

Total Intact PTH Assay

Immunoradiometric Assay (IRMA)
(Coated Tube-Technology)
For the quantitative determination
of human Total Intact PTH.
For *in vitro diagnostic* Use Only



Scantibodies

(Part Number: 3KG013)

Store at 2 – 8° C

INTENDED USE

This kit has been designed for the quantitative determination of total immunoreactive intact PTH (Total Intact PTH) in blood samples. The Total Intact PTH level is the sum of PTH (1-84) and N-truncated PTH fragments.

PHYSIOLOGY

The cyclase activating 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 kidneys and the skeleton. PTH binds to receptors, which stimulate adenylate-cyclase to produce cyclic adenosine monophosphate (cAMP) from adenosine triphosphate (ATP). The biological activity of PTH resides in the first two amino acids of the N-terminal portion of the molecule. PTH is metabolized either intraglandular or in the peripheral organs into fragments. Circulation PTH are immunologically heterogenous. A recent study of circulation immunoreactive PTH showed that significant amounts of a large carboxyl-terminal PTH fragment presented in blood samples from uremic patients. Biologically inactive fragments with molecular weights of 4000-7000 Daltons circulate with a half-life of 30 minutes in healthy persons.

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 pseudo-hypoparathyroidism result in elevated concentrations of PTH. 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 Total Intact PTH Coated Tube Kit is an immunoradiometric (IRMA) assay utilizing a polyclonal

1-84 PTH antibody with a tendency to bind in the N terminal region of 1-84 PTH (Label Antibody), and a polyclonal 1-84 PTH antibody with a tendency to bind in the C terminal region of 1-84 PTH (Capture Antibody). The use of these antibodies guarantees that Whole PTH (1-84 PTH) and truncated PTH fragments are detected. The Label Antibody is labeled with ¹²⁵I. The Capture Antibody is fixed to the tubes. The Total Intact PTH in patient samples is bound both to the tubes and the Label Antibody. After incubation free ¹²⁵I antibodies and bound ¹²⁵I antibody fractions are separated by discarding the supernatant. 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 Total Intact PTH is directly proportional to the radioactivity bound to the tubes after separation. The concentration of PTH in unknown patient samples and controls is determined by interpolation using a calibration curve.

REAGENTS

The Scantibodies Total Intact PTH Kit contains sufficient reagents for 100 single determinations. The kit is stable at 2 - 8° C until the stated expiration date.

Scantibodies PTH Calibrators

One set of calibrators consists of seven vials containing lyophilized human serum with nominal PTH concentrations. The lyophilized calibrators are prepared in stabilized human serum containing sodium azide 0.1% (w/v). The PTH concentrations are declared on the vial label.

Scantibodies PTH Controls

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

Scantibodies Total Intact PTH Tracer

One set of tracer consists of two bottles of ¹²⁵I-anti PTH (1-34). Each bottle contains polyclonal goat anti PTH (1-34) which is labeled with ¹²⁵I and dissolved in 5 ml phosphate buffered saline with sodium azide 0.1% (w/v) and protein stabilizers. The maximum radioactivity in a bottle is <370 kBq (<10 μCi). This kit contains ¹²⁵I (half life: 60 Days), emitting ionizing X (28 keV) and Gamma γ (35,5 keV) radiations.

Scantibodies PTH (39-84) Antibody Coated Tubes

2 packages of 50 tubes each plus desiccant. The tubes are coated with polyclonal goat anti-PTH (39-

84). The desiccant contains silica.

Scantibodies Wash Concentrate

One bottle contains 30 ml of a 30 fold concentrate of phosphate buffered saline with sodium azide 1.5% (w/v) and detergent.

PREPARATION AND STORAGE OF REAGENTS

Scantibodies PTH Calibrators

The Scantibodies Laboratory, Inc. Total Intact PTH Coated Tube Diagnostic Kit contains the PTH standards prepared analytically on a mass basis from purified synthetic intact PTH (1-84). These standards are further evaluated against "primary standards" which are stored at -70° C to maintain calibration.

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

Scantibodies PTH 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. Do not use controls that exhibit precipitation or unusual color.

Scantibodies Total Intact PTH Tracer

The tracer is ready to use. Store the tracer at 2 - 8° C until the stated expiration date. Do not use tracer that shows precipitation or unusual color.

Scantibodies PTH (39-84) Antibody Coated Tubes

The antibody coated tubes are ready to use. Store the tubes at 2 - 8° C until the stated expiration date. Allow the tubes to equilibrate to ambient temperature prior to use. Reseal the package immediately after removing the required number of tubes.

Scantibodies Wash Concentrate

Dilute and thoroughly mix the 30 ml of wash concentrate with 870 ml of distilled or deionized water (1:30). Store the diluted wash solution at room temperature (18 - 25° C) until the stated expiration date. Do not use wash solution that shows precipitation.

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 calibrators and controls as a potential biohazard and handle them with the same precautions as applied to any untested patient sample.

Radioactivity Warning

This radioactive material may be received, acquired, possessed, or used only by physicians, clinical laboratories, or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

All radioactive materials must be disposed of according to the regulations (regulations differ from country to country) and guidelines of the agencies with jurisdiction over the laboratory. Do not eat, drink, smoke or apply cosmetics in areas where radioactive materials are used. Storage of radioactive materials should be limited to specifically designated and appropriately secured areas. Access to radioactive materials should be limited to authorized and trained personnel only. Do not pipette radioactive solutions by mouth. Avoid direct contact with radioactive materials by using protective articles such as lab coats and disposable gloves. Radioactive materials must be stored in designated areas in their original containers or in containers providing equivalent radiation protection. A record of disposal of all radioactive materials must be kept. Immediately remove spilled solutions and decontaminate contaminated devices. Check laboratory equipment and glassware regularly to detect contamination with radioisotopes.

Sodium Azide (NaN₃) Warning

Some reagents in the Scantibodies 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.

SAMPLE PREPARATION AND STORAGE

Specimen Collection

The determination of human Total Intact PTH must be made on EDTA-plasma or serum. Four hundred microliters of plasma or serum are required to assay one sample in duplicate for Total Intact PTH values. To obtain plasma, collect blood by venipuncture into EDTA tube. Centrifuge the sample at 2 - 8° C and separate

the plasma from the cells. Plasma and serum should be stored at -20° C or lower. To obtain serum, collect blood by venipuncture into serum collection tubes. Allow the blood to clot in an ice bath for 1 – 3 hours. Centrifuge the sample at 2 - 8° C and separate the serum from the cells. 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 patient samples with PTH concentrations greater than the highest calibrator with Scantibodies PTH Zero Calibrator 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 Total Intact PTH Coated Tube Kit (Part No. 3KG013) is supplied with the following:

| Description | Number |
|---|------------------------|
| Scantibodies PTH Calibrators Part Nos. 3CA647, 3CB647, 3CC647, 3CD647, 3CE647, 3CF647, 3CG647 | 7 vials |
| Scantibodies PTH Controls Part Nos. 3CA648, 3CB648 | 2 vials |
| Scantibodies PTH (39-84) Antibody Coated Tubes Part No. 3KT001 | 2 packages of 50 tubes |
| Scantibodies Total Intact PTH Tracer Part No. 3KL127 | 2 vials |
| Scantibodies Wash Concentrate Part No. 3KW001 | 1 bottle |
| Directional Insert Part No. 7KI017 | 1 insert |

Materials And Equipment Required But Not Provided:

Distilled or deionized water
 Round-bottomed polypropylene or polystyrene test tubes (12 x 55, 12 x 75, 12 x 70 mm or equivalent)
 Pipettor with disposable tips: 0.2 ml
 Repeating dispenser: 0.1 ml
 Wash station
 Vortex mixer
 Gamma counter calibrated to detect ¹²⁵I

Preparation for Assay

For each assay, prepare the following groups of tubes and place them in a test tube rack (double determination):

- 2 total count tubes (optional for QC) (use polypropylene tubes)
- 2 Bo tubes (NSB) - provided with kit
- 2 tubes for each calibrator concentration – provided with kit
- 2 tubes for each control concentration– provided with kit
- 2 tubes for each patient sample– provided with kit

Pipetting and Incubation Steps

1. Pipette 0.2 mL of calibrators, samples and controls into the corresponding tubes.
2. Pipette 0.1 ml of Total Intact PTH Tracer into each tube.
3. Gently vortex all tubes.
4. Seal the tubes and incubate them for 18 - 24 hours at room temperature (18 - 25° C).
5. Aspirate the supernatant from each tube except for the total count tubes. Wash the tubes 3 times with 2 ml of diluted wash solution. After each addition of diluted wash solution aspirate all of the wash solution.
6. Count each tube for at least 1 minute in a gamma counter calibrated to detect ¹²⁵I. The total count tube should contain approximately 300,000 CPM (assuming the counter has an efficiency of 70% - 80%) when freshly iodinated tracer is used. The total activity of the tracer decreases according to the half-life of ¹²⁵I.

PIPETTING GUIDE

| Additive To Tube | Total Count Tubes | Bo Tubes | Calibrator Tubes | Control Tubes | Sample Tubes |
|-------------------------|-------------------|----------|------------------|---------------|--------------|
| Calibrator | - | 200 µl | 200 µl | | - |
| Control | - | - | - | 200 µl | |
| Sample | - | - | - | - | 200 µl |
| Total Intact PTH Tracer | 100 µl | 100 µl | 100 µl | 100 µl | 100 µl |

Vortex mix all tubes, except for the TC tubes. Incubate tubes for 18 - 24 hours at room temperature (18 - 25° C).

Aspirate the supernatant from all of the tubes except the total count tubes. Wash all tubes except the total count tubes by adding 2 ml of diluted wash solution and aspirating the wash solution. Repeat this wash step two more times for a total of three times.

Count each tube for at least 1 minute in a gamma counter.

PROCEDURAL COMMENTS

Known Interferences:

Samples containing up to 250 mg/dL triglyceride, 15 mg/dl hemoglobin and 15 mg/dl bilirubin do not exhibit

any effect on the assay within the medical decision point for this assay.

Grossly hemolyzed or lipemic samples.

Samples from patients receiving radioisotopes for diagnostic or therapeutic purposes.

Contamination of the sample or assay tube with ¹²⁵I or other radioisotopes.

Reagents from different lot numbers must not be interchanged.

The patient sample or calibrator and tracer should be pipetted carefully into the bottom one-fourth of the assay tube. This is to avoid losing liquid on the surface of the tube as the liquid runs down the tube.

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.

It is recommended that calibrators and patient samples be assayed in duplicate. The average counts per minute of each duplicate should then be used for data reduction and the calculation of results.

Standards must be frozen immediately after use and may only be thawed and reused a maximum of two times provided acceptable control results are obtained. Avoid sample to sample contamination by using a new pipette tip for each sample.

Proper reconstitution of the controls and standards in the assay is a critical specification as any under or over reconstitution may result in a faulty result including, poor recovery and precision.

Studies have shown that samples stored at 2 - 8° C or room temperature for any significant amount of time may degrade.

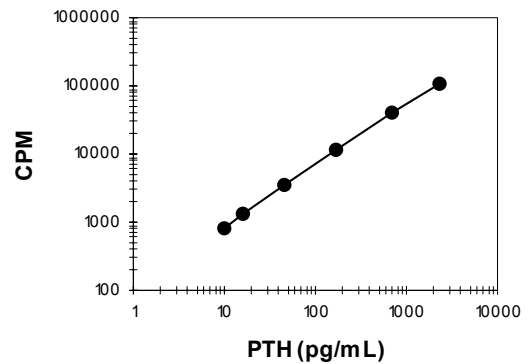
CALCULATION OF RESULTS

Calculation

1. Calculate the average CPM for each double determination.
2. Subtract the average CPM of the zero calibrator tubes from the CPM's from all other tubes in order to obtain the corrected CPM for each tube.
3. Corrected CPM = average CPM of duplicate samples - average CPM of duplicate zero calibrators.
4. Draw the calibration curve by plotting the average corrected CPM from each duplicate calibrator level (ordinate) against the respective concentration declared on the calibrator vial (absolute) using log-log graph paper. Obtain sample concentrations by interpolation of average sample CPM on the calibration curve.
5. 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.

REPRESENTATIVE STANDARD CURVE



Automated data reduction can also be used to construct the Scantibodies Total Intact 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 calibrator. The lowest level measurable is approximately 1.0 pg/ml.

EXPECTED VALUES

The normal value range was determined following the NCCLS guidelines (C28-A) using 252 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.

| PATIENT CLASSIFICATION | Total Intact PTH RANGE pg/ml |
|------------------------|------------------------------|
| Normal | 10 - 57 |
| Hyperparathyroidism | > 57 |

PERFORMANCE CHARACTERISTICS

Accuracy, Recovery

Different serum samples with low concentrations of PTH were spiked with 2 amounts of PTH. The % recovery was determined following assay of the spiked samples. In addition, one plasma sample was spiked with 2 amounts of PTH.

Total Intact PTH

| Sample # | Sample value (pg/ml) | Added (1-84) PTH (pg/ml) | Measured value (pg/ml) | Expected value (pg/ml) | Recovery (%) |
|----------|----------------------|--------------------------|------------------------|------------------------|--------------|
| 1 serum | 39.66 | 37.8 | 72.49 | 77.44 | 93.6 |
| | | 107.6 | 161.64 | 147.30 | 109.7 |
| 2 serum | 209.75 | 40.8 | 248.21 | 250.52 | 99.1 |
| | | 136.7 | 344.91 | 346.50 | 99.5 |
| 3 serum | 424.47 | 37.1 | 465.37 | 461.61 | 100.8 |
| | | 170.5 | 618.46 | 594.97 | 103.9 |
| 4 plasma | 1117.9 | 43.17 | 579.56 | 580.54 | 99.83 |
| | | 379.71 | 743.51 | 748.81 | 98.09 |

| Sample # | Sample value (pg/ml) | Added (7-84) PTH (pg/ml) | Measured value (pg/ml) | Expected value (pg/ml) | Recovery (%) |
|----------|----------------------|--------------------------|------------------------|------------------------|--------------|
| 1 serum | 39.66 | 36.3 | 68.89 | 75.92 | 90.7 |
| | | 99.6 | 126.11 | 139.3 | 90.5 |
| 2 serum | 209.75 | 39.1 | 235.43 | 248.82 | 94.6 |
| | | 139.3 | 333.06 | 349.04 | 95.4 |
| 3 serum | 424.47 | 41.7 | 475.38 | 466.12 | 102.0 |
| | | 143.0 | 564.34 | 567.45 | 99.5 |

Accuracy, Dilution

Different serum samples with high concentrations of PTH were diluted in a sample with low concentrations of PTH. The % recovery was determined following assay of the diluted samples.

| Total Intact PTH Accuracy, Dilution | | | | |
|-------------------------------------|-----------|------------------------|------------------------|------------|
| Sample | Dilution | Measured value (pg/ml) | Expected value (pg/ml) | % Recovery |
| 1 serum | Neat | 431.20 | - | - |
| | 1:2 | 210.64 | 215.6 | 97.7 |
| | 1:4 | 95.62 | 107.8 | 88.7 |
| | 1:8 | 41.61 | 53.9 | 77.2 |
| 2 serum | Neat | 1073.30 | - | - |
| | 1:2 | 535.11 | 536.65 | 99.7 |
| | 1:4 | 259.60 | 268.32 | 96.8 |
| | 1:8 | 121.15 | 134.16 | 90.3 |
| | 1:16 | 58.62 | 67.08 | 87.4 |
| 3 serum | Neat | 1494.10 | - | - |
| | 1:2 | 748.58 | 747.05 | 100.2 |
| | 1:4 | 376.70 | 373.52 | 100.9 |
| | 1:8 | 184.88 | 186.76 | 99.0 |
| | 1:16 | 88.69 | 93.38 | 95.0 |
| | 1:32 | 43.12 | 46.69 | 92.4 |
| 4 serum | Neat | 2458 | - | - |
| | 2:3 (v/v) | 1754.5 | 1638.7 | 107.1 |
| | 3:4 (v/v) | 1993.3 | 1843.5 | 108.1 |

High Dose Hook Response

The high dose hook response of the Total Intact PTH kit was determined as 20,000 pg/ml of synthetic PTH (1-84) and PTH (7-84). Samples greater than the highest standard (approximately 2300 pg/ml) and up to 20,000 pg/ml PTH will read CPM values greater than that of the highest standard.

Precision

Precision inter-assay coefficient of variation was

Insert 7KI017 Vs. 04
12 June 2007

evaluated by performing 20 different assays on three EDTA plasma samples.

| Total Intact PTH Precision Interassay | | | | |
|---------------------------------------|--------|--------------------|-----------------|------|
| Kit Batch | Sample | Mean value (pg/ml) | Std Dev (pg/ml) | % CV |
| E1 | 1 | 39.31 | 1.62 | 4.13 |
| | 2 | 204.16 | 9.62 | 4.71 |
| | 3 | 419.79 | 14.12 | 3.36 |
| E2 | 1 | 37.17 | 3.28 | 8.82 |
| | 2 | 209.66 | 7.17 | 3.42 |
| E2 | 3 | 424.54 | 25.21 | 5.94 |
| E3 | 1 | 39.52 | 1.77 | 4.47 |
| | 2 | 200.71 | 9.23 | 4.60 |
| E3 | 3 | 416.15 | 11.07 | 2.66 |

Intra-assay coefficient of variation was evaluated by performing 20 replicate determinations on three EDTA plasma samples in the same assay.

| Total Intact PTH Precision Intra-assay | | | | |
|--|--------|--------------------|-----------------|------|
| Kit Batch | Sample | Mean value (pg/ml) | Std Dev (pg/ml) | % CV |
| E1 | 1 | 40.98 | 1.04 | 2.54 |
| | 2 | 211.49 | 3.56 | 1.69 |
| | 3 | 437.56 | 5.32 | 1.22 |
| E2 | 1 | 36.56 | 1.65 | 4.51 |
| | 2 | 208.33 | 6.50 | 3.12 |
| E2 | 3 | 408.4 | 15.73 | 3.85 |
| E3 | 1 | 39.08 | 1.05 | 2.69 |
| | 2 | 199.39 | 2.47 | 1.24 |
| E3 | 3 | 411.90 | 5.68 | 1.38 |

Sensitivity

The detection limit of the assay is defined as the lowest measurable value distinguishable from zero. This sensitivity was determined by assaying the zero calibrator 20 times in the same assay. The detection limits determined is approximately 1.0 pg/ml for Total Intact PTH IRMA at 2 standard deviation above the geometric mean of PTH zero calibrator. The functional sensitivity is defined as being the measured concentration by imprecision profile for a CV equal to 20%. It has been assessed as being 7 pg/mL.

Specificity

The assay does not show any cross-reactivity to the fragments listed below.

| Total Intact PTH Specificity | | | |
|------------------------------|------------------------------|------------------|---|
| Peptide Fragment | Peptide Sample Concentration | Recovery (pg/mL) | % |
| 1 to 34 | 100,000 | 0 | 0 |
| 39 to 68 | 100,000 | 0 | 0 |
| 53 to 84 | 100,000 | 0 | 0 |
| 44 to 68 | 100,000 | 0 | 0 |
| 39 to 84 | 100,000 | 0 | 0 |

The total Intact PTH assay, has almost 100% cross-reaction to PTH (7-84) fragment.

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 Laboratory, Inc. (SLI) Total Intact PTH Specific IRMA Tube Assay. A correlation coefficient (r) of 1.00 (n=243) was obtained with a slope of 1.05 and intercept of -2.20 where x represents the predicate device data and y represents the SLI Total Intact PTH Specific IRMA Tube data. Calculations were made with plasma samples ranging from 8 - 2024 pg/mL.

| | |
|-----------------------------------|--|
| Chemical Characterization: | 1) Antibodies coated on to polystyrene Tubes |
| | 2) Radioactive Isotope containing Iodine-125 with radioactivity <10 µCi and Sodium Azide @ 0.1%. |
| | 3) Calibrators & Controls – Human Serum containing Sodium Azide @ 0.1% |
| | 4) Wash Concentrate containing sodium azide @ 1.5%. |
| Hazardous Ingredients: | Radioactive Isotope (Iodine-125) @ <10 µCi/Vial (<370 kBq) CAS Number: 7553-56-2 Symbols: Harmful Xn R-phrases: R22, R52/53 S-phrases: S28, S45, S53, S60, S61 |
| Hazardous Ingredients: | Sodium Azide @ 0.1% CAS Number: 026628-22-8 Symbols: N/A R-phrases: N/A S-phrases: N/A |
| | Sodium Azide @ 1.5% CAS Number: 026628-22-8 Symbols: Very Toxic T+; N R-phrases: R28, R32, R50/53 S-phrases: S28, S45, S53, S60, S61 |

| Symbol | Used for | Symbol | Used for |
|--------|-------------------------------------|--------|-------------------------------------|
| | | | Community |
| | Contains Sufficient for < n > Tests | | For IVD Performance Evaluation Only |
| | In vitro Diagnostic Medical Device | | Upper Limit of Temperature |
| | Lower Limit of Temperature | | Temperature Limitation |
| | Consult Instructions for Use | | Positive Control |
| | Control | | Negative Control |
| | Antibody Coated Beads | | Antibody Coated Tubes |
| | Radioactive Iodine Tracer | | Wash Solution |
| | Reconstituted with 2 mL Water | | Reconstituted with 5 mL Water |
| | European Conformity Mark | | Radioactive |
| | Toxic | | Harmful |
| | Corrosive | | Oxidizing |

| Symbol | Used for | Symbol | Used for |
|--------|---|--------|---|
| | Do Not Reuse | | Use By YYYY-MM-DD or YYYY-MM |
| | Batch Code | | Serial Number |
| | Date of Manufacture | | Sterile |
| | Sterilized Using Aseptic Processing Technique | | Catalog Number |
| | Caution, Consult Accompanying Documents | | Biological Risks |
| | Manufacturer | | Authorized Representative in the European |

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