

Chemistry Calibrator

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 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.^{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.

REF C7506-50

LOT 011802

 2014-03

 2°C - 8°C

IVD



Manufactured for
Pointe Scientific, Inc.

Manufactured for Pointe Scientific, Inc.
5449 Research Drive, Canton, MI 48188



European Authorized Representative:
Obelis s.a.

Boulevard Général Wahis 53
1030 Brussels, BELGIUM

Tel: (32)2.732.59.54 Fax:(32)2.732.60.03 email: mail@obelis.net

Chemistry Calibrator

LOT# 011802 EXP: 2014-03

ANALYTE	Pointe 180	Pointe 360	ATAC 8000	COBAS MIRA	ChemWell	Olympus AU 400 /600	Hitachi 717	Hitachi 917	Beckman CX System	Mindray BS200	Selectra	Units
Albumin	3.9	3.9	4.0	4.0	4.5	4.1	4.0	4.2	4.1	4.3	4.0	g/dl
T. Bilirubin	4.4	4.3	4.1	4.5	3.2	3.9	3.8	4.1	4.4	4.5	4.4	mg/dl
D.Bilirubin	---	3.0	1.6	1.7	---	3.0	2.8	3.1	3.1	3.0	2.3	mg/dl
BUN	51	50	51	51	57	50	51	50	51	49	46	mg/dl
Calcium	9.8	9.8	10.3	10.1	9.6	10.1	9.7	9.6	9.8	10.1	9.9	mg/dl
CO2	20	21	---	21	---	21	26	24	21	20	22	mEq/L
Chloride	93	---	---	103	96	---	---	---	---	---	---	mEq/L
Cholesterol	185	191	193	190	191	189	191	197	200	189	193	mg/dl
Creatinine	4.5	4.5	4.4	4.6	4.4	4.9	5.0	4.5	4.0	4.7	4.5	mg/dl
Glucose Hx.	192	185	192	206	194	198	195	195	196	200	200	mg/dl
Glucose Ox.	197	---	---	---	---	---	194	---	191	197	---	mg/dl
Iron	---	205	---	190	---	198	205	178	191	200	---	ug/dl
Magnesium	3.5	3.5	3.3	3.2	---	3.2	3.2	3.2	3.1	3.1	3.3	mg/dl
Phosphorus	4.9	5.3	4.6	5.5	5.8	4.7	5.3	5.3	4.9	5.3	5.0	mg/dl
Total Protein	6.6	6.1	6.3	5.7	5.9	6.0	5.8	5.8	6.0	6.0	6.2	g/dl
Trig.-GPO	139	129	127	142	137	142	136	134	136	136	140	mg/dl
Uric Acid	7.0	---	---	5.6	---	---	---	---	---	---	---	mg/dl
Uric Acid Liq	---	6.6	6.3	6.2	---	6.8	6.3	7.0	7.0	6.8	6.7	mg/dl