

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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Please see the corresponding US participant summary for any statistics not represented in this supplement.

International Data Supplement
2018 MLE-M1



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EVALUATION CRITERIA

The evaluation criteria used in the MLE Program is in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) federal requirements for proficiency testing. The criteria are included below.

Qualitative

For qualitative procedures, evaluation is based on participant or referee consensus. A minimum percentage of participants must receive a passing score or the challenge is not evaluated due to lack of consensus. These percentages are listed below.

Antimicrobial Susceptibility Testing	80% Consensus
Antinuclear Antibody	80% Consensus
Blood Bank	95% Consensus
Cytomegalovirus	80% Consensus
Microalbumin (Semi-Quantitative)	80% Consensus
Parasite Identification	80% Consensus
Rubella	80% Consensus
Syphilis Serology	80% Consensus
Toxoplasma	80% Consensus
Urine Dipstick	80% Consensus
Urine hCG	80% Consensus
Viral Markers	80% Consensus

Quantitative

For quantitative procedures, a mean and standard deviation (SD) are calculated for each peer group consisting of 10 or more laboratories. Acceptable performance is established based on a target value \pm the intervals below. An explanation on how to calculate the range of acceptability based upon these limits is also provided in your MLE Program Guide on page 37 under the heading "Acceptable Ranges for Quantitative Results."

Activated Partial Thromboplastin Time	\pm 15%
Automated Differential	\pm 3 SD
CK-MB (U/L)	\pm 3 SD
Cytomegalovirus	\pm 2 SD
Fibrinogen	\pm 20%
Hematocrit	\pm 6%
Hemoglobin	\pm 7%
International Normalized Ratio (INR)	\pm 20%
Platelet Count	\pm 25%
Prothrombin Time	\pm 15%
Red Blood Cell Count	\pm 6%
Rubella	\pm 3 SD
Specific Gravity	\pm 0.010
Toxoplasma	\pm 2 SD
White Blood Cell Count	\pm 15%

HEMATOLOGY W/ 5-PART DIFFERENTIAL—WHITE BLOOD CELL COUNT (x K/uL)

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	57	19.72	1.80	9.1	19.9	16.7 - 22.7	v	2.79	0.57	20.5	3.0	2.3 - 3.3
All Abbott Cell-Dyn Instruments	31	20.95	1.16	5.5	20.8	17.8 - 24.1	38	3.25	0.22	6.6	3.2	2.7 - 3.8
Abbott Cell-Dyn Ruby	27	21.12	0.95	4.5	20.9	17.9 - 24.3	32	3.28	0.22	6.7	3.2	2.7 - 3.8
Orpheo Mythic 22	24	18.07	0.84	4.7	18.2	15.3 - 20.8	28	2.16	0.16	7.4	2.1	1.8 - 2.5
Specimen CL-3						Specimen CL-4						
All Method	58	7.13	0.72	10.2	7.5	6.0 - 8.2	58	2.93	0.45	15.3	3.1	2.4 - 3.4
All Abbott Cell-Dyn Instruments	32	7.71	0.28	3.7	7.7	6.5 - 8.9	30	3.30	0.11	3.3	3.3	2.8 - 3.8
Abbott Cell-Dyn Ruby	28	7.77	0.22	2.9	7.7	6.6 - 9.0	27	3.30	0.10	3.0	3.3	2.8 - 3.8
Orpheo Mythic 22	24	6.37	0.28	4.4	6.4	5.4 - 7.4	24	2.47	0.17	6.8	2.4	2.0 - 2.9
Specimen CL-5												
All Method	57	19.61	1.80	9.2	20.1	16.6 - 22.6						
All Abbott Cell-Dyn Instruments	31	20.89	1.06	5.1	20.8	17.7 - 24.1						
Abbott Cell-Dyn Ruby	27	21.06	0.88	4.2	20.8	17.9 - 24.3						
Orpheo Mythic 22	24	17.89	0.78	4.4	18.0	15.2 - 20.6						

HEMATOLOGY W/ 5-PART DIFFERENTIAL—RED BLOOD CELL COUNT (x M/uL)

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	57	5.280	0.131	2.5	5.28	4.96 - 5.60	58	2.171	0.051	2.3	2.18	2.04 - 2.31
All Abbott Cell-Dyn Instruments	29	5.344	0.110	2.1	5.34	5.02 - 5.67	31	2.190	0.051	2.3	2.18	2.05 - 2.33
Abbott Cell-Dyn Ruby	26	5.353	0.111	2.1	5.36	5.03 - 5.68	28	2.186	0.045	2.0	2.18	2.05 - 2.32
Orpheo Mythic 22	26	5.220	0.112	2.1	5.23	4.90 - 5.54	26	2.158	0.053	2.4	2.15	2.02 - 2.29
Specimen CL-3						Specimen CL-4						
All Method	60	4.489	0.113	2.5	4.50	4.21 - 4.76	59	2.164	0.054	2.5	2.17	2.03 - 2.30
All Abbott Cell-Dyn Instruments	32	4.517	0.100	2.2	4.53	4.24 - 4.79	32	2.178	0.043	2.0	2.17	2.04 - 2.31
Abbott Cell-Dyn Ruby	28	4.534	0.079	1.7	4.54	4.26 - 4.81	28	2.175	0.042	1.9	2.17	2.04 - 2.31
Orpheo Mythic 22	26	4.461	0.121	2.7	4.43	4.19 - 4.73	25	2.149	0.061	2.8	2.14	2.01 - 2.28
Specimen CL-5												
All Method	60	5.251	0.148	2.8	5.27	4.93 - 5.57						
All Abbott Cell-Dyn Instruments	32	5.302	0.129	2.4	5.33	4.98 - 5.62						
Abbott Cell-Dyn Ruby	28	5.329	0.111	2.1	5.34	5.00 - 5.65						
Orpheo Mythic 22	26	5.200	0.149	2.9	5.16	4.88 - 5.52						

HEMATOLOGY W/ 5-PART DIFFERENTIAL—HEMOGLOBIN (g/dL)

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	60	16.09	1.00	6.2	16.3	14.9 - 17.3	60	5.11	0.54	10.6	5.4	4.7 - 5.5
All Abbott Cell-Dyn Instruments	31	16.87	0.39	2.3	16.8	15.6 - 18.1	32	5.59	0.16	2.8	5.6	5.1 - 6.0
Abbott Cell-Dyn Ruby	27	16.90	0.37	2.2	16.8	15.7 - 18.1	28	5.55	0.11	2.0	5.6	5.1 - 6.0
Orpheo Mythic 22	26	15.13	0.36	2.3	15.1	14.0 - 16.2	26	4.55	0.11	2.3	4.5	4.2 - 4.9
Specimen CL-3						Specimen CL-4						
All Method	59	12.58	1.02	8.1	13.1	11.7 - 13.5	60	5.14	0.55	10.8	5.5	4.7 - 5.6
All Abbott Cell-Dyn Instruments	32	13.46	0.27	2.0	13.4	12.5 - 14.5	29	5.54	0.08	1.5	5.5	5.1 - 6.0
Abbott Cell-Dyn Ruby	28	13.50	0.25	1.9	13.5	12.5 - 14.5	28	5.55	0.08	1.5	5.5	5.1 - 6.0
Orpheo Mythic 22	25	11.52	0.24	2.1	11.5	10.7 - 12.4	25	4.55	0.11	2.5	4.5	4.2 - 4.9
Specimen CL-5												
All Method	60	16.01	0.92	5.8	16.1	14.8 - 17.2						
All Abbott Cell-Dyn Instruments	32	16.78	0.39	2.3	16.8	15.6 - 18.0						
Abbott Cell-Dyn Ruby	28	16.81	0.35	2.1	16.8	15.6 - 18.0						
Orpheo Mythic 22	26	15.12	0.37	2.4	15.1	14.0 - 16.2						

HEMATOLOGY W/ 5-PART DIFFERENTIAL—HEMATOCRIT (percent)

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	60	46.66	2.19	4.7	46.7	43.8 - 49.5	57	15.74	0.81	5.1	15.7	14.7 - 16.7
All Abbott Cell-Dyn Instruments	32	45.64	2.11	4.6	45.8	42.8 - 48.4	30	15.14	0.44	2.9	15.1	14.2 - 16.1
Abbott Cell-Dyn Ruby	28	45.38	1.70	3.7	45.7	42.6 - 48.2	28	15.16	0.40	2.6	15.1	14.2 - 16.1
Orpheo Mythic 22	26	47.95	1.63	3.4	47.7	45.0 - 50.9	24	16.44	0.49	3.0	16.4	15.4 - 17.5
Specimen CL-3						Specimen CL-4						
All Method	59	38.35	1.76	4.6	38.2	36.0 - 40.7	58	15.73	0.89	5.6	15.6	14.7 - 16.7
All Abbott Cell-Dyn Instruments	30	37.16	1.23	3.3	37.2	34.9 - 39.4	30	15.11	0.56	3.7	15.0	14.2 - 16.1
Abbott Cell-Dyn Ruby	27	37.03	0.97	2.6	37.2	34.8 - 39.3	28	15.01	0.38	2.5	15.0	14.1 - 16.0
Orpheo Mythic 22	26	39.61	1.23	3.1	39.6	37.2 - 42.0	24	16.35	0.47	2.8	16.3	15.3 - 17.4
Specimen CL-5												
All Method	59	46.36	2.18	4.7	46.1	43.5 - 49.2						
All Abbott Cell-Dyn Instruments	31	45.37	2.14	4.7	45.0	42.6 - 48.1						
Abbott Cell-Dyn Ruby	27	44.82	1.33	3.0	44.9	42.1 - 47.6						
Orpheo Mythic 22	26	47.58	1.67	3.5	47.4	44.7 - 50.5						

HEMATOLOGY W/ 5-PART DIFFERENTIAL-PLATELET COUNT (x K/uL)

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	60	497.0	35.0	7.0	499	372 - 622	59	92.9	16.0	17.2	89	69 - 117
All Abbott Cell-Dyn Instruments	31	488.9	27.5	5.6	484	366 - 612	30	80.6	6.4	7.9	80	60 - 101
Abbott Cell-Dyn Ruby	28	489.0	28.1	5.8	483	366 - 612	27	79.7	5.8	7.3	79	59 - 100
Orpheo Mythic 22	26	503.5	35.9	7.1	504	377 - 630	26	105.4	10.0	9.5	104	79 - 132
Specimen CL-3						Specimen CL-4						
All Method	60	282.2	21.2	7.5	278	211 - 353	59	91.5	14.2	15.5	88	68 - 115
All Abbott Cell-Dyn Instruments	32	274.3	11.4	4.2	272	205 - 343	31	81.2	6.4	7.9	81	60 - 102
Abbott Cell-Dyn Ruby	28	273.5	11.5	4.2	272	205 - 342	28	80.0	5.4	6.7	81	60 - 101
Orpheo Mythic 22	26	292.7	24.8	8.5	294	219 - 366	25	103.1	10.5	10.2	103	77 - 129
Specimen CL-5												
All Method	60	489.7	32.9	6.7	489	367 - 613						
All Abbott Cell-Dyn Instruments	32	483.8	25.9	5.3	486	362 - 605						
Abbott Cell-Dyn Ruby	28	487.5	22.7	4.6	487	365 - 610						
Orpheo Mythic 22	26	497.7	38.8	7.8	498	373 - 623						

HEMATOLOGY W/ 5-PART DIFFERENTIAL—NEUTROPHILS (percent)

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	58	75.78	2.61	3.4	76.1	67.9 - 83.7	57	46.76	2.02	4.3	46.6	40.7 - 52.9
All Abbott Cell-Dyn Instruments	30	77.23	0.97	1.3	77.5	74.3 - 80.2	30	47.55	2.13	4.5	47.2	41.1 - 54.0
Abbott Cell-Dyn Ruby	27	77.41	0.71	0.9	77.5	75.2 - 79.6	27	47.79	2.09	4.4	47.4	41.5 - 54.1
Orpheo Mythic 22	24	75.08	0.82	1.1	75.3	72.6 - 77.6	26	45.77	1.40	3.1	46.0	41.5 - 50.0
Specimen CL-3						Specimen CL-4						
All Method	58	62.54	2.34	3.7	63.3	55.5 - 69.6	58	46.07	1.28	2.8	46.0	42.2 - 49.9
All Abbott Cell-Dyn Instruments	32	64.05	0.87	1.4	64.1	61.4 - 66.7	31	46.62	0.97	2.1	46.8	43.7 - 49.6
Abbott Cell-Dyn Ruby	28	64.04	0.71	1.1	64.1	61.9 - 66.2	28	46.67	0.93	2.0	46.8	43.8 - 49.5
Orpheo Mythic 22	24	60.87	2.10	3.4	61.1	54.5 - 67.2	26	45.38	1.30	2.9	45.2	41.4 - 49.3
Specimen CL-5												
All Method	56	76.22	1.68	2.2	76.0	71.1 - 81.3						
All Abbott Cell-Dyn Instruments	30	77.34	1.24	1.6	77.5	73.6 - 81.1						
Abbott Cell-Dyn Ruby	26	77.38	1.04	1.3	77.5	74.2 - 80.6						
Orpheo Mythic 22	24	75.08	0.88	1.2	75.2	72.4 - 77.8						

HEMATOLOGY W/ 5-PART DIFFERENTIAL—LYMPHOCYTES (percent)

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	57	15.16	2.25	14.9	15.7	8.4 - 22.0	60	35.93	7.93	22.1	38.5	12.1 - 59.8
All Abbott Cell-Dyn Instruments	30	16.57	1.19	7.2	16.5	13.0 - 20.2	31	42.17	2.46	5.8	42.1	34.7 - 49.6
Abbott Cell-Dyn Ruby	27	16.64	0.97	5.8	16.4	13.7 - 19.6	28	41.96	2.46	5.9	41.9	34.5 - 49.4
Orpheo Mythic 22	25	13.67	2.18	16.0	13.7	7.1 - 20.3	26	29.88	5.86	19.6	29.0	12.3 - 47.5
Specimen CL-3												
All Method	59	23.65	5.92	25.0	27.1	5.9 - 41.4	60	36.46	7.99	21.9	39.3	12.4 - 60.5
All Abbott Cell-Dyn Instruments	31	28.21	1.05	3.7	28.2	25.0 - 31.4	31	42.85	2.00	4.7	43.1	36.8 - 48.9
Abbott Cell-Dyn Ruby	28	28.23	1.07	3.8	28.3	25.0 - 31.5	28	42.75	2.04	4.8	43.1	36.6 - 48.9
Orpheo Mythic 22	25	19.14	4.56	23.8	18.8	5.4 - 32.9	25	29.46	4.58	15.6	29.7	15.7 - 43.3
Specimen CL-5												
All Method	57	15.25	2.35	15.4	15.6	8.2 - 22.3						
All Abbott Cell-Dyn Instruments	31	16.65	1.58	9.5	16.8	11.9 - 21.4						
Abbott Cell-Dyn Ruby	27	16.72	1.44	8.6	16.6	12.3 - 21.1						
Orpheo Mythic 22	25	13.56	2.05	15.1	13.5	7.4 - 19.8						

HEMATOLOGY W/ 5-PART DIFFERENTIAL—MONOCYTES (percent)

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	56	5.84	3.37	57.8	3.7	0.0 - 16.0	57	13.09	8.23	62.9	8.0	0.0 - 37.8
All Abbott Cell-Dyn Instruments	29	2.83	0.43	15.3	2.7	1.5 - 4.2	29	5.77	0.87	15.1	5.7	3.1 - 8.4
Abbott Cell-Dyn Ruby	27	2.81	0.44	15.6	2.7	1.4 - 4.2	26	5.86	0.85	14.5	5.7	3.3 - 8.5
Orpheo Mythic 22	24	9.20	1.24	13.5	9.0	5.4 - 13.0	25	20.92	4.43	21.2	19.9	7.6 - 34.3
Specimen CL-3												
All Method	56	9.68	6.51	67.3	4.4	0.0 - 29.3	58	12.98	8.11	62.5	8.6	0.0 - 37.4
All Abbott Cell-Dyn Instruments	29	3.70	0.45	12.2	3.8	2.3 - 5.1	31	6.00	1.39	23.1	5.7	1.8 - 10.2
Abbott Cell-Dyn Ruby	26	3.70	0.47	12.6	3.8	2.3 - 5.1	28	6.09	1.43	23.5	6.0	1.7 - 10.4
Orpheo Mythic 22	25	16.08	2.64	16.4	16.3	8.1 - 24.0	25	20.98	4.28	20.4	20.3	8.1 - 33.9
Specimen CL-5												
All Method	55	6.16	3.66	59.4	4.8	0.0 - 17.2						
All Abbott Cell-Dyn Instruments	27	2.77	0.44	15.8	2.8	1.4 - 4.1						
Abbott Cell-Dyn Ruby	25	2.79	0.45	16.0	2.8	1.4 - 4.2						
Orpheo Mythic 22	25	9.56	1.83	19.2	9.4	4.0 - 15.1						

HEMATOLOGY W/ 5-PART DIFFERENTIAL—EOSINOPHILS (percent)

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	60	2.23	0.78	35.3	2.5	0.0 - 4.6	59	3.59	0.87	24.2	3.7	0.9 - 6.2
All Abbott Cell-Dyn Instruments	29	2.73	0.20	7.5	2.7	2.1 - 3.4	29	3.97	0.48	12.2	4.0	2.5 - 5.5
Abbott Cell-Dyn Ruby	27	2.74	0.21	7.6	2.7	2.1 - 3.4	26	3.98	0.45	11.4	4.0	2.6 - 5.4
Orpheo Mythic 22	26	1.69	0.77	45.4	1.6	0.0 - 4.0	25	3.28	0.78	23.8	3.4	0.9 - 5.7
Specimen CL-3							Specimen CL-4					
All Method	56	3.47	0.73	21.0	3.5	1.2 - 5.7	59	3.67	0.77	20.8	3.7	1.3 - 6.0
All Abbott Cell-Dyn Instruments	31	3.62	0.29	8.0	3.6	2.7 - 4.5	30	3.94	0.40	10.2	4.1	2.7 - 5.2
Abbott Cell-Dyn Ruby	27	3.63	0.29	7.9	3.6	2.7 - 4.5	27	3.97	0.40	10.0	4.1	2.7 - 5.2
Orpheo Mythic 22	26	3.70	2.02	54.5	3.3	0.0 - 9.8	26	3.42	0.94	27.6	3.4	0.5 - 6.3
Specimen CL-5												
All Method	59	2.20	0.78	35.3	2.4	0.0 - 4.6						
All Abbott Cell-Dyn Instruments	29	2.69	0.19	7.1	2.7	2.1 - 3.3						
Abbott Cell-Dyn Ruby	26	2.68	0.20	7.3	2.7	2.0 - 3.3						
Orpheo Mythic 22	25	1.54	0.59	38.4	1.6	0.0 - 3.4						

HEMATOLOGY W/ 5-PART DIFFERENTIAL–BASOPHILS (percent)

<i>Instrument</i>	Specimen CL-1						Specimen CL-2					
	<i>Labs</i>	<i>Mean</i>	<i>SD</i>	<i>CV</i>	<i>Median</i>	<i>Range</i>	<i>Labs</i>	<i>Mean</i>	<i>SD</i>	<i>CV</i>	<i>Median</i>	<i>Range</i>
All Method	59	0.35	0.22	63.1	0.3	0.0 - 1.1	58	0.56	0.67	118.3	0.4	0.0 - 2.6
All Abbott Cell-Dyn Instruments	32	0.29	0.20	67.5	0.3	0.0 - 0.9	30	0.38	0.32	86.1	0.3	0.0 - 1.4
Abbott Cell-Dyn Ruby	28	0.29	0.21	72.4	0.2	0.0 - 1.0	26	0.34	0.27	80.2	0.3	0.0 - 1.2
Orpheo Mythic 22	26	0.42	0.24	56.5	0.4	0.0 - 1.2	26	0.61	0.43	71.5	0.6	0.0 - 2.0
Specimen CL-3							Specimen CL-4					
All Method	57	0.31	0.29	92.8	0.2	0.0 - 1.2	56	0.60	0.95	158.9	0.5	0.0 - 3.5
All Abbott Cell-Dyn Instruments	30	0.13	0.14	113.4	0.1	0.0 - 0.6	29	0.36	0.31	87.6	0.3	0.0 - 1.3
Abbott Cell-Dyn Ruby	26	0.13	0.15	114.8	0.1	0.0 - 0.6	26	0.36	0.33	89.9	0.3	0.0 - 1.4
Orpheo Mythic 22	24	0.48	0.26	54.0	0.5	0.0 - 1.3	25	0.62	0.42	68.0	0.5	0.0 - 1.9
Specimen CL-5												
All Method	56	0.31	0.20	64.8	0.3	0.0 - 1.0						
All Abbott Cell-Dyn Instruments	30	0.21	0.13	62.2	0.2	0.0 - 0.6						
Abbott Cell-Dyn Ruby	26	0.22	0.12	56.8	0.3	0.0 - 0.6						
Orpheo Mythic 22	26	0.46	0.28	59.8	0.4	0.0 - 1.3						

BLOOD BANK

ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-1	Group AB	38	100%	Acceptable
BB-2	Group B	38	100%	Acceptable
BB-3	Group A	38	100%	Acceptable
BB-4	Group A	38	100%	Acceptable
BB-5	Group O	38	100%	Acceptable

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-1	Rh Negative	38	100%	Acceptable
BB-2	Rh Positive	37	97.37%	Acceptable
	Rh Negative	1	2.63%	
BB-3	Rh Negative	38	100%	Acceptable
BB-4	Rh Positive	38	100%	Acceptable
BB-5	Rh Positive	38	100%	Acceptable

BLOOD BANK

UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	Unexpected antibody detected	23	95.83%	Acceptable
	No unexpected antibody detected	1	4.17%	
AB-2	No unexpected antibody detected	23	95.83%	Acceptable
	Unexpected antibody detected	1	4.17%	
AB-3	No unexpected antibody detected	23	95.83%	Acceptable
	Unexpected antibody detected	1	4.17%	
AB-4	No unexpected antibody detected	23	95.83%	Acceptable
	Unexpected antibody detected	1	4.17%	
AB-5	Unexpected antibody detected	23	95.83%	Acceptable
	No unexpected antibody detected	2	6.67%	

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	Anti-E	12	92.31%	Acceptable
	Anti-M	1	7.69%	
AB-2	No antibody detected	13	100%	Acceptable
	No antibody detected	13	100%	Acceptable
AB-4	No antibody detected	13	100%	Acceptable
	Anti-S	12	92.31%	Acceptable
AB-5	Anti-E	1	7.69%	

BLOOD BANK

COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	Compatible	25	100%	Acceptable
AB-2	Compatible	25	100%	Acceptable
AB-3	Compatible	25	100%	Acceptable
AB-4	Compatible	25	100%	Acceptable
AB-5	Not Compatible	24	96.00%	Acceptable
	Compatible	1	4.00%	

Coagulation

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-1						Specimen CG-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	104	29.87	4.47	15.0	31.0	25.3 - 34.4	104	22.41	2.97	13.2	23.2	19.0 - 25.8
Dade Innovin												
Dade Behring BFT II	5	27.53	1.52	5.5	28.1	23.3 - 31.7	5	19.33	0.34	1.8	19.4	16.4 - 22.3
Sysmex CA-500/600 series	20	26.19	1.45	5.5	26.5	22.2 - 30.2	20	19.79	0.85	4.3	20.0	16.8 - 22.8
All Coagulation Instruments	27	26.35	1.44	5.5	26.3	22.3 - 30.4	27	19.69	0.76	3.9	19.6	16.7 - 22.7
Diag Stago STA Neoplastine Cl+												
Diagnostica Stago STA Compact	11	32.62	2.10	6.4	33.0	27.7 - 37.6	11	23.63	1.06	4.5	23.7	20.0 - 27.2
Diagnostica Stago STart 4/8	5	33.00	3.32	10.0	33.7	28.0 - 38.0	5	24.10	2.40	9.9	23.4	20.4 - 27.8
RAL Clot-SP	19	33.88	1.14	3.4	33.8	28.7 - 39.0	19	25.60	0.73	2.9	25.7	21.7 - 29.5
All Coagulation Instruments	38	33.13	2.10	6.3	33.6	28.1 - 38.1	38	24.56	1.60	6.5	24.9	20.8 - 28.3
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	31.00	1.29	4.2	31.2	26.3 - 35.7	5	22.63	1.24	5.5	22.8	19.2 - 26.1
IL TEST PT Fibrinogen												
IL ACL, all models	5	20.94	1.02	4.9	20.7	17.7 - 24.1	5	17.30	0.71	4.1	17.4	14.7 - 19.9
IL TEST PT-FIB HS PLUS												
IL ACL, all models	13	33.39	2.08	6.2	33.4	28.3 - 38.5	13	24.77	1.52	6.1	24.7	21.0 - 28.5

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-3						Specimen CG-4					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	104	13.38	1.59	11.9	13.5	11.3 - 15.4	102	12.47	1.31	10.5	12.8	10.6 - 14.4
Dade Innovin												
Dade Behring BFT II	5	10.35	0.30	2.9	10.4	8.7 - 12.0	5	9.75	0.06	0.6	9.8	8.2 - 11.3
Sysmex CA-500/600 series	20	11.57	0.41	3.6	11.6	9.8 - 13.3	19	11.17	0.28	2.5	11.2	9.4 - 12.9
All Coagulation Instruments	27	11.47	0.69	6.0	11.6	9.7 - 13.2	26	10.94	0.58	5.3	11.0	9.3 - 12.6
Diag Stago STA Neoplastine CI+												
Diagnostic Stago STA Compact	11	14.07	0.48	3.4	14.0	11.9 - 16.2	10	12.89	0.34	2.6	12.8	10.9 - 14.9
Diagnostic Stago STart 4/8	5	13.50	1.08	8.0	13.6	11.4 - 15.6	5	12.92	0.94	7.2	13.0	10.9 - 14.9
RAL Clot-SP	19	15.02	0.69	4.6	14.9	12.7 - 17.3	19	13.93	0.36	2.6	13.9	11.8 - 16.1
All Coagulation Instruments	38	14.43	0.93	6.4	14.5	12.2 - 16.6	37	13.46	0.66	4.9	13.5	11.4 - 15.5
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	12.20	0.42	3.5	12.3	10.3 - 14.1	5	10.78	0.33	3.1	10.9	9.1 - 12.4
IL TEST PT Fibrinogen												
IL ACL, all models	5	12.88	0.24	1.9	12.9	10.9 - 14.9	5	12.14	0.18	1.5	12.1	10.3 - 14.0
IL TEST PT-FIB HS PLUS												
IL ACL, all models	13	14.73	0.97	6.6	14.8	12.5 - 17.0	13	13.08	0.79	6.0	13.2	11.1 - 15.1

PROTHROMBIN TIME (seconds)

Specimen CG-5

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	69	34.22	4.90	14.3	35.0	29.0 - 39.4
Dade Innovin						
Dade Behring BFT II	5	25.80	0.76	3.0	25.8	21.9 - 29.7
Sysmex CA-500/600 series	1	-	-	-	28.3	22.6 - 30.7
All Coagulation Instruments	7	26.64	1.24	4.7	26.6	22.6 - 30.7
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STA Compact	10	36.36	2.01	5.5	35.9	30.9 - 41.9
Diagnostica Stago STart 4/8	5	35.68	2.57	7.2	34.4	30.3 - 41.1
RAL Clot-SP	18	36.74	1.45	3.9	37.2	31.2 - 42.3
All Coagulation Instruments	35	36.24	1.98	5.5	36.2	30.8 - 41.7
HemosIL RecombiPlasTin 2G						
IL ACL, all models	2	-	-	-	28.5	29.0 - 39.4
IL TEST PT Fibrinogen						
IL ACL, all models	5	26.23	4.21	16.1	27.8	22.2 - 30.2
IL TEST PT-FIB HS PLUS						
IL ACL, all models	11	38.13	4.28	11.2	39.6	32.4 - 43.9

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-1						Specimen CG-2					
	Labs	Mean	SD	CV	Median	Range	Labs	Mean	SD	CV	Median	Range
All Method	99	2.85	0.46	16.2	2.8	2.2 - 3.5	99	2.04	0.26	12.9	2.0	1.6 - 2.5
Dade Innovin												
Dade Behring BFT II	5	2.68	0.13	4.7	2.7	2.1 - 3.3	5	1.95	0.06	3.0	2.0	1.5 - 2.4
Sysmex CA-500/600 series	18	2.60	0.08	3.2	2.6	2.0 - 3.2	19	1.96	0.10	5.2	2.0	1.5 - 2.4
All Coagulation Instruments	25	2.60	0.10	3.9	2.6	2.0 - 3.2	26	1.95	0.09	4.9	1.9	1.5 - 2.4
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STA Compact	7	2.99	0.48	16.0	2.9	2.3 - 3.6	7	1.97	0.28	14.3	2.1	1.5 - 2.4
Diagnostica Stago STart 4/8	5	3.46	0.40	11.7	3.4	2.7 - 4.2	5	2.32	0.31	13.4	2.3	1.8 - 2.8
RAL Clot-SP	17	3.39	0.17	4.9	3.4	2.7 - 4.1	17	2.33	0.12	5.2	2.3	1.8 - 2.8
All Coagulation Instruments	28	3.35	0.28	8.5	3.4	2.6 - 4.1	29	2.24	0.25	11.2	2.3	1.7 - 2.7
Diagnostica Stago Neoplastine CI Plus												
All Coagulation Instruments	5	3.18	0.18	5.6	3.3	2.5 - 3.9	5	2.14	0.15	7.1	2.2	1.7 - 2.6
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	2.70	0.35	12.8	2.8	2.1 - 3.3	5	2.13	0.46	21.5	2.1	1.7 - 2.6
IL TEST PT Fibrinogen												
IL ACL, all models	5	2.76	0.27	9.8	2.8	2.2 - 3.4	5	1.98	0.22	10.9	1.9	1.5 - 2.4
IL TEST PT-FIB HS PLUS												
IL ACL, all models	12	2.80	0.27	9.6	2.8	2.2 - 3.4	12	1.99	0.19	9.4	2.0	1.5 - 2.4

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-3						Specimen CG-4					
	Labs	Mean	SD	CV	Median	Range	Labs	Mean	SD	CV	Median	Range
All Method	97	1.12	0.10	8.5	1.1	0.8 - 1.4	95	1.02	0.09	8.4	1.0	0.8 - 1.3
Dade Innovin												
Dade Behring BFT II	5	1.15	0.06	5.0	1.2	0.9 - 1.4	5	1.10	0.01	0.0	1.1	0.8 - 1.4
Sysmex CA-500/600 series	19	1.13	0.07	5.8	1.1	0.9 - 1.4	18	1.08	0.04	3.5	1.1	0.8 - 1.3
All Coagulation Instruments	26	1.13	0.07	6.1	1.1	0.9 - 1.4	25	1.08	0.04	3.5	1.1	0.8 - 1.4
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STA Compact	7	1.04	0.14	13.4	1.1	0.8 - 1.3	5	0.96	0.09	9.3	1.0	0.7 - 1.2
Diagnostica Stago STart 4/8	5	1.12	0.11	9.8	1.2	0.8 - 1.4	5	1.04	0.09	8.6	1.0	0.8 - 1.3
RAL Clot-SP	17	1.16	0.08	6.9	1.2	0.9 - 1.4	17	1.04	0.06	5.9	1.0	0.8 - 1.3
All Coagulation Instruments	29	1.12	0.11	9.7	1.1	0.8 - 1.4	27	1.02	0.08	7.3	1.0	0.8 - 1.3
Diagnostica Stago Neoplastine CI Plus												
All Coagulation Instruments	5	1.06	0.09	8.4	1.1	0.8 - 1.3	5	0.94	0.09	9.5	1.0	0.7 - 1.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	1.05	0.13	12.3	1.1	0.8 - 1.3	5	0.90	0.08	9.1	0.9	0.7 - 1.1
IL TEST PT Fibrinogen												
IL ACL, all models	5	1.20	0.01	0.0	1.2	0.9 - 1.5	5	1.06	0.05	5.2	1.1	0.8 - 1.3
IL TEST PT-FIB HS PLUS												
IL ACL, all models	12	1.10	0.07	6.7	1.1	0.8 - 1.4	12	0.97	0.07	6.7	1.0	0.7 - 1.2

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

Specimen CG-5

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	64	3.43	0.66	19.2	3.6	2.7 - 4.2
Dade Innovin						
Dade Behring BFT II	5	2.55	0.10	3.9	2.5	2.0 - 3.1
Sysmex CA-500/600 series	1	-	-	-	2.4	2.0 - 3.1
All Coagulation Instruments	7	2.56	0.11	4.4	2.5	2.0 - 3.1
Diag Stago STA Neoplastine Cl+						
Diagnostica Stago STA Compact	6	3.57	0.59	16.6	3.8	2.8 - 4.3
Diagnostica Stago STart 4/8	5	3.78	0.36	9.6	3.9	3.0 - 4.6
RAL Clot-SP	16	3.79	0.17	4.5	3.8	3.0 - 4.6
All Coagulation Instruments	26	3.78	0.25	6.7	3.8	3.0 - 4.6
Diagnostica Stago Neoplastine CI Plus						
All Coagulation Instruments	5	3.34	0.27	8.1	3.5	2.6 - 4.1
HemosIL RecombiPlasTin 2G						
IL ACL, all models	3	-	-	-	2.5	2.7 - 4.2
IL TEST PT Fibrinogen						
IL ACL, all models	3	-	-	-	4.6	3.7 - 5.7
IL TEST PT-FIB HS PLUS						
IL ACL, all models	10	3.37	0.46	13.7	3.4	2.6 - 4.1

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

<u>Reagent/Instrument</u>	Specimen CG-1						Specimen CG-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	63	44.7	6.1	13.7	45	38 - 52	62	39.0	4.8	12.4	39	33 - 45
Dade Actin FSL												
Sysmex CA-500/600 series	10	38.4	1.6	4.3	39	32 - 45	10	34.5	1.6	4.6	34	29 - 40
All Coagulation Instruments	12	38.7	1.6	4.2	39	32 - 45	12	34.5	1.4	4.2	34	29 - 40
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	11	48.4	2.7	5.6	47	41 - 56	11	41.7	2.0	4.7	41	35 - 48
Diagnostica Stago STArt 4/8	5	49.7	4.5	9.1	50	42 - 58	5	41.3	3.2	7.8	40	35 - 48
All Coagulation Instruments	15	48.5	3.0	6.1	47	41 - 56	15	41.6	2.1	5.0	41	35 - 48
IL TEST APTT-SP												
IL ACL, all models	15	45.2	3.0	6.7	45	38 - 52	15	38.4	1.9	5.0	39	32 - 45

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

<u>Reagent/Instrument</u>	Specimen CG-3						Specimen CG-4					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	63	29.7	4.0	13.3	30	25 - 35	62	29.8	4.8	16.0	30	25 - 35
Dade Actin FSL												
Sysmex CA-500/600 series	10	24.8	1.0	4.2	25	21 - 29	10	23.9	0.7	3.1	24	20 - 28
All Coagulation Instruments	12	25.2	1.3	5.3	25	21 - 29	12	24.0	0.7	3.1	24	20 - 28
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	11	33.6	1.7	5.0	34	28 - 39	10	33.0	1.4	4.3	33	28 - 38
Diagnostica Stago STArt 4/8	5	32.0	2.0	6.3	32	27 - 37	5	33.0	2.6	8.0	32	28 - 38
All Coagulation Instruments	15	33.2	1.8	5.4	33	28 - 39	14	33.1	1.7	5.0	33	28 - 39
IL TEST APTT-SP												
IL ACL, all models	15	30.5	1.4	4.6	30	25 - 36	15	29.7	1.1	3.8	30	25 - 35
Specimen CG-5												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	46	78.0	12.9	16.5	78	66 - 90						
Dade Actin FSL												
Sysmex CA-500/600 series	10	67.5	9.0	13.4	69	57 - 78						
All Coagulation Instruments	12	67.7	8.9	13.2	69	57 - 78						
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	10	88.9	6.0	6.7	88	75 - 103						
Diagnostica Stago STArt 4/8	5	90.0	11.1	12.4	88	76 - 104						
All Coagulation Instruments	13	89.2	6.9	7.8	88	75 - 103						
IL TEST APTT-SP												
IL ACL, all models	7	79.1	6.6	8.4	79	67 - 92						

FIBRINOGEN (mg/dL)

<u>Reagent/Instrument</u>	Specimen CG-1						Specimen CG-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	35	288.9	40.6	14.1	288	231 - 347	34	294.3	36.8	12.5	291	235 - 354
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	12	263.1	26.7	10.1	268	210 - 316	12	276.5	17.7	6.4	279	221 - 332
All Coagulation Instruments	14	264.2	25.9	9.8	268	211 - 318	14	275.8	17.3	6.3	279	220 - 331
IL Fibrinogen-C												
IL ACL, all models	6	313.2	28.7	9.2	303	250 - 376	6	325.3	35.4	10.9	312	260 - 391
IL TEST PT-FIB HS PLUS												
IL ACL, all models	9	319.4	37.8	11.8	327	255 - 384	9	312.1	37.6	12.0	316	249 - 375
Specimen CG-3							Specimen CG-4					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	35	288.9	29.2	10.1	290	231 - 347	34	420.2	45.6	10.8	425	336 - 505
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	12	281.3	18.6	6.6	286	225 - 338	12	399.9	98.9	24.7	416	319 - 480
All Coagulation Instruments	14	280.8	17.7	6.3	285	224 - 337	13	426.5	34.1	8.0	426	341 - 512
IL Fibrinogen-C												
IL ACL, all models	6	340.2	36.5	10.7	329	272 - 409	6	464.0	35.0	7.5	453	371 - 557
IL TEST PT-FIB HS PLUS												
IL ACL, all models	9	291.3	30.6	10.5	292	233 - 350	9	395.9	34.9	8.8	391	316 - 476
Specimen CG-5												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	27	101.6	12.9	12.7	101	81 - 122						
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	11	98.3	10.2	10.4	99	78 - 118						
All Coagulation Instruments	12	98.5	9.8	9.9	100	78 - 119						
IL Fibrinogen-C												
IL ACL, all models	5	96.0	18.7	19.5	89	76 - 116						
IL TEST PT-FIB HS PLUS												
IL ACL, all models	7	103.6	10.2	9.9	103	82 - 125						

URINALYSIS DIPSTICK-SPECIFIC GRAVITY

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	359	1.0225	0.0056	0.6	1.020	1.012 - 1.033
All Arkay Methods	16	1.0275	0.0023	0.2	1.028	1.017 - 1.038
All DIRUI Methods	20	1.0240	0.0040	0.4	1.025	1.013 - 1.034
All Iris Diagnostics Methods	16	1.0268	0.0008	0.1	1.027	1.016 - 1.037
All Refractive Index Methods	43	1.0280	0.0024	0.2	1.028	1.018 - 1.039
All Roche Methods	118	1.0182	0.0048	0.5	1.015	1.008 - 1.029
All Siemens Methods	34	1.0194	0.0023	0.2	1.020	1.009 - 1.030
77 Elektronika LabUMat/2	18	1.0299	0.0027	0.3	1.031	1.019 - 1.040
Arkray Auton Sticks	12	1.0273	0.0024	0.2	1.027	1.017 - 1.038
DIRUI H-100 / H-500 Urine Analyzer	15	1.0230	0.0025	0.2	1.025	1.013 - 1.033
Iris Diagnostics iChem Velocity Strips	13	1.0268	0.0009	0.1	1.027	1.016 - 1.037
Other Analyzer Method	14	1.0260	0.0054	0.5	1.025	1.016 - 1.036
Roche Chemstrips / Combur	15	1.0190	0.0039	0.4	1.020	1.009 - 1.029
Roche cobas 6500 / u 601	10	1.0302	0.0012	0.1	1.031	1.020 - 1.041
Roche cobas u 411	74	1.0165	0.0022	0.2	1.015	1.006 - 1.027
Roche Urisys	43	1.0209	0.0064	0.6	1.020	1.010 - 1.031
SD UroColor Reagent Strips	21	1.0279	0.0030	0.3	1.030	1.017 - 1.038
Siemens Clinitek Advantus	18	1.0203	0.0021	0.2	1.020	1.010 - 1.031
Siemens Clinitek Status / Status+	15	1.0183	0.0025	0.2	1.020	1.008 - 1.029
UriScan Pro/II	10	1.0212	0.0048	0.5	1.020	1.011 - 1.032
UriScan Reagent Strips	17	1.0247	0.0021	0.2	1.025	1.014 - 1.035

URINALYSIS DIPSTICK-pH

Specimen UA-1

<u>Method</u>	<u>Labs</u>	Participant Results											
		<u>≤3.5</u>	<u>4.0</u>	<u>4.5</u>	<u>5.0</u>	<u>5.5</u>	<u>6.0</u>	<u>6.5</u>	<u>7.0</u>	<u>7.5</u>	<u>8.0</u>	<u>8.5</u>	<u>≥9.0</u>
ALL METHODS	384	-	-	-	294	54	35	1	-	-	-	-	-
77 Elektronika LabUMat/2	19	-	-	-	19	-	-	-	-	-	-	-	-
Acon Laboratories	10	-	-	-	6	1	3	-	-	-	-	-	-
Analyticon CombiScan 500	3	-	-	-	3	-	-	-	-	-	-	-	-
Arkray Aution Jet	3	-	-	-	2	1	-	-	-	-	-	-	-
Arkray Aution Sticks	16	-	-	-	12	3	1	-	-	-	-	-	-
Combi-Screen Test Strips	9	-	-	-	9	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	15	-	-	-	9	5	1	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	5	-	-	-	1	3	1	-	-	-	-	-	-
HUMAN Combilyzer	2	-	-	-	2	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	1	1	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	12	-	-	-	12	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	-	-	-	3	-	-	-	-	-	-	-	-
Other Analyzer Method	15	-	-	-	9	6	-	-	-	-	-	-	-
Other Dipstick Method	8	-	-	-	5	1	2	-	-	-	-	-	-
Plasmatec URIPATH	2	-	-	-	2	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	20	-	-	-	20	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	10	-	-	-	10	-	-	-	-	-	-	-	-
Roche cobas u 411	76	-	-	-	74	-	2	-	-	-	-	-	-
Roche UriSys	43	-	-	-	41	-	1	1	-	-	-	-	-
SD UroColor Reagent Strips	20	-	-	-	9	3	8	-	-	-	-	-	-
Siemens Clinitek 500	1	-	-	-	-	-	1	-	-	-	-	-	-
Siemens Clinitek Advantus	20	-	-	-	2	16	2	-	-	-	-	-	-
Siemens Clinitek Atlas	2	-	-	-	1	1	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	15	-	-	-	7	8	-	-	-	-	-	-	-
Siemens Reagent Strips	15	-	-	-	6	-	9	-	-	-	-	-	-
Siemens Uristix	1	-	-	-	1	-	-	-	-	-	-	-	-
Urinometer	2	-	-	-	-	2	-	-	-	-	-	-	-
UriScan Pro/II	9	-	-	-	7	1	1	-	-	-	-	-	-
UriScan Reagent Strips	18	-	-	-	16	1	1	-	-	-	-	-	-
URIT Medical Uritest Analyzers	1	-	-	-	-	1	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	1	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–PROTEIN QUALITATIVE

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>10 - 20 mg/dL</u>	<u>30 - 70 mg/dL</u>	<u>75 mg/dL</u>	<u>100 - 200 mg/dL</u>	<u>≥300 - 600 mg/dL</u>	<u>>600 or ≥1000 mg/dL</u>
ALL METHODS	384	379	2	1	-	-	-	2	-	-	-	-	-
77 Elektronika LabUMat/2	19	19	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	10	9	-	-	-	-	-	1	-	-	-	-	-
Analyticon CombiScan 500	3	3	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	3	3	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	16	15	-	1	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	1	1	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	9	9	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	16	16	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	4	4	-	-	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	2	2	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	12	12	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	3	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	17	17	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	8	8	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	2	2	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	20	20	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	10	10	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	76	76	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	42	41	-	-	-	-	-	1	-	-	-	-	-
SD UroColor Reagent Strips	20	19	1	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	1	1	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	20	20	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	2	2	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	15	15	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	15	15	-	-	-	-	-	-	-	-	-	-	-
Siemens Uristix	1	1	-	-	-	-	-	-	-	-	-	-	-
Urinometer	2	2	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	9	9	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	18	17	1	-	-	-	-	-	-	-	-	-	-
URIT Medical Uriptest Analyzers	1	1	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uriptest Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Negative or Normal</u>	<u>Trace</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>Participant Results</u>			
								<u>30 - 100 mg/dL</u>	<u>150 - 300 mg/dL</u>	<u>500 mg/dL</u>	<u>>500 or ≥1000 or ≥2000 mg/dL</u>
ALL METHODS	386	8	21	42	24	20	63	13	33	19	143
77 Elektronika LabUMat/2	19	-	-	-	1	-	10	-	-	-	8
Acon Laboratories	10	1	-	-	1	1	3	-	3	1	-
Analyticon CombiScan 500	3	-	-	-	-	-	-	-	-	1	2
Arkray Aution Jet	3	-	-	-	-	-	3	-	-	-	-
Arkray Aution Sticks	16	-	-	-	-	1	10	-	1	2	2
Arkray PocketChem UA	1	-	-	-	-	-	-	-	-	-	1
Combi-Screen Test Strips	9	-	-	-	-	-	1	-	1	2	5
DIRUI H-100 / H-500 Urine Analyzer	16	1	-	8	1	-	1	3	1	1	-
DIRUI H-800 Urine Analyzer	4	-	-	-	1	2	-	-	-	1	-
HUMAN Combilyzer	2	-	-	-	-	1	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	2	-	-	-	-
Iris Diagnostics iChem Velocity Strips	12	-	-	-	1	2	-	-	4	5	-
Iris Ichem VELOCITY Urine Chemistry System	3	-	-	-	1	-	-	-	1	1	-
Other Analyzer Method	17	1	-	1	3	-	5	-	2	-	5
Other Dipstick Method	8	-	1	2	-	1	3	-	-	-	1
Plasmatec URIPATH	2	2	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	20	-	-	-	2	4	11	1	-	-	2
Roche cobas 6500 / u 601	10	-	-	-	-	-	1	-	-	1	8
Roche cobas u 411	76	-	-	-	-	1	1	-	3	1	70
Roche Urisys	43	-	-	-	-	1	8	-	1	-	33
SD UroColor Reagent Strips	21	-	1	5	2	3	1	1	4	2	2
Siemens Clinitek 500	1	-	-	-	-	-	-	1	-	-	-
Siemens Clinitek Advantus	20	-	7	3	-	-	-	4	6	-	-
Siemens Clinitek Atlas	2	-	-	-	-	-	-	-	-	-	2
Siemens Clinitek Status / Status+	15	-	6	8	1	-	-	-	-	-	-
Siemens Reagent Strips	16	3	6	4	1	-	-	-	2	-	-
Siemens Uristix	1	-	-	-	-	-	-	-	-	-	1
Urinometer	2	-	-	-	1	-	-	-	-	1	-
UriScan Pro/II	9	-	-	3	2	-	-	2	2	-	-
UriScan Reagent Strips	17	-	-	7	6	2	-	-	2	-	-
URIT Medical Uritest Analyzers	1	-	-	-	-	-	1	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	1	-	-	-	-	-

URINALYSIS DIPSTICK-KETONES

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>Participant Results</u>								
							<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>5 - 10 mg/dL</u>	<u>15 - 25 mg/dL</u>	<u>40 - 60 mg/dL</u>	<u>80 - 100 mg/dL</u>	<u>≥150 mg/dL</u>
ALL METHODS	385	2	-	-	-	-	20	104	52	8	10	6	102	21	60
77 Elektronika LabUMat/2	19	-	-	-	-	-	1	10	-	-	-	1	7	-	-
Acon Laboratories	10	1	-	-	-	-	-	2	2	1	1	-	1	1	1
Analyticon CombiScan 500	3	-	-	-	-	-	-	1	-	-	-	-	-	2	-
Arkray Aution Jet	3	-	-	-	-	-	-	3	-	-	-	-	-	-	-
Arkray Aution Sticks	16	-	-	-	-	-	-	10	2	1	1	-	-	1	1
Arkray PocketChem UA	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Combi-Screen Test Strips	9	-	-	-	-	-	1	1	-	-	-	-	-	7	-
DIRUI H-100 / H-500 Urine Analyzer	16	-	-	-	-	-	7	6	-	-	1	1	1	-	-
DIRUI H-800 Urine Analyzer	4	-	-	-	-	-	1	2	-	-	-	-	1	-	-
HUMAN Combilyzer	2	-	-	-	-	-	-	1	1	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	-	2	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	12	-	-	-	-	-	-	1	1	-	-	-	10	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	-	-	-	-	-	-	-	-	-	-	-	3	-	-
Other Analyzer Method	17	-	-	-	-	-	1	8	2	-	-	2	3	1	-
Other Dipstick Method	8	-	-	-	-	-	-	4	2	-	1	-	-	1	-
Plasmatec URIPATH	2	-	-	-	-	-	1	1	-	-	-	-	-	-	-
Roche Chemstrips / Combur	20	-	-	-	-	-	2	8	8	-	-	-	-	-	2
Roche cobas 6500 / u 601	10	-	-	-	-	-	-	-	-	1	-	-	6	-	3
Roche cobas u 411	76	1	-	-	-	-	-	-	2	1	-	-	37	1	34
Roche UriSys	44	-	-	-	-	-	1	1	4	2	-	1	15	2	18
SD UroColor Reagent Strips	20	-	-	-	-	-	1	4	7	-	4	1	2	-	1
Siemens Clinitek 500	1	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Siemens Clinitek Advantus	20	-	-	-	-	-	1	9	-	-	-	-	9	1	-
Siemens Clinitek Atlas	2	-	-	-	-	-	-	-	-	-	-	-	2	-	-
Siemens Clinitek Status / Status+	15	-	-	-	-	-	-	7	8	-	-	-	-	-	-
Siemens Reagent Strips	15	-	-	-	-	-	-	3	9	2	-	-	-	1	-
Urinometer	2	-	-	-	-	-	-	-	1	-	-	-	-	1	-
UriScan Pro/II	9	-	-	-	-	-	1	4	-	-	2	-	1	1	-
UriScan Reagent Strips	18	-	-	-	-	-	1	13	2	-	-	-	2	-	-
URIT Medical Uritest Analyzers	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	Participant Results						
							<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>0.5 - 1.0 mg/dL</u>	<u>2.0 - 4.0 mg/dL</u>	<u>6.0 - 10.0 mg/dL</u>
ALL METHODS	368	368	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	19	19	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	10	10	-	-	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	4	4	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	3	3	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	16	16	-	-	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	1	1	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	8	8	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	16	16	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	4	4	-	-	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	2	2	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	13	13	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	3	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	17	17	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	8	8	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	2	2	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	18	18	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	10	10	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	76	76	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	43	43	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	19	19	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	1	1	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	20	20	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	2	2	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	15	15	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	3	3	-	-	-	-	-	-	-	-	-	-	-
Siemens Uristix	1	1	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	9	9	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	17	17	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>				
		<u>Normal or 0.0 - 0.2 mg/dL or <3.2 µmol/L</u>	<u>1.0 or <2.0 mg/dL or 16 µmol/L</u>	<u>2.0/3.0 mg/dL or 34 or 35 µmol/L</u>	<u>4.0 or 4.0/6.0 mg/dL or 70 µmol/L</u>	<u>>/=8.0 or 12.0 mg/dL or >/=140 or 200 µmol/L</u>
ALL METHODS	402	400	1	1	-	-
77 Elektronika LabUMat/2	15	15	-	-	-	-
Acon Laboratories	9	9	-	-	-	-
Analyticon CombiScan 500	3	3	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-
Arkray Aution Sticks	8	8	-	-	-	-
Arkray PocketChem UA	3	3	-	-	-	-
Combi-Screen Test Strips	12	12	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	16	16	-	-	-	-
DIRUI H-800 Urine Analyzer	4	4	-	-	-	-
HUMAN Combiblizer	1	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	12	12	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	3	-	-	-	-
Other Analyzer Method	14	14	-	-	-	-
Other Dipstick Method	10	10	-	-	-	-
Plasmatec URIPATH	2	2	-	-	-	-
Roche Chemstrips / Combur	19	19	-	-	-	-
Roche cobas 6500 / u 601	9	9	-	-	-	-
Roche cobas u 411	86	86	-	-	-	-
Roche Miditron Junior/II	1	1	-	-	-	-
Roche Urisys	48	48	-	-	-	-
SD UroColor Reagent Strips	23	22	1	-	-	-
Siemens Clinitek 500	2	2	-	-	-	-
Siemens Clinitek Advantus	36	35	-	1	-	-
Siemens Clinitek Atlas	4	4	-	-	-	-
Siemens Clinitek Status / Status+	6	6	-	-	-	-
Siemens Reagent Strips	2	2	-	-	-	-
Siemens Uristix	1	1	-	-	-	-
Urinometer	1	1	-	-	-	-
UriScan Pro/II	16	16	-	-	-	-
UriScan Reagent Strips	27	27	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>(5+)</u>	<u>5 - 25 Ery/µL</u>	<u>50 - 100 Ery/µL</u>	<u>250 Ery/µL</u>	<u>±0.03 mg/dL</u>	<u>0.06 - 0.10 mg/dL</u>	<u>0.2 - 0.5 mg/dL</u>	<u>≥ 1.0 mg/dL</u>
ALL METHODS	384	378	5	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
77 Elektronika LabUMat/2	18	18	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	2	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	13	12	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	17	17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	8	8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URI PATH	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	19	19	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	10	10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	74	74	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Miditron Junior/II	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Uri lux S	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	43	42	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	20	18	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	20	19	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	15	15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Uristix	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	17	17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-1

<u>Method</u>	<u>Participant Results</u>													
	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>15 or 25 µL</u>	<u>75 or 100 µL</u>	<u>250 or 500 µL</u>	
ALL METHODS	369	7	1	2	1	-	31	38	78	3	4	24	180	
77 Elektronika LabUMat/2	19	-	-	-	-	-	-	1	11	-	-	-	7	
Acon Laboratories	10	1	-	-	-	-	-	7	-	-	-	2	-	
Analyticon CombiScan 500	3	-	-	-	-	-	-	-	-	-	-	1	2	
Arkray Aution Jet	3	-	-	-	-	-	-	-	-	-	-	-	3	
Arkray Aution Sticks	15	-	-	-	-	-	-	1	2	-	-	1	11	
Arkray PocketChem UA	1	-	-	-	-	-	-	-	-	-	-	-	1	
Combi-Screen Test Strips	10	-	-	-	-	-	-	1	1	-	-	1	7	
DIRUI H-100 / H-500 Urine Analyzer	16	-	-	-	-	-	4	5	3	-	2	2	-	
DIRUI H-800 Urine Analyzer	4	-	-	-	-	-	-	-	3	-	-	-	1	
HUMAN Combilyzer	2	-	-	-	-	-	1	-	1	-	-	-	-	
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	-	1	-	-	-	-	1	
Iris Diagnostics iChem Velocity Strips	13	-	-	-	-	-	-	-	7	-	-	-	6	
Iris Ichem VELOCITY Urine Chemistry System	3	-	-	-	-	-	-	-	-	-	-	-	3	
Other Analyzer Method	16	-	-	-	-	-	1	2	6	1	-	1	5	
Other Dipstick Method	8	-	-	-	-	-	-	2	2	-	1	-	3	
Plasmatec URIPATH	2	-	-	-	-	-	-	-	2	-	-	-	-	
Roche Chemstrips / Combur	19	-	-	-	-	-	-	-	16	1	-	-	2	
Roche cobas 6500 / u 601	10	-	-	-	-	-	-	-	1	-	-	-	9	
Roche cobas u 411	76	-	-	-	-	-	-	-	1	1	-	1	73	
Roche Urisys	43	-	-	-	-	-	-	-	8	-	-	-	35	
SD UroColor Reagent Strips	20	3	-	-	-	-	2	4	4	-	-	2	5	
Siemens Clinitek 500	1	-	-	-	-	-	-	-	-	-	-	1	-	
Siemens Clinitek Advantus	20	1	-	1	-	-	12	-	-	-	-	6	-	
Siemens Clinitek Atlas	2	-	-	-	-	-	-	-	-	-	-	2	-	
Siemens Clinitek Status / Status+	15	-	1	1	1	-	8	4	-	-	-	-	-	
Siemens Reagent Strips	3	-	-	-	-	-	1	1	-	-	-	1	-	
Siemens Uristix	1	-	-	-	-	-	-	-	-	-	-	1	-	
Urinometer	2	-	-	-	-	-	-	-	1	-	-	-	1	
UriScan Pro/II	8	1	-	-	-	-	1	1	1	-	1	-	3	
UriScan Reagent Strips	16	1	-	-	-	-	1	6	7	-	-	1	-	
URIT Medical Uriptest Analyzers	1	-	-	-	-	-	-	-	1	-	-	-	-	
URIT Medical Uriptest Reagent Strips	1	-	-	-	-	-	-	1	-	-	-	-	-	

URINALYSIS DIPSTICK–NITRITE

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	373	238	135
77 Elektronika LabUMat/2	19	5	14
Acon Laboratories	10	8	2
Analyticon CombiScan 500	3	2	1
Arkray Aution Jet	3	-	3
Arkray Aution Sticks	15	5	10
Arkray PocketChem UA	1	-	1
Combi-Screen Test Strips	9	4	5
DIRUI H-100 / H-500 Urine Analyzer	16	15	1
DIRUI H-800 Urine Analyzer	4	4	-
HUMAN Combilyzer	2	2	-
Iris Diagnostics Aution Max AX-4280	2	1	1
Iris Diagnostics iChem Velocity Strips	13	2	11
Iris Ichem VELOCITY Urine Chemistry System	3	-	3
Other Analyzer Method	17	12	5
Other Dipstick Method	8	5	3
Plasmatec URIPATH	2	-	2
Roche Chemstrips / Combur	20	11	9
Roche cobas 6500 / u 601	10	6	4
Roche cobas u 411	76	63	13
Roche Urisys	43	36	7
SD UroColor Reagent Strips	21	14	7
Siemens Clinitek 500	1	1	-
Siemens Clinitek Advantus	20	11	9
Siemens Clinitek Atlas	2	2	-
Siemens Clinitek Status / Status+	15	4	11
Siemens Reagent Strips	3	2	1
Siemens Uristix	1	1	-
Urinometer	2	2	-
UriScan Pro/II	9	9	-
UriScan Reagent Strips	17	7	10
URIT Medical Uriptest Analyzers	1	1	-
URIT Medical Uriptest Reagent Strips	1	1	-

Urine Nitrite is not graded due lack of participant consensus. Nitrite was targeted to be Positive.

URINALYSIS –MICROALBUMIN (dipstick only)

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>10 mg/L</u>	<u>20 mg/L</u>	<u>30 mg/L</u>	<u>50 mg/L</u>	<u>80 mg/L</u>	<u>100 mg/L</u>	<u>150 mg/L</u>	<u>+ (4 - 8 mg/dL)</u>	<u>++ (>8 mg/dL)</u>
ALL METHODS	24	19	3	1	-	1	-	-	-	-	-
Abbott Architect	1	1	-	-	-	-	-	-	-	-	-
Beckman Coulter ICON microALB	1	1	-	-	-	-	-	-	-	-	-
Other Analyzer Method	6	5	1	-	-	-	-	-	-	-	-
Roche cobas 6000 / c 501	3	3	-	-	-	-	-	-	-	-	-
Roche cobas c 111	1	1	-	-	-	-	-	-	-	-	-
Roche Micral - 1 minute	5	3	-	1	-	1	-	-	-	-	-
Roche Urisys	1	1	-	-	-	-	-	-	-	-	-
Siemens Clinitek Microalbumin	2	1	1	-	-	-	-	-	-	-	-

URINALYSIS –URINE hCG

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	101	-	101
77 Elektronika LabUMat/2	1	-	1
Acon Laboratories	4	-	4
Alere Clearview hCG Cassette	8	-	8
Alere Clearview25 hCG Combo	2	-	2
Alere hCG Cassette	10	-	10
Biotron 1-Step	1	-	1
Medline hCG Test Strip	1	-	1
Other Dipstick Method	2	-	2
Quidel QuickVue One-Step Combo	18	-	18
SD Bioline hCG	8	-	8
Siemens Clinitek Status / Status+	10	-	10
Stanbio QuStick	1	-	1

MISCELLANEOUS CULTURES

Specimen BA-1 – CSF Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Cronobacter sakazakii	91	81.98%	Acceptable
Cronobacter sp.	3	2.70%	Acceptable
Enterobacter sp.	7	6.31%	
Enterobacter cloacae	7	6.31%	
Streptococcus mitis	1	0.90%	
Aeromonas sp.	1	0.90%	
Klebsiella pneumoniae	1	0.90%	

Organism(s) present: *Cronobacter sakazakii*.

Specimen BA-2 – Sputum Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Haemophilus parahaemolyticus	17	8.59%	Acceptable
Haemophilus sp.	23	11.62%	Acceptable
Gram negative bacilli	6	3.03%	Acceptable
Enterococcus faecalis	88	44.44%	Acceptable
Enterococcus sp.	11	5.56%	Acceptable
Gram positive cocci	1	0.51%	Acceptable
Streptococcus non-hemolytic	1	0.51%	Acceptable
Growth, referred for identification	1	0.51%	Acceptable
Haemophilus parainfluenzae	21	10.61%	
Haemophilus influenzae	13	6.57%	
Enterobacter sp.	2	1.01%	
Pasteurella sp.	2	1.01%	
Cronobacter sakazakii	2	1.01%	
Gram positive bacilli	1	0.51%	
Normal flora	1	0.51%	
Contaminated specimen	1	0.51%	
Other organism, not listed	1	0.51%	
Eikenella sp.	1	0.51%	
Moraxella sp.	1	0.51%	
Proteus mirabilis	1	0.51%	
Pseudomonas sp.	1	0.51%	
Staph – coagulase neg.	1	0.51%	
Streptococcus alpha-hemolytic	1	0.51%	

Organism(s) present: *Haemophilus parahaemolyticus* and *Enterococcus faecalis*.

MISCELLANEOUS CULTURES

Specimen BA-3 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Acinetobacter baumannii	98	59.04%	Acceptable
Acinetobacter sp.	10	6.02%	Acceptable
Finegoldia magna	19	11.45%	Acceptable
Finegoldia sp.	1	0.60%	Acceptable
Gram positive cocci	6	3.61%	Acceptable
Anaerobe present – would refer	10	6.02%	Acceptable
Anaerobe present – no ID	6	3.61%	Acceptable
Anaerobic cultures not performed	5	3.01%	Acceptable
Growth, referred for identification	1	0.60%	Acceptable
Peptostreptococcus sp.	4	2.41%	
Staphylococcus sp.	1	0.60%	
Staphylococcus aureus	1	0.60%	
Staphylococcus epidermidis	1	0.60%	
Staphylococcus saprophyticus	1	0.60%	
Gram positive bacilli	1	0.60%	
Aeromonas hydrophila	1	0.60%	

Organism(s) present: *Acinetobacter baumannii* and *Finegoldia magna*.

ANTIMICROBIAL SUSCEPTIBILITY TESTING

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>	
	Interpretative category data				Interpretative category data					
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>		
Amikacin	43	40	1	2	124	105	10	9	84.88%	
Amoxicillin/Clavulanate	3	-	-	3	7	-	-	7	Inappropriate drug ¹	
Ampicillin	3	-	-	3	19	-	-	19	Inappropriate drug ¹	
Ampicillin/Sulbactam	3	-	-	3	16	-	-	16	Inappropriate drug ¹	
Aztreonam	23	22	-	1	38	36	-	2	93.55%	
Carbenicillin	-	-	-	-	1	-	-	1	Inappropriate drug ¹	
Cefaclor	2	-	-	2	1	-	-	1	Inappropriate drug ¹	
Cefamandole	-	-	-	-	1	1	-	-	Inappropriate drug ¹	
Cefazolin	1	-	-	1	16	-	-	16	Inappropriate drug ¹	
Cefepime	35	30	1	4	141	135	4	2	93.41%	
Cefixime	4	-	-	4	2	1	-	1	Inappropriate drug ¹	
Cefoperazone	7	7	-	-	2	1	-	1	Inappropriate drug ¹	
Cefotaxime	5	1	2	2	16	1	1	14	Inappropriate drug ¹	
Cefotetan	-	-	-	-	2	1	-	1	Inappropriate drug ¹	
Cefoxitin	-	-	-	-	7	-	-	7	Inappropriate drug ¹	
Cefpodoxime	-	-	-	-	3	1	-	2	Inappropriate drug ¹	
Ceftazidime	42	35	1	6	139	136	1	2	94.57%	
Ceftizoxime	-	-	-	-	2	1	-	1	Inappropriate drug ¹	
Ceftriaxone	11	6	-	5	17	1	1	15	Inappropriate drug ¹	
Cefuroxime	4	-	-	4	9	-	-	9	Inappropriate drug ¹	
Cephalexin	3	1	-	2	3	1	-	2	Inappropriate drug ¹	
Cephalothin	1	1	-	-	4	1	-	3	Inappropriate drug ¹	
Ciprofloxacin	46	26	18	2	145	51	86	8	93.37%	
Colistin	5	5	-	-	22	20	1	1	92.59%	
Daptomycin	-	-	-	-	1	1	-	-	Inappropriate drug ¹	
Doripenem	4	4	-	-	17	17	-	-	100.00%	
Doxycycline	-	-	-	-	1	-	-	1	Inappropriate drug ¹	
Ertapenem	1	1	-	-	8	1	-	7	Inappropriate drug ¹	
Fosfomycin	2	-	1	1	8	6	-	2	Inappropriate drug ¹	
Gatifloxacin	1	-	1	-	2	1	1	-	100%	

¹ This is an inappropriate drug for organism and/or source.

ANTIMICROBIAL SUSCEPTIBILITY TESTING (cont'd)

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>	
	Interpretative category data				Interpretative category data					
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>		
Gentamicin	39	25	8	6	113	10	74	29	81.71%	
Imipenem	33	33	-	-	110	110	-	-	99.32%	
Kanamycin	-	-	-	-	2	2	-	-	Inappropriate drug ¹	
Levofloxacin	20	6	3	11	64	12	26	26	80.54%	
Meropenem	33	33	-	-	117	115	1	1	98.68%	
Nalidixic Acid	2	-	1	1	4	-	-	4	Inappropriate drug ¹	
Netilmicin	8	7	1	-	2	2	-	-	100.00%	
Nitrofurantoin	10	-	-	10	22	1	-	21	Inappropriate drug ¹	
Norfloxacin	15	12	2	1	21	13	6	2	89.44%	
Ofloxacin	10	-	-	10	-	-	-	-	100.00%	
Penicillin	1	-	-	1	1	1	-	-	Inappropriate drug ¹	
Piperacillin	2	1	-	1	9	8	-	1	83.33%	
Piperacillin/Tazobactam	30	30	-	-	105	98	6	1	99.28%	
Sulfisoxazole	-	-	-	-	1	1	-	-	Inappropriate drug ¹	
Tetracycline	1	-	-	1	1	-	-	1	Inappropriate drug ¹	
Ticarcillin	-	-	-	-	4	4	-	-	Inappropriate drug ¹	
Ticarcillin/Clavulanate	1	1	-	-	5	5	-	-	100%	
Tigecycline	-	-	-	-	2	-	-	2	Inappropriate drug ¹	
Tobramycin	8	7	-	1	34	33	1	-	95.35%	
Trimethoprim	-	-	-	-	2	-	-	2	Inappropriate drug ¹	
Trimethoprim/Sulfamethoxazole	7	-	-	7	20	-	-	20	Inappropriate drug ¹	

Organism(s) present: *Pseudomonas aeruginosa*.

NOTE: Please be aware that CLSI issues annual editions of M100, the standards used by all proficiency testing programs for grading of susceptibilities. Drugs considered appropriate may change significantly with subsequent editions. The current edition of the CLSI M100 document is accessible online at CLSI.org under Standards>Free Resources.

PARASITOLOGY (PA Specimens)

Specimen PA-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Protozoan seen but no ID	1	12.50%	Acceptable
Endolimax nana	1	12.50%	Acceptable
Entamoeba histolytica	3	37.50%	
Entamoeba hartmanni	1	12.50%	
No parasite seen	1	12.50%	
Cryptosporidium sp., oocysts	1	12.50%	

Parasite(s) present: *Endolimax nana*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	5	83.33%	Acceptable
No parasite seen	1	16.67%	

Parasite(s) present: *Giardia lamblia*. This specimen is graded to US statistics.

Specimen PA-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	20	52.63%	Acceptable
Trichuris trichiura eggs	18	47.37%	Acceptable

Parasite(s) present: *Ascaris lumbricoides eggs* and *Trichuris trichiura eggs*.

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Schistosoma haematobium eggs	18	81.82%	Acceptable
Schistosoma sp. eggs	2	9.09%	Acceptable
Schistosoma japonicum eggs	1	4.55%	
Giardia lamblia	1	4.55%	

Parasite(s) present: *Schistosoma haematobium* eggs.

Specimen PA-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Trypanosoma sp.	14	66.67%	Acceptable
Trypanosoma cruzi	6	28.57%	Acceptable
Leishmania sp.	1	4.76%	

Parasite(s) present: *Trypanosoma cruzi*.

PARASITOLOGY (FP Specimens)

Specimen FP-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	227	42.27%	Acceptable
Entamoeba coli	158	29.42%	Acceptable
Entamoeba histolytica	75	13.97%	Acceptable
Parasite egg seen but no ID	1	0.19%	Acceptable
Endolimax nana	28	5.21%	
Blastocystis hominis	22	4.10%	
Iodamoeba buetschlii	18	3.35%	
Entamoeba hartmanni	3	0.56%	
Giardia lamblia	1	0.19%	
Balantidium coli	1	0.19%	
Strongyloides stercoralis larvae	1	0.19%	
Taenia sp. eggs	1	0.19%	
No parasite seen	1	0.19%	

Parasite(s) present: *Ascaris lumbricoides*, *Entamoeba coli* and *Entamoeba histolytica*.

Specimen FP-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	257	94.80%	Acceptable
Protozoan seen but no ID	1	0.40%	Acceptable
No parasite seen	4	1.60%	
Blastocystis hominis	2	0.80%	
Endolimax nana	2	0.80%	
Entamoeba coli	1	0.40%	
Entamoeba histolytica	1	0.40%	
Hookworm	1	0.40%	
Parasite egg seen but no ID	1	0.40%	

Parasite(s) present: *Giardia lamblia*.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	237	96.73%	Acceptable
Strongyloides stercoralis larvae	3	1.22%	
Giardia lamblia	2	0.82%	
Hookworm	2	0.82%	
Ascaris lumbricoides eggs	1	0.41%	

Parasite(s) present: No parasite seen.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. eggs	215	70.26%	Acceptable
Blastocystis hominis	43	14.05%	Acceptable
Parasite egg seen but no ID	1	0.33%	Acceptable
Endolimax nana	11	3.59%	
Ascaris lumbricoides eggs	9	2.94%	
No parasite seen	7	2.29%	
Entamoeba histolytica	5	1.63%	
Hymenolepis diminuta eggs	4	1.31%	
Hymenolepis nana eggs	2	0.65%	
Entamoeba hartmanni	2	0.65%	
Giardia lamblia	2	0.65%	
Fasciola hepatica eggs	1	0.33%	
Iodamoeba buetschlii	1	0.33%	
Entamoeba coli	1	0.33%	
Chilomastix mesnili	1	0.33%	
Cryptosporidium sp., oocysts	1	0.33%	

Parasite(s) present: *Taenia* sp. eggs and *Blastocystis hominis*.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Microfilaria seen but no ID	65	26.64%	Acceptable
Microfilaria sheathed	38	15.57%	Acceptable
Brugia malayi	17	6.97%	Acceptable
Wuchereria bancrofti	69	28.28%	
No parasite seen	28	11.48%	
Microfilaria, unsheathed	8	3.28%	
Loa loa	5	2.05%	
Onchocerca volvulus	4	1.64%	
Plasmodium falciparum	2	0.82%	
Plasmodium vivax	1	0.41%	
Trypanosoma sp.	1	0.41%	
Trypanosoma cruzi	1	0.41%	
Plasmodium sp.	1	0.41%	
Mansonella ozzardi	1	0.41%	

Parasite(s) present: *Brugia malayi*. This challenge was graded by 82% referee consensus.

Antinuclear Antibody (ANA) - Qualitative

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	2	1	18	-	19
Bio-Rad	1	-	-	1	-	1
BioSystems	2	-	-	2	-	2
Immuno Concepts	3	-	-	3	-	3
INOVA Diagnostics	5	2	1	6	-	7
Kallestad	2	-	-	2	-	2
Zeus	1	-	-	1	-	1
<u>Method</u>	Specimen AE-4		Specimen AE-5			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	17	2	v	2		
Bio-Rad	1	-	2	-		
BioSystems	2	-	2	-		
Immuno Concepts	2	1	1	-		
INOVA Diagnostics	6	1	4	2		
Kallestad	2	-	1	-		
Zeus	1	-	1	-		

Antinuclear Antibody (ANA)—Quantitative (Titer)

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>8/ 10</u>	<u>16/ 20</u>	<u>32/ 40</u>	<u>64/ 80</u>	<u>128/ 160</u>	<u>256/ 320</u>	<u>512/ 640</u>	<u>>640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
Specimen AE-1												
ALL METHODS	2	1	-	-	-	3	5	1	-	1	-	-
Immuno Concepts	-	-	-	-	-	-	2	-	-	-	-	-
INOVA Diagnostics	2	1	-	-	-	1	1	-	-	1	-	-
Kallestad	-	-	-	-	-	-	2	-	-	-	-	-
Zeus	-	-	-	-	-	1	-	-	-	-	-	-

Antinuclear Antibody (ANA)—Quantitative (Titer)

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>8/ 10</u>	<u>16/ 20</u>	<u>32/ 40</u>	<u>64/ 80</u>	<u>128/ 160</u>	<u>256/ 320</u>	<u>512/ 640</u>	<u>>640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
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Specimen AE-2

ALL METHODS	12	-	-	-	-	-	-	1	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	5	-	-	-	-	-	-	1	-	-	-	-
Kallestad	2	-	-	-	-	-	-	-	-	-	-	-
Zeus	1	-	-	-	-	-	-	-	-	-	-	-

Specimen AE-3

ALL METHODS	13	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	6	-	-	-	-	-	-	-	-	-	-	-
Kallestad	2	-	-	-	-	-	-	-	-	-	-	-
Zeus	1	-	-	-	-	-	-	-	-	-	-	-

Specimen AE-4

ALL METHODS	1	-	-	-	-	-	1	3	2	4	2	-
Immuno Concepts	-	-	-	-	-	-	-	2	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	1	-	1	2	1	-
Kallestad	-	-	-	-	-	-	-	1	-	-	1	-
Zeus	-	-	-	-	-	-	-	-	-	1	-	-

Specimen AE-5

ALL METHODS	12	-	-	-	-	-	1	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	5	-	-	-	-	-	1	-	-	-	-	-
Kallestad	2	-	-	-	-	-	-	-	-	-	-	-
Zeus	1	-	-	-	-	-	-	-	-	-	-	-

Anti-dsDNA

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	1	1	17	-	18
BioSystems	2	-	-	2	-	2
INOVA Diagnostics	8	1	1	8	-	9
Kallestad	1	-	-	1	-	1
Zeus	1	-	-	1	-	1

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	17	1	17
BioSystems	-	2	-	2
INOVA Diagnostics	1	8	1	8
Kallestad	-	1	-	1
Zeus	-	1	-	1

Anti-RNP

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	4	-	12	1	11
INOVA Diagnostics	8	1	-	9	1	8

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	1	-	12
INOVA Diagnostics	8	1	-	9

Specimen AE-1 is an ungraded challenge due to less than 80% participant consensus

Anti-RNP/Sm

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	5	-	6	-	6

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	1	-	6

Anti-SSA

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	-	-	17	-	17
Immuno Concepts	1	-	-	1	-	1
INOVA Diagnostics	8	-	-	8	-	8

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	17	-	17
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	8	-	8

Anti-SSB

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	-	18	-	18
INOVA Diagnostics	-	10	-	10	-	10
<u>Method</u>	Specimen AE-4		Specimen AE-5			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	-	18	-	17		
INOVA Diagnostics	-	10	-	9		

Anti-SSA/SSB

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	-	-	-	-	-
<u>Method</u>	Specimen AE-4		Specimen AE-5			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	-	-	-	-		

Anti-Sm

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	-	18	-	18
INOVA Diagnostics	-	10	-	10	-	10
<u>Method</u>	Specimen AE-4		Specimen AE-5			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	5	13	-	18		
INOVA Diagnostics	5	5	-	10		

Specimen AE-4 is an ungraded challenge due to less than 80% participant consensus.

Rubella—Qualitative

<u>Method</u>	Specimen RU-1		Specimen RU-2		Specimen RU-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	15	2	-	17	-	17
Abbott Architect	11	2	-	13	-	13
Roche cobas 6000 / e 601	1	-	-	1	-	1
Roche cobas e 411	1	-	-	1	-	1
Siemens ADVIA Centaur	1	-	-	1	-	1
VITROS ECI	1	-	-	1	-	1

<u>Method</u>	Specimen RU-4		Specimen RU-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	17	15	2
Abbott Architect	-	13	11	2
Roche cobas 6000 / e 601	-	1	1	-
Roche cobas e 411	-	1	1	-
Siemens ADVIA Centaur	-	1	1	-
VITROS ECI	-	1	1	-

Rubella—Quantitative (IU/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen RU-1						
All Method	19	54.03	45.87	84.9	26.0	0.0 - 191.7
Abbott Architect	12	24.42	2.04	8.4	25.3	18.2 - 30.6
Specimen RU-2						
All Method	18	0.04	0.08	175.6	0.0	0.0 - 0.3
Abbott Architect	11	0.00	0.01	0.0	0.0	0.0 - 0.1
Specimen RU-3						
All Method	19	0.06	0.09	166.7	0.0	0.0 - 0.4
Abbott Architect	11	0.00	0.01	0.0	0.0	0.0 - 0.1
Specimen RU-4						
All Method	20	0.24	0.61	254.3	0.0	0.0 - 2.1
Abbott Architect	11	0.00	0.01	0.0	0.0	0.0 - 0.1
Specimen RU-5						
All Method	19	55.27	47.91	86.7	26.1	0.0 - 199.0
Abbott Architect	12	24.39	1.61	6.6	24.7	19.5 - 29.3

Syphilis Serology—Qualitative: VDRL Slide

<u>Method</u>	Specimen SY-1			Specimen SY-2			Specimen SY-3		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	45	-	-	-	-	45	45	-	-
Abbott Architect	2	-	-	-	-	2	2	-	-
Acon Laboratories	1	-	-	-	-	1	1	-	-
Human	1	-	-	-	-	1	1	-	-
Omega Diagnostics	1	-	-	-	-	1	1	-	-
Plasmatec	3	-	-	-	-	3	3	-	-
SPINREACT	4	-	-	-	-	4	4	-	-
Standard Diagnostics	1	-	-	-	-	1	1	-	-
Wiener Lab	27	-	-	-	-	27	27	-	-
<u>Method</u>	Specimen SY-4			Specimen SY-5					
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>			
ALL METHODS	44	1	-	-	-	45			
Abbott Architect	2	-	-	-	-	2			
Acon Laboratories	1	-	-	-	-	1			
Human	1	-	-	-	-	1			
Omega Diagnostics	1	-	-	-	-	1			
Plasmatec	3	-	-	-	-	3			
SPINREACT	4	-	-	-	-	4			
Standard Diagnostics	1	-	-	-	-	1			
Wiener Lab	26	1	-	-	-	27			

Syphilis Serology—Quantitative: VDRL Slide Titer

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>0 dil</u>	<u>1 dil</u>	<u>2 dil</u>	<u>4 dil</u>	<u>8 dil</u>	<u>16 dil</u>	<u>32 dil</u>	<u>>32 dil</u>
Specimen SY-1									
ALL METHODS	-	-	1	4	14	17	2	1	-
Plasmatec	-	-	-	-	2	1	-	-	-
SPINREACT	-	-	-	-	1	-	-	-	-
Wiener Lab	-	-	1	3	10	13	1	1	-
Specimen SY-2									
ALL METHODS	38	-	-	1	-	-	-	-	-
Plasmatec	3	-	-	-	-	-	-	-	-
SPINREACT	1	-	-	-	-	-	-	-	-
Wiener Lab	28	-	-	1	-	-	-	-	-
Specimen SY-3									
ALL METHODS	-	1	3	11	20	3	-	-	1
Plasmatec	-	-	-	2	1	-	-	-	-
SPINREACT	-	-	-	1	-	-	-	-	-
Wiener Lab	-	1	2	8	15	2	-	-	1

Syphilis Serology—Quantitative: VDRL Slide Titer

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>0 dil</u>	<u>1 dil</u>	<u>2 dil</u>	<u>4 dil</u>	<u>8 dil</u>	<u>16 dil</u>	<u>32 dil</u>	<u>>32 dil</u>
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Specimen SY-4

ALL METHODS	1	1	3	13	17	2	1	1	-
Plasmatec	-	-	-	2	1	-	-	-	-
SPINREACT	-	-	-	1	-	-	-	-	-
Wiener Lab	1	1	2	9	14	1	-	1	-

Specimen SY-5

ALL METHODS	39	-	-	-	-	-	-	-	-
Plasmatec	3	-	-	-	-	-	-	-	-
SPINREACT	1	-	-	-	-	-	-	-	-
Wiener Lab	29	-	-	-	-	-	-	-	-

Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	19	-	2	17	19	-
Abbott Architect	3	-	-	3	3	-
Biokit	1	-	-	1	1	-
Human	1	-	-	1	1	-
Plasmatec	5	-	-	5	5	-
Serodia	3	-	1	2	3	-
SPINREACT	1	-	-	1	1	-
Wiener Lab	2	-	-	2	2	-
Specimen SY-4		Specimen SY-5				
<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>			
ALL METHODS	19	-	-	19		
Abbott Architect	3	-	-	3		
Biokit	1	-	-	1		
Human	1	-	-	1		
Plasmatec	5	-	-	5		
Serodia	3	-	-	3		
SPINREACT	1	-	-	1		
Wiener Lab	2	-	-	2		

Syphilis Serology—Qualitative: *Treponema pallidum* Antibodies

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	45	-	-	45	45	-
Abbott Architect	9	-	-	9	9	-
bioMerieux	1	-	-	1	1	-
Human	2	-	-	2	2	-
Plasmatec	3	-	-	3	3	-
Roche cobas 6000 / c 501	2	-	-	2	2	-
Roche cobas e 411	1	-	-	1	1	-
Serodia	9	-	-	9	9	-
Siemens ADVIA Centaur	1	-	-	1	1	-
SPINREACT	1	-	-	1	1	-
Standard Diagnostics	5	-	-	5	5	-
Wiener Lab	1	-	-	1	1	-
Zeus	1	-	-	1	1	-
Specimen SY-4		Specimen SY-5				
<u>Reactive</u>		<u>Reactive</u>		<u>Non-Reactive</u>		
ALL METHODS	45	-	-	45		
Abbott Architect	9	-	-	9		
bioMerieux	1	-	-	1		
Human	2	-	-	2		
Plasmatec	3	-	-	3		
Roche cobas 6000 / c 501	2	-	-	2		
Roche cobas e 411	1	-	-	1		
Serodia	9	-	-	9		
Siemens ADVIA Centaur	1	-	-	1		
SPINREACT	1	-	-	1		
Standard Diagnostics	5	-	-	5		
Wiener Lab	1	-	-	1		
Zeus	1	-	-	1		

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	80	1	2	79	80	1
Abbott Architect	1	-	-	1	1	-
Becton Dickinson	1	-	-	1	1	-
bioMerieux	5	-	1	4	5	-
BioSystems	13	-	-	13	13	-
Human	8	-	-	8	8	-
Omega Diagnostics	11	-	-	11	11	-
Plasmatec	16	-	1	15	16	-
Pulse Scientific	1	-	-	1	1	-
SPINREACT	18	-	-	18	18	-
Standard Diagnostics	1	-	-	1	1	-
Specimen SY-4		Specimen SY-5				
<u>Reactive</u>		<u>Reactive</u>		<u>Non-Reactive</u>		
ALL METHODS	80	1	1	80		
Abbott Architect	1	-	-	1		
Becton Dickinson	1	-	-	1		
bioMerieux	5	-	-	5		
BioSystems	13	-	-	13		
Human	8	-	-	8		
Omega Diagnostics	11	-	-	11		
Plasmatec	16	-	-	16		
Pulse Scientific	1	-	1	-		
SPINREACT	18	-	-	18		
Standard Diagnostics	1	-	-	1		

Syphilis Serology—Quantitative: RPR (Titer)

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>
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Specimen SY-1

ALL METHODS	1	1	11	33	17	5	-	1	-
Becton Dickinson	-	-	-	-	1	-	-	-	-
bioMerieux	-	-	-	2	1	1	-	-	-
BioSystems	-	1	2	3	5	-	-	-	-
Human	-	-	1	6	1	-	-	-	-
Omega Diagnostics	1	-	2	5	1	1	-	-	-
Plasmatec	-	-	1	7	3	1	-	1	-
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	-	2	8	4	2	-	-	-
Wiener Lab	-	-	-	-	1	-	-	-	-

Specimen SY-2

ALL METHODS	67	1	1	-	-	-	-	-	-
Becton Dickinson	1	-	-	-	-	-	-	-	-
bioMerieux	3	-	1	-	-	-	-	-	-
BioSystems	11	-	-	-	-	-	-	-	-
Human	8	-	-	-	-	-	-	-	-
Omega Diagnostics	10	-	-	-	-	-	-	-	-
Plasmatec	12	1	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	16	-	-	-	-	-	-	-	-
Wiener Lab	1	-	-	-	-	-	-	-	-

Syphilis Serology—Quantitative: RPR (Titer) cont'd

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>
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Specimen SY-3

ALL METHODS	1	4	31	23	7	1	1	1	-
Becton Dickinson	-	-	-	1	-	-	-	-	-
bioMerieux	-	-	2	-	1	-	1	-	-
BioSystems	-	1	5	4	1	-	-	-	-
Human	-	-	5	3	-	-	-	-	-
Omega Diagnostics	1	1	3	3	1	1	-	-	-
Plasmatec	-	-	6	5	1	-	-	1	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	-	7	6	3	-	-	-	-
Wiener Lab	-	-	-	1	-	-	-	-	-

Specimen SY-4

ALL METHODS	1	7	28	26	5	1	-	1	-
Becton Dickinson	-	-	-	1	-	-	-	-	-
bioMerieux	-	-	2	-	1	1	-	-	-
BioSystems	-	3	4	4	-	-	-	-	-
Human	-	1	3	4	-	-	-	-	-
Omega Diagnostics	1	1	3	4	1	-	-	-	-
Plasmatec	-	-	6	6	-	-	-	1	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	-	7	6	3	-	-	-	-
Wiener Lab	-	-	-	1	-	-	-	-	-

Syphilis Serology—Quantitative: RPR (Titer) cont'd

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>
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Specimen SY-5

ALL METHODS	69	-	-	-	-	-	-	-	-
Becton Dickinson	1	-	-	-	-	-	-	-	-
bioMerieux	4	-	-	-	-	-	-	-	-
BioSystems	11	-	-	-	-	-	-	-	-
Human	8	-	-	-	-	-	-	-	-
Omega Diagnostics	10	-	-	-	-	-	-	-	-
Plasmatec	13	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	16	-	-	-	-	-	-	-	-
Wiener Lab	1	-	-	-	-	-	-	-	-

Viral Markers – Anti-HBc (IgM)

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	49	-	3	46	-	30	18	1
Abbott Architect	-	24	-	1	23	-	23	1	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-	1	-	-
bioMerieux Vidas, Mini									
Vidas	-	1	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	12	-	-	12	-	-	12	-
Roche cobas e 411	-	2	-	-	2	-	-	2	-
Roche Modular Analytics	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	1	-	-	1	-	1	-	-
VITROS 3600/4600/5600	-	3	-	-	3	-	-	2	1
VITROS ECI	-	1	-	1	-	-	1	-	-
Specimen VM-4					Specimen VM-5				
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>		<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>		
	5	44	-		-	49	-		
ALL METHODS	5	44	-		-	49	-		
Abbott Architect	2	22	-		-	24	-		
Beckman ACCESS / 2 / Dxl	-	1	-		-	1	-		
bioMerieux Vidas, Mini									
Vidas	-	1	-		-	1	-		
Roche cobas 6000 / e 601	1	11	-		-	12	-		
Roche cobas e 411	-	2	-		-	2	-		
Roche Modular Analytics	-	1	-		-	1	-		
Siemens ADVIA Centaur	-	1	-		-	1	-		
VITROS 3600/4600/5600	-	3	-		-	3	-		
VITROS ECI	1	-	-		-	1	-		

Viral Markers – Anti-HBc (Total / IgG)

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	71	-	72	-	-	71	1	-
Abbott Architect	-	42	-	42	-	-	42	-	-
Beckman ACCESS / 2 / Dxl	-	1	-	1	-	-	1	-	-
Bio-Rad Evolis	1	-	-	1	-	-	1	-	-
bioMerieux Vidas, Mini									
Vidas	-	1	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	-	11	-	11	-	-	11	-	-
Roche cobas e 411	-	3	-	3	-	-	3	-	-
Roche Modular Analytics	-	1	-	1	-	-	1	-	-
Siemens ADVIA Centaur	-	3	-	3	-	-	3	-	-
VITROS 3600/4600/5600	-	3	-	3	-	-	3	-	-
VITROS ECI	-	1	-	1	-	-	1	-	-
Specimen VM-4					Specimen VM-5				
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	69	3	-	-	71	-			
Abbott Architect	42	-	-	-	41	-			
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-			
Bio-Rad Evolis	-	1	-	-	1	-			
bioMerieux Vidas, Mini									
Vidas	1	-	-	-	1	-			
Roche cobas 6000 / e 601	11	-	-	-	11	-			
Roche cobas e 411	3	-	-	-	3	-			
Roche Modular Analytics	1	-	-	-	1	-			
Siemens ADVIA Centaur	3	-	-	-	3	-			
VITROS 3600/4600/5600	3	-	-	-	3	-			
VITROS ECI	1	-	-	-	1	-			

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	169	2	-	2	169	-	2	168	1
Abbott Architect	69	1	-	-	70	-	-	70	-
Acon Laboratories	1	-	-	-	1	-	-	1	-
Alere Determine HIV - moderate	5	-	-	-	5	-	-	5	-
Beckman ACCESS / 2 / Dxl	4	-	-	-	4	-	-	4	-
bioMerieux Vidas, Mini Vidas	3	-	-	-	3	-	-	3	-
DiaSorin	2	-	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	34	1	-	2	33	-	1	33	1
Roche cobas e 411	15	-	-	-	15	-	-	15	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-	-	1	-
Roche Modular Analytics	2	-	-	-	2	-	-	2	-
Siemens ADVIA Centaur	8	-	-	-	8	-	-	8	-
Standard Diagnostics	2	-	-	-	2	-	-	2	-
VITROS 3600/4600/5600	5	-	-	-	5	-	-	5	-
VITROS ECI	6	-	-	-	6	-	-	6	-

Viral Markers – Anti-HIV- cont'd

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	160	10	1	3	167	-
Abbott Architect	68	1	1	-	69	-
Acon Laboratories	1	-	-	-	1	-
Alere Determine HIV - moderate	2	3	-	-	5	-
Beckman ACCESS / 2 / Dxl	4	-	-	-	4	-
bioMerieux Vidas, Mini Vidas	3	-	-	-	3	-
DiaSorin	2	-	-	-	2	-
Roche cobas 6000 / e 601	34	1	-	1	34	-
Roche cobas e 411	15	-	-	-	15	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-
Roche Modular Analytics	2	-	-	1	1	-
Siemens ADVIA Centaur	8	-	-	-	8	-
Standard Diagnostics	2	-	-	-	2	-
VITROS 3600/4600/5600	5	-	-	-	5	-
VITROS ECI	6	-	-	-	6	-

Viral Markers – Anti-HAV (IgM)

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	59	-	-	60	-	-	60	-
Abbott Architect	-	29	-	-	29	-	-	29	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	16	-	-	16	-	-	16	-
Roche cobas e 411	1	2	-	-	3	-	-	3	-
Roche Modular Analytics	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	4	-	-	4	-	-	4	-
Standard Diagnostics	-	2	-	-	2	-	-	2	-
Specimen VM-4					Specimen VM-5				
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>			
	-	60	-	1	58	-			
ALL METHODS	-	29	-	-	28	-			
Abbott Architect	-	3	-	-	3	-			
bioMerieux Vidas, Mini Vidas	-	16	-	-	16	-			
Roche cobas 6000 / e 601	-	3	-	1	2	-			
Roche cobas e 411	-	1	-	-	1	-			
Roche Modular Analytics	-	4	-	-	4	-			
Siemens ADVIA Centaur	-	2	-	-	2	-			

Viral Markers – Anti-HAV (Total/IgG)

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	50	1	-	1	50	-	1	50	-
Abbott Architect	24	-	-	-	24	-	-	24	-
bioMerieux Vidas, Mini									
Vidas	3	-	-	-	3	-	-	3	-
Roche cobas 6000 / e 601	12	-	-	-	12	-	-	12	-
Roche cobas e 411	2	-	-	1	1	-	1	1	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-	-	1	-
Roche Modular Analytics	1	-	-	-	1	-	-	1	-
Siemens ADVIA Centaur	4	-	-	-	4	-	-	4	-
Standard Diagnostics	-	1	-	-	1	-	-	1	-
VITROS 3600/4600/5600	1	-	-	-	1	-	-	1	-
Specimen VM-4					Specimen VM-5				
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
	2	49	-		50	1	-	-	-
ALL METHODS	1	23	-	24	-	-			
Abbott Architect									
bioMerieux Vidas, Mini									
Vidas	-	3	-	3	-	-			
Roche cobas 6000 / e 601	-	12	-	12	-	-			
Roche cobas e 411	1	1	-	2	-	-			
Roche Elecsys 1010 / 2010	-	1	-	1	-	-			
Roche Modular Analytics	-	1	-	1	-	-			
Siemens ADVIA Centaur	-	4	-	4	-	-			
Standard Diagnostics	-	1	-	-	1	-			
VITROS 3600/4600/5600	-	1	-	1	-	-			

Viral Markers – HBeAg

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	39	-	1	38	-	-	39	-
Abbott Architect	-	16	-	-	16	-	-	16	-
bioMerieux Vidas, Mini									
Vidas	-	3	-	-	3	-	-	3	-
DiASorin	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	12	-	-	12	-	-	12	-
Roche cobas e 411	-	2	-	-	2	-	-	2	-
Roche Modular Analytics	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	2	-	-	2	-	-	2	-
Specimen VM-4					Specimen VM-5				
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
	38	1	-		-	39	-		
ALL METHODS	38	1	-	-	39	-			
Abbott Architect	16	-	-	-	16	-			
bioMerieux Vidas, Mini									
Vidas	3	-	-	-	3	-			
DiASorin	1	-	-	-	1	-			
Roche cobas 6000 / e 601	12	-	-	-	12	-			
Roche cobas e 411	2	-	-	-	2	-			
Roche Modular Analytics	1	-	-	-	1	-			
Siemens ADVIA Centaur	2	-	-	-	2	-			

Viral Markers – Anti-HBs

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	110	5	-	58	57	-	6	109	-
Abbott Architect	47	-	-	47	-	-	-	47	-
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-	2	-	-
bioMerieux Vidas, Mini									
Vidas	2	-	-	-	2	-	-	2	-
DiASorin	-	1	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	29	2	-	4	27	-	2	29	-
Roche cobas e 411	9	-	-	1	8	-	1	8	-
Roche Elecsys 1010 / 2010	2	-	-	1	1	-	-	2	-
Roche Modular Analytics	1	-	-	-	1	-	-	1	-
Siemens ADVIA Centaur	6	-	-	-	6	-	-	6	-
Standard Diagnostics	-	1	-	-	1	-	-	1	-
VITROS 3600/4600/5600	5	-	-	-	5	-	-	5	-
VITROS ECI	2	-	-	-	2	-	-	2	-
Specimen VM-4					Specimen VM-5				
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	83	30	2	111	4	-			
Abbott Architect	24	22	1	47	-	-			
Beckman ACCESS / 2 / Dxl	2	-	-	2	-	-			
bioMerieux Vidas, Mini									
Vidas	1	-	1	2	-	-			
DiASorin	1	-	-	-	1	-			
Roche cobas 6000 / e 601	30	1	-	30	1	-			
Roche cobas e 411	9	-	-	9	-	-			
Roche Elecsys 1010 / 2010	2	-	-	2	-	-			
Roche Modular Analytics	1	-	-	1	-	-			
Siemens ADVIA Centaur	2	4	-	6	-	-			
Standard Diagnostics	-	1	-	-	1	-			
VITROS 3600/4600/5600	5	-	-	5	-	-			
VITROS ECI	2	-	-	2	-	-			

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3			
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	
ALL METHODS	-	170	1	170	1	-	148	21	2	
Abbott Architect	-	65	1	66	-	-	64	1	1	
Beckman ACCESS / 2 / Dxl	-	4	-	4	-	-	4	-	-	
bioMerieux Vidas, Mini Vidas	-	3	-	3	-	-	3	-	-	
DiaSorin	-	1	-	1	-	-	1	-	-	
Roche cobas 6000 / e 601	-	37	-	36	1	-	35	2	-	
Roche cobas e 411	-	17	-	17	-	-	17	-	-	
Roche Elecsys 1010 / 2010	-	1	-	1	-	-	1	-	-	
Roche Modular Analytics	-	2	-	2	-	-	2	-	-	
Siemens ADVIA Centaur	-	6	-	6	-	-	4	1	1	
Standard Diagnostics	-	6	-	6	-	-	1	5	-	
VITROS 3600/4600/5600	-	5	-	5	-	-	5	-	-	
VITROS ECi	-	6	-	6	-	-	5	1	-	
Specimen VM-4			Specimen VM-5							
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>				
ALL METHODS	145	24	2	1	168	1				
Abbott Architect	65	1	-	1	63	1				
Beckman ACCESS / 2 / Dxl	4	-	-	-	4	-				
bioMerieux Vidas, Mini Vidas	2	-	1	-	3	-				
DiaSorin	1	-	-	-	1	-				
Roche cobas 6000 / e 601	37	-	-	-	37	-				
Roche cobas e 411	17	-	-	-	17	-				
Roche Elecsys 1010 / 2010	1	-	-	-	1	-				
Roche Modular Analytics	2	-	-	-	2	-				
Siemens ADVIA Centaur	5	-	1	-	6	-				
Standard Diagnostics	1	5	-	-	6	-				
VITROS 3600/4600/5600	1	4	-	-	5	-				
VITROS ECi	4	2	-	-	6	-				

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	153	-	151	2	-	1	152	-
Abbott Architect	-	67	-	67	-	-	-	67	-
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	-	-	2	-
Bio-Rad Evolis	-	1	-	1	-	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	2	-	2	-	-	-	2	-
Roche cobas 6000 / e 601	-	28	-	27	1	-	-	28	-
Roche cobas e 411	-	13	-	13	-	-	-	13	-
Roche Elecsys 1010 / 2010	-	1	-	1	-	-	-	1	-
Roche Modular Analytics	-	2	-	2	-	-	-	2	-
Siemens ADVIA Centaur	-	5	-	5	-	-	-	5	-
Standard Diagnostics	-	6	-	6	-	-	-	6	-
VITROS 3600/4600/5600	-	5	-	5	-	-	-	5	-
VITROS ECI	-	5	-	5	-	-	-	5	-
Specimen VM-4			Specimen VM-5						
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>			
ALL METHODS	2	151	-	-	152	-			
Abbott Architect	-	67	-	-	66	-			
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-			
Bio-Rad Evolis	-	1	-	-	1	-			
bioMerieux Vidas, Mini Vidas	-	2	-	-	2	-			
Roche cobas 6000 / e 601	1	27	-	-	28	-			
Roche cobas e 411	1	12	-	-	13	-			
Roche Elecsys 1010 / 2010	-	1	-	-	1	-			
Roche Modular Analytics	-	2	-	-	2	-			
Siemens ADVIA Centaur	-	5	-	-	5	-			
Standard Diagnostics	-	6	-	-	6	-			
VITROS 3600/4600/5600	-	5	-	-	5	-			
VITROS ECI	-	5	-	-	5	-			

Toxoplasma gondii Antibody (IgG) - Qualitative

<u>Method</u>	Specimen TOX-1			Specimen TOX-2		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	18	-	-	-	18	-
Abbott Architect	12	-	-	-	12	-
bioMerieux Vidas, Mini						
Vidas	1	-	-	-	1	-
Roche cobas 6000 / e 601	1	-	-	-	1	-
Roche cobas e 411	1	-	-	-	1	-

Toxoplasma gondii Antibody (IgG) —Quantitative (IU/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen TOX-1						
ALL METHODS	12	53.883	7.765	14.4	54.50	38.35 - 69.42
Abbott Architect	12	53.883	7.765	14.4	54.50	38.35 - 69.42
Specimen TOX-2						
ALL METHODS	18	0.228	0.145	63.6	0.20	0.00 - 0.52
Abbott Architect	12	0.275	0.122	44.2	0.25	0.03 - 0.52

Toxoplasma gondii Antibody (IgM) - Qualitative

<u>Method</u>	Specimen TOX-1			Specimen TOX-2		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	16	6	1	1	22	-
Abbott Architect	13	1	-	1	13	-
bioMerieux Vidas, Mini						
Vidas	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	3	-	-	3	-
Roche cobas e 411	-	1	1	-	2	-

Toxoplasma gondii Antibody (IgM) —Quantitative (IU/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
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Specimen TOX-1

ALL METHODS	15	1.047	0.338	32.3	1.00	0.37 - 1.73
Abbott Architect	10	0.998	0.094	9.4	1.01	0.80 - 1.19

Specimen TOX-2

ALL METHODS	15	0.154	0.034	22.1	0.15	0.08 - 0.23
Abbott Architect	10	0.145	0.025	17.6	0.15	0.09 - 0.20

Cytomegalovirus (CMV) Antibodies (IgG) - Qualitative

<u>Method</u>	Specimen CMV-1			Specimen CMV-2		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	11	1	-	12	-	-
Abbott Architect	11	-	-	11	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-

Cytomegalovirus (CMV) Antibodies (IgG) —Quantitative (U/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
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Specimen CMV-1

All Method	9	37.644	9.557	25.4	37.60	18.53 - 56.76
Abbott Architect	8	39.725	7.737	19.5	38.60	24.25 - 55.20

Specimen CMV-2

All Method	12	127.896	30.729	24.0	123.15	66.43 - 189.36
Abbott Architect	8	125.025	19.333	15.5	123.15	86.35 - 163.70

Cytomegalovirus (CMV) Antibodies (IgM) - Qualitative

<u>Method</u>	Specimen CMV-1			Specimen CMV-2		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	15	1	-	1	15	-
Abbott Architect	12	1	-	1	12	-
Roche cobas 6000 / e 601	2	-	-	-	2	-
Roche cobas e 411	1	-	-	-	1	-

Cytomegalovirus (CMV) Antibodies (IgM) —Quantitative (U/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
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Specimen CMV-1

All Method	10	3.723	1.154	31.0	3.89	1.41 - 6.04
Abbott Architect	8	4.108	0.895	21.8	4.10	2.31 - 5.90

Specimen CMV-2

All Method	10	0.464	0.162	34.9	0.48	0.13 - 0.79
Abbott Architect	8	0.524	0.115	21.9	0.50	0.29 - 0.76

CK-MB - Quantitative (U/L)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen CK-1						
All Method	1	-	-	-	5.4	5.3 - 5.5
Specimen CK-2						
All Method	1	-	-	-	41.5	41.4 - 41.6
Specimen CK-3						
All Method	1	-	-	-	23.5	23.4 - 23.6
Specimen CK-4						
All Method	1	-	-	-	13.8	13.7 - 13.9
Specimen CK-5						
All Method	1	-	-	-	76.2	76.1 - 76.3

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