

REF 77111

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Revised October 2011

Intended Use

Eon Serum Calibrator is intended to calibrate the Eon 100 Analyzer for the quantitative determination of albumin, calcium, cholesterol, CO₂, creatinine, direct bilirubin, glucose, total iron, magnesium, phosphorus, total bilirubin, total protein, triglycerides, urea nitrogen and uric acid.

Summary

The serum calibrator contains albumin, bilirubin, calcium, cholesterol, CO₂, creatinine, glucose, iron, magnesium, phosphorus, protein, triglycerides, urea and uric acid in a human serum matrix. The cholesterol set point value is traceable to the Cholesterol Reference Method Laboratory Network. The remaining set point values are traceable to NIST or analytical reference standards where available.

Reagents

Composition

After reconstitution, the Eon Serum Calibrator contains the constituents listed in the set point table in a human serum matrix.

Warnings And Precautions

For *in vitro* diagnostic use.

Handle and dispose of Eon Serum Calibrator and all human blood products as though capable of transmitting infectious agents. Use the Centers for Disease Control and Prevention (CDC) recommended universal precautions¹ for handling Eon Serum Calibrator and human specimens. Do not pipette by mouth; do not eat, drink, smoke or apply cosmetics in areas where specimens are handled. Clean up spills immediately with a 0.5% sodium hypochlorite solution.

Eon Serum Calibrator is made from human serum. The source materials in this product have been tested for human immunodeficiency virus (HIV1, HIV2) antibody, hepatitis B surface antigen (HBsAg), and hepatitis C (HCV) antibody and found to be non-reactive. However, no known test method can assure that products derived from human blood are free of infectious agents.

Preparation

Remove the caps and stoppers from both the Eon **CAL** and **DIL** vials. Pour the entire contents of the **DIL** vial into the **CAL** vial. Replace the stopper and cap of the **CAL** vial and let it stand for 30 minutes away from bright light at room temperature. Gently swirl the vial several times during the reconstitution period to ensure that the contents are completely dissolved. Alternatively, the vial may be transferred to a laboratory rocker and mixed for 30 minutes. After reconstitution, examine the vial for undissolved material. If any remains, dissolve it by swirling the vial. Record the preparation date on the label.

Storage and Stability

Store the Eon **CAL** and **DIL** at 2 to 8 °C and away from light. Do not freeze. Do not use unopened Eon **CAL** and **DIL** beyond the expiration date printed on the labels.

Store the reconstituted serum calibrator at 2 to 8 °C and protected from light. After reconstitution, the serum calibrator is stable for 7 days. Do not use the serum calibrator if there are signs of bacterial contamination.

Procedure

Materials Provided

The Eon Serum Calibrator includes the following components:

4 x 10 mL Eon **CAL**

4 x 10 mL Eon **DIL**

Materials Required But Not Provided

Laboratory rocker if used for reconstitution.

Serum Calibrator Use

Before use, the serum calibrator must be reconstituted as described in the Reagents section under Preparation. Mix the serum calibrator by swirling prior to each use. When not in use, seal the bottle and store between 2 to 8 °C and protected from light. Do not reconstitute Eon **CAL** until you are ready to use the calibrator on the Eon 100. Refer to the user manual² for additional information on entering set points and calibrating the instrument.

The Eon Serum Calibrator set points for the Eon 100 Analyzer are listed in the table on the back of this page.

Calculations

All calculations are performed by the Eon 100.

Limitations

Do not reconstitute an Eon **CAL** vial with an Eon **DIL** vial from a kit with a different lot number. The set points for the Eon Serum Calibrator are valid only for the Eon 100 Analyzer and only for the reagent products listed.

References

1. Department of Health and Human Services (US) [HHS] Recommendations for Prevention of HIV Transmission in Health Care Settings. MMWR 36(SU02); 001 1987, August 21. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/00023587.htm> (Accessed 30 March 2010).
2. Eon 100 User Manual (L7283) Vital Diagnostics, Lincoln, RI.

Eon is a registered trademark of Vital Diagnostics.

GLOSSARY OF SYMBOLS

	Manufacturer	LOT	Batch code / Lot number	IVD	<i>In vitro</i> diagnostic medical device
CONT	Contents		Caution		Consult instructions for use
REF	Catalog number		Temperature limitation		Use by / Expiration date
OPENED	Date opened / Preparation date		Biological risks	EC REP	Authorized Representative in the European Community
CAL	Serum Calibrator	DIL	Calibrator Diluent		

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EON[®] 100

Set Point Values

EON[®] SERUM CALIBRATOR

CAL **LOT** 0611E10



REF 77111

DIL **LOT** 0611E20

REF	Chemistry	Method	Code	SI		non SI	
				Value	Units	Value	Units
77220	Albumin	Brocresol Green	ALB	44.5	g/L	4.45	g/dL
77475	Bicarbonate (CO2)	Enzymatic/PEPC	CO2	27.5	mmol/L	27.5	mEq/L
77260	Bilirubin, Direct	Diazo (Blanked)	DBIL	35.6	µmol/L	2.08	mg/dL
77270	Bilirubin, Total	Diazo (Blanked)	TBIL	71.3	µmol/L	4.17	mg/dL
77440	BUN (Urea N)	Urease/GLDH Rate	URE	—		34.0	mg/dL
77280	Calcium	Arsenazo	CA	2.56	mmol/L	10.25	mg/dL
77290	Cholesterol, Total	Enzymatic, Liquid	CHO	4.74	mmol/L	183.2	mg/dL
77331	Creatinine	Kinetic Alkaline Picrate	CRE	433	µmol/L	4.90	mg/dL
77340	Glucose	Hexokinase UV	GLU	9.4	mmol/L	169.1	mg/dL
77360	Iron, Total	Ferrozine (Blanked)	IRON	37.3	µmol/L	208	mg/dL
77400	Magnesium	Xylidyl Blue (Magon)	MG	1.20	mmol/L	2.92	mg/dL
77410	Phosphate, Inorganic	Phosphomolybdate UV	IP	1.80	mmol/L	5.57	mg/dL
77420	Protein, Total	Modified, Biuret	TP	64.9	g/L	6.49	g/dL
77430	Triglycerides	Enzymatic/GPO	TG	2.33	mmol/L	206.4	mg/dL
77440	Urea	Urease/GLDH Rate	URE	12.1	mmol/L	72.6	mg/dL
77450	Uric Acid	Uricase/Peroxidase	UA	398	µmol/L	6.70	mg/dL

→ Table updated with SI Values