POINTE SCIENTIFIC
A MEDTEST COMPANY

Chemistry Controls

LEVEL II CONTROL
Lot: 717402
Exp.: 2020-05-31

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, including common drugs and thyroids. The assayed multi-analyte control product is packaged with one level of analytes.

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 Scientific 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 Scientific, Inc. at 800-445-9853 or 800-757-5313 or by fax at 734-483-1592.

REF C7591-50

LOT 717402

2020-05-31

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

CE

EXPECTED VALUES **LEVEL II CONTROL** **LOT: 717402 EXP.: 2020-05-31**

ANALYTE	Hitachi 717	Beckman AU 400 /640	Cobas Mira	Pointe 180	Pointe C2000 / Mindray BS-200	Mindray BS-480	General Assay Range	Units
Acid Phos	18.2 ± 3.6	--------	--------	--------	--------	--------	18.2 ± 3.6	U/L
Albumin	4.2 ± 0.4	4.5 ± 0.5	4.4 ± 0.4	3.9 ± 0.4	4.2 ± 0.4	4.6 ± 0.5	4.3 ± 0.4	g/dl
Alk Phos	211 ± 63	247 ± 74	223 ± 67	230 ± 69	207 ± 62	176 ± 53	216 ± 65	U/L
ALT (SGPT)	139 ± 28	131 ± 26	143 ± 29	140 ± 28	153 ± 31	146 ± 29	142 ± 29	U/L
Amylase	482 ± 145	456 ± 137	506 ± 152	507 ± 152	584 ± 175	430 ± 129	494 ± 148	U/L
AST (SGOT)	259 ± 52	235 ± 47	273 ± 55	269 ± 54	255 ± 51	253 ± 51	257 ± 52	U/L
Direct Bilirubin	6.2 ± 1.2	5.1 ± 1.0	3.8 ± 0.8	5.3 ± 1.1	5.3 ± 1.1	4.9 ± 1.0	5.1 ± 1.0	mg/dl
Total Bilirubin	5.6 ± 1.1	5.5 ± 1.0	7.4 ± 1.5	7.1 ± 1.4	6.5 ± 1.3	5.3 ± 1.1	6.2 ± 1.2	mg/dl
BUN	54 ± 5	53 ± 5	53 ± 5	49 ± 4	51 ± 5	49 ± 4	52 ± 5	mg/dl
Calcium (CPC)	12.8 ± 1.0	13.5 ± 1.0	13.5 ± 1.0	13.0 ± 1.0	--------	--------	13.2 ± 1.0	mg/dl
Calcium (AR-III)	--------	12.4 ± 1.0	14.0 ± 1.0	--------	12.9 ± 1.0	12.6 ± 1.0	13.0 ± 1.0	mg/dl
Chloride	122 ± 6	128 ± 6	--------	--------	126 ± 6	124 ± 6	125 ± 6	mEq/L
Cholesterol	301 ± 30	299 ± 30	296 ± 30	300 ± 30	303 ± 30	303 ± 30	300 ± 30	mg/dl
Carbon Dioxide	28 ± 5	23 ± 5	25 ± 5	25 ± 5	25 ± 5	26 ± 5	25 ± 5	mEq/L
CK/CPK	268 ± 80	355 ± 107	314 ± 94	328 ± 98	294 ± 88	247 ± 74	301 ± 90	U/L
Creatinine	5.52 ± 0.83	5.27 ± 0.79	4.83 ± 0.72	4.73 ± 0.71	5.18 ± 0.78	5.36 ± 0.80	5.15 ± 0.77	mg/dl
GGTP	138 ± 28	133 ± 27	148 ± 30	146 ± 29	141 ± 28	142 ± 28	141 ± 28	U/L
Glucose Hex	284 ± 28	310 ± 31	305 ± 31	289 ± 29	310 ± 31	281 ± 28	297 ± 30	mg/dl
Glucose Ox	301 ± 30	---------	--------	257 ± 26	297 ± 30	--------	285 ± 29	mg/dl
HDL (auto)	*189 ± 57	*193 ± 58	*199 ± 60	--------	*203 ± 61	*183 ± 55	*193 ± 58	mg/dl
HDL (PEG)	---------	---------	45 ± 14	37 ± 11	---------	---------	41 ± 13	mg/dl
Iron	178 ± 36	160 ± 32	165 ± 33	193 ± 39	143 ± 29	158 ± 32	166 ± 34	µg/dl
Lactate	2.7 ± 0.2	---------	2.6 ± 0.2	2.8 ± 0.2	2.7 ± 0.2	2.7 ± 0.2	2.7 ± 0.2	mmol/L
LDH	348 ± 70	336 ± 67	342 ± 68	357 ± 71	358 ± 72	341 ± 68	347 ± 69	U/L
Lipase (color)	146 ± 44	141 ± 42	--------	--------	140 ± 42	--------	142 ± 43	U/L
Magnesium	3.3 ± 0.8	3.5 ± 0.9	3.6 ± 0.9	3.3 ± 0.8	3.4 ± 0.9	3.3 ± 0.8	3.4 ± 0.9	mg/dl
Phosphorus	7.4 ± 0.8	7.8 ± 0.8	9.4 ± 1.0	8.1 ± 0.9	8.5 ± 0.9	8.9 ± 1.0	8.4 ± 0.9	mg/dl
Potassium	6.6 ± 0.5	7.1 ± 0.5	--------	--------	6.7 ± 0.5	7.1 ± 0.5	6.9 ± 0.5	mEq/L
Sodium	161 ± 4	169 ± 4	--------	--------	171 ± 4	177 ± 4	170 ± 4	mEq/L
TIBC direct	--------	401 ± 100	--------	--------	400 ± 100	419 ± 105	407 ± 102	µg/dl
Total Protein	6.6 ± 0.7	7.0 ± 0.7	7.4 ± 0.7	6.0 ± 0.6	7.0 ± 0.7	6.7 ± 0.7	6.8 ± 0.7	g/dl
Trig-GPO	195 ± 49	199 ± 50	192 ± 48	171 ± 43	203 ± 51	201 ± 50	194 ± 49	mg/dl
UIBC	220 ± 55	--------	258 ± 65	--------	--------	--------	239 ± 60	µg/dl
Uric Acid	8.7 ± 1.5	8.9 ± 1.5	10.3 ± 1.8	9.7 ± 1.6	9.5 ± 1.6	9.8 ± 1.7	9.5 ± 1.6	mg/dl

* Control diluted 1:1 before analysis.