

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 Values¹

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 Stability¹

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 for 48 hours 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.^{2,3} 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. 17th, 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 714401

 2020-03-31





 2°C - 8°C

IVD



 Manufactured for
Pointe Scientific, Inc.

Symbol Key

 Use by (YYYY-MM-DD)	LOT Lot and batch code
REF Catalog number	 Manufacturer
 Temperature limitation	 Consult instructions for use
IVD <i>In vitro</i> diagnostic medical device	

Manufactured for Pointe Scientific, Inc.
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Chemistry Calibrator

LOT#: 714401 EXP.: 2020-03-31

ANALYTE	Pointe 180	COBAS MIRA	Olympus AU 400 /600	Hitachi 717	Pointe C2000 Mindray BS200	Mindray BS480	Biolis 24i	Units
Albumin	3.5	3.4	3.9	3.5	3.6	3.8	3.7	g/dl
	35.0	34.0	39.0	35.0	36.0	38.0	37.0	g/L
T. Bilirubin	5.7	5.6	4.6	4.6	5.1	4.7	4.3	mg/dl
	97.5	95.8	78.7	78.7	87.2	80.4	73.5	umol/L
D. Bilirubin	---	3.1	3.2	3.5	3.6	3.7	4.3	mg/dl
	---	53.0	54.7	59.9	61.6	63.3	73.5	umol/L
BUN	48	53	52	54	52	50	52	mg/dl
	17.1	18.9	18.6	19.3	18.6	17.9	18.6	mmol/L
Calcium	10.9	11.2	11.0	10.9	11.0	10.8	10.9	mg/dl
	2.73	2.80	2.75	2.73	2.75	2.70	2.73	mmol/L
CO2	33	33	26	33	31	30	32	mEq/L
	33	33	26	33	31	30	32	mmol/L
Cholesterol	183	195	190	185	189	190	194	mg/dl
	4.74	5.05	4.92	4.79	4.90	4.92	5.03	mmol/L
Creatinine	5.09	5.09	5.10	5.15	5.25	5.10	5.20	mg/dl
	450	450	451	455	464	451	460	umol/L
Glucose Hx.	151	166	166	155	160	155	164	mg/dl
	8.4	9.2	9.2	8.6	8.9	8.6	9.1	mmol/L
Glucose Ox.	147	---	---	160	164	---	160	mg/dl
	8.2	---	---	8.9	9.1	---	8.9	mmol/L
Iron	---	174	160	180	174	179	175	ug/dl
	---	31.1	28.6	32.2	31.1	32.0	31.3	umol/L
Magnesium	2.7	2.8	2.8	2.7	2.8	2.6	2.6	mg/dl
	1.11	1.15	1.15	1.11	1.15	1.07	1.07	mmol/L
Phosphorus	4.8	5.5	4.6	4.6	5.5	5.4	4.8	mg/dl
	1.55	1.78	1.49	1.49	1.78	1.74	1.55	mmol/L
Total Protein	4.8	6.2	6.0	5.8	5.6	5.5	5.6	g/dl
	48	62	60	58	56	55	56	g/L
Trig.-GPO	65	84	87	91	89	84	88	mg/dl
	0.73	0.95	0.98	1.03	1.01	0.95	0.99	mmol/L
Uric Acid Liq	8.0	8.3	7.6	7.2	7.6	8.0	8.0	mg/dl
	0.48	0.49	0.45	0.43	0.45	0.48	0.48	mmol/L