free human serum albumin. Refer to vial label for exact PTH concentrations. The standards are prepared analytically on a mass basis from purified synthetic intact PTH (1-84).
4. **PTH Controls (C1 and C2)** (3C-IPT-16 and 3C-IPT-17)  
Each lyophilized vial is labeled 'C1' (Control 1) and 'C2' (Control 2) containing intact PTH in a PTH-free human serum albumin. Refer to the technical data sheet for PTH concentration ranges.
5. **PBS Wash buffer (10 x concentrated) (W1)** (3C-UVL-00)  
One vial labeled 'W1' containing 30 mL of 10 times concentrated phosphate buffered saline with 0.09 % sodium azide as a preservative.
6. **Non-coated Strip Plate (P2)** (3C-UVL-03)  
1 Microtiter strip plate (96 wells), with clear non-coated wells: for the purpose of collecting and aliquoting of standards, controls and patient plasma samples.
7. **Activators (A1 and A2)** (3C-UVL-01 and 3C-UVL-02)  
Two bottles labeled 'A1' (Activator 1) and 'A2' (Activator 2,) each containing 30 mL Activator Solutions to generate the chemiluminescence light signal. Activator 1 (A1) contains 4% sodium hydroxide (NaOH). Activator 2 (A2) contains 0.12% hydrogen peroxide.

#### 4.2 Additional materials and instruments required

**This procedure is developed for use with the Future Diagnostics STAT-System (Catalogue Number 9K-SIO-xx). Refer to the Future Diagnostics STAT-System Reference Guide (Catalogue Number 8L-SIO-xx) for a description of the system features and operational guidelines.**

1. Precision pipettes and pipette tips: 150 µL and 1000 µL
2. Distilled or deionized water
3. Multichannel Timer – 3 settings
4. EDTA tube: 5 mL
5. Serum tube: 5 mL (optional)
6. Graduated cylinder
7. Plastic transfer pipettes
8. 1.5 mL microcentrifuge tubes
9. Tissues or gauze
10. Calculator
11. Personal Protective Equipment

### 4.3 Reagent preparation and storage

1. **Ready To Use Strip Plate (P1)** Prior to opening the plate pouch, bring the plate to room temperature for 10 minutes. Tap the plate on the table prior to removing the seal from the wells to ensure accuspheres are on bottom of wells. Remove protective seal from RTU strips to be used prior to addition of sample. Return the unused sealed strips to the plate pouch. Do not remove the desiccants. Securely seal plate pouch with the closure clip. The RTU strips with the protective seals still on top can be stored for 1 month after opening of the pouch, if it is stored together with the desiccants, in a sealed pouch, at 2-8°C.
2. **PTH Zero Standard (S0)** Before use, reconstitute the vial labeled 'S0' with 2.0 mL of distilled or deionized water and throw away the stopper and cap. Allow the vial to stand for 15 minutes at room temperature, then mix by gentle shaking to ensure complete reconstitution. After use, discard all remaining components.
3. **PTH Standards (S1 – S5)** Before use, reconstitute the vials labeled 'S1' through 'S5' with 1.0 mL of distilled or deionized water and throw away the stopper and cap. Allow the vials to stand for 15 minutes at room temperature, then mix by gentle shaking to ensure complete reconstitution. Avoid contact between the solution and the stopper. Do not use a roller-shaker. Use the standards immediately after reconstitution. After use, discard all remaining components.
4. **PTH Controls (C1 and C2)** Before use, reconstitute the vials labeled 'C1' and 'C2' with 1.0 mL of distilled or deionized water and throw away the stopper and cap. Allow the vials to stand for 15 minutes at room temperature, then mix by gentle shaking to ensure complete reconstitution. Avoid contact between the solution and the stopper. Do not use a roller-shaker. Use the controls immediately after reconstitution. After use, discard all remaining components.
5. **Wash Solution (W1)** Store the Wash Solution at 2-8 °C. Dilute the Wash Concentrate with 270 mL of distilled or deionized water and mix. The Concentrated Wash Solution (W1) may crystallise due to the cold storage of this concentrated buffer. Allow the crystals to dissolve when diluting the concentrated Wash Buffer with Distilled Water. After use, discard the remaining solution. The diluted wash solution is stable for 1 week.
6. **Non-coated Strip Plate (P2)** After performing the assay, discard the used strips.
7. **Activator Solutions (A1 and A2)** The Activator Solutions must be brought to room temperature (15-30 °C) prior to use, to avoid problems in the chemiluminescence reaction. Cold Activators (When they are taken directly from Cold Storage) may cause low response in the STAT-Read. Store the Activator Solutions away from direct light until expiration date on the bottle. After opening the Activator solutions can be stored for 1 month at room temperature (15-30 °C).
8. Mix all reagents completely before use. Mix by gentle shaking to ensure complete reconstitution.
9. Upon receipt:  
**Store at: 2 – 8 °C**  
**Store Activator Solutions (A1 and A2) away from direct light**

#### **4.4 Chemical or physical indications of instability**

Alteration in the physical appearance of test kit materials may indicate instability or deterioration. Expiry dates shown on component labels indicate the date beyond which components should not be used.

#### **5. Specimen collection and preparation of samples**

The determination of PTH should be performed in serum or EDTA plasma. It is recommended to perform the assay in duplicate, for this purpose at least 300  $\mu$ L of patient sample is needed.

1. Proper sample collection from the patient in surgery requires one, non-diluted blood sample to be drawn. If drawn through an I.V. infusion line, discard the first 10 mL. The second 6-8 mL (cc) blood sample is drawn; then  $\pm$  3 mL (cc) blood sample is immediately transferred into the appropriately labeled EDTA tube which is shaken head over tail for 5 times to ensure proper anticoagulant mixing.  
(The remaining  $\pm$  3 mL blood sample is transferred into an appropriately labeled serum tube (no additives) for optional serum analysis at a later date. Allow the blood to clot. Keep the tube on ice until it can be centrifuged. Centrifuge the tube for 10 minutes at 5000 g-force and aliquot the serum supernatant. Freeze the serum sample immediately.)
2. Transfer 2 aliquots of 1 mL EDTA blood sample into two-labeled microfuge tubes.
3. Centrifuge the tubes for approximately 30 seconds at 1100 g-force (5000 rpm on the STAT-Centrifuge).
4. The EDTA plasma supernatant is used for immediate analysis.

#### **6. STAT-IntraOperative-Intact-PTH test Procedure**

The Future Diagnostics STAT-System Startup procedure must be followed according to the instructions in the STAT-System Reference Guide.

- Initialize
- Check liquid levels
- Prime system
- Measure background and lightcheck

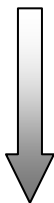
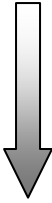
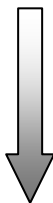
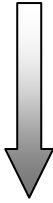
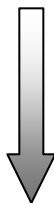
##### **6.1 Procedure and flow chart**

1. Reconstitute Standards and Controls. Allow 15 minute reconstitution time. Mix gently before use.
2. Remove micro titer strips from package. Load labeled Ready-to-Use strips (P1) on the far left side of the strip holder following the pipetting sequence in the STAT-System Reference Guide. Load the corresponding labeled non-coated strips (P2) in center of strip holder.
3. Transfer 150  $\mu$ L of each standard, control, and patient sample in duplicate to the appropriately labeled non-coated strip (P2) with a pipet .
4. Equip the STAT-Pipet with eight tips. Transfer 100  $\mu$ L of each standard, control and patient sample from the labeled non-coated strip (P2) to the labeled RTU (P1)

strip in one smooth step. All standard, control and patient sample must be assayed in duplicate.

5. Secure the strip holder on the STAT-Shake. Incubate for 5 minutes  $\pm$  10 seconds.
6. At the end of the 5 minute incubation time, place the strip holder in the STAT-Wash. The RTU strips will be washed three times with 500  $\mu$ L working wash solution. The washed strips must be analyzed within 15 minutes on the STAT-Read.
7. Load the RTU strips into the programmed STAT-Read. 100  $\mu$ L Activator A 1 and 100  $\mu$ L Activator A 2 are injected into each well and counted for 3 seconds.
8. The Standard curve is generated; controls and patient samples are calculated from the standard curve on the STAT-Read. Refer to STAT-System Reference Guide for details on the calculation of results.

**Flow chart STAT-IO-I-PTH assay.**

Well Sample ID	Load Non-Coated Strip	Transfer to RTU strip	Incubate at 22-25 °C	Wash	Measure
Standard S0 Standard S1 Standard S2 Standard S3 Standard S4 Standard S5 Control C1 Control C2 Patient Sample 1 Patient Sample 2 Patient Sample 3 Patient Sample 4 Patient Sample 5	150 $\mu$ L of Standard, control, or patient sample in duplicate  	Using STAT-Pipette Transfer 100 $\mu$ L  	5 minutes $\pm$ 10 seconds on STAT-Shake  	3 times 500 $\mu$ L on STAT-Wash  	Count 3 seconds on STAT-Read  100 $\mu$ L A1 100 $\mu$ L A2 injected by STAT-Read  

**6.2 Procedural notes**

1. PTH 1-84 is a very labile molecule. Set up the assay within a maximum of 30 minutes from reconstitution of all the Standards and Controls.
2. Discard all consumed reagents; Standards, Controls, Wash solution, Activator solutions, and Plate strips upon completion of procedure in compliance with local biohazardous waste regulations.
3. Standards, Controls and Patient Samples should be assayed in duplicate. Average RLU's of duplicate sets should be used for reduction of data and the calculation of results.
4. Careful analytical techniques and strict adherence to the directions in the Test Instructions and the STAT-System Reference guide are essential to obtain reliable results.
5. Samples with discrepant results should be verified by repeat assays.

6. Patient samples with values greater than the highest standard (S5) may be diluted with Zero Standard (S0) and re-assayed. Result values must be multiplied by the dilution factor.
7. The entire chemiluminescence reaction is complete in 3 seconds. This reaction is irreversible, so each well can only be read once.
8. Each component used in any one assay should be of the same lot number of the total test kit and stored under identical conditions. Do not pool reagents from different lots.
9. The Activator 1 includes 4% sodium hydroxide solution (NaOH) and the Activator 2 includes a 0.12% hydrogen peroxide solution. If the NaOH solution or the hydrogen peroxide solution splashes into eyes, immediate wash thoroughly with water or a suitable buffer solution. A physician should be consulted.
10. Activator 1 and Activator 2 must be loaded onto corresponding injectors of the STAT-Read for proper analysis.
11. If the kit is damaged upon receipt, please contact your local distributor and/or Future Diagnostics BV.



## 7. Quantitative results

The Future Diagnostics STAT-Read performs the following calculations:

1. The mean RLU for each set of duplicates for the Standards, Controls and Patient Samples is determined.
2. The Standard curve is prepared by plotting the mean RLU's corresponding to the concentrations of the prepared PTH Standards (pg/mL). RLU values of the Standards are plotted on the Y-axis versus the corresponding concentrations of PTH (pg/mL) on the X-axis. Refer to the STAT-System Reference Guide for additional details on calibration and data reduction.
3. The RLU values of Controls and Patient Samples are read from the Standard curve to obtain their corresponding concentration of PTH in pg/mL.
4. Conversion factor from pg/mL to pmol/L:  $1 \text{ pg/mL} \times 0.105 = \text{pmol/L}$

## 8. Interpretation of results

### STAT-IO-I-PTH Standard Curve

The following is a representative standard dose-response curve to be used only as an example.

Well ID	RLU	Mean RLU	PTH pg/ml
Standard S0	541 619	580	0
Standard S1	1963 1874	1918	30
Standard S2	4188 3910	4049	90
Standard S3	11431 11172	11301	270
Standard S4	33173 33659	33416	810
Standard S5	107904 107921	107912	2500
Control C1	2128 2177	2152	38.5
Control C2	22805 24009	23407	576
Patient Sample 1	2071 2064	2069	36.4
Patient Sample 2	4870 4857	4863	107
<i>Etc.</i>			

### Assay range

Measurement Range (Reportable Range)

The measurement range for the Future Diagnostics STAT-IO-I-PTH assay is 6.0 pg/mL to 2500 pg/mL

### Quality control

Two distinct levels of intact PTH controls are provided in each kit for quality control purposes. Additional levels of controls may be analyzed in addition to those provided. Established statistical methods for analyzing control values and trends should be employed.

If the precision of the assay does not comply with the established limits and repetition excludes errors in technique, check the following areas:

1. Expiration date on reagent package and prepared reagents.
2. Timer.
3. Thoroughness of washing step.
4. Storage and incubation conditions.
5. Cleanliness of all system components.
6. Purity of water.

### Expected values

Future Diagnostics recommends that each laboratory establish its own range of expected values for clinical situations where PTH values are used for diagnosis. The following is a guideline for some of the values:

Normal range, 10 - 65 pg/mL with calcium values ranging from 8.8 - 10.5 mg/dL;  
patients with hypercalcemia of malignancy, from undetectable to 22 pg/ml with calcium values ranging from 10.5 - 17.6 mg/dL

patients with hypoparathyroidism, from undetectable to 21 pg/mL with calcium values ranging from 6.3 - 8.5 mg/dL.

Because of the interplay between calcium and PTH levels in various parathyroid/calcium metabolism disorders, interpretation of PTH results should take the serum calcium concentrations into account.

### **Standardization**

The Future Diagnostics STAT-IO-I-PTH assay is traceable to World Health Organization preparation 79/500. The average recovery of WHO preparation 79/500 is 51% over the whole assay range.

## **9. Limitations of the procedure**

1. The STAT-IO-I-PTH kit is intended strictly as an aid during surgery of hypersecreting parathyroid tissue.
2. The STAT-IO-I-PTH assay shows no high dose hook effect from 0 to 500,000 pg/mL of intact-PTH.
3. Samples expected to have PTH values above the highest standard (S5) must be diluted with the Zero Standard (S0). The resulting value should then be multiplied by the appropriate dilution factor.
4. The Future Diagnostics STAT-IO-I-PTH assay is optimized and calibrated for the determination of intact PTH antigens. Genetic variations or degradation of antigens into subunits or other fragments may alter antibody binding characteristics and affect final results. Such samples may exhibit discordant results between different assays, as the effect of such altered states is particular to each defined antibody assay.
5. Since highly lipemic and/or jaundice serum samples can affect immunochemical reactions, Future Diagnostics recommends that such samples not be used in the STAT-IO-I-PTH assay.
6. The user must be trained by a Future Diagnostics representative or local distributor. The user should have a laboratory or medical education or have gained appropriate experience in the field of laboratory or medical practices.

## **10. Performance characteristics**

### **Precision and Reproducibility**

The precision (intra-assay variation) of the Future Diagnostics STAT-IO-I-PTH assay was calculated from replicate determinations on each of four samples in a single assay (n=20). The reproducibility (inter-assay variation) was calculated from data obtained on five samples in 27 assays.

#### Intra-Assay Variation

Mean PTH Value (pg/mL) from the Curve	% Coefficient of Variation	N
41	10.7	20
77	9.8	20
255	4.9	20
540	6.2	20

### Inter-Assay / Total Variation

Mean PTH Value (pg/mL) from the Curve	% Coefficient of Variation	N
38	12.7	27
103	15.3	27
295	14.5	27
512	10.0	27
842	15.0	27

### **Accuracy**

The Future Diagnostics STAT-IO-I-PTH assay was compared to a commercially available PTH immunochemiluminescent assay (ICMA). A population of 67 samples was assayed by each method. The range of values obtained using the commercially available PTH immunochemiluminescent assay (ICMA) ranged from 6,7 to 1029 pg/mL. Values obtained with the Future Diagnostics STAT-IO-I-PTH assay (Y) ranged from < 6 to 947 pg/mL. A correlation coefficient of (r) = 0.98 with a regression formula  $Y = 0.99X - 1.3$  was obtained from linear regression analysis of the data.

### **Sensitivity**

The sensitivity of this assay is defined as the smallest single value, which could be distinguished from zero with 95% confidence. The Future Diagnostics STAT-IO-I-PTH assay has a calculated sensitivity of 6 pg/mL.

### **Recovery**

PTH serum samples were mixed in 2 to 1, 1 to 1 and 1 to 2 ratios and assayed. The results are described in the following table:

Serum Sample	Observed PTH value in pg/mL	Expected PTH value in pg/mL	% Rec
Undiluted high patient	630		
2 to 1	435	449.3	97
1 to 1	340	359.0	95
1 to 2	257	268.7	96
Undiluted low patient	88		
Undiluted high patient	676		
2 to 1	467	479.7	97
1 to 1	358	381.5	94
1 to 2	272	283.3	96
Undiluted low patient	87		
Undiluted high patient	620		
2 to 1	429	430.0	100
1 to 1	331	335.0	99
1 to 2	247	240.0	103
Undiluted low patient	50		

## Parallelism

Three human serum samples were diluted with Zero Standard (S0). Results in pg/mL are shown below:

Serum Sample	Dilution Factor	Measured pg/mL	Expected pg/mL	% Recovery
A	undiluted	715.9		
	2	379.1	358.0	106
	4	164.5	179.0	92
	8	71.9	89.5	80
B	undiluted	835.8		
	2	388.4	417.9	93
	4	185.2	209.0	89
	8	91.3	104.5	87
C	undiluted	1039.9		
	2	539.6	520.0	104
	4	238.7	260.0	92
	8	103.8	130.0	80

## Specificity and Cross-Reactivity

The antibody pair in the Intact PTH kit comprises the antibody which recognizes the 39-84 segment (coated in the well) and the other labeled with isoluminol which recognizes the N-terminal 1-34 amino acid sequence of PTH. Therefore, the sandwich-complex is formed only with the intact PTH molecule. This results in minor (< 0.5%) cross-reactivity with any other PTH fragments.

The following substances were added to a pool containing 320 pg/mL PTH and to the Zero Standard (S0). All samples have been assayed using the Future Diagnostics STAT-IO-I-PTH assay.

Cross reactant	Concentration of Cross Reactant (pg/mL)	Observed value (pg/mL) in pool and in zero standard	
PTH 1-34	400	285	ND
PTH 39-68	10,000	255	25
PTH53-84	10,000	267	14
PTH 44-68	10,000	244	29
PTH 39-84	10,000	290	55

N.D. Not Detectable

## 11. References

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## 12. Availability

To place an order:

Contact our Customer Service Department:

Tel: +31(0) 246452900

Fax: +31(0) 246452899

E-mail: sales@future-diagnostics.nl

In the USA contact:

Tel: 17812666054

For technical assistance please refer to the Catalogue Numbers:

Kit # 4K-IPT-00

Test Instructions # 3L-IPT-00

Effective: 04/11

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Nieuweweg 279  
6603 BN, Wijchen  
The Netherlands

931 Calle Negocio Ste G  
San Clemente, CA 92673  
USA

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