

### Intended Use

The Multi-Analyte Chemistry calibrator is for use as a calibrator of Pointe Scientific Inc. clinical chemistry assays. This calibrator material is well suited for automated and semi-automated analytical procedures.

### Summary

The Pointe Scientific, Inc. Multi-Analyte calibrator is a human based serum. The concentration of the calibrator components have been adjusted to ensure optimal calibration of the Pointe Scientific, Inc. methods on specified analyzers.

### Product Description

The product consists of lyophilized human serum and a diluent for reconstitution. The human serum contains additives to provide the defined assay values. The concentrations of the calibrator components are lot-specific.

### Calibrator Values<sup>1</sup>

The calibrator values were determined using Pointe Scientific, Inc. reagent methods and the analyzers listed in the value assignment table. (See reverse side of package insert.) Determinations were performed under strictly standardized conditions, utilizing known reference materials. Traceability information available upon request.

### Calibrator Storage and Stability<sup>1</sup>

Unreconstituted chemistry calibrator is stable until the expiration date when stored at 2-8°C. Reconstituted chemistry calibrator is stable for seven days when stored at 2-8°C with the exception of Bilirubin, which is stable five days at 2-8°C. Store calibrator tightly capped and protected from light when not in use.

### Precautions

For *in vitro* diagnostic use only. Human serum was used in the manufacture of this product. Each donor unit was tested for antibodies to HIV1/2, HCV and found to be non-reactive for HBsAg and HIV-1Ag by FDA accepted test methods. Because no test method can offer complete assurance that products derived from blood will not transmit infectious agents, it is recommended that this product be handled with the same precautions used for patient specimens. In the event of exposure, the directives of the responsible health authorities should be followed.<sup>2,3</sup> Safety data sheets are available upon request. Disposal of all waste material should be in accordance with local guidelines.

### Handling Instructions

Carefully open one bottle, avoiding the loss of lyophilizate. Using a volumetric pipette, add exactly 5.0 ml of diluent to the lyophilized serum. Gently invert the vial intermittently over a period of 20 minutes to ensure complete dissolution of contents. Immediately prior to use, gently invert the vial 5 -10 times.

### Materials Provided

Multi-Analyte calibrator with Diluent.

### Materials Required but not Provided

1. Accurate volumetric pipetting devices
2. Timer
3. Chemistry analyzer
4. General laboratory equipment.

### Assay


Follow the calibration procedure recommended by the instrument manufacturer.

### References

1. Data on file at Pointe Scientific, Inc.
2. Department of Labor, Occupational Safety and Health Standards: Bloodborne pathogens. (29CFR part 1910.1030). Federal register. July 1, 1998; 6:267-280.
3. Council Directive (2000/54EC). Official Journal of the European Communities No. L262 from Oct. 17<sup>th</sup>, 2000.
4. International Federation of Clinical Chemistry (IFCC) Education Division, Expert Panel of Quantities and Units: *A Protocol for the Conversion of Clinical Laboratory data*, Journal of Automatic Chemistry Vol. 11, No 5 (Sept – Oct 1989), pp. 223-226

**REF** C7506-50


**LOT** 430802

 2018-09

 2°C - 8°C

**IVD**



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Pointe Scientific, Inc.

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# Chemistry Calibrator

LOT# 430802 EXP: 2018-09

ANALYTE	COBAS MIRA	Olympus AU 400 /600	Hitachi 717	Hitachi 917	Beckman CX System	Mindray BS200	Units
Albumin	3.7	4.0	3.8	3.9	4.0	3.8	g/dl
	37.0	40.0	38.0	39.0	40.0	38.0	g/L
T. Bilirubin	4.2	3.0	3.0	3.6	4.0	3.7	mg/dl
	71.8	51.3	51.3	61.6	68.4	63.3	umol/L
D. Bilirubin	1.9	2.9	3.5	3.7	3.3	3.1	mg/dl
	32.5	49.6	59.9	63.3	56.4	53.0	umol/L
BUN	48	47	49	47	49	46	mg/dl
	17.1	16.8	17.9	16.8	17.9	16.4	mmol/L
Calcium	10.4	9.7	9.2	9.5	9.8	10.3	mg/dl
	2.60	2.43	2.30	2.38	2.45	2.58	mmol/L
CO2	20	18	21	19	19	19	mEq/L
	20	18	21	19	19	19	mmol/L
Cholesterol	185	188	190	192	191	190	mg/dl
	4.79	4.86	4.92	4.97	4.95	4.92	mmol/L
Creatinine	4.86	4.80	5.26	4.81	4.20	4.47	mg/dl
	430	424	465	425	371	395	umol/L
Glucose Hx.	180	188	182	190	206	190	mg/dl
	10.0	10.4	10.1	10.5	11.4	10.5	mmol/L
Glucose Ox.	---	---	182	---	185	185	mg/dl
	---	---	10.1	---	10.3	10.3	mmol/L
Iron	209	215	224	202	250	216	ug/dl
	37.4	38.5	40.1	36.2	44.8	38.7	umol/L
Magnesium	3.6	3.5	3.5	3.6	3.5	3.5	mg/dl
	1.48	1.44	1.44	1.48	1.44	1.44	mmol/L
Phosphorus	5.6	4.9	4.8	5.0	5.0	5.4	mg/dl
	1.81	1.58	1.55	1.62	1.62	1.74	mmol/L
Total Protein	6.0	5.6	5.7	5.7	5.7	5.9	g/dl
	60	56	57	57	57	59	g/L
Trig.-GPO	113	125	130	128	138	129	mg/dl
	1.28	1.41	1.47	1.45	1.56	1.46	mmol/L
Uric Acid Liq	7.8	6.7	6.5	6.9	7.4	7.3	mg/dl
	0.46	0.40	0.39	0.41	0.44	0.43	mmol/L