Multi-Analyte Serum Calibrator and Diluent

Order No. Description
R60010 10 x 3 mL

INTENDED USE
Multi-Analyte Serum Calibrator is used for the calibration of clinical chemistry assays. The material is well suited for automated analyzers.

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.

REAGENTS CONTENTS AND CONCENTRATION
Multi-Analyte Serum Calibrator
Reactive Ingredients:
Human serum with added chemicals, human and animal tissue extracts.
Constituent concentrations are specific for each lot. The sources of the added biological constituents are as follows:

<table>
<thead>
<tr>
<th>Constituent</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>Bovine Serum</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>Bovine Serum</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>Chicken Egg Yolk</td>
</tr>
</tbody>
</table>

The concentrations of the analytes in the Multi-Analyte Serum Calibrator, with the exceptions of Triglycerides and Phosphorus, 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). The Phosphorus concentration is referenced to independent standards prepared with Reagent Grade Potassium Phosphate (ACS).

CALIBRATOR DILUENT
Non-reactive Ingredients:
Buffers and stabilizers

PRECAUTIONS AND WARNINGS
For In Vitro Diagnostic Use.

Exercise the normal precautions required for handling all laboratory reagents. 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. However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be treated just as carefully as patient specimens. In the event of exposure, the directives of the responsible health authorities should be followed.

STORAGE AND STABILITY
Store unopened Multi-Analyte Serum Calibrator and Multi-Analyte Serum Calibrator Diluent at 2-8°C.
Each vial bears the expiration date on the label.
Stability of the reconstituted calibrator:
at 25°C 8 hours
at 4°C 2 days

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.

PROCEDURE
Materials Provided
Multi-Analyte Serum Calibrator (bottle 1)
Calibrator Diluent (bottle 2)

Materials Required (but not provided)
Volumetric pipette (3.0 ml)
0.9% NaCl (Required only for HDL Cholesterol)

ASSAY
Dispense the required volume of the reconstituted Multi-Analyte Serum Calibrator into a sample cup. Use according to instructions in the appropriate assay package insert, application sheet and/or operator’s manual.

REFERENCES

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## MULTI-ANALYTE SERUM CALIBRATOR (R60010)
### LOT SPECIFIC ASSAY DATA

**Kit LOT** 1707097  
**Exp Date:** 2019-04  
**Multi-Analyte Serum Calibrator (Bottle 1) LOT** 1401196D  
**Calibrator Diluent (Bottle 2) LOT** 1704017B

<table>
<thead>
<tr>
<th>Cobas Mira</th>
<th>Cat. No</th>
<th>Method</th>
<th>Value</th>
<th>SIU VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin, Total</td>
<td>R83087</td>
<td>Malloy-Evelyn, Modified</td>
<td>3.97 mg/dL</td>
<td>67.9 µmol/L</td>
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<tr>
<td>Blood Urea Nitrogen</td>
<td>R84533</td>
<td>Urease/GLDH Liquid, Cobas Mira®</td>
<td>43.1 mg/dL</td>
<td>15.4 mmol/L</td>
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<tr>
<td>Calcium</td>
<td>R85188</td>
<td>Arsenazo III</td>
<td>9.21 mg/dL</td>
<td>2.30 mmol/L</td>
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<tr>
<td>Cholesterol, Total</td>
<td>R80035</td>
<td>Enzymatic Rapid Liquid Cobas Mira®</td>
<td>213 mg/dL</td>
<td>5.51 mmol/L</td>
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<tr>
<td>Glucose</td>
<td>R85411</td>
<td>Hexokinase</td>
<td>189 mg/dL</td>
<td>10.5 mmol/L</td>
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<tr>
<td>Phosphorus</td>
<td>R85168</td>
<td>Direct Phosphomolydbdate</td>
<td>6.17 mg/dL</td>
<td>1.99 mmol/L</td>
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<tr>
<td>Triglycerides</td>
<td>R85457</td>
<td>Rapid Liquid</td>
<td>139 mg/dL</td>
<td>1.57 mmol/L</td>
</tr>
</tbody>
</table>

For in vitro diagnostic use

See package insert for proper use

**SALES AND TECHNICAL SUPPORT**  
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**RE-ORDER INFORMATION**  
Multi-Analyte Serum Calibrator

**Catalog No.**  
**REF** R60010

Made in the USA