

Intended Use

These Human Urine Controls are intended for use as a control for human urine assay methods. Control materials having known component concentrations are an integral part of diagnostic procedures. Daily monitoring of control values establishes intralaboratory parameters for accuracy and precision of the test method. **Rx Only**

For *IN VITRO* diagnostic use only.

Product Description

These Human Urine Controls are supplied as a ready-to-use liquid requiring no reconstitution. They are prepared from human urine. The Human Urine Controls are fortified to target levels with human proteins and reagent grade chemicals. Preservatives have been added to inhibit microbial growth.

Warnings and Precautions

POTENTIAL BIOHAZARDOUS MATERIAL. Contains human urine. All blood donor units comprising the source plasma used in the manufacture of the albumin and globulin used in this product have been tested and found non-reactive for Hepatitis B Surface Antigen, Hepatitis C and HIV 1 & 2 antibody when tested by FDA accepted methods.

No known test method can assure that a product derived from human blood does not contain Hepatitis or HIV virus. It is recommended such samples be handled according to the Centers for Disease Control's Biosafety Level 2 recommendations.

Storage and Stability

1. Store the controls at 2-8°C.
2. When stored at 2-8°C the controls are stable until the expiration date stated on the label.
3. The control has an open vial stability of 24 months from the date of manufacture or until the expiration date.
4. Discard the controls if turbid or if there is any evidence of microbial contamination. Discard controls in the same manner as other biological specimens, according to local guidelines.

Procedure

1. Remove the controls from the refrigerator and allow to come to room temperature (18-25°C) for 30 to 60 minutes depending on remaining volume.
2. Invert gently to assure homogeneity of the contents. Avoid foaming. Treat the controls as you would a patient sample in accordance with the manufacturer's requirements of the test method.
3. Immediately recap the controls and return to 2-8°C when not in use.

Expected Values


Expected values for the listed lots of controls have been established from interlaboratory data using instrument manufacturers' reagents. Individual laboratory means should fall within the ranges listed. These values should be used as a guide in evaluating the performance of the test methods. Each laboratory should establish its own precision parameters for the methods used to measure each analyte.

Mean values and expected ranges apply to all models of the instrument listed unless otherwise noted.






Limitations

The expected mean and ranges were established using instrument manufacturer's reagents available at the time of assay. Any future changes made by the manufacturer of a test method may give different values from those previously recovered. Use of methods other than the ones used to establish the expected values may give different values from the ones indicated. Limitations of the test method are included in the package insert for the reagent or instrument being used.

Depending on the instrument and the reagents used to measure creatinine, the mean creatinine values listed may decrease up to 10% over the entire shelf life of the control.

REF P7582-CTL **LOT** 313802  2024-11-30

Symbol Key

 Use by (YYYY-MM-DD)	LOT Lot and batch code
REF Catalog number	 Manufacturer
IVD <i>In vitro</i> 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



2°C - 8°C



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 5449 Research Drive, Canton, MI 48188



European Authorized Representative:

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Certified Performance Guarantee

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.

Pointe
Human Urine Control Set
Lot 313802, Expiration: 2024-11-30

Analytes / Instruments	Units	Level 1		Level 2		SI Units ¹	Level 1		Level 2	
		Mean	Range	Mean	Range		Mean	Range	Mean	Range
Amylase										
Abbott Architect	U/L	88	70-105	171	137-205	U/L	88	70-105	171	137-205
Beckman Coulter® AU™ Instruments*	U/L	81	64-97	153	123-184	U/L	81	64-97	153	123-184
Siemens Dimension® *	U/L	98	79-118	193	154-231	U/L	98	79-118	193	154-231
Siemens Dimension Vista®*	U/L	101	81-121	195	156-234	U/L	101	81-121	195	156-234
Calcium										
Abbott Architect	mg/dL	6.8	5.5-8.2	10.4	8.3-12.5	mmol/L	1.71	1.37-2.05	2.60	2.08-3.12
Beckman Coulter AU Instruments*	mg/dL	8.0	6.4-9.6	12.0	9.6-14.4	mmol/L	2.00	1.60-2.40	3.00	2.40-3.60
Roche Cobas / Cobas Integra*	mg/dL	7.3	5.8-8.7	10.9	8.7-13.1	mmol/L	1.82	1.45-2.18	2.73	2.19-3.28
Siemens Dimension *	mg/dL	7.7	6.1-9.2	11.6	9.3-13.9	mmol/L	1.91	1.53-2.30	2.90	2.32-3.48
Siemens Dimension Vista*	mg/dL	7.5	6.0-9.0	11.7	9.3-14.0	mmol/L	1.88	1.50-2.26	2.92	2.34-3.51
Chloride										
Abbott Architect	mEq/L	86	69-103	132	106-159	mmol/L	86	69-103	132	106-159
Beckman Coulter AU Instruments*	mEq/L	88	70-105	137	110-164	mmol/L	88	70-105	137	110-164
Roche Cobas / Cobas Integra*	mEq/L	82	65-98	130	104-156	mmol/L	82	65-98	130	104-156
Siemens Dimension *	mEq/L	100	80-120	158	126-189	mmol/L	100	80-120	158	126-189
Siemens Dimension Vista*	mEq/L	97	77-116	159	127-191	mmol/L	97	77-116	159	127-191
Creatinine										
Abbott Architect	mg/dL	81	65-97	153	122-184	mmol/L	7.17	5.73-8.60	13.53	10.82-16.23
Beckman Coulter AU Instruments*	mg/dL	76	61-92	136	109-164	mmol/L	6.74	5.39-8.09	12.05	9.64-14.45
Roche Cobas / Cobas Integra*	mg/dL	88	70-105	163	130-195	mmol/L	7.75	6.20-9.30	14.38	11.50-17.26
Siemens Dimension *	mg/dL	81	65-97	157	125-188	mmol/L	7.14	5.71-8.57	13.85	11.08-16.62
Siemens Dimension Vista®*	mg/dL	82	65-98	161	128-193	mmol/L	7.23	5.79-8.68	14.19	11.35-17.03
Glucose										
Abbott Architect*	mg/dL	50	40-60	299	240-359	mmol/L	2.8	2.23-3.35	16.6	13.29-19.94
Beckman Coulter AU Instruments*	mg/dL	51	41-61	292	234-351	mmol/L	2.8	2.3-3.4	16.2	13.0-19.5
Siemens Dimension *	mg/dL	52	42-63	297	238-357	mmol/L	2.9	2.3-3.5	16.5	13.2-19.8
Siemens Dimension Vista*	mg/dL	54	43-65	301	241-362	mmol/L	3.0	2.4-3.6	16.7	13.4-20.1
Magnesium										
Abbott Architect	mg/dL	7.7	6.2-9.3	15.4	12.3-18.5	mmol/L	3.18	2.55-3.82	6.34	5.07-7.61
Beckman Coulter AU Instruments	mg/dL	7.7	6.1-9.2	14.0	11.2-16.8	mmol/L	3.15	2.52-3.78	5.75	4.60-6.90
Siemens Dimension	mg/dL	8.0	6.4-9.6	15.2	12.2-18.3	mmol/L	3.29	2.64-3.95	6.26	5.01-7.51
Siemens Dimension Vista	mg/dL	8.2	6.5-9.8	15.6	12.4-18.7	mmol/L	3.35	2.68-4.02	6.39	5.11-7.67
Osmolality										
Advanced Instruments	M0sm/Kg	455	364-546	776	621-931	mmol/kg	455	364-546	776	621-931
Phosphorus										
Abbott Architect	mg/dL	22.5	18.0-27.0	46.9	37.5-56.2	mmol/L	7.26	5.81-8.71	15.14	12.11-18.17
Beckman Coulter AU Instruments*	mg/dL	24.3	19.5-29.2	49.8	39.9-59.8	mmol/L	7.86	6.29-9.43	16.10	12.88-19.32
Roche Cobas / Cobas Integra*	mg/dL	22.8	18.3-27.4	48.0	38.4-57.6	mmol/L	7.38	5.90-8.85	15.50	12.40-18.60
Siemens Dimension *	mg/dL	24.6	19.7-29.6	50.5	40.4-60.6	mmol/L	7.96	6.37-9.55	16.32	13.06-19.58
Siemens Dimension Vista*	mg/dL	25.4	20.3-30.4	51.0	40.8-61.2	mmol/L	8.19	6.55-9.83	16.48	13.19-19.78

Pointe
Human Urine Control Set
Lot 313802, Expiration: 2024-11-30

Analytes / Instruments	Level 1		Level 2		SI Units ¹	Level 1		Level 2		
	Mean	Range	Mean	Range		Mean	Range	Mean	Range	
Potassium										
Abbott Architect*	mEq/L	35.3	28.2-42.4	71.1	56.9-85.3	mmol/L	35.3	28.2-42.4	71.1	56.9-85.3
Beckman Coulter AU Instruments*	mEq/L	33.4	26.8-40.1	66.2	52.9-79.4	mmol/L	33.4	26.8-40.1	66.2	52.9-79.4
Roche Cobas / Cobas Integra*	mEq/L	35.7	28.5-42.8	71.3	57.1-85.6	mmol/L	35.7	28.5-42.8	71.3	57.1-85.6
Siemens Dimension *	mEq/L	35.3	28.3-42.4	70.5	56.4-84.6	mmol/L	35.3	28.3-42.4	70.5	56.4-84.6
Siemens Dimension Vista*	mEq/L	35.9	28.7-43.1	70.0	56.0-84.0	mmol/L	35.9	28.7-43.1	70.0	56.0-84.0
Sodium										
Abbott Architect	mEq/L	89	71-107	151	120-181	mmol/L	89	71-107	151	120-181
Beckman Coulter AU Instruments*	mEq/L	90	72-108	151	121-182	mmol/L	90	72-108	151	121-182
Roche Cobas / Cobas Integra*	mEq/L	91	72-109	154	123-184	mmol/L	91	72-109	154	123-184
Siemens Dimension *	mEq/L	88	70-106	143	114-171	mmol/L	88	70-106	143	114-171
Siemens Dimension Vista*	mEq/L	90	72-108	144	115-172	mmol/L	90	72-108	144	115-172
Total Protein										
Abbott Architect*	mg/dL	15.3	12.2-18.4	49.1	39.3-58.9	g/L	0.15	0.12-0.18	0.49	0.39-0.59
Beckman Coulter AU Instruments (Pyrogallol Red)	mg/dL	16.5	13.2-19.8	56.5	45.2-67.8	g/L	0.17	0.13-0.20	0.57	0.45-0.68
Beckman Coulter AU Instruments (QTT Red) *	mg/dL	15.6	12.5-18.7	49.9	39.9-59.9	g/L	0.16	0.12-0.19	0.50	0.40-0.60
Pointe Scientific (Pyrogallol Red) All Instruments*	mg/dL	13.2	10.6-15.8	49.2	39.4-59.0	g/L	0.13	0.11 - 0.16	0.49	0.39 - 0.59
Siemens Dimension (Pyrogallol Red) *	mg/dL	21.9	17.5-26.2	66.9	53.5-80.3	g/L	0.22	0.17-0.26	0.67	0.54-0.80
Siemens Dimension Vista* (Pyrogallol Red) *	mg/dL	22.2	17.8-26.6	67.6	54.1-81.1	g/L	0.22	0.18-0.27	0.68	0.54-0.81
Urea Nitrogen³										
Abbott Architect*	mg/dL	404	323-484	653	523-784	mmol/L	144	115-180	233	187-265
Beckman Coulter AU Instruments*	mg/dL	444	355-533	708	566-849	mmol/L	159	127-190	253	202-303
Siemens Dimension *	mg/dL	455	364-546	711	568-853	mmol/L	162	130-195	254	203-304
Siemens Dimension Vista*	mg/dL	460	368-552	706	565-847	mmol/L	164	131-197	252	202-302
Uric Acid										
Abbott Architect*	mg/dL	7.0	5.6-8.4	16.7	13.4-20.1	µmol/L	417	334-501	994	795-1193
Beckman Coulter AU Instruments*	mg/dL	8.0	6.4-9.6	19.1	15.3-23.0	µmol/L	475	380-570	1139	911-1366
Siemens Dimension *	mg/dL	11.0	8.8-13.2	19.8	15.8-23.8	µmol/L	653	523-784	1177	942-1413
Siemens Dimension Vista*	mg/dL	11.8	9.4-14.2	20.5	16.4-24.6	µmol/L	702	561-842	1220	976-1464

* Mean and range based on limited data. Each lab should establish its own mean and range.

(1) SI International System of Units

(3) To convert the product insert values from Urea Nitrogen to Urea: mg Urea Nitrogen x 2.146 = mg Urea