

## Intended Use

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

## Summary

The Pointe Multi-Analyte calibrator is a human based serum. The concentration of the calibrator components have been adjusted to ensure optimal calibration of the HORIBA Medical 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 HORIBA Instruments 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 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.<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 HORIBA Instruments Incorporated.
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

**LOT** 012001

 2023-10-31

## Symbol Key

 Use by (YYYY-MM-DD)	<b>LOT</b> Lot and batch code
<b>REF</b> Catalog number	 Manufacturer
<b>IVD</b> <i>In vitro</i> diagnostic medical device	 Temperature limitation
 Consult instructions for use	<b>Rx Only:</b> Prescription Use Only
 CE mark	<b>EC REP</b> Authorized representative in the European Community

**REF** C7506-50



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## Certified to Perform Reagents

The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

# Pointe Chemistry Calibrator

LOT#: 012001 EXP.: 2023-10-31

ANALYTE	Pointe 180	COBAS MIRA	Olympus AU 400 /600	Hitachi	Pointe C2000 Mindray BS200	Mindray BS480	Mindray BA800	Biolis 24i	Units
Albumin	3.8	3.5	3.8	3.7	3.8	3.9	3.6	3.8	g/dl
	38.0	35.0	38.0	37.0	38.0	39.0	36.0	38.0	g/L
T. Bilirubin	5.4	5.6	4.7	4.6	5.3	4.7	4.6	4.6	mg/dl
	92.3	95.8	80.4	78.7	90.6	80.4	78.7	78.7	umol/L
D. Bilirubin	---	2.8	3.1	2.8	3.7	3.8	3.6	3.1	mg/dl
	---	47.9	53.0	47.9	63.3	65.0	61.6	53.0	umol/L
BUN	49	49	50	52	52	49	49	51	mg/dl
	17.5	17.5	17.9	18.6	18.6	17.5	17.5	18.2	mmol/L
Calcium	10.5	10.2	10.2	9.9	10.2	10.2	9.8	9.8	mg/dl
	2.63	2.55	2.55	2.48	2.55	2.55	2.45	2.45	mmol/L
CO2	33	31	28	31	31	30	30	---	mEq/L
	33	31	28	31	31	30	30	---	mmol/L
Cholesterol	189	206	202	202	208	207	199	202	mg/dl
	4.90	5.34	5.23	5.23	5.39	5.36	5.15	5.23	mmol/L
Creatinine	5.16	5.16	5.10	5.20	5.10	5.00	5.10	4.96	mg/dl
	456	456	451	460	451	442	451	438	umol/L
Glucose Hexokinase	178	180	189	183	181	180	180	189	mg/dl
	9.9	10.0	10.5	10.2	10.0	10.0	10.0	10.5	mmol/L
Glucose Oxidase	178	---	---	181	180	---	---	189	mg/dl
	9.9	---	---	10.0	10.0	---	---	10.5	mmol/L
Iron	---	179	165	186	185	184	183	185	ug/dl
	---	32.0	29.5	33.3	33.1	32.9	32.8	33.1	umol/L
Magnesium	2.8	2.8	2.8	2.7	2.7	2.5	2.5	2.5	mg/dl
	1.15	1.15	1.15	1.11	1.11	1.03	1.03	1.03	mmol/L
Phosphorus	4.9	5.8	5.2	5.0	5.6	5.8	4.9	4.9	mg/dl
	1.58	1.87	1.68	1.62	1.81	1.87	1.58	1.58	mmol/L
Total Protein	5.3	6.3	6.0	5.8	5.8	5.6	5.8	5.7	g/dl
	53	63	60	58	58	56	58	57	g/L
Triglycerides.-GPO	70	87	95	99	94	96	92	89	mg/dl
	0.79	0.98	1.07	1.12	1.06	1.08	1.04	1.01	mmol/L
Uric Acid Liquid	9.0	8.1	7.9	7.7	8.4	8.1	7.5	8.2	mg/dl
	0.53	0.48	0.47	0.46	0.50	0.48	0.45	0.49	mmol/L