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 Values[1]
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[1]
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 lypohilizate. 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.

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2°C 8°C

IVD

Manufactured for
Pointe Scientific, Inc.

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ANALYTE	Pointe 180	Pointe 360	Chemwell	COBAS MIRA	Olympus AU 400 /600	Hitachi 717	Hitachi 917	Beckman CX System	Mindray BS200	Selectra	Units
Albumin	4.0	3.8	4.0	3.9	4.0	3.9	4.0	4.2	4.2	4.2	g/dl
T. Bilirubin	3.8	3.5	3.8	4.1	3.4	3.1	3.7	3.8	4.1	4.3	mg/dl
D.Bilirubin	---	3.0	---	1.6	3.0	2.9	3.2	3.1	2.9	2.4	mg/dl
BUN	49	53	52	52	51	50	48	52	47	47	mg/dl
Calcium	9.5	10.0	10.3	10.0	9.8	9.7	9.6	9.9	10.3	9.7	mg/dl
CO2	19	17	---	17	18	18	20	20	18	21	mEq/L
Chloride	94	---	---	101	---	---	---	---	---	---	mEq/L
Cholesterol	195	220	197	198	197	199	200	203	198	206	mg/dl
Creatinine	4.5	4.5	4.7	4.4	5.0	4.8	4.3	4.2	4.5	4.7	mg/dl
Glucose Hx.	197	202	196	210	196	202	193	200	196	211	mg/dl
Glucose Ox.	208	---	---	---	---	198	---	197	193	---	mg/dl
Iron	---	207	---	198	198	205	181	207	213	---	ug/dl
Magnesium	3.9	3.6	---	3.3	3.5	3.6	3.2	3.4	3.4	3.3	mg/dl
Phosphorus	4.8	5.5	4.9	5.4	5.2	5.1	5.3	5.2	5.2	5.0	mg/dl
Total Protein	6.9	6.3	5.9	5.8	6.2	5.8	5.7	6.4	6.2	6.4	g/dl
Trig.-GPO	132	129	131	135	133	130	130	132	126	139	mg/dl
Uric Acid	7.1	---	---	5.6	---	---	---	---	---	---	mg/dl
Uric Acid Liq	---	7.3	6.2	6.5	6.7	6.2	6.9	7.2	6.8	6.7	mg/dl

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