INTENDED USE
FOR IN VITRO DIAGNOSTIC USE
Raichem Multi-Analyte Serum Calibrator is used for the calibration of clinical chemistry assays.

SUMMARY
Multi-Analyte Serum Calibrator is a lyophilized human calibration serum. Biological materials are added as required to obtain desired component levels. The concentrations and activities have been selected to ensure optimum calibration of automatic analyzers that do not use a continuous-flow system. The concentrations of the analytes in the Multi-Analyte Serum Calibrator, with the exception of Triglycerides, are referenced to National Institute of Standards and Technology (NIST) Standard Reference Materials. The Triglycerides concentration is referenced to independent standards prepared with Reagent Grade Glycerol (ACS). Constituent concentrations are specific for each lot.

CALIBRATOR PREPARATION
1. Using a Class A volumetric pipette, carefully add 3.0 mL of diluent (bottle 2) to the open calibrator (bottle 1). Distilled or deionized water may be substituted for the diluent.
2. Close the calibrator and swirl the bottle gently, dissolving the contents completely for 15 minutes. Avoid the formation of foam. DO NOT VORTEX. Improper handling and/or storage of the calibrator can affect results. Inaccurate reconstitution of the calibrator and errors in assay technique can cause erroneous results.

STORAGE AND STABILITY
Store unopened Multi-Analyte Serum Calibrator and Multi-Analyte Serum Calibrator Diluent at 2-8°C.

Stability of the reconstituted calibrator:
- 15-30°C: 8 hours
- 2-8°C: 2 days
- ≤-20°C: 1 month

Indications of Instability or Deterioration
1. Physical appearance: The reconstituted Multi-Analyte Serum Calibrator should be yellow and contain no precipitate. Moderate turbidity in the reconstituted calibrator is normal.
2. Control Values: Failure to obtain control values within the expected range may be the result of reagent or calibrator deterioration, procedural errors or instrument malfunction.

WARNINGS AND PRECAUTIONS
Human serum was used in the manufacture of this product. This product has been prepared exclusively from the blood of donors tested individually and shown by FDA-approved methods to be free from HBsAg and antibodies to HIV and HCV.
1. Good laboratory safety practices should be followed when handling any laboratory reagent. Refer to a recognized laboratory safety program for additional information. (See GP17-T, Clinical Laboratory Safety; Tentative Guideline (1994), National Committee on Clinical Laboratory Standards, Wayne, PA.)
2. Results should be interpreted considering all other test results and clinical status of the patient.
3. Avoid contact with skin and eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable gloves and eye/face protection. In case of accident or if you feel unwell, seek medical advice immediately.

PROCEDURE
Materials provided
- R60010 Calibrator 10 x 3 mL
- R60010V1 Diluent 10 x 4 mL

Materials required but not provided
1. Automated chemistry analyzer.
2. Volumetric pipette (3.0 ml)

REFERENCES

RE-ORDER INFORMATION
Multi-Analyte Serum Calibrator with Diluent

Catalog No.
- REF R60010
  - 10 x 3 mL + 10 x 4 mL

For in vitro diagnostic use
See package insert for proper use

SALES AND TECHNICAL SUPPORT
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EC REP
For IVD
See package insert for proper use
### MULTI-ANALYTE SERUM CALIBRATOR (R60010)
#### LOT SPECIFIC ASSAY DATA

**Kit Lot No. 0906182  Exp Date: 2011-04**
Multi-Analyte Serum Calibrator (Bottle 1) Lot No. 0812166A
Calibrator Diluent (Bottle 2) Lot No. 0904075B

<table>
<thead>
<tr>
<th>Cobas Mira</th>
<th>Cat. No.</th>
<th>Method</th>
<th>Value</th>
<th>SIU Value</th>
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<tbody>
<tr>
<td>Albumin</td>
<td>R85211</td>
<td>B.C.G.</td>
<td>5.03 g/dL</td>
<td>50.3 g/L</td>
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<tr>
<td>Bilirubin, Total</td>
<td>R83087</td>
<td>Malloy-Evelyn, Modified</td>
<td>4.10 mg/dL</td>
<td>70.1 µmol/L</td>
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<td>Blood Urea Nitrogen</td>
<td>R82042/R82043/R85139</td>
<td>Urease/GLDH</td>
<td>42.4 mg/dL</td>
<td>15.1 mmol/L</td>
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<tr>
<td>Blood Urea Nitrogen</td>
<td>R84533/R85558</td>
<td>Urease/GLDH Liquid, Cobas Mira®</td>
<td>41.7 mg/dL</td>
<td>14.9 mmol/L</td>
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<tr>
<td>Calcium</td>
<td>R85188</td>
<td>Arsenazo III</td>
<td>10.1 mg/dL</td>
<td>2.52 mmol/L</td>
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<td>Chloride</td>
<td>R85133</td>
<td>Mercuric Thiocyanate</td>
<td>93.4 mmol/L</td>
<td>93.4 mmol/L</td>
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<tr>
<td>Cholesterol, Total</td>
<td>R85464/R85465/R85545</td>
<td>Enzymatic Rapid Liquid Cobas Mira®</td>
<td>206 mg/dL</td>
<td>5.33 mmol/L</td>
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<tr>
<td>Creatinine</td>
<td>R83069</td>
<td>Rate Jaffe Cobas Mira®</td>
<td>3.44 mg/dL</td>
<td>304 µmol/L</td>
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<tr>
<td>Creatinine</td>
<td>R85546/R85559</td>
<td>Jaffe</td>
<td>3.51 mg/dL</td>
<td>310 µmol/L</td>
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<tr>
<td>Glucose</td>
<td>R80017/R80036/R85411</td>
<td>Hexokinase (Sample Blanked)</td>
<td>198 mg/dL</td>
<td>11.0 mmol/L</td>
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<tr>
<td>Glucose</td>
<td>R85548/R84682</td>
<td>Hexokinase, Liquid, Cobas Mira®</td>
<td>201 mg/dL</td>
<td>11.2 mmol/L</td>
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<tr>
<td>Glucose</td>
<td>R80038/R80039</td>
<td>Oxidase-Color</td>
<td>215 mg/dL</td>
<td>11.9 mmol/L</td>
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<tr>
<td>Magnesium</td>
<td>R85207</td>
<td>Colorimetric-Xylidyl Blue I</td>
<td>3.14 mg/dL</td>
<td>1.29 mmol/L</td>
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<td>Phosphorus, Inorganic</td>
<td>R85551/R85562</td>
<td>Phosphomolybdate</td>
<td>5.47 mg/dL</td>
<td>1.77 mmol/L</td>
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<td>Phosphorus</td>
<td>R85168/R85245</td>
<td>Direct Phosphomolybdate</td>
<td>6.73 mg/dL</td>
<td>2.17 mmol/L</td>
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<td>Total Protein</td>
<td>R84086/R85246</td>
<td>Biuret</td>
<td>7.70 g/dL</td>
<td>77.0 g/L</td>
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<tr>
<td>Total Protein</td>
<td>R85552/R85557</td>
<td>Biuret (Mira®)</td>
<td>7.03 g/dL</td>
<td>70.3 g/L</td>
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<tr>
<td>Triglycerides</td>
<td>R80009</td>
<td>INT-Colorimetric Cobas Mira®</td>
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<td>Triglycerides</td>
<td>R85553/R85457</td>
<td>Rapid Liquid</td>
<td>154 mg/dL</td>
<td>1.74 mmol/L</td>
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<td>Triglycerides</td>
<td>R84098</td>
<td>Trinder, GPO Cobas Mira®</td>
<td>162 mg/dL</td>
<td>1.83 mmol/L</td>
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<td>Uric Acid AOX</td>
<td>R85555</td>
<td>Enzymatic Colorimetric Cobas Mira®</td>
<td>5.61 mg/dL</td>
<td>334 µmol/L</td>
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<td>Uric Acid</td>
<td>R80040/R80041/R85228</td>
<td>Enzymatic-Color</td>
<td>8.58 mg/dL</td>
<td>510 µmol/L</td>
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*Data not reported*