POINTE Chemistry Controls Level I Control

Lot: 303701, Exp.: 2026-12-31

HORIBA Instruments Incorporated
5449 Research Drive, Canton, MI 48188
Phone: 734-487-8300; (800) 445-9853

Intended Use

For *in vitro* diagnostic use only.
The Chemistry Control is to be used for monitoring the accuracy and precision of clinical chemistry procedures. This control contains constituents commonly of interest in a general chemistry control. The assayed multi-analyte control product is packaged with one level of analytes. **Rx Only**

Product Description

The quality control material is prepared from human serum with enzymes, nonprotein constituents, non-human protein, and bacteriostatic agents added. The constituents were adjusted to the levels listed in Expected Values.

Precautions

BIOHAZARD: Human source material. Handle as if potentially infectious. Human serum was used in the manufacture of this product. Each donor unit used was tested by FDA-approved methods and found nonreactive for hepatitis B surface antigen (HBsAg), Hepatitis C (HCV), and HIV 1 and HIV 2. Because no known test method can offer complete assurance that infectious agents are absent, all products containing human source material should be handled in accordance with recommendations from Centers for Disease Control/National Institute of Health Manual, "*Biosafety in Microbiological and Biomedical Laboratories*, 1999."

This product contains less then 0.1% sodium azide that may react with lead and copper plumbing to form potentially explosive metal azides. On disposal, flush with large volumes of water to prevent azide build-up.

Storage and Stability

Ensure that you tightly seal the vials after reconstitution and use to prevent evaporation during storage. Ensure that you store the vials upright to prevent spills or leakage. CK and Bilirubin are sensitive to light. Store the vials away from light.

	Storage	Stability
Unreconstituted	2-8°C	Refer to the label on each vial and on the package for the expiration date.
Reconstituted	2-8°C	7 days Exceptions: Bilirubin and Alkaline Phosphatase which are stable 48hrs. ALP may increase with time.

General Instructions for Use

Use the quality control material according to the directions accompanying the instrument or the assay procedure used. Treat the quality control material in the same manner as patient samples.

1. Remove the screw cap and gently remove the rubber stopper from the vial.
2. Pipette exactly 5.0 mL of distilled or deionized water to the vial using a volumetric pipette.
3. Replace the stopper in the vial, allow the vial to sit for 10 minutes.
4. Gently invert the vial three (3) times and swirl until the contents are homogenous.
5. Record the results according to your quality assurance program.

Expected Results

Refer to the Expected Values table supplied for assay mean and ranges. Before use, verify that the vial lot number corresponds to the lot number listed on the Expected Values table.
The Expected Values and ranges are target values derived from inter laboratory data. The expected range values include variations of instrument and laboratory handling. The assay values were obtained using in-date POINTE reagents available at the time of testing. Updates to the listed values may be made based upon additional data that becomes available or, if necessitated by a modification to a test method. The mean values established for your laboratory should fall within the ranges shown in Expected Values; however laboratory means may vary during the life of the control. Each laboratory should establish its own mean and precision parameters.

Limitations

The results obtained using the quality control material are dependant upon several factors: erroneous results can occur from improper storage, reconstitution errors, inadequate mixing, or sample handling errors associated with instrument or assay procedures. Do not use the quality control material if there is visible evidence of microbial growth in the vial or a lack of vacuum when opening the vial for the first time. For more information about procedural limitations, refer to your instrument manual or assay product insert.

Disposing of Materials

Dispose of hazardous or biologically contaminated materials according to your institution's practices. Discard all materials in a safe and acceptable manner that is in compliance with all country, state, and local requirements.

Technical Assistance

For technical assistance and customer service contact POINTE at 800-445-9853 or 800-757-5313 or by fax at 734-483-1592.

REF C7590 Manufactured for HORIBA: POINTE Brand 5449 Research Drive Canton, MI 48188 2°C 8°C IVD

Symbol Key

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

Manufactured for HORIBA: POINTE Brand
5449 Research Drive, Canton, MI 48188

EC REP
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CE

Certified to Perform

POINTE certifies that all of our products are manufactured according to specified parameters. Any product not meeting specifications through their listed expiration date will be remedied immediately without charge.

EXPECTED VALUES **LEVEL I CONTROL** **LOT: 303701 EXP.: 2026-12-31**

ANALYTE	Beckman AU 400 / 640	Hitachi 717	Pointe C2000 / Mindray BS-200	Mindray BS-480	Pointe 180	General Assay Range	Units
Acid Phos	--------	8.6 ± 1.7	--------	--------	--------	8.6 ± 1.7	U/L
Albumin	2.2 ± 0.2	2.1 ± 0.2	2.3 ± 0.2	2.7 ± 0.3	2.5 ± 0.3	2.4 ± 0.2	g/dl
Alk Phos	86 ± 26	80 ± 24	80 ± 24	85 ± 26	101 ± 30	86 ± 26	U/L
ALT (SGPT)	49 ± 10	49 ± 10	57 ± 11	51 ± 10	52 ± 10	52 ± 10	U/L
Amylase	208 ± 62	191 ± 57	251 ± 75	219 ± 66	202 ± 61	214 ± 64	U/L
AST (SGOT)	65 ± 13	62 ± 12	61 ± 12	59 ± 12	63 ± 13	62 ± 12	U/L
Direct Bilirubin	0.5 ± 0.4	0.4 ± 0.4	0.6 ± 0.4	0.6 ± 0.4	0.7 ± 0.4	0.6 ±0.4	mg/dl
Total Bilirubin	0.6 ± 0.4	0.7 ± 0.4	0.8 ± 0.4	0.7 ± 0.4	1.1 ± 0.4	0.8 ± 0.4	mg/dl
BUN	13 ± 2	12 ± 2	13 ± 2	12 ± 2	13 ± 2	13 ± 2	mg/dl
Calcium (CPC)	9.6 ± 1.0	8.5 ± 1.0	--------	--------	8.9 ± 1.0	9.0 ± 1.0	mg/dl
Calcium (AR-III)	9.8 ± 1.0	--------	9.1 ± 1.0	9.3 ± 1.0	--------	9.4 ± 1.0	mg/dl
Chloride	89 ± 4	--------	--------	89 ± 4	--------	89 ± 4	mEq/L
Cholesterol	111 ± 11	100 ± 10	110 ± 11	110 ± 11	98 ± 10	106 ± 11	mg/dl
Carbon Dioxide	6 ± 5	9 ± 5	10 ± 5	9 ± 5	11 ± 5	9 ± 5	mEq/L
CK/CPK	104 ± 31	104 ± 31	123 ± 37	116 ± 35	117 ± 35	113 ± 34	U/L
Creatinine	1.05 ± 0.30	1.01 ± 0.30	0.86 ± 0.30	0.89 ± 0.30	1.36 ± 0.30	1.03 ± 0.30	mg/dl
GGTP	45 ± 14	41 ± 12	41 ± 12	40 ± 12	60 ± 18	45 ± 14	U/L
Glucose (Hex)	93 ± 9	80 ± 8	80 ± 8	82 ± 8	81 ± 8	83 ± 8	mg/dl
Glucose (Ox)	---------	79 ± 8	83 ± 8	---------	80 ± 8	81 ± 8	mg/dl
HDL (auto)	60 ± 18	49 ± 15	48 ± 14	54 ± 16	--------	53 ± 16	mg/dl
HDL (PEG)	---------	---------	---------	--------	--------	--------	mg/dl
Iron	67 ± 13	78 ± 16	76 ± 15	79 ± 16	69 ± 14	74 ± 15	µg/dl
Lactate	--------	1.5 ± 0.2	1.5 ± 0.2	1.5 ± 0.2	1.4 ± 0.2	1.5 ± 0.2	mmol/L
LDH	98 ± 20	101 ± 20	100 ± 20	109 ± 22	69 ± 14	95 ± 19	U/L
Lipase (color)	--------	--------	35 ± 11	--------	--------	35 ± 11	U/L
Magnesium	1.7 ± 0.4	1.5 ± 0.4	1.5 ± 0.4	1.5 ± 0.4	1.4 ± 0.4	1.5 ± 0.4	mg/dl
Phosphorus	3.7 ± 0.4	3.5 ± 0.4	3.8 ± 0.4	4.1 ± 0.4	3.8 ± 0.4	3.8 ± 0.4	mg/dl
Potassium	3.7 ± 0.5	--------	--------	3.7 ± 0.5	--------	3.7 ± 0.5	mEq/L
Sodium	122 ± 4	--------	--------	126 ± 4	--------	124 ± 4	mEq/L
TIBC direct	254 ± 64	--------	233 ± 58	253 ± 63	--------	247 ± 62	µg/dl
Total Protein	4.2 ± 0.4	3.4 ± 0.3	3.4 ± 0.3	3.4 ± 0.3	2.7 ± 0.3	3.4 ± 0.3	g/dl
Trig-GPO	82 ± 21	80 ± 20	79 ± 20	78 ± 20	72 ± 18	78 ± 20	mg/dl
UIBC	--------	182 ± 46	--------	--------	--------	182 ± 46	µg/dl
Uric Acid	4.5 ± 0.8	4.0 ± 0.7	4.8 ± 0.8	4.7 ± 0.8	4.7 ± 0.8	4.5 ± 0.8	mg/dl