POINTE SCIENTIFIC
A MEDTEST COMPANY

Human Urine Control Set

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.

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. 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 18 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.

Note:
When using Vitros Slides for creatinine with this control, dilute the control 1:42 instead of the normal 1:21. Run as usual and correct for the dilution.

REF P7582-CTL

LOT 514102

2016-10-31

2°C 8°C

IVD

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Pointe Scientific, Inc.

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CE

P803-P7582-06 Rev. 06/15 MO43038A-11/13

Human Urine Control Set

Analytes/Instruments	Level 1	Lot# 514102	Level 2	Lot# 514102	Units	Level 1	Lot# 514102	Level 2	Lot# 514102	S.I. Unit
	Mean	Expected Range	Mean	Expected Range		Mean	Expected Range	Mean	Expected Range	(1)
Amylase										
Abbott Architect	95	76-114	179	143-214	U/L	95	76-114	179	143-214	U/L
Beckman Coulter® AU™ Instruments	76	61-92	142	114-170	U/L	76	61-92	142	114-170	U/L
Siemens Dimension®	98	78-117	191	153-229	U/L	98	78-117	191	153-229	U/L
Siemens Dimension Vista®*	103	82-123	195	156-234	U/L	103	82-123	195	156-234	U/L
Calcium										
Abbott Architect	6.7	5.4-8.1	10.6	8.5-12.7	mg/dL	1.68	1.35-2.02	2.65	2.12-3.18	mmol/L
Beckman Coulter AU Instruments	6.7	5.4-8.1	10.9	8.7-13.0	mg/dL	1.68	1.35-2.03	2.73	2.18-3.25	mmol/L
Beckman Coulter Synchron	7.0	5.6-8.3	10.6	8.5-12.8	mg/dL	1.74	1.39-2.09	2.66	2.13-3.19	mmol/L
Roche cobas® 8000 modular analyzer (cobas® c502)*	7.0	5.6-8.4	11.1	8.9-13.3	mg/dL	1.75	1.40-2.11	2.77	2.21-3.32	mmol/L
Siemens Advia®*	7.0	5.6-8.4	10.9	8.7-13.1	mg/dL	1.74	1.39-2.09	2.73	2.19-3.28	mmol/L
Siemens Dimension	7.3	5.9-8.8	11.7	9.3-14.0	mg/dL	1.83	1.48-2.20	2.93	2.33-3.50	mmol/L
Siemens Dimension Vista*	7.3	5.8-8.7	11.3	9.1-13.6	mg/dL	1.81	1.45-2.18	2.83	2.26-3.10	mmol/L
Chloride										
Abbott Architect	86	69-103	127	102-153	mEq/L	86	69-103	127	102-153	mmol/L
Beckman Coulter® AU™	91	73-109	135	108-162	mEq/L	91	73-109	135	108-162	mmol/L
Beckman Coulter Synchron®	86	69-103	129	103-155	mEq/L	86	69-103	129	103-155	mmol/L
Roche cobas® 8000 modular analyzer (cobas® c502)*	78	63-94	123	98-148	mEq/L	78	63-94	123	98-148	mmol/L
Siemens Advia®*	89	71-107	133	106-159	mEq/L	89	71-107	133	106-159	mmol/L
Siemens Dimension®*	100	80-119	154	123-185	mEq/L	100	80-119	154	123-185	mmol/L
Siemens Dimension Vista®*	94	75-113	145	116-174	mEq/L	94	75-113	145	116-174	mmol/L
Creatinine										
Abbott Architect	79	63-95	152	122-182	mg/dL	7.00	5.60-8.40	13.43	10.74-16.12	mmol/L
Beckman Coulter AU Instruments	93	74-111	165	132-198	mg/dL	8.22	6.54-9.81	14.59	11.67-17.50	mmol/L
Beckman Coulter Synchron	84	67-101	158	127-190	mg/dL	7.45	5.96-8.94	13.99	11.19-16.79	mmol/L
Roche cobas® 8000 modular analyzer (cobas® c502)*	78	62-93	149	119-178	mg/dL	6.85	5.48-8.22	13.13	10.50-15.75	mmol/L
Siemens Advia*	81	65-97	150	120-180	mg/dL	7.17	5.74-8.61	13.24	10.59-15.89	mmol/L
Siemens Dimension	80	64-96	156	125-187	mg/dL	7.07	5.66-8.49	13.79	11.05-16.53	mmol/L
Siemens Dimension Vista*	81	65-98	158	126-190	mg/dL	7.19	5.75-8.63	13.97	11.18-16.77	mmol/L
Glucose										
Abbott Architect	48	39-58	292	234-351	mg/dL	2.7	2.1-3.2	16.2	13.0-19.5	mmol/L
Beckman Coulter AU Instruments	51	41-61	300	240-359	mg/dL	2.8	2.3-3.4	16.7	13.3-19.9	mmol/L
Beckman Coulter Synchron	50	40-60	289	231-347	mg/dL	2.8	2.2-3.3	16.1	12.8-19.3	mmol/L
Siemens Advia*	49	39-59	287	230-345	mg/dL	2.7	2.2-3.3	15.9	12.8-19.1	mmol/L
Siemens Dimension	49	40-59	289	231-346	mg/dL	2.7	2.2-3.3	16.0	12.8-19.2	mmol/L
Siemens Dimension Vista*	47	38-57	276	221-332	mg/dL	2.6	2.1-3.1	15.3	12.3-18.4	mmol/L
Magnesium										
Abbott Architect	7.7	6.2-9.3	13.6	10.9-16.3	mg/dL	3.18	2.55-3.82	5.60	4.48-6.72	mmol/L
Beckman Coulter AU Instruments*[4]	9.4	7.5-11.2	15.6	12.5-18.7	mg/dL	3.86	3.08-4.60	6.41	5.14-7.69	mmol/L
Beckman Coulter Synchron	7.3	5.8-8.7	12.3	9.8-14.8	mg/dL	2.99	2.39-3.58	5.05	4.04-6.06	mmol/L
Roche cobas® 8000 modular analyzer (cobas® c502)*	9.6	7.7-11.5	16.0	12.8-19.2	mg/dL	3.95	3.16-4.73	6.56	5.25-7.87	mmol/L
Siemens Advia*	7.9	6.3-9.5	13.4	10.7-16.1	mg/dL	3.25	2.60-3.89	5.50	4.40-6.60	mmol/L
Siemens Dimension	9.0	7.2-10.8	15.2	12.2-18.3	mg/dL	3.70	2.96-4.44	6.25	5.01-7.52	mmol/L
Siemens Dimension Vista*	9.2	7.4-11.0	15.3	12.3-18.4	mg/dL	3.78	3.02-4.54	6.30	5.04-7.56	mmol/L

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Osmolality										
Advanced Instruments Micro-Osmometer / Fiske Osmometer	451	361-541	774	619-928	mOsm/Kg	451	361-541	774	766-782	mmol/Kg
Phosphorus										
Abbott Architect	24.3	19.4-29.1	47.1	37.7-56.5	mg/dL	7.84	6.27-9.41	15.22	12.17-18.26	mmol/L
Beckman Coulter AU Instruments	25.4	20.3-30.4	50.1	40.1-60.1	mg/dL	8.20	6.56-9.82	16.18	12.95-19.41	mmol/L
Beckman Coulter Synchron	24.3	19.4-29.1	48.3	38.6-58.0	mg/dL	7.83	6.27-9.40	15.60	12.48-18.72	mmol/L
Roche cobas® 8000 modular analyzer (cobas® c502)*	25.5	20.4-30.6	49.5	39.6-59.4	mg/dL	8.24	6.59-9.88	15.99	12.79-19.19	mmol/L
Siemens Advia*	25.9	20.7-31.1	49.4	39.5-59.2	mg/dL	8.36	6.69-10.04	15.94	12.75-19.13	mmol/L
Siemens Dimension	25.2	20.2-30.3	49.5	39.6-59.4	mg/dL	8.14	6.52-9.79	15.99	12.79-19.19	mmol/L
Siemens Dimension Vista*	23.1	18.5-27.7	46.0	36.8-55.1	mg/dL	7.46	5.97-8.96	14.84	11.87-17.81	mmol/L
Potassium										
Abbott Architect	35.0	28.0-42.0	68.3	54.6-81.9	mEq/L	35.0	28.0-42.0	68.3	54.6-81.9	mmol/L
Beckman Coulter AU Instruments	34.7	27.8-41.6	69.0	55.2-82.8	mEq/L	34.7	27.8-41.6	69.0	55.2-82.8	mmol/L
Beckman Coulter Synchron	34.9	27.9-41.9	68.0	54.4-81.6	mEq/L	34.9	27.9-41.9	68.0	54.4-81.6	mmol/L
Roche cobas® 8000 modular analyzer (cobas® c502)*	35.7	28.5-42.8	69.7	55.7-83.6	mEq/L	35.7	28.5-42.8	69.7	55.7-83.6	mmol/L
Siemens Advia*	35.1	28.1-42.2	69.7	55.7-83.6	mEq/L	35.1	28.1-42.2	69.7	55.7-83.6	mmol/L
Siemens Dimension	33.5	26.8-40.2	64.1	51.3-77.0	mEq/L	33.5	26.8-40.2	64.1	51.3-77.0	mmol/L
Siemens Dimension Vista*	31.6	25.3-37.9	59.7	47.7-71.6	mEq/L	31.6	25.3-37.9	59.7	47.7-71.6	mmol/L
Sodium										
Abbott Architect	86	69-103	147	117-176	mEq/L	86	69-103	147	117-176	mmol/L
Beckman Coulter AU Instruments	87	70-105	151	121-182	mEq/L	87	70-105	151	121-182	mmol/L
Beckman Coulter Synchron	88	71-106	147	117-176	mEq/L	88	71-106	147	117-176	mmol/L
Roche cobas® 8000 modular analyzer (cobas® c502)*	91	73-109	152	121-182	mEq/L	91	73-109	152	121-182	mmol/L
Siemens Advia*	88	70-105	148	118-177	mEq/L	88	70-105	148	118-177	mmol/L
Siemens Dimension	86	68-103	139	112-167	mEq/L	86	68-103	139	112-167	mmol/L
Siemens Dimension Vista*	82	66-99	131	105-157	mEq/L	82	66-99	131	105-157	mmol/L
Total Protein										
Abbott Architect	10.9	8.7-13.1	39.6	31.7-47.5	mg/dL	0.11	0.09-0.13	0.40	0.32-0.48	g/L
Beckman Coulter AU Instruments (Pyrogallol Red)*	13.2	10.6-15.9	48.7	39.0-58.5	mg/dL	0.13	0.11-0.16	0.49	0.39-0.59	g/L
Beckman Coulter AU Instruments (QTT Red Reagent)*	10.4	8.3-12.5	41.4	33.1-49.6	mg/dL	0.10	0.08-0.13	0.41	0.33-0.50	g/L
Beckman Coulter Synchron (Pyrogallol Red)	15.4	12.3-18.5	58.3	46.7-70.0	mg/dL	0.15	0.12-0.19	0.58	0.47-0.70	g/L
Pointe Scientific* (Pyrogallol Red)	10.1	8.1-12.1	43.9	35.1-52.7	mg/dL	0.10	0.08-0.12	0.44	0.35-0.53	g/L
Roche cobas® 8000 modular analyzer (cobas® c502)* (Benzethonium Chloride)*	9.0	7.0-11.0	38.7	30.9-46.4	mg/dL	0.09	0.07-0.11	0.39	0.31-0.46	g/L
Siemens Advia (Pyrogallol Red)*	9.4	7.5-11.3	45.0	36.0-54.0	mg/dL	0.09	0.08-0.11	0.45	0.36-0.54	g/L
Siemens Dimension (Pyrogallol Red)	18.4	14.7-22.1	58.5	46.8-70.2	mg/dL	0.18	0.15-0.22	0.59	0.47-0.70	g/L
Siemens Dimension Vista (Pyrogallol Red)*	19.1	15.3-23.0	60.1	48.0-72.1	mg/dL	0.19	0.15-0.23	0.60	0.48-0.72	g/L
Urea Nitrogen (3)										
Abbott Architect	408	326-489	613	490-735	mg/dL	146	116-175	219	175-263	mmol/L
Beckman Coulter AU Instruments	448	358-538	672	537-806	mg/dL	160	128-192	240	192-288	mmol/L
Beckman Coulter Synchron	439	351-527	657	526-789	mg/dL	157	125-188	235	188-282	mmol/L
Roche cobas® 8000 modular analyzer (cobas® c502)*	444	355-532	666	533-799	mg/dL	158	127-190	238	190-285	mmol/L
Siemens Advia*	457	366-549	682	545-818	mg/dL	163	131-196	243	195-292	mmol/L
Siemens Dimension	450	360-540	677	541-812	mg/dL	161	129-193	242	193-290	mmol/L
Siemens Dimension Vista*	423	338-508	635	508-763	mg/dL	151	121-181	227	181-272	mmol/L
Uric Acid										

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Abbott Architect	6.8	5.4-8.1	15.0	12.0-18.0	mg/dL	403	323-484	892	713-1070	umol/L
Beckman Coulter AU Instruments	7.9	6.3-9.5	17.8	14.3-21.4	mg/dL	470	375-565	1059	851-1273	umol/L
Beckman Coulter Synchron®	8.1	6.5-9.8	16.7	13.3-20.0	mg/dL	484	387-581	991	793-1190	umol/L
Roche cobas® 8000 modular analyzer (cobas® c502)*	6.7	5.4-8.0	15.8	12.6-18.9	mg/dL	399	319-478	937	749-1124	umol/L
Siemens Advia*	7.3	5.8-8.8	15.7	12.6-18.9	mg/dL	434	347-521	935	748-1122	umol/L
Siemens Dimension	7.5	6.0-9.0	15.6	12.5-18.7	mg/dL	446	357-535	928	744-1112	umol/L
Siemens Dimension Vista*	7.1	5.7-8.5	14.3	11.4-17.1	mg/dL	423	338-507	850	680-1019	umol/L

* Mean and range based on limited data.
(1) SI International System of Units
(2) Dilute 1:42 (See limitations section)
(3) To convert the product insert values from Urea Nitrogen to Urea: mg Urea Nitrogen x 2.146 = mg Urea
(4) Dilute 1:2