Whole PTH (1-84) Specific ImmunoChemiluminoMetric Assay (ICMA)
(Coated Plate-Technology)
For the quantitative determination of human Whole PTH
**For In Vitro Diagnostic Use Only**

INTENDED USE
This kit has been designed for the quantitative determination of human whole parathyroid hormone (PTH) without cross-reaction to PTH (7-84) fragment in plasma samples.32,33,34,35

PHYSIOLOGY
The Whole PTH peptide (1-84) is secreted by parathyroid glands under the regulation of the extracellular concentration of ionized calcium, vitamin D and magnesium. PTH acts with respect to calcium on the kidney and the skeleton4,5. PTH binds to receptors, which stimulate adenylate-cyclase to produce cyclic adenosine monophosphate (cAMP) from adenosine triphosphate (ATP)10,13. The biological activity of PTH resides in the first 3 amino acids of the N-terminal portion of the molecule. PTH is metabolized either intraglandular or in the peripheral organs into fragments. Circulatory PTH are immunologically heterogenous7,6,12,13,18,19. A recent study of circulation immunoreactive PTH showed that significant amounts of a large carboxyl-terminal PTH fragment, PTH (7-84), presented in blood samples from uremic patients31. Biologically inactive fragments with molecular weights of 4000 - 7000 Daltons circulate with a half-life of 30 minutes in healthy persons4,5. cAMP or other PTH dependent processed metabolites (e.g. hypophosphatemia) stimulate the renal hydroxylation of 25-(OH) vitamin D to 1,25-(OH)2 vitamin D. This vitamin D metabolite stimulates calcium absorption by the small intestine. Severe vitamin D deficiency results in an enhanced secretion of PTH compared to the secretion of calcium. Hypomagnesemia in the primary stage stimulates hypocalcemia. Severe hypomagnesemia results in the reduced secretion of PTH. Primary and secondary hyperparathyroidism, kidney insufficiency, malabsorption-syndrome and pseudohypoparathyroidism result in elevated concentrations of PTH.14,15,16 Decreased concentrations of PTH coincide with high doses of vitamin-D, milk-alkali-syndrome, Morbus Boeck, hyperthyreosis, ingestion of thiazide and hypercalcemia of malignancy. PTH concentration is also decreased with absorptive hypercalciuria and hypoparathyroidism.

PRINCIPLE OF PROCEDURE
Scantibodies 1-84 PTH or Whole PTH Kit is an immunochemiluminometric assay (ICMA) utilizing a polyclonal PTH 1-84 antibody with a tendency to bind in the N-terminal region of PTH 1-84 (Label Antibody), and a polyclonal PTH 1-84 antibody with a tendency to bind in the C-terminal region of PTH 1-84 (Capture Antibody). The use of these antibodies guarantees that only Whole PTH (CAP) is detected. The Label Antibody is labeled with isoluminol. The Capture Antibody is fixed to the wells of the microtiter plate. 1-84 PTH or Whole PTH (CAP) in patient samples is bound both to the wells of the microtiter plate strips and to the Label Antibody. After incubation simple wash steps reduce the non-specific binding (NSB) to a minimum for increased precision at the low end of the calibration curve. The concentration of Whole PTH (CAP) is directly proportional to the photons emitted from the wells upon addition of triggering reagents. The concentration of PTH in unknown patient samples and controls is determined by interpolation using a calibration curve.30

REAGENTS
The Scantibodies Whole PTH Kit contains sufficient reagents for 96 single determinations. The kit is stable at 2° - 8° C until the stated expiration date.

WHOLE PTH ICMA STANDARDS
Standards consist of seven vials containing lyophilized human serum with nominal Whole PTH (CAP) concentrations. The lyophilized standards are prepared in stabilized human serum containing sodium azide 0.1% (w/v). The Whole PTH (CAP) concentrations are declared on the vial label.

WHOLE PTH ICMA CONTROLS
One set of controls consists of two vials containing Whole PTH (CAP) in lyophilized human serum with 0.1% (w/v) sodium azide. The concentration ranges of Whole PTH (CAP) are declared on the vial labels.

WHOLE PTH TRACER FOR ICMA
The tracer consists of one bottle of goat anti N-terminal PTH antibodies labeled with isoluminol and
dissolved in 10 ml phosphate buffered saline with a non-azide, non-mercury preservative 0.2% (v/v) and protein stabilizers.

**PTH (39–84) ANTIBODY COATED PLATE**
One plate contains 12 strips (96 wells) in a frame plus desiccant. The strip wells are coated with the capture antibody. The desiccant contains silica.

**WASH SOLUTION CONCENTRATE**
One bottle contains 30 ml of a 10 fold concentrate of phosphate buffered saline with sodium azide 0.6% (w/v) and detergent.

A<sub>1</sub>-TRIGGER 1, ICMA
One bottle contains 28 ml of ready to use reagent [Caution! Contains 1M sodium hydroxide]

A<sub>2</sub>-TRIGGER 2, ICMA
One bottle contains 28 ml of ready to use reagent

**PREPARATION AND STORAGE OF REAGENTS**

**WHOLE PTH ICMA STANDARDS**
The Scantibodies Whole PTH Kit contains PTH standards prepared analytically on a mass basis from purified synthetic Whole PTH (1-84). These standards are further evaluated against lyophilized "primary standards" which are stored at -70° C to maintain potency.

Reconstitute the zero standard with 5 ml of distilled or deionized water. Reconstitute the remaining standards with 2 ml of distilled or deionized water. After addition of the water, mix each vial thoroughly but gently. Use the reconstituted standards within 1 hour. Store the unused portion of the standards below -20° C until the stated expiration date. Do not store the standards at room temperature for more than one hour at any given time. Do not thaw any standard vial more than two times.

**WHOLE PTH ICMA CONTROLS**
Reconstitute the vials of controls with 2 ml of distilled or deionized water. After addition of the water, mix each vial thoroughly but gently. Use the reconstituted controls within 1 hour. Store the unused portion of the controls below -20° C until the stated expiration date. Do not store the controls at room temperature for more than one hour at any given time. Do not thaw any control vial more than two times.

**WHOLE PTH TRACER FOR ICMA**
The tracer is ready to use. Store the tracer at 2° - 8° C until the stated expiration date.

**PTH (39-84) ANTIBODY COATED PLATE**
The antibody coated plate is ready to use. Store the plate at 2° - 8° C until the stated expiration date. Allow the plate to equilibrate to ambient temperature prior to opening package. Reseal the package immediately after removing the required number of strips.

**WASH SOLUTION CONCENTRATE (10X), ICMA**
Mix the contents of the wash concentrate thoroughly with 270 ml of distilled or deionized water (1:10) to make the wash solution. Store the wash solution at room temperature (18° - 25° C) until the stated expiration date. **Note:** On occasion, the wash concentrate may partially crystallize depending on individual storage conditions. In this case, additional mixing may be required in order to achieve complete dissolution of the reagent.

A<sub>1</sub>-TRIGGER 1, ICMA
The reagent is ready to use. Store at 2° - 8° C until the stated expiration date.

A<sub>2</sub>-TRIGGER 2, ICMA
The reagent is ready to use. Store at 2° - 8° C until the stated expiration date.

**WARNINGS AND PRECAUTIONS FOR USERS**

**Use of the Assay**
The reagents are for in vitro diagnostic use only.

**Human Serum Caution**
The human serum in this kit has been prepared from human donors and it has been tested by FDA approved immunoassays and found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), Anti HIV I/II and Anti HCV. However, it is recommended to consider the standards and controls as a potential biohazard and handle them with the same precautions as applied to any untested patient sample.

**Sodium Azide (NaN<sub>3</sub>) Warning**
Some reagents in the Scantibodies Whole PTH assay contain sodium azide. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal flush the drain with a large volume of water to prevent azide build-up. Avoid direct contact with skin and mucous membranes.

**Corrosive Warning**
Trigger 1 reagent contains 1M sodium hydroxide which is very corrosive. Do not allow to contact skin or splash into eyes. Wear gloves and goggles when handling this reagent. Dispose of any unused reagent in a safe manner according to local regulations.
**SAMPLE PREPARATION AND STORAGE**

**Specimen Collection**
The determination of human Whole PTH should be made on EDTA-plasma. 200 ml of plasma are required to assay one sample in duplicate. To obtain plasma, collect blood by venipuncture into a tube containing EDTA. Invert the tube gently 5 - 6 times after collection to ensure adequate mixing. Whole blood may be stored refrigerated for up to 48 hours prior to centrifugation. Centrifuge the sample and separate the plasma from the cells. Plasma should be stored at -20° C or lower. Avoid repeated freezing and thawing of plasma. Do not use patient samples which have been frozen and thawed more than two times.

**Dilution of Patient Samples**
Dilute plasma samples with PTH concentrations greater than the highest standard with Scantibodies Whole PTH Zero Standard before assay. The dilution factor is applied to the diluted sample assay result in order to determine the PTH concentration in the undiluted sample.

**Quality Control**
Two levels of controls are provided with each assay kit. The values assigned to these controls are printed on the container label. The control value should fall within the specified range when tested in the same manner as the unknowns. Controls should be included in each assay. If the control values do not meet the established range, the assay may be invalid and should be repeated.

**ASSAY PROCEDURE**

**Materials Provided**
The Scantibodies Whole PTH Kit (Part No. 3KG002) is supplied with the following:

<table>
<thead>
<tr>
<th>Description</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole PTH ICMA Standards</td>
<td>7 vials</td>
</tr>
<tr>
<td>Part Nos. 3CA610, 3CB610, 3CC610, 3CD610, 3CE610, 3CF610, 3CG610</td>
<td></td>
</tr>
<tr>
<td>Whole PTH ICMA Controls</td>
<td>2 vials</td>
</tr>
<tr>
<td>Part Nos. 3CA611, 3CB611</td>
<td></td>
</tr>
<tr>
<td>PTH (39-84) Antibody Coated Plate</td>
<td>1 Plate (12 Strips)</td>
</tr>
<tr>
<td>Part No. 3KP004</td>
<td></td>
</tr>
<tr>
<td>Whole PTH Tracer For ICMA</td>
<td>1 vial</td>
</tr>
<tr>
<td>Part No. 3KL102</td>
<td></td>
</tr>
<tr>
<td>Wash Solution Concentrate (10X), ICMA</td>
<td>1 bottle</td>
</tr>
<tr>
<td>Part No. 3KW002</td>
<td></td>
</tr>
<tr>
<td>A⁺-Trigger 1, ICMA</td>
<td>1 bottle</td>
</tr>
<tr>
<td>Part No. 3KL057</td>
<td></td>
</tr>
<tr>
<td>A⁻-Trigger 2, ICMA</td>
<td>1 bottle</td>
</tr>
<tr>
<td>Part No. 3KL055</td>
<td></td>
</tr>
<tr>
<td>Directional Insert</td>
<td>1 insert</td>
</tr>
</tbody>
</table>

**Materials And Equipment Required But Not Provided:**
- Distilled or deionized water
- Pipettors with disposable tips: 0.05 and 0.1 ml
- Wash station
- VWR orbital shaker Model DS-500 or equivalent
- Microplate luminometer equipped with dual injectors capable of delivering 100 μl each.

**Preparation for Assay**
For each assay, prepare the following number of strips for double determination:
- 2 strips for standards A – G and control I
- 2 strips for control II and samples 1 through 7
- 2 strips for samples 8 through 15, etc.

Place any unused strips back into the resealable foil pouch and store at 2° - 8° C

**Pipetting and Incubation Steps**
1. Pipette 100 μl of standards, controls and samples into the bottom of the corresponding strip wells. (Plate mapping forms are useful for recording sample locations on the plate.)
2. Pipette 100 μl of Whole PTH tracer into each well changing pipet tips between each well.
3. Place the plate securely on an orbital shaker and rotate the plate for 2 hours to 2½ hours at 160 to 180 RPM at room temperature (18° – 25° C). There is no need to cover the plate or protect from the light.
4. After the incubation time is completed, wash the plate strips by aspirating the contents of each well completely and dispensing 350 to 400 μl of wash solution into each well. Repeat this procedure 3 to 5 times aspirating the wash solution completely after the last washing step. (Slapping the plate on absorbent material after washing is **not** recommended).
5. While the plate is being washed, prime the luminometer with enough of the trigger solutions to fully expel any air or liquid in the system.
6. Set up a standard curve in the instrument using the concentrations listed on the standard vials for the determination of the unknown samples.
7. Set the luminometer to inject 100 μl of trigger 1 followed by 100 μl of trigger 2 with a 0.5 second delay prior to reading and an integration time of 1.5 seconds. The delay and integration settings are general guidelines. Different instruments may require some adjustments to obtain optimal results.
8. Read the plate within 5 minutes after the washing step is completed.
PIPETTING GUIDE

<table>
<thead>
<tr>
<th>Additive to well</th>
<th>Standard Wells</th>
<th>Control Wells</th>
<th>Sample Wells</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard</td>
<td>100 μl</td>
<td>-----</td>
<td>100 μl</td>
</tr>
<tr>
<td>Control</td>
<td>-----</td>
<td>100 μl</td>
<td>-----</td>
</tr>
<tr>
<td>Sample</td>
<td>-----</td>
<td>100 μl</td>
<td>100 μl</td>
</tr>
<tr>
<td>Tracer</td>
<td>100 μl</td>
<td>100 μl</td>
<td>100 μl</td>
</tr>
</tbody>
</table>

Rotate the uncovered plate at 160 to 180 RPM on an orbital shaker for 2 to 2½ hours.

Wash the strips 3 to 5 times with the diluted wash solution.

Read the strips on a luminometer equipped with dual injectors primed with the two trigger solutions and set to deliver 100 μl of trigger 1 followed by 100 μl of trigger 2 with a 0.5 second delay prior to reading and a 1.5 second integration time, within 5 minutes after the washing step is completed.

PROCEDURAL COMMENTS

Interferences:
Samples containing up to 250 mg/dl triglyceride, 15 mg/dl hemoglobin and 30 mg/dl bilirubin do not exhibit any significant effect on the assay. However, it is strongly recommended that grossly hemolyzed or lipemic samples not be used in this assay.

Reagents from different lot numbers must not be interchanged.

The patient sample or standard should be pipetted carefully into the very bottom of the assay well. The tracer should be pipetted onto the side of the well just above the liquid level.

Accurate and complete reconstitution of the controls and standards is essential to achieving accurate assay results.

The washing step is an important step in the assay procedure. Accurate dispensing of the wash solution and complete aspiration of the tube contents is essential to achieving assay sensitivity, low background and assay precision. Washing the wells 5 times with the provided wash reagent is recommended.

It is recommended that standards and patient samples be assayed in duplicate. The average Relative Light Units (RLU) of each duplicate should then be used for data reduction and the calculation of results.

Avoid sample to sample contamination by using a new pipette tip for each sample.

CALCULATION OF RESULTS

Evaluation

1. Calculate the average RLU for each double determination.
2. Draw the calibration curve by plotting the average RLU from each duplicate standard level (ordinate) against the respective concentration declared on the standard vial (abscissa) using log-log graph paper. Obtain sample concentrations by interpolation of average sample RLU on the calibration curve.
3. If samples were run with dilution, multiply the diluted sample assay results from the curve by the appropriate dilution factors to obtain the undiluted sample assay results.

SAMPLE DATA

<table>
<thead>
<tr>
<th>Wells</th>
<th>RLU</th>
<th>Ave. RLU</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 pg/ml</td>
<td>394</td>
<td>387</td>
</tr>
<tr>
<td>5.7 pg/ml</td>
<td>1085</td>
<td>1050</td>
</tr>
<tr>
<td>14.0 pg/ml</td>
<td>2043</td>
<td>2027</td>
</tr>
<tr>
<td>32 pg/ml</td>
<td>4352</td>
<td>4344</td>
</tr>
<tr>
<td>145 pg/ml</td>
<td>16414</td>
<td>16603</td>
</tr>
<tr>
<td>805 pg/ml</td>
<td>96843</td>
<td>90659</td>
</tr>
<tr>
<td>2294 pg/ml</td>
<td>242130</td>
<td>239475</td>
</tr>
</tbody>
</table>

NOTE: The data presented are for demonstration purposes only and must not be used in place of data generated at the time of the assay.

REPRESENTATIVE STANDARD CURVE

Automated data reduction can also be used to construct the Scantibodies Whole PTH calibration curve. To
program automated data reduction systems or to adapt an existing program consult the data processor manufacturer or the programmer.

LIMITATIONS OF THE PROCEDURE
For diagnostic purposes PTH values should be used in addition to other diagnostic data and clinical information available to the physician.

The assay procedure must be followed exactly; careful technique must be used to obtain valid results. Any modification of the assay procedure is likely to alter the results.

Grossly hemolyzed, lipemic or icteric samples are likely to give non valid results.

The highest concentration of PTH measurable without sample dilution is the concentration of the highest standard. The lowest level measurable is below 1.2 pg/ml.

EXPECTED VALUES
The normal value range was determined following the NCCLS guidelines (C28-A) using 120 samples from apparently healthy individuals. It is recommended that each laboratory establish its own range of normal values. The values given are only indicative and may vary from other published data.

<table>
<thead>
<tr>
<th>PATIENT CLASSIFICATION</th>
<th>Whole PTH RANGE (pg/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>5 - 39</td>
</tr>
<tr>
<td>Hyperparathyroidism</td>
<td>&gt; 39</td>
</tr>
</tbody>
</table>

PERFORMANCE CHARACTERISTICS
Accuracy, Recovery
Three different samples with known concentrations of PTH were spiked with known amounts of PTH. The % recovery was determined following assay of the spiked samples.

<table>
<thead>
<tr>
<th>Sample value (pg/ml)</th>
<th>Added PTH (pg/ml)</th>
<th>Measured value (pg/ml)</th>
<th>Expected value (pg/ml)</th>
<th>Recovery (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>132.41</td>
<td>58.41</td>
<td>190.04</td>
<td>78.8</td>
<td></td>
</tr>
<tr>
<td>456.23</td>
<td>52.15</td>
<td>508.38</td>
<td>97.3</td>
<td></td>
</tr>
<tr>
<td>1213.50</td>
<td>147.14</td>
<td>1360.64</td>
<td>105.3</td>
<td></td>
</tr>
</tbody>
</table>

Accuracy, Dilution
Patient samples with high concentrations of PTH were diluted with Standard A. The % recovery was determined following assay of the diluted samples.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean value (pg/ml)</th>
<th>SD (pg/ml)</th>
<th>% CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>68.70</td>
<td>5.51</td>
<td>8.02</td>
</tr>
<tr>
<td>2</td>
<td>208.90</td>
<td>13.53</td>
<td>6.47</td>
</tr>
<tr>
<td>3</td>
<td>501.90</td>
<td>36.59</td>
<td>7.29</td>
</tr>
</tbody>
</table>

The intra-assay precision was evaluated by performing 20 replicates in the Whole PTH (CAP) assays on three samples.

<table>
<thead>
<tr>
<th>Kit Batch</th>
<th>Sample</th>
<th>Mean value (pg/ml)</th>
<th>SD (pg/ml)</th>
<th>% CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1</td>
<td>1</td>
<td>60.94</td>
<td>4.28</td>
<td>7.03</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>203.31</td>
<td>7.14</td>
<td>3.51</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>477.49</td>
<td>37.31</td>
<td>7.81</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>63.07</td>
<td>2.99</td>
<td>4.75</td>
</tr>
</tbody>
</table>
**Precision (Intra-assay)**

<table>
<thead>
<tr>
<th>Kit Batch</th>
<th>Sample</th>
<th>Mean value (pg/ml)</th>
<th>SD (pg/ml)</th>
<th>% CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2</td>
<td>2</td>
<td>199.88</td>
<td>8.19</td>
<td>4.10</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>483.60</td>
<td>29.30</td>
<td>6.06</td>
</tr>
<tr>
<td>E3</td>
<td>1</td>
<td>70.44</td>
<td>3.15</td>
<td>4.47</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>196.85</td>
<td>6.96</td>
<td>3.54</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>430.38</td>
<td>13.51</td>
<td>3.14</td>
</tr>
</tbody>
</table>

**Sensitivity**
The detection limit of the assay is defined as the lowest measurable value distinguishable from standard A. The sensitivity was determined by assaying standard A 20 times in the same assay. The minimum detectable dose was below 1.2 pg/ml at 2 standard deviations above the first PTH standard.

**Specificity**
This Whole PTH (CAP) assay does not show any cross-reaction to PTH (7-84) fragment when the synthetic PTH (7-84) peptide is serially diluted with standard A matrix and assayed.

<table>
<thead>
<tr>
<th>PTH (7 -84) Conc. Sample (pg/ml)</th>
<th>Measured PTH conc. (pg/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2500</td>
<td>undetectable</td>
</tr>
<tr>
<td>5000</td>
<td>undetectable</td>
</tr>
<tr>
<td>10000</td>
<td>undetectable</td>
</tr>
<tr>
<td>20000</td>
<td>undetectable</td>
</tr>
</tbody>
</table>

A high degree of correlation exists between the PTH levels of duplicate samples measured by a commercially available predicate PTH kit and those levels measured by the Scantibodies Whole PTH Assay. A correlation coefficient (r) of 0.984 (n=240) was obtained with a slope of 0. 976 and intercept of 6.901 where x represents the predicate device data and y represents the SLI Whole PTH ICMA data. Calculations were made with samples ranging from 1.23 – 995.82 pg/mL.

**Chemical Characterization:**
1) Antibodies coated on to 96 well polystyrene plates packaged with silica desiccant.
2) Antibody Tracer labeled with Luminol in a phosphate stabilizer with a mercury preservative @ 0.2%.
3) Standards & controls – human serum containing Sodium Azide @ 0.1%
4) Antibody Trigger containing Sodium Hydroxide @ 0.4%.
5) Antibody Trigger containing Hydrogen Peroxide @ 0.5%.
6) Wash Concentrate containing Sodium Azide @ 0.9%.

**Hazardous Ingredients:**
Sodium Hydroxide @ 0.4%
CAS Number: 1310-73-2
Symbols: Very Toxic; Corrosive
R-phrases: R25, R31, R52/53
S-phrases: S28, S45, S53

Hydrogen Peroxide @ 0.5%
CAS Number: 7722-84-1
Symbols: Very Toxic; Corrosive; Oxidizing
R-phrases: R20/21/22, R28, R32, R50/53
S-phrases: S1/2, S3, S28, S36/39, S45, S53

Sodium Azide @ 0.1%
CAS Number: 026628-22-8
Symbols: N/A
R-phrases: N/A
S-phrases: N/A

Sodium Azide @ 0.9%
CAS Number: 026628-22-8
Symbols: Toxic
R-phrases: R25, R31, R52/53
S-phrases: S28, S45, S53, S60, S61

**Symbol** | **Used for** | **Symbol** | **Used for**
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>✗</td>
<td>Do Not Reuse</td>
<td>✗</td>
<td>Do Not Reuse</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch Code</td>
<td>SN</td>
<td>Serial Number</td>
</tr>
<tr>
<td>DATE</td>
<td>Date of Manufacture</td>
<td>STERILE</td>
<td>Sterile</td>
</tr>
<tr>
<td>REF</td>
<td>Sterilized Using Aseptic Processing Technique</td>
<td>Catalog Number</td>
<td></td>
</tr>
<tr>
<td>CAUTION</td>
<td>Caution, Consult</td>
<td>Catalog Number</td>
<td></td>
</tr>
<tr>
<td>BIO</td>
<td>Biological Risks</td>
<td>Catalog Number</td>
<td></td>
</tr>
<tr>
<td>REP</td>
<td>Manufacturer</td>
<td>Authorized Representative in the European Community</td>
<td></td>
</tr>
<tr>
<td>N&gt;</td>
<td>Contains</td>
<td>Catalog Number</td>
<td></td>
</tr>
<tr>
<td>n&lt;br&gt;</td>
<td>Contains</td>
<td>For IVD Performance Evaluation Only</td>
<td></td>
</tr>
<tr>
<td>IVD</td>
<td>In vitro Diagnostic Medical Device</td>
<td>Upper Limit of Temperature</td>
<td></td>
</tr>
<tr>
<td>D&lt;br&gt;</td>
<td>Lower Limit of Temperature</td>
<td>Temperature Limitation</td>
<td></td>
</tr>
<tr>
<td>CONS&lt;br&gt;</td>
<td>Consult Instructions for Use</td>
<td>Positive Control</td>
<td></td>
</tr>
<tr>
<td>+</td>
<td>CONTROL+</td>
<td>CONTROL+</td>
<td></td>
</tr>
<tr>
<td>-</td>
<td>CONTROL-</td>
<td>CONTROL-</td>
<td></td>
</tr>
</tbody>
</table>
PTH LITERATURES


21. Mallette, L.E., Tuma, S.N., Berger, R.E. and Kirkland, J.L. "Radioimmunoassay for the Middle Region of Human Parathyroid Hormone Using a Homologous Antiserum with a Carboxyl-terminal


