**MicroVue™ Calcitonin EIA Summary**

**Reagent, Standards and Controls Preparation**
- Dilute Wash Buffer Concentrate 1:20 with DI Water. Store at room temperature.
- Reconstitute Standard A with 2.0 mL of DI Water.
- Reconstitute the Standards B-F and Controls with 1 mL of Reconstitution Buffer (RGT 3), 10 minutes prior to use.

**Assay Procedure**

1. Pipette 100 µL, Standards, Controls, and Specimens into assay wells
2. Pipette 50 µL of Biotinylated Antibody and 50 µL of Enzyme Labeled Antibody into assay wells
3. Incubate 4 hours ± 30 minutes with shaking (170 ± 10 rpm) at 22 - 28°C in the dark.
4. Wash 5 times with 1X Wash Solution
5. Pipette 150 µL Substrate Solution
6. Incubate 30 ± 5 minutes with shaking (170 ± 10 rpm) at 22 - 28°C in the dark
7. Pipette 100 µL Stop Solution (read results within 10 minutes)
8. Read the Optical Density at 450 nm and again at 405 nm. Analyze the assay results using a cubic spline, 4-parameter curve fit or point-to-point interpolation

**INTENDED USE**

The MicroVue Calcitonin Enzyme Immunoassay is intended for the quantitative determination of Calcitonin in human serum. This assay is intended for in vitro diagnostic use.

**SUMMARY AND EXPLANATION**

Calcitonin, a 32-amino-acid polypeptide, is secreted primarily by the thyroidal parafollicular C-cells. Its main biological effect is to inhibit osteoclastic bone resorption. This property has led to Calcitonin’s use for disorders characterized by increased resorption such as Paget’s disease, for some patients with osteoporosis.

The most prominent clinical syndrome associated with a disordered hypersecretion of Calcitonin is medullary carcinoma of the thyroid (MTC). MTC is a tumor of the Calcitonin producing C-cells of the thyroid gland. Although MTC is rare, comprising 5 - 10% of all thyroid cancer, it is often fatal. It may occur sporadically or in a familial form that is transmitted as an autosomal dominant trait. MTC has great clinical importance because of its familial distribution. Further, it can be diagnosed early by serum Calcitonin and total cure for early sub-clinical disease is possible. This is frequently associated with other clinical features and it has good potential for cure with surgery. Although a rare tumor, it can occur in a familial pattern as a Type II multiple endocrine neoplasia. These tumors usually produce diagnostically elevated serum concentrations of Calcitonin. Therefore, the immunoassay for Calcitonin in serum can be used to diagnose the presence of MTC with an exceptional degree of accuracy and specificity. In the small but increasing percentage of patients, however, basal hormone levels are indistinguishable from normal. Some of these subjects represent the early stages of C-cell neoplasia or hyperplasia that are most amenable to surgical cure. To identify these patients with early disease, provocative tests for Calcitonin secretion is necessary to preclude false negatives if only basal Calcitonin determination are performed. Most tumors respond with increased Calcitonin level to the administration of either calcium or pentagastrin or their combination, but either agent can still give misleading results. Therefore, in cases with clinical manifestations, both agents should be considered for diagnostic testing. Further, Calcitonin measurements can also be used to monitor the efficacy of therapy in patients with Calcitonin producing tumors. It has been reported that multiple forms of immunoreactive Calcitonin are found in either normal subjects or patients with MTC. These various forms of Calcitonin have molecular weights varying from 3,400 (monomeric) up to 70,000 Dalton (polymeric). Neoplastic disorders of other neuroendocrine cells can also elevate Calcitonin. The best example is small cell lung cancer. Other tumors such as carcinoids and islet cell tumors of the pancreas can also result in elevated serum Calcitonin. Increases in serum Calcitonin has also been noted in both acute and chronic renal failure, hypercalciuria and hypercalcemia.
PRINCIPLE OF THE PROCEDURE

The MicroVue Calcitonin Enzyme Immunoassay for the quantitation of calcitonin in human serum is a two-step procedure utilizing (1) a microassay plate coated with streptavidin and a biotinylated mouse monoclonal antibody that binds specifically to human Calcitonin 11-23, (2) a HRP-conjugated mouse monoclonal anti-human Calcitonin 21-32 antibody, and (3) a chromogenic substrate.

In Step 1, Standards, Controls, and test specimens are added to microassay wells pre-coated with streptavidin. Biotin-conjugated primary monoclonal anti-human Calcitonin 11-23 antibody and horseradish peroxidase (HRP)-conjugated secondary monoclonal anti-human Calcitonin 21-32 antibody is added to each test well. Calcitonin present in the Standards, Controls or specimens are captured in the microassay wells through binding of the biotinylated primary antibody to the streptavidin immobilized on the plate and simultaneously detected by the HPR-conjugated secondary antibody. At the end of the assay incubation, a wash cycle removes unbound material.

In Step 2, a chromogenic enzyme substrate is added to each microassay well. The bound HRP-conjugate reacts with the substrate, forming a blue color. After incubation the enzyme reaction is stopped chemically, the color changes to yellow, and the color intensity is measured spectrophotometrically at 450 nm. The color intensity of the reaction mixture is proportional to the concentration of Calcitonin present in the test specimens, Standards, and Controls.

REAGENTS AND MATERIALS PROVIDED

Calcitonin Enzyme Immunoassay contains the following:

A. Calcitonin Standards
   - Parts CAL A-CAL F
     - 1 ea x 2 mL (CAL A)
     - 1 ea x 1 mL (CAL B-F)

B. Lyophilized. Each contains purified synthetic human Calcitonin with an assigned protein concentration (pg/mL) in BSA solution, calibrated to WHO 2nd IS 89/620. Zero standard is BSA solution.

L. Calcitonin Control 1
   - Part CTRL 1
     - 1 mL
   (lyophilized) When reconstituted, contains synthetic human Calcitonin (1-32) in BSA solution.

H. Calcitonin Control 2
   - Part CTRL 2
     - 1 mL
   (lyophilized) When reconstituted, contains synthetic human Calcitonin (1-32) in BSA solution.

Microassay Plate
   - Part PLA
     - 12 x 8 wells

Stop Solution
   - Part SOLN
     - 20 mL
     - Contains 1N (3%) Sulfuric Acid (H2SO4)

20X Wash Concentrate
   - Part RGT A
     - 30 mL
     - Contains saline with surfactant

TMB Substrate
   - Part RGT B
     - 20 mL
     - Ready to use. Contains 3,3’,5,5’-tetramethylbenzidine (TMB) and Hydrogen Peroxide (H2O2)

B. Biotinylated Calcitonin Antibody
   - Part RGT 1
     - 7 mL
     - Contains biotin-conjugated monoclonal anti-human Calcitonin 11-23 antibody

Enzyme Labeled Calcitonin Antibody
   - Part RGT 2
     - 7 mL
     - Contains horseradish Peroxidase conjugated monoclonal anti-human Calcitonin 21-32 antibody

Reconstitution Solution
   - Part RGT 3
     - 10 mL
     - Contains EDTA

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer (60 minute range)
- Clean, unused microassay plates, 96 well dilution plate and/or test tubes and racks
- Container for wash buffer dilution
- Wash bottle or other validated immunoassay washing system
- Micropipettes and pipette tips
- Adjustable multichannel pipette (8 or 12 channels) or repeating micropipettes
- Clean pipettes, 1 mL, 5 mL, and 10 mL
- Reagent reservoirs for adding antibodies, substrate and stop solutions to plate (use clean, unused reservoirs for each reagent)
- Plate reader capable of optical density A450 and A405 readings between 0.0 and 4.0
- Deionized or distilled water
- Shaker/rotator capable of 170 ± 10 rpm

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use.
2. Calcitonin is a very labile molecule. Set up the assay immediately upon the reconstitution of the thawing of all standards, controls, and patient samples.
3. Treat specimen samples as potentially biohazardous material. Follow Universal Precautions when handling contents of this kit and any patient samples.
4. Wear suitable protective clothing, gloves, and eye/face protection when handling contents of this kit.
5. Use the supplied reagents as an integral unit prior to the expiration date indicated on the package label.
6. Reagents from different lot numbers must not be interchanged.
7. Store assay reagents as indicated.
8. Do not use Coated Strips if pouch is punctured.
9. The Stop Solution is considered corrosive and can cause irritation. Do not ingest. Avoid contact with eyes, skin, and clothing. If contact is made, immediately rinse affected area with water. If ingested, call a physician.
10. Use of multichannel pipettes or repeat pipettors is recommended to ensure timely delivery of reagents.
11. For accurate measurement of samples, add samples and standards precisely. Pipette carefully using only calibrated equipment.
12. Proper collection and storage of test specimens are essential for accurate results (see SPECIMEN HANDLING AND PREPARATION).
13. Avoid microbial or cross-contamination of specimens or reagents.
14. Test each sample in duplicate.
15. Do not use any single microassay well for more than one test.
16. Using incubation times and temperatures other than those indicated in the Procedure section may give erroneous results.
17. The TMB Substrate must be protected from light and contact with metal or rubber during storage and incubation. Avoid contact with eyes, skin, and clothing. If contact is made, immediately rinse affected area with water.
18. Do not allow microassay wells to dry once the assay has begun.
19. When removing liquid from the microassay wells, do not scrape or touch the bottom of the wells.
20. To avoid aerosol formation during washing, use an apparatus to aspirate the wash fluid into a bottle containing household bleach.
21. A wash bottle or automated filling device should be used to wash the plate (ASSAY PROCEDURE, step 5). For best results, do not use a multichannel pipette to wash the microassay plate.
22. Dispose of containers and unused contents in accordance with Federal, State and Local regulations.
23. For more information, consult the Material Safety Data Sheet available on guidel.com.

STORAGE

All reagents except the Standards, kit controls and the Wash Concentrate are ready-to-use. Store all kit components at 2–8°C, except the Wash Concentrate, and stop solution which should be kept at room temperature until dilution to avoid precipitation.

REAGENT PREPARATION

Bring all reagents and materials to room temperature before use.

After removing the needed reagents and materials, return the unused items to their appropriate storage temperatures (see STORAGE).

Microassay Strips

Determine the number of strips needed for the assay. Guidel recommends testing the blank wells, Standards and Controls in duplicate. Remove the unneeded strips, place them in the storage bag, reseal the bag and return it to 2–8°C. Secure the strips to be used in the assay in the assay plate frame.

Wash Solution (RGT A)

Mix the 20X Wash Solution Concentrate by inverting the bottle several times. If the 20X Wash Solution Concentrate has been stored at 2–8°C, crystals may have formed. To dissolve the crystals, warm the bottle in a 37°C water bath until all crystals have dissolved and follow by mixing thoroughly. Prepare the Wash Solution by diluting the entire contents of the bottle of 20X Wash Solution Concentrate (30 mL) in 570 mL distilled or deionized water. Mix thoroughly. The Wash Solution is stable for 90 days when stored in a clean container at room temperature.

Standards and Controls

For the Zero Standard (CAL A) reconstitute with 2.0 mL distilled or deionized water and mix. For each of the Standards (CAL B through F) and kit controls 1 and 2, reconstitute each vial with 1.0 mL of Reconstitution Solution (RGT 3) and mix. Allow the vials to stand for 10 minutes and then mix thoroughly by gentle inversion to insure complete reconstitution. Calcitonin is a very labile molecule. Use the Standards and Controls immediately after reconstitution. Freeze (-20°C) the remaining Standards and Controls as soon as possible after use. Standards and Controls are stable at -20°C for 6 weeks after reconstitution with up to 3 freeze/thaw cycles when handled as recommended.

Antibody Solutions (Optional)

If preferred, mix equal volumes of the Biotinylated Antibody (RGT 1) and Enzyme Labeled Antibody (RGT 2) in a clean, amber bottle; preparing sufficient quantity for the assay. Then, add 100 µL of the mixed antibody into each well. This alternative method will replace Step 3 and Step 4 of the Assay Procedure, followed by incubation with the orbital shaker.

SPECIMEN COLLECTION AND STORAGE

Handle and dispose of all specimens using Universal Precautions.

Specimen Collection

CAUTION: Treat all specimens as potentially infectious. Use Universal Precautions. Do not use contaminated or improperly stored specimens.

Serum

The determination of Calcitonin should be performed with serum. Serum specimens should be collected aseptically using standard techniques. After allowing blood to clot, the serum should be promptly separated, preferably in a refrigerated centrifuge, and stored at -20°C or lower. Avoid grossly hemolyzed or grossly lipemic samples.

ASSAY PROCEDURE

Read the entire product insert before beginning the assay.

See WARNINGS AND PRECAUTIONS and REAGENT PREPARATION.

1. Place sufficient Streptavidin Coated Strips in a holder to run all six (6) of the Calcitonin Standards [A – F, exact concentration is stated on the vial label], kit controls and patient samples.
2. Add 100 µL of Standard, Control or sample into the designated or mapped well. Freeze (-20°C) the remaining Standards and Controls as soon as possible after use.
3. Add or dispense 50 µL of the Biotinylated Antibody (RGT 1) into each of the wells containing Standard, Control or sample.
4. Add or dispense 50 μL of the Enzyme Labeled Antibody (RGT 2) into each of the same wells. Cover the microplate(s) with aluminum foil or a tray to avoid exposure to light. Place on an orbital shaker or rotator at 170 ± 10 rpm at room temperature (22 - 28°C) for 4 hours ± 30 minutes.

5. Wash the microassay wells using the following procedure:
   a. Aspirate the contents from each well.
   b. Using a wash bottle or automated plate washing device, add approximately 350 μL Wash Solution to each well.
   c. Aspirate the contents from each well.
   d. Repeat steps a-c four (4) additional times for a total of five (5) washes.

6. Add or dispense 150 μL of the TMB Substrate (RGT B) into each washed test well.

7. With appropriate cover to avoid light exposure, place the microplate(s) on an orbital shaker or rotator at 170 ± 10 rpm at room temperature (22 - 28°C) for 30 ± 5 minutes.

8. Add or dispense 100 μL of Stop Solution to each well to stop the enzymatic reaction.

9. Gently tap the plate on the bench top to disperse the color development completely and evenly.

10. Determine the absorbance reading at 450 nm of each test well within 10 minutes after the addition of the Stop Solution (step 8), making a blank correction in accordance with the spectrophotometric system in use. Read the plate again at 405 nm making a blank correction in accordance with the spectrophotometric system in use (blank correction: 250 μL distilled or deionized water).

**NOTE:** The second reading is designed to extend the analytical validity of the calibration curve to the value represented by the highest calibrator, which is approximately 1,000 pg/mL. Hence, patient samples with Calcitonin > 300 pg/mL can be quantified against a calibration curve consisting of the readings all the way up to the concentration equivalent to the highest calibrator using the 405 nm reading, away from the wavelength of maximum absorbance. In general, patient and control samples should be read using the 450 nm for Calcitonin concentrations up to 300 pg/mL. Calcitonin concentrations above 300 pg/mL should be interpolated using the 405 nm reading. Patient samples with values greater than the highest standard, CAL F, need to be diluted with CAL A and reassayed. Multiply the results by the dilution factor.

11. Determine the concentration of samples and Controls from the standard curve.

12. Dispose of the remaining specimens, substrate, and the used microassay strips (see WARNINGS AND PRECAUTIONS).

**QUALITY CONTROL**

The Certificate of Analysis included in this kit is lot specific and is to be used to verify that the results obtained by your laboratory are similar to those obtained at Quidel Corporation. The optical density values provided are intended as a guideline only. The results obtained by your laboratory may differ.

**INTERPRETATION OF RESULTS**

**Use of the Standard Curve**

Using the final absorbance values obtained in Step 10 of the Assay Procedure, construct a calibration curve via cubic spline, 4 parameter logistics, or point-to-point interpolation to quantify the concentration of Calcitonin. Most plate reading software and computers are capable of performing these calculations.

Alternatively, the data may be graphed manually. For the 450 nm readings, construct a calibration curve using the first five Standards provided, i.e. Standards A – E. For the 405 nm readings, construct a second calibration curve using the three Standards with the highest concentrations, i.e. D – F. The values (pg/mL) of the test samples can be read directly from the best-fit line of the calibration curve.

**Table 1. Sample Data at 450 nm**

<table>
<thead>
<tr>
<th>Sample</th>
<th>Average A450</th>
<th>Calcitonin pg/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard A</td>
<td>0.0085</td>
<td>0</td>
</tr>
<tr>
<td>Standard B</td>
<td>0.0615</td>
<td>10</td>
</tr>
<tr>
<td>Standard C</td>
<td>0.190</td>
<td>30</td>
</tr>
<tr>
<td>Standard D</td>
<td>0.590</td>
<td>100</td>
</tr>
<tr>
<td>Standard E</td>
<td>1.891</td>
<td>300</td>
</tr>
<tr>
<td>Control 1</td>
<td>0.125</td>
<td>20.6</td>
</tr>
<tr>
<td>Control 2</td>
<td>2.560</td>
<td>*</td>
</tr>
<tr>
<td>Patient Sample 1</td>
<td>0.037</td>
<td>4.7</td>
</tr>
<tr>
<td>Patient Sample 2</td>
<td>0.101</td>
<td>16.3</td>
</tr>
<tr>
<td>Patient Sample 3</td>
<td>0.404</td>
<td>68.7</td>
</tr>
<tr>
<td>Patient Sample 4</td>
<td>2.184</td>
<td>*</td>
</tr>
</tbody>
</table>

* Because the concentration readout is > 300 pg/mL, it is recommended to use the data obtained at 405 nm (see Table 2 below).

**Table 2. Sample Data at 405 nm**

<table>
<thead>
<tr>
<th>Sample</th>
<th>Average A405</th>
<th>Calcitonin pg/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard A</td>
<td>0.005</td>
<td>0</td>
</tr>
<tr>
<td>Standard D</td>
<td>0.193</td>
<td>100</td>
</tr>
<tr>
<td>Standard E</td>
<td>0.599</td>
<td>300</td>
</tr>
<tr>
<td>Standard F</td>
<td>1.904</td>
<td>1000</td>
</tr>
<tr>
<td>Control 1</td>
<td>0.045</td>
<td>**</td>
</tr>
<tr>
<td>Control 2</td>
<td>0.815</td>
<td>403</td>
</tr>
<tr>
<td>Patient Sample 1</td>
<td>0.018</td>
<td>**</td>
</tr>
<tr>
<td>Patient Sample 2</td>
<td>0.037</td>
<td>**</td>
</tr>
<tr>
<td>Patient Sample 3</td>
<td>0.131</td>
<td>**</td>
</tr>
<tr>
<td>Patient Sample 4</td>
<td>0.693</td>
<td>345</td>
</tr>
</tbody>
</table>

** For samples with readout < 300 pg/mL, it is recommended to use the data obtained at 405 nm (see Table 2 above). This practice should give the results with optimum sensitivity of the assay.
LIMITATIONS OF THE PROCEDURE

The MicroVue Calcitonin EIA has exhibited no “high dose hook effect” with samples spiked with 1,000,000 pg/mL of pure intact Calcitonin (1-32). Samples with Calcitonin levels greater than the highest standard, however, should be diluted and re-assayed for correct values. Like any analyte used as a diagnostic adjunct, Calcitonin results must be interpreted carefully with the overall clinical presentations and other supportive diagnostic tests.

OBSERVED VALUES

Serum specimens from fifty-nine (59) female and fifty-two (52) male apparently normal donors were tested in the MicroVue Calcitonin Enzyme Immunoassay kit. The results are presented below.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean ± 2SD (pg/mL)</th>
<th>Range (pg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>0.07 – 12.97</td>
<td>0.1 – 10.9</td>
</tr>
<tr>
<td>Male</td>
<td>0.68 – 30.26</td>
<td>0.2 – 27.7</td>
</tr>
</tbody>
</table>

NOTE: The mean and Standard Deviation (SD) behavior of Calcitonin concentrations determined for serum samples may vary between laboratories. Therefore, it is recommended that each laboratory determine the mean Calcitonin concentration and standard deviation values for samples.

PERFORMANCE OF THE TEST

ACCURACY

Seventy-seven patient samples, with Calcitonin values ranging from 0.8 to 3,113 pg/mL were assayed by the MicroVue ELISA procedure and an ImmunoRadioMetricAssay Calcitonin (IRMA Kit). Linear regression analysis gives the following statistics:

MicroVue Elisa = 0.940 IRMA Kit + 6.55 pg/mL
r = 0.993 n = 123

Further, fifty-one patient samples with Calcitonin values ranging from < 0.7 to 2,240 pg/mL were assayed by the MicroVue ELISA procedure and Chemiluminescence Immunoassay for Calcitonin Kit (or ImmunoChemiluminescent MetricAssay (ICMA). Linear regression analysis gives the following statistics:

MicroVue Elisa = 1.094 ICMA Kit - 6.13 pg/mL
r = 0.995 n = 123

Limits

LOD: The limit of detection (LOD) for the Calcitonin EIA is 1.0 pg/mL, defined as the smallest single value which can be distinguished from zero at the 95% confidence limit.

Precision

Intra-assay precision was determined by assaying 20 replicates of 3 samples.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean Value (pg/mL)</th>
<th>n</th>
<th>Intra-assay C.V. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample A</td>
<td>24.3</td>
<td>20</td>
<td>5.7</td>
</tr>
<tr>
<td>Sample B</td>
<td>94.9</td>
<td>20</td>
<td>4.3</td>
</tr>
<tr>
<td>Sample C</td>
<td>403</td>
<td>20</td>
<td>2.8</td>
</tr>
</tbody>
</table>

Inter-assay precision was determined by assaying 3 samples in 15 different assays, by three technicians on two different lots of reagents, over a three-week period.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean Value (pg/mL)</th>
<th>n</th>
<th>Inter-assay C.V. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample A</td>
<td>16.5</td>
<td>15</td>
<td>7.4</td>
</tr>
<tr>
<td>Sample B</td>
<td>64.5</td>
<td>15</td>
<td>7.4</td>
</tr>
<tr>
<td>Sample C</td>
<td>340</td>
<td>15</td>
<td>6.1</td>
</tr>
</tbody>
</table>

Linearity

Linearity was performed by diluting serum samples with Standard A (Zero Calibrator). Results are shown below:

<table>
<thead>
<tr>
<th>Sample</th>
<th>Dilution Factor</th>
<th>Expected (pg/mL)</th>
<th>Observed (pg/mL)</th>
<th>Recovery (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Undiluted</td>
<td>-</td>
<td>343</td>
<td>-</td>
</tr>
<tr>
<td>A</td>
<td>1:2</td>
<td>172</td>
<td>168</td>
<td>98</td>
</tr>
<tr>
<td></td>
<td>1:4</td>
<td>85.8</td>
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<td>95</td>
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<td></td>
<td>1:8</td>
<td>42.9</td>
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<td>94</td>
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<td></td>
<td>Undiluted</td>
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<td>-</td>
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<tr>
<td>B</td>
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<td></td>
<td>1:4</td>
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<td>C</td>
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<tr>
<td></td>
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<td>-</td>
<td>&gt;1000</td>
<td>-</td>
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<td></td>
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<tr>
<td></td>
<td>1:16</td>
<td>125</td>
<td>119</td>
<td>95</td>
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</tbody>
</table>

Specificity and Cross-Reactivity

Each crossreactant was spiked into a sample containing Calcitonin. Calcitonin level is measured before and after the spike. None of the crossreactants interfere with this Calcitonin EIA. The small changes in Calcitonin measured are well within the intra-assay precision statistics. Results are provided below:
### Kinetic Effect of the Assay

To determine whether there is any systematic kinetic effect between the beginning of the run and the end of the run, three spiked patient serum pools, selected to represent a good cross section of the Calcitonin concentration, were placed in a sequence throughout the run of one microplate or 96 wells (with twelve 8-well strips).

#### Spike Recovery

Spike recovery was performed by adding various amounts of Calcitonin to four different patient sera and comparing observed values with expected values. Results are provided below:

<table>
<thead>
<tr>
<th>Serum Sample</th>
<th>Endogenous Calcitonin (pg/mL)</th>
<th>Calcitonin Added (pg/mL)</th>
<th>Expected Value (pg/mL)</th>
<th>Observed Value (pg/mL)</th>
<th>Recovery (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>0</td>
<td>100</td>
<td>100</td>
<td>110</td>
<td>110</td>
</tr>
<tr>
<td>B</td>
<td>9.7</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>C</td>
<td>0</td>
<td>100</td>
<td>100</td>
<td>104</td>
<td>104</td>
</tr>
<tr>
<td>D</td>
<td>5.7</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

#### CUSTOMER ASSISTANCE

For services outside the U.S., please contact your local distributor.

Additional information about Quidel and Quidel’s products and distributors can be found on our website at [quidel.com](http://quidel.com).

### REFERENCES

GLOSSARY

Intended Use

REF 8043 – MicroVue Calcitonin EIA Kit

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