

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
MLE-M3**



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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	± 3 SD
CK-MB (U/L)	± 3 SD
Cytomegalovirus	± 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	± 3 SD
Specific Gravity	± 0.010
Toxoplasma	± 2 SD
White Blood Cell Count	$\pm 15\%$

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

Specimen CL-11							Specimen CL-12					
<u>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	78	2.98	0.36	12.2	3.1	2.5 - 3.5	78	7.72	0.73	9.4	8.0	6.5 - 8.9
All Abbott Cell-Dyn Instruments	59	3.16	0.13	4.2	3.2	2.6 - 3.7	60	8.05	0.32	4.0	8.1	6.8 - 9.3
Abbott Cell-Dyn Ruby	44	3.16	0.13	4.2	3.2	2.6 - 3.7	44	8.10	0.24	2.9	8.1	6.8 - 9.4
Orphee Mythic 22	16	2.33	0.11	4.8	2.3	1.9 - 2.7	16	6.42	0.22	3.4	6.4	5.4 - 7.4
Specimen CL-13							Specimen CL-14					
All Method	78	24.67	2.12	8.6	25.4	20.9 - 28.4	78	3.11	0.46	14.9	3.2	2.6 - 3.6
All Abbott Cell-Dyn Instruments	59	25.64	1.06	4.1	25.7	21.7 - 29.5	58	3.30	0.18	5.5	3.3	2.8 - 3.8
Abbott Cell-Dyn Ruby	43	25.79	0.61	2.4	25.9	21.9 - 29.7	43	3.36	0.18	5.5	3.4	2.8 - 3.9
Orphee Mythic 22	17	21.16	0.81	3.8	21.2	17.9 - 24.4	16	2.29	0.09	4.0	2.3	1.9 - 2.7
Specimen CL-15												
All Method	79	7.74	0.74	9.6	8.0	6.5 - 8.9						
All Abbott Cell-Dyn Instruments	60	8.10	0.28	3.4	8.1	6.8 - 9.4						
Abbott Cell-Dyn Ruby	44	8.14	0.27	3.3	8.1	6.9 - 9.4						
Orphee Mythic 22	17	6.41	0.15	2.3	6.4	5.4 - 7.4						

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

Specimen CL-11							Specimen CL-12					
<u>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	77	2.200	0.070	3.2	2.20	2.06 - 2.34	78	4.553	0.153	3.4	4.58	4.28 - 4.83
All Abbott Cell-Dyn Instruments	60	2.221	0.060	2.7	2.22	2.08 - 2.36	60	4.609	0.113	2.4	4.61	4.33 - 4.89
Abbott Cell-Dyn Ruby	44	2.225	0.062	2.8	2.23	2.09 - 2.36	44	4.638	0.106	2.3	4.63	4.36 - 4.92
Orphee Mythic 22	16	2.106	0.056	2.7	2.11	1.97 - 2.24	16	4.338	0.090	2.1	4.36	4.07 - 4.60
Specimen CL-13							Specimen CL-14					
All Method	78	6.336	0.234	3.7	6.40	5.95 - 6.72	77	2.190	0.069	3.1	2.19	2.05 - 2.33
All Abbott Cell-Dyn Instruments	60	6.423	0.156	2.4	6.45	6.03 - 6.81	60	2.212	0.054	2.4	2.21	2.07 - 2.35
Abbott Cell-Dyn Ruby	44	6.468	0.127	2.0	6.48	6.07 - 6.86	44	2.220	0.054	2.4	2.22	2.08 - 2.36
Orphee Mythic 22	16	6.011	0.193	3.2	5.99	5.65 - 6.38	16	2.091	0.066	3.2	2.10	1.96 - 2.22
Specimen CL-15												
All Method	79	4.540	0.154	3.4	4.58	4.26 - 4.82						
All Abbott Cell-Dyn Instruments	60	4.602	0.107	2.3	4.62	4.32 - 4.88						
Abbott Cell-Dyn Ruby	44	4.631	0.091	2.0	4.65	4.35 - 4.91						
Orphee Mythic 22	17	4.324	0.092	2.1	4.34	4.06 - 4.59						

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

Specimen CL-11							Specimen CL-12					
<u>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	78	5.50	0.30	5.5	5.6	5.1 - 5.9	78	13.25	0.68	5.2	13.5	12.3 - 14.2
All Abbott Cell-Dyn Instruments	60	5.64	0.13	2.3	5.7	5.2 - 6.1	60	13.58	0.23	1.7	13.5	12.6 - 14.6
Abbott Cell-Dyn Ruby	44	5.61	0.12	2.2	5.6	5.2 - 6.1	44	13.60	0.20	1.5	13.6	12.6 - 14.6
Orphee Mythic 22	16	4.96	0.12	2.3	5.0	4.6 - 5.4	16	11.99	0.23	1.9	12.0	11.1 - 12.9
Specimen CL-13							Specimen CL-14					
All Method	78	19.59	0.85	4.3	19.9	18.2 - 21.0	78	5.48	0.29	5.3	5.6	5.0 - 5.9
All Abbott Cell-Dyn Instruments	60	19.98	0.41	2.1	20.0	18.5 - 21.4	60	5.62	0.11	1.9	5.6	5.2 - 6.1
Abbott Cell-Dyn Ruby	44	20.09	0.32	1.6	20.1	18.6 - 21.5	44	5.60	0.10	1.8	5.6	5.2 - 6.0
Orphee Mythic 22	17	18.04	0.51	2.8	18.0	16.7 - 19.3	16	4.96	0.13	2.5	5.0	4.6 - 5.4
Specimen CL-15												
All Method	79	13.21	0.73	5.5	13.5	12.2 - 14.2						
All Abbott Cell-Dyn Instruments	60	13.57	0.24	1.8	13.6	12.6 - 14.6						
Abbott Cell-Dyn Ruby	44	13.60	0.24	1.7	13.6	12.6 - 14.6						
Orphee Mythic 22	17	11.89	0.21	1.8	11.9	11.0 - 12.8						

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

Specimen CL-11							Specimen CL-12					
<u>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	76	15.65	0.72	4.6	15.6	14.7 - 16.6	77	38.62	1.76	4.6	38.3	36.3 - 41.0
All Abbott Cell-Dyn Instruments	53	15.37	0.52	3.4	15.4	14.4 - 16.3	53	37.94	1.32	3.5	38.0	35.6 - 40.3
Abbott Cell-Dyn Ruby	44	15.37	0.55	3.6	15.4	14.4 - 16.3	44	38.07	1.34	3.5	38.0	35.7 - 40.4
Orphee Mythic 22	16	16.07	0.54	3.3	16.1	15.1 - 17.1	16	39.36	1.24	3.2	39.3	36.9 - 41.8
Specimen CL-13							Specimen CL-14					
All Method	77	54.38	2.31	4.2	54.1	51.1 - 57.7	77	15.59	0.71	4.5	15.5	14.6 - 16.6
All Abbott Cell-Dyn Instruments	53	53.46	1.58	2.9	53.5	50.2 - 56.7	53	15.29	0.45	2.9	15.3	14.3 - 16.3
Abbott Cell-Dyn Ruby	44	53.61	1.58	3.0	53.8	50.3 - 56.9	44	15.32	0.47	3.1	15.4	14.4 - 16.3
Orphee Mythic 22	16	55.38	2.03	3.7	56.0	52.0 - 58.7	16	15.95	0.59	3.7	15.9	14.9 - 17.0
Specimen CL-15												
All Method	78	38.60	1.71	4.4	38.4	36.2 - 41.0						
All Abbott Cell-Dyn Instruments	53	37.92	1.24	3.3	38.0	35.6 - 40.2						
Abbott Cell-Dyn Ruby	44	38.10	1.20	3.2	38.1	35.8 - 40.4						
Orphee Mythic 22	17	39.23	1.28	3.3	39.3	36.8 - 41.6						

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

Specimen CL-11							Specimen CL-12					
<u>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	75	76.8	8.7	11.3	75	57 - 97	78	254.4	16.0	6.3	253	190 - 318
All Abbott Cell-Dyn Instruments	60	73.4	4.9	6.7	73	55 - 92	60	252.3	15.5	6.1	252	189 - 316
Abbott Cell-Dyn Ruby	44	73.3	5.0	6.9	74	54 - 92	44	254.0	15.1	5.9	253	190 - 318
Orphee Mythic 22	16	95.7	10.5	11.0	93	71 - 120	16	264.8	13.0	4.9	266	198 - 331
Specimen CL-13							Specimen CL-14					
All Method	77	578.7	37.5	6.5	581	434 - 724	77	77.7	10.8	13.9	75	58 - 98
All Abbott Cell-Dyn Instruments	58	590.5	30.8	5.2	589	442 - 739	59	73.1	5.6	7.6	73	54 - 92
Abbott Cell-Dyn Ruby	42	595.1	27.0	4.5	594	446 - 744	43	72.3	4.9	6.8	71	54 - 91
Orphee Mythic 22	17	546.9	31.4	5.7	540	410 - 684	16	93.9	10.4	11.0	93	70 - 118
Specimen CL-15												
All Method	78	254.1	17.7	7.0	254	190 - 318						
All Abbott Cell-Dyn Instruments	60	252.0	15.0	5.9	253	188 - 315						
Abbott Cell-Dyn Ruby	44	254.2	13.9	5.5	254	190 - 318						
Orphee Mythic 22	16	265.3	21.6	8.1	265	198 - 332						

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

Specimen CL-11							Specimen CL-12					
<u>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	78	49.44	2.01	4.1	49.6	43.4 - 55.5	77	62.15	1.43	2.3	62.4	57.8 - 66.5
All Abbott Cell-Dyn Instruments	59	50.02	1.42	2.8	50.0	45.7 - 54.3	59	62.60	0.91	1.5	62.6	59.8 - 65.4
Abbott Cell-Dyn Ruby	42	50.22	1.15	2.3	50.4	46.7 - 53.7	44	62.66	0.79	1.3	62.6	60.2 - 65.1
Orphee Mythic 22	17	47.78	2.46	5.1	47.1	40.4 - 55.2	16	60.12	0.85	1.4	59.9	57.5 - 62.7
Specimen CL-13							Specimen CL-14					
All Method	76	73.99	1.36	1.8	74.3	69.9 - 78.1	78	50.86	2.34	4.6	50.7	43.8 - 57.9
All Abbott Cell-Dyn Instruments	57	74.42	0.82	1.1	74.5	71.9 - 76.9	59	51.43	1.75	3.4	51.2	46.1 - 56.7
Abbott Cell-Dyn Ruby	44	74.40	0.76	1.0	74.4	72.1 - 76.7	44	51.84	1.95	3.8	51.8	46.0 - 57.7
Orphee Mythic 22	17	72.15	1.44	2.0	72.1	67.8 - 76.5	17	48.45	2.31	4.8	48.4	41.5 - 55.4
Specimen CL-15												
All Method	77	62.34	1.34	2.2	62.4	58.3 - 66.4						
All Abbott Cell-Dyn Instruments	60	62.76	1.08	1.7	62.7	59.5 - 66.1						
Abbott Cell-Dyn Ruby	43	62.87	0.91	1.4	62.9	60.1 - 65.6						
Orphee Mythic 22	17	60.55	1.13	1.9	60.8	57.1 - 64.0						

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

Specimen CL-11							Specimen CL-12					
<u>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	75	37.21	4.31	11.6	38.6	24.2 - 50.2	77	24.56	3.99	16.3	26.0	12.5 - 36.6
All Abbott Cell-Dyn Instruments	58	38.71	1.65	4.3	38.9	33.7 - 43.7	60	26.23	0.95	3.6	26.3	23.3 - 29.1
Abbott Cell-Dyn Ruby	43	38.49	1.68	4.4	38.9	33.4 - 43.6	44	26.17	0.97	3.7	26.2	23.2 - 29.1
Orphee Mythic 22	16	27.99	4.78	17.1	28.4	13.6 - 42.4	16	16.94	3.33	19.7	17.7	6.9 - 27.0
Specimen CL-13							Specimen CL-14					
All Method	77	14.59	1.32	9.0	14.2	10.6 - 18.6	76	36.09	4.22	11.7	37.3	23.4 - 48.8
All Abbott Cell-Dyn Instruments	58	14.59	1.08	7.4	14.3	11.3 - 17.9	59	37.60	2.00	5.3	38.0	31.6 - 43.6
Abbott Cell-Dyn Ruby	41	14.32	0.59	4.2	14.2	12.5 - 16.2	43	37.10	1.93	5.2	37.4	31.3 - 42.9
Orphee Mythic 22	16	14.19	1.67	11.7	14.2	9.1 - 19.2	16	28.48	4.76	16.7	28.1	14.1 - 42.8
Specimen CL-15												
All Method	78	24.35	3.89	16.0	25.9	12.6 - 36.1						
All Abbott Cell-Dyn Instruments	57	26.04	0.96	3.7	26.0	23.1 - 29.0						
Abbott Cell-Dyn Ruby	42	26.26	1.09	4.2	26.1	22.9 - 29.6						
Orphee Mythic 22	16	17.77	2.93	16.5	17.9	8.9 - 26.6						

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

Specimen CL-11							Specimen CL-12					
<u>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	75	8.67	5.63	64.9	6.1	0.0 - 25.6	77	8.62	5.34	62.0	6.0	0.0 - 24.7
All Abbott Cell-Dyn Instruments	57	6.04	0.97	16.0	6.0	3.1 - 9.0	57	6.00	0.58	9.7	6.0	4.2 - 7.8
Abbott Cell-Dyn Ruby	42	6.05	0.78	12.9	6.0	3.7 - 8.4	44	6.03	0.62	10.3	6.0	4.1 - 7.9
Orphee Mythic 22	14	20.52	4.20	20.5	19.8	7.9 - 33.2	16	18.46	3.40	18.4	17.9	8.2 - 28.7
Specimen CL-13							Specimen CL-14					
All Method	71	4.73	2.05	43.4	4.0	0.0 - 10.9	71	7.76	4.70	60.6	6.0	0.0 - 21.9
All Abbott Cell-Dyn Instruments	55	3.85	0.44	11.4	3.9	2.5 - 5.2	56	5.78	0.59	10.2	5.8	4.0 - 7.6
Abbott Cell-Dyn Ruby	42	3.87	0.34	8.8	3.9	2.8 - 4.9	42	5.78	0.58	10.0	5.8	4.0 - 7.6
Orphee Mythic 22	14	8.96	1.64	18.3	8.8	4.0 - 13.9	14	19.74	4.47	22.6	19.9	6.3 - 33.2
Specimen CL-15												
All Method	78	8.36	4.80	57.4	6.0	0.0 - 22.8						
All Abbott Cell-Dyn Instruments	56	5.93	0.45	7.6	5.9	4.5 - 7.3						
Abbott Cell-Dyn Ruby	42	5.91	0.40	6.8	5.9	4.6 - 7.2						
Orphee Mythic 22	16	17.18	3.20	18.7	17.5	7.5 - 26.8						

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

Specimen CL-11							Specimen CL-12					
<u>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	76	3.98	0.46	11.6	4.0	2.5 - 5.4	75	4.59	0.37	8.0	4.6	3.4 - 5.7
All Abbott Cell-Dyn Instruments	58	4.06	0.37	9.0	4.0	2.9 - 5.2	60	4.68	0.30	6.5	4.7	3.7 - 5.6
Abbott Cell-Dyn Ruby	42	4.09	0.40	9.7	4.1	2.8 - 5.3	44	4.74	0.28	6.0	4.8	3.8 - 5.6
Orphee Mythic 22	17	3.65	0.61	16.7	3.5	1.8 - 5.5	15	4.17	0.45	10.8	4.3	2.8 - 5.6
Specimen CL-13							Specimen CL-14					
All Method	75	6.17	0.92	14.8	6.5	3.4 - 9.0	77	4.01	0.56	13.9	4.0	2.3 - 5.7
All Abbott Cell-Dyn Instruments	60	6.56	0.35	5.4	6.6	5.5 - 7.7	59	4.14	0.42	10.2	4.1	2.8 - 5.5
Abbott Cell-Dyn Ruby	44	6.57	0.35	5.3	6.6	5.5 - 7.7	44	4.21	0.46	11.0	4.1	2.8 - 5.7
Orphee Mythic 22	15	4.43	0.89	20.2	4.3	1.7 - 7.2	16	3.42	0.52	15.1	3.5	1.8 - 5.0
Specimen CL-15												
All Method	75	4.61	0.37	8.0	4.6	3.5 - 5.8						
All Abbott Cell-Dyn Instruments	60	4.68	0.29	6.1	4.7	3.8 - 5.6						
Abbott Cell-Dyn Ruby	44	4.63	0.29	6.2	4.6	3.7 - 5.5						
Orphee Mythic 22	15	4.21	0.64	15.1	4.3	2.2 - 6.2						

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

Specimen CL-11							Specimen CL-12					
<u>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	75	0.79	0.38	48.3	0.8	0.0 - 2.0	75	0.41	0.27	65.8	0.4	0.0 - 1.3
All Abbott Cell-Dyn Instruments	59	0.87	0.37	42.9	0.9	0.0 - 2.0	58	0.39	0.25	64.6	0.4	0.0 - 1.2
Abbott Cell-Dyn Ruby	43	0.85	0.33	39.1	0.9	0.0 - 1.9	43	0.37	0.25	66.6	0.3	0.0 - 1.2
Orphee Mythic 22	16	0.51	0.28	55.1	0.5	0.0 - 1.4	16	0.43	0.27	62.6	0.4	0.0 - 1.3
Specimen CL-13							Specimen CL-14					
All Method	76	0.63	0.30	48.2	0.6	0.0 - 1.6	75	0.75	0.42	56.1	0.7	0.0 - 2.1
All Abbott Cell-Dyn Instruments	59	0.63	0.28	44.3	0.6	0.0 - 1.5	59	0.83	0.42	50.9	0.8	0.0 - 2.1
Abbott Cell-Dyn Ruby	43	0.70	0.26	37.8	0.7	0.0 - 1.5	43	0.83	0.38	46.1	0.8	0.0 - 2.0
Orphee Mythic 22	16	0.62	0.39	63.3	0.6	0.0 - 1.8	16	0.48	0.29	61.7	0.4	0.0 - 1.4
Specimen CL-15												
All Method	74	0.40	0.25	62.2	0.4	0.0 - 1.2						
All Abbott Cell-Dyn Instruments	57	0.40	0.23	58.4	0.4	0.0 - 1.1						
Abbott Cell-Dyn Ruby	41	0.33	0.19	57.4	0.4	0.0 - 1.0						
Orphee Mythic 22	16	0.36	0.24	66.0	0.3	0.0 - 1.1						

BLOOD BANK
ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Group O	133	99.25%	Acceptable
	Group AB	1	0.75%	
BB-12	Group A	134	99.26%	Acceptable
	Group AB	1	0.74%	
BB-13	Group B	128	97.71%	Acceptable
	Group AB	3	2.29%	
BB-14	Group O	135	100%	Acceptable
BB-15	Group A	135	99.26%	Acceptable
	Group O	1	0.74%	

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Rh Negative	134	99.26%	Acceptable
	Rh Positive	1	0.74%	
BB-12	Rh Positive	135	99.26%	Acceptable
	Ph Negative	1	0.74%	
BB-13	Rh Positive	130	98.48%	Acceptable
	Rh Negative	2	1.52%	
BB-14	Rh Positive	134	98.53%	Acceptable
	Rh Negative	2	1.47%	
BB-15	Rh Negative	136	99.27%	Acceptable
	Rh Positive	1	0.73%	

BLOOD BANK

UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	No unexpected antibody detected	96	97.96%	Acceptable
	Unexpected antibody detected	2	2.04%	
AB-12	No unexpected antibody detected	96	97.96%	Acceptable
	Unexpected antibody detected	2	2.04%	
AB-13	Unexpected antibody detected	95	96.94%	Acceptable
	No unexpected antibody detected	3	3.06%	
AB-14	No unexpected antibody detected	92	93.88%	Acceptable
	Unexpected antibody detected	6	6.12%	
AB-15	Unexpected antibody detected	96	97.96%	Acceptable
	No unexpected antibody detected	2	2.04%	

Specimen AB-14 was graded by 100% referee consensus.

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	No antibody detected	45	93.75%	Acceptable
	Anti-c	1	2.08%	
	Anti-e	1	2.08%	
	Unable to identify, referred	1	2.08%	
AB-12	No antibody detected	45	91.84%	Acceptable
	Anti-C	1	2.04%	
	Anti-c	1	2.04%	
	Anti-e	1	2.04%	
	Anti-k	1	2.04%	
AB-13	AntiE	46	95.83%	Acceptable
	Anti-e	1	2.08%	
	Anti-c	1	2.08%	
AB-14	No antibody detected	45	91.84%	Acceptable
	Anti-C	1	2.04%	
	Anti-c	1	2.04%	
	Anti-e	1	2.04%	
	Unable to identify, referred	1	2.04%	
AB-15	Anit-D	45	93.75%	Acceptable
	Anti-e	1	2.08%	
	Anti-Fy(b)	1	2.08%	
	Anti-c	1	2.08%	

Specimens AB-11, AB-12, AB-14 and AB-15 were graded by 100% referee consensus.

BLOOD BANK

COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	Compatible	104	96.30%	Acceptable
	Not Compatible	4	3.70%	
AB-12	Compatible	105	97.22%	Acceptable
	Not Compatible	3	2.78%	
AB-13	Compatible	97	90.65%	Acceptable
	Not Compatible	10	9.35%	
AB-14	Compatible	98	91.59%	Acceptable
	Not Compatible	9	8.41%	
AB-15	Not Compatible	102	94.44%	Acceptable
	Compatible	6	5.56%	

Specimens AB-13, AB-14 and AB-15 were graded by 100% referee consensus.

Coagulation

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<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	131	29.34	4.64	15.8	30.4	24.9 - 33.8	130	50.68	9.88	19.5	52.6	43.0 - 58.3
Dade Innovin												
Dade Behring BFT II	5	25.78	2.05	7.9	25.5	21.9 - 29.7	5	44.98	3.85	8.6	44.3	38.2 - 51.8
Sysmex CA-500/600 series	26	25.29	0.89	3.5	25.2	21.4 - 29.1	26	42.64	1.77	4.1	42.5	36.2 - 49.1
All Coagulation Instruments	35	25.40	1.17	4.6	25.4	21.5 - 29.3	36	43.40	2.92	6.7	42.7	36.8 - 50.0
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	6	34.98	1.73	4.9	35.7	29.7 - 40.3	6	62.65	3.42	5.5	63.4	53.2 - 72.1
Diagnostica Stago STart 4/8	11	33.49	2.46	7.3	32.9	28.4 - 38.6	11	59.64	8.36	14.0	57.8	50.6 - 68.6
RAL Clot-SP	18	32.36	1.28	3.9	32.4	27.5 - 37.3	18	56.81	2.62	4.6	57.0	48.2 - 65.4
All Coagulation Instruments	41	33.02	1.70	5.1	32.9	28.0 - 38.0	41	58.02	4.85	8.4	57.8	49.3 - 66.8
Diagon Dia-PT												
Coalyzer-410	6	29.42	1.50	5.1	29.4	25.0 - 33.9	6	52.87	3.12	5.9	52.3	44.9 - 60.8
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	30.30	2.05	6.8	30.6	25.7 - 34.9	6	52.18	4.06	7.8	53.1	44.3 - 60.1
IL TEST PT Fibrinogen												
IL ACL, all models	9	20.89	0.67	3.2	21.0	17.7 - 24.1	9	31.33	1.23	3.9	31.7	26.6 - 36.1
IL TEST PT-FIB HS PLUS												
IL ACL, all models	15	32.89	2.60	7.9	33.8	27.9 - 37.9	15	58.05	2.67	4.6	58.8	49.3 - 66.8

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-13						Specimen CG-14					
	<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	131	11.93	1.40	11.7	12.1	10.1 - 13.8	130	12.66	1.57	12.4	13.1	10.7 - 14.6
Dade Innovin												
Dade Behring BFT II	5	9.26	0.58	6.2	9.2	7.8 - 10.7	5	9.46	0.74	7.8	9.3	8.0 - 10.9
Sysmex CA-500/600 series	27	10.44	0.32	3.1	10.4	8.8 - 12.1	27	10.98	0.28	2.5	10.9	9.3 - 12.7
All Coagulation Instruments	36	10.22	0.62	6.1	10.3	8.6 - 11.8	36	10.68	0.75	7.0	10.9	9.0 - 12.3
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	6	12.77	0.34	2.7	12.9	10.8 - 14.7	6	13.30	0.46	3.5	13.3	11.3 - 15.3
Diagnostica Stago STart 4/8	11	12.66	0.85	6.7	12.4	10.7 - 14.6	11	13.80	1.02	7.4	13.5	11.7 - 15.9
RAL Clot-SP	18	13.38	0.48	3.6	13.4	11.3 - 15.4	18	14.11	0.46	3.2	14.1	11.9 - 16.3
All Coagulation Instruments	43	13.04	0.67	5.1	13.0	11.0 - 15.1	42	13.82	0.57	4.1	13.9	11.7 - 15.9
Diagon Dia-PT												
Coalyzer-410	6	12.43	0.76	6.1	12.3	10.5 - 14.3	6	14.05	2.42	17.3	13.5	11.9 - 16.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	11.17	0.30	2.7	11.2	9.4 - 12.9	6	12.33	0.33	2.7	12.4	10.4 - 14.2
IL TEST PT Fibrinogen												
IL ACL, all models	9	11.36	0.36	3.2	11.4	9.6 - 13.1	9	11.74	0.21	1.8	11.7	9.9 - 13.6
IL TEST PT-FIB HS PLUS												
IL ACL, all models	14	13.10	0.44	3.4	13.2	11.1 - 15.1	15	13.70	0.66	4.8	13.8	11.6 - 15.8

PROTHROMBIN TIME (seconds)

Specimen CG-15						
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	128	13.47	1.16	8.6	13.5	11.4 - 15.5
Dade Innovin						
Dade Behring BFT II	5	11.58	0.55	4.8	11.6	9.8 - 13.4
Sysmex CA-500/600 series	27	12.59	0.39	3.1	12.6	10.6 - 14.5
All Coagulation Instruments	36	12.37	0.61	4.9	12.5	10.5 - 14.3
Diag Stago STA Neoplastine Cl+						
bioMerieux Thrombolyzer Compact X/XR	6	14.23	0.44	3.1	14.2	12.0 - 16.4
Diagnostica Stago STart 4/8	11	13.95	1.57	11.3	13.5	11.8 - 16.1
RAL Clot-SP	18	14.83	0.55	3.7	14.7	12.6 - 17.1
All Coagulation Instruments	42	14.30	0.75	5.3	14.3	12.1 - 16.5
Diagon Dia-PT						
Coalyzer-410	5	13.22	0.76	5.7	13.0	11.2 - 15.3
HemosIL RecombiPlasTin 2G						
IL ACL, all models	6	12.10	0.47	3.9	12.4	10.2 - 14.0
IL TEST PT Fibrinogen						
IL ACL, all models	9	13.31	0.32	2.4	13.3	11.3 - 15.4
IL TEST PT-FIB HS PLUS						
IL ACL, all models	15	14.52	0.33	2.3	14.5	12.3 - 16.7

PROTHROMBIN TIME-INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<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	128	2.84	0.48	17.0	2.8	2.2 - 3.5	127	5.45	1.53	28.0	5.4	4.3 - 6.6
Dade Innovin												
Dade Behring BFT II	5	2.46	0.15	6.2	2.4	1.9 - 3.0	5	3.94	0.28	7.1	3.8	3.1 - 4.8
Sysmex CA-500/600 series	27	2.44	0.12	5.0	2.4	1.9 - 3.0	27	4.09	0.25	6.1	4.0	3.2 - 5.0
All Coagulation Instruments	36	2.44	0.13	5.5	2.5	1.9 - 3.0	36	4.06	0.27	6.7	4.0	3.2 - 4.9
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	6	3.65	0.54	14.8	3.9	2.9 - 4.4	6	7.70	1.29	16.8	8.0	6.1 - 9.3
Diagnostica Stago STart 4/8	9	3.42	0.33	9.7	3.4	2.7 - 4.2	9	7.24	0.97	13.4	7.2	5.7 - 8.7
RAL Clot-SP	16	3.23	0.22	6.9	3.2	2.5 - 3.9	16	6.77	0.52	7.7	6.9	5.4 - 8.2
All Coagulation Instruments	38	3.33	0.37	11.2	3.3	2.6 - 4.1	37	6.98	0.95	13.5	7.2	5.5 - 8.4
Diagon Dia-PT												
Coalyzer-410	6	2.82	0.29	10.1	2.9	2.2 - 3.4	6	5.88	0.87	14.8	5.7	4.7 - 7.1
HemosIL RecombiPlasTin 2G												
IL ACL, all models	7	2.80	0.23	8.2	2.8	2.2 - 3.4	7	4.93	0.51	10.3	5.0	3.9 - 6.0
IL TEST PT Fibrinogen												
IL ACL, all models	9	2.89	0.27	9.2	2.9	2.3 - 3.5	9	5.88	0.58	9.9	5.8	4.7 - 7.1
IL TEST PT-FIB HS PLUS												
IL ACL, all models	15	2.74	0.37	13.6	2.8	2.1 - 3.3	15	5.21	0.63	12.0	5.4	4.1 - 6.3

PROTHROMBIN TIME-INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-13						Specimen CG-14					
	<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	128	0.99	0.08	8.5	1.0	0.7 - 1.2	127	1.06	0.11	10.0	1.1	0.8 - 1.3
Dade Innovin												
Dade Behring BFT II	5	1.02	0.04	4.4	1.0	0.8 - 1.3	5	1.06	0.05	5.2	1.1	0.8 - 1.3
Sysmex CA-500/600 series	27	1.02	0.07	7.2	1.0	0.8 - 1.3	27	1.07	0.05	5.1	1.1	0.8 - 1.3
All Coagulation Instruments	36	1.02	0.07	7.1	1.0	0.8 - 1.3	36	1.07	0.06	5.5	1.1	0.8 - 1.3
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	6	0.98	0.10	10.0	1.0	0.7 - 1.2	6	1.02	0.12	11.5	1.1	0.8 - 1.3
Diagnostica Stago STart 4/8	9	0.97	0.10	10.3	0.9	0.7 - 1.2	9	1.07	0.14	13.3	1.0	0.8 - 1.3
RAL Clot-SP	16	1.00	0.07	7.3	1.0	0.8 - 1.2	16	1.06	0.06	5.8	1.1	0.8 - 1.3
All Coagulation Instruments	38	0.99	0.09	8.6	1.0	0.7 - 1.2	37	1.05	0.08	8.0	1.1	0.8 - 1.3
Diagon Dia-PT												
Coalyzer-410	6	0.95	0.08	8.8	0.9	0.7 - 1.2	5	1.14	0.32	28.2	1.0	0.9 - 1.4
HemosIL RecombiPlasTin 2G												
IL ACL, all models	7	1.00	0.06	5.8	1.0	0.8 - 1.2	7	1.11	0.07	6.2	1.1	0.8 - 1.4
IL TEST PT Fibrinogen												
IL ACL, all models	9	0.99	0.06	6.1	1.0	0.7 - 1.2	9	1.02	0.07	6.5	1.0	0.8 - 1.3
IL TEST PT-FIB HS PLUS												
IL ACL, all models	15	0.93	0.09	9.6	1.0	0.7 - 1.2	15	0.98	0.09	8.8	1.0	0.7 - 1.2

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

Specimen CG-15

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	126	1.14	0.12	10.5	1.1	0.9 - 1.4
Dade Innovin						
Dade Behring BFT II	5	1.28	0.04	3.5	1.3	1.0 - 1.6
Sysmex CA-500/600 series	27	1.21	0.08	6.2	1.2	0.9 - 1.5
All Coagulation Instruments	36	1.22	0.07	6.1	1.2	0.9 - 1.5
Diag Stago STA Neoplastine CI+						
bioMerieux Thrombolyzer Compact X/XR	6	1.13	0.12	10.7	1.2	0.9 - 1.4
Diagnostica Stago STart 4/8	9	1.11	0.15	13.1	1.1	0.8 - 1.4
RAL Clot-SP	16	1.14	0.05	4.4	1.1	0.9 - 1.4
All Coagulation Instruments	38	1.12	0.10	8.9	1.1	0.8 - 1.4
Diagon Dia-PT						
Coalyzer-410	5	1.02	0.11	10.7	1.0	0.8 - 1.3
HemosIL RecombiPlasTin 2G						
IL ACL, all models	7	1.11	0.07	6.2	1.1	0.8 - 1.4
IL TEST PT Fibrinogen						
IL ACL, all models	9	1.28	0.07	5.2	1.3	1.0 - 1.6
IL TEST PT-FIB HS PLUS						
IL ACL, all models	14	1.07	0.05	4.4	1.1	0.8 - 1.3

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<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	74	52.0	7.6	14.6	49	44 - 60	75	78.4	14.8	18.9	71	66 - 91
Dade Actin												
Sysmex CA-500/600 series	3	74.3	7.8	10.4	72	63 - 86	3	110.7	13.7	12.3	117	94 - 128
All Coagulation Instruments	4	73.0	6.9	9.4	71	62 - 84	4	109.0	11.6	10.7	111	92 - 126
Dade Actin FSL												
Sysmex CA-500/600 series	14	47.1	1.3	2.8	48	40 - 55	14	69.2	2.0	3.0	70	58 - 80
All Coagulation Instruments	15	47.4	1.8	3.8	48	40 - 55	15	69.8	3.0	4.3	70	59 - 81
Diagnostica Stago STA C.K. Prest												
bioMerieux Thrombolyzer Compact X/XR	5	52.2	2.7	5.1	51	44 - 61	5	74.8	6.3	8.4	73	63 - 87
Diagnostica Stago STA Compact	3	49.0	2.6	5.4	48	41 - 57	4	73.3	4.3	5.9	74	62 - 85
Diagnostica Stago STart 4/8	5	50.6	5.1	10.1	52	43 - 59	4	81.3	9.1	11.3	83	69 - 94
All Coagulation Instruments	15	50.9	3.5	6.9	51	43 - 59	15	76.3	7.0	9.2	77	64 - 88
Diagnostica Stago STA-PTT												
All Coagulation Instruments	3	54.7	4.9	9.0	57	46 - 63	3	77.7	3.2	4.1	79	66 - 90
Diagon Dia-PTT												
Coalyzer-410	3	109.0	15.5	14.2	110	92 - 126	3	265.3	19.5	7.4	274	225 - 306
Hemoliance SynthASil												
IL ACL, all models	5	59.4	1.1	1.9	59	50 - 69	5	88.2	3.8	4.3	91	74 - 102
IL TEST APTT-SP												
IL ACL, all models	23	46.6	2.3	4.8	47	39 - 54	23	68.4	2.4	3.5	69	58 - 79

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

Specimen CG-13							Specimen CG-14					
<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	80	27.7	3.1	11.1	27	23 - 32	78	32.4	3.2	9.9	31	27 - 38
Dade Actin												
Sysmex CA-500/600 series	3	26.7	1.5	5.7	27	22 - 31	2	-	-	-	36	29 - 40
All Coagulation Instruments	4	26.8	1.3	4.7	27	22 - 31	3	34.7	2.9	8.3	33	29 - 40
Dade Actin FSL												
Sysmex CA-500/600 series	14	24.6	0.5	2.0	25	20 - 29	13	30.5	0.7	2.2	31	25 - 36
All Coagulation Instruments	15	24.7	0.6	2.4	25	21 - 29	14	30.6	0.7	2.4	31	26 - 36
Diagnostica Stago STA C.K. Prest												
bioMerieux Thrombolyzer Compact X/XR	5	31.4	1.5	4.8	31	26 - 37	5	35.6	1.8	5.1	35	30 - 41
Diagnostica Stago STA Compact	4	29.8	1.5	5.0	29	25 - 35	4	34.3	1.3	3.7	34	29 - 40
Diagnostica Stago STart 4/8	4	29.0	2.7	9.3	30	24 - 34	4	32.8	3.9	11.8	35	27 - 38
All Coagulation Instruments	15	30.2	1.9	6.4	30	25 - 35	15	34.2	2.4	7.1	34	29 - 40
Diagnostica Stago STA-PTT												
All Coagulation Instruments	4	32.5	2.4	7.3	33	27 - 38	4	37.3	3.2	8.6	38	31 - 43
Diagon Dia-PTT												
Coalyzer-410	3	30.3	2.5	8.3	30	25 - 35	3	35.3	4.0	11.4	36	30 - 41
Hemoliance SynthASil												
IL ACL, all models	5	31.0	0.1	0.0	31	26 - 36	5	31.2	0.4	1.4	31	26 - 36
IL TEST APTT-SP												
IL ACL, all models	24	25.6	1.0	3.8	25	21 - 30	24	30.4	2.0	6.5	30	25 - 35
Specimen CG-15												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	79	36.2	5.3	14.5	35	30 - 42						
Dade Actin												
Sysmex CA-500/600 series	2	-	-	-	33	27 - 38						
All Coagulation Instruments	3	32.7	1.5	4.7	33	27 - 38						
Dade Actin FSL												
Sysmex CA-500/600 series	14	29.0	0.1	0.0	29	24 - 34						
All Coagulation Instruments	14	29.0	0.1	0.0	29	24 - 34						
Diagnostica Stago STA C.K. Prest												
bioMerieux Thrombolyzer Compact X/XR	5	41.2	1.8	4.3	41	35 - 48						
Diagnostica Stago STA Compact	4	38.3	1.3	3.3	38	32 - 44						
Diagnostica Stago STart 4/8	4	37.5	3.1	8.3	39	31 - 44						
All Coagulation Instruments	15	39.1	2.4	6.2	39	33 - 46						
Diagnostica Stago STA-PTT												
All Coagulation Instruments	4	42.8	2.2	5.2	43	36 - 50						
Diagon Dia-PTT												
Coalyzer-410	3	38.3	1.2	3.0	39	32 - 45						
Hemoliance SynthASil												
IL ACL, all models	5	46.8	1.1	2.3	46	39 - 54						
IL TEST APTT-SP												
IL ACL, all models	24	34.9	1.1	3.1	35	29 - 41						

FIBRINOGEN (mg/dL)

Specimen CG-11							Specimen CG-12					
<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	33	328.3	46.9	14.3	320	262 - 394	34	337.3	51.1	15.2	336	269 - 405
Diagnostica Stago STA Fibrinogen												
bioMerieux Thrombolyzer Compact												
X/XR	4	-	-	-	278	231 - 348	5	281.6	18.6	6.6	289	225 - 338
All Coagulation Instruments	8	289.6	35.4	12.2	295	231 - 348	9	285.3	15.1	5.3	289	228 - 343
IL TEST PT-FIB HS PLUS												
IL ACL, all models	11	358.1	30.6	8.5	363	286 - 430	12	379.0	35.7	9.4	376	303 - 455
IL TEST PT-FIB Recombinant												
IL ACL, all models	5	370.2	45.8	12.4	379	296 - 445	5	370.2	49.6	13.4	366	296 - 445
Specimen CG-13							Specimen CG-14					
<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	36	357.7	31.4	8.8	349	286 - 430	31	546.1	51.6	9.4	540	436 - 656
Diagnostica Stago STA Fibrinogen												
bioMerieux Thrombolyzer Compact												
X/XR	5	339.2	35.1	10.3	345	271 - 408	4	-	-	-	557	438 - 658
All Coagulation Instruments	9	342.2	27.4	8.0	345	273 - 411	8	548.0	39.3	7.2	540	438 - 658
IL TEST PT-FIB HS PLUS												
IL ACL, all models	12	359.3	29.3	8.2	354	287 - 432	12	543.2	50.8	9.3	532	434 - 652
IL TEST PT-FIB Recombinant												
IL ACL, all models	5	382.8	21.4	5.6	383	306 - 460	5	578.6	43.1	7.5	579	462 - 695
Specimen CG-15												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	34	151.3	22.6	15.0	151	121 - 182						
Diagnostica Stago STA Fibrinogen												
bioMerieux Thrombolyzer Compact												
X/XR	5	146.8	16.8	11.4	153	117 - 177						
All Coagulation Instruments	9	151.0	13.5	8.9	153	120 - 182						
IL TEST PT-FIB HS PLUS												
IL ACL, all models	10	143.2	15.0	10.5	144	114 - 172						
IL TEST PT-FIB Recombinant												
IL ACL, all models	5	134.2	20.5	15.3	127	107 - 162						

URINALYSIS DIPSTICK–SPECIFIC GRAVITY

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	423	1.0156	0.0049	0.5	1.015	1.005 - 1.026
All Refractive Index Methods	11	1.0204	0.0041	0.4	1.020	1.010 - 1.031
All Roche Methods	142	1.0141	0.0043	0.4	1.015	1.004 - 1.025
All Siemens Methods	49	1.0142	0.0041	0.4	1.015	1.004 - 1.025
Arkray Aution Sticks	15	1.0221	0.0058	0.6	1.020	1.012 - 1.033
Combi-Screen Test Strips	12	1.0146	0.0025	0.3	1.015	1.004 - 1.025
DIRUI H-100 / H-500 Urine Analyzer	19	1.0142	0.0020	0.2	1.015	1.004 - 1.025
Other Analyzer Method	14	1.0191	0.0053	0.5	1.021	1.009 - 1.030
Roche Chemstrips / Combur	27	1.0111	0.0032	0.3	1.010	1.001 - 1.022
Roche cobas u 411	87	1.0132	0.0034	0.3	1.015	1.003 - 1.024
Roche Urisys	48	1.0163	0.0049	0.5	1.019	1.006 - 1.027
SD UroColor Reagent Strips	23	1.0211	0.0036	0.4	1.020	1.011 - 1.032
Siemens Clinitek Advantus	30	1.0125	0.0029	0.3	1.010	1.002 - 1.023
Siemens Clinitek Status / Status+	10	1.0165	0.0024	0.2	1.015	1.006 - 1.027
UriScan Reagent Strips	34	1.0178	0.0051	0.5	1.020	1.007 - 1.028

URINALYSIS DIPSTICK–pH

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<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	443	-	-	-	-	1	7	71	345	16	3	-	-
Acon Laboratories	9	-	-	-	-	-	-	2	6	-	1	-	-
Analyticon CombiScan 500	2	-	-	-	-	-	1	-	1	-	-	-	-
Arkray Aution Jet	3	-	-	-	-	-	-	1	2	-	-	-	-
Arkray Aution Sticks	15	-	-	-	-	-	-	5	9	1	-	-	-
Arkray PocketChem UA	3	-	-	-	-	-	-	-	3	-	-	-	-
Combi-Screen Test Strips	14	-	-	-	-	-	-	-	14	-	-	-	-
Diagnostic Test Group Clarity Urocheck	1	-	-	-	-	-	-	-	1	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	21	-	-	-	-	-	-	9	6	6	-	-	-
DIRUI H-800 Urine Analyzer	7	-	-	-	-	-	-	1	5	1	-	-	-
HUMAN Combilyzer	2	-	-	-	-	-	-	-	2	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	-	1	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	-	-	-	-	-	-	6	2	-	-	-	-
Other Analyzer Method	16	-	-	-	-	-	-	8	8	-	-	-	-
Other Dipstick Method	8	-	-	-	-	-	2	3	2	-	1	-	-
Plasmatec URIPATH	2	-	-	-	-	-	-	-	2	-	-	-	-
Roche Chemstrip 101	5	-	-	-	-	-	-	-	5	-	-	-	-
Roche Chemstrips / Combur	29	-	-	-	-	-	-	-	28	-	1	-	-
Roche cobas u 411	87	-	-	-	-	-	-	2	85	-	-	-	-
Roche Mditron Junior/II	2	-	-	-	-	-	-	-	2	-	-	-	-
Roche Urilux S	2	-	-	-	-	-	-	-	2	-	-	-	-
Roche Urisys	49	-	-	-	-	-	-	1	47	1	-	-	-
SD UroColor Reagent Strips	24	-	-	-	-	1	-	7	15	1	-	-	-
Siemens Clinitek 50	1	-	-	-	-	-	-	-	-	1	-	-	-
Siemens Clinitek 500	2	-	-	-	-	-	-	-	2	-	-	-	-
Siemens Clinitek Advantus	30	-	-	-	-	-	-	2	28	-	-	-	-
Siemens Clinitek Atlas	6	-	-	-	-	-	-	-	6	-	-	-	-
Siemens Clinitek Status / Status+	11	-	-	-	-	-	-	-	11	-	-	-	-
Siemens Multistix Pro	6	-	-	-	-	-	-	-	5	1	-	-	-
Siemens Reagent Strips	18	-	-	-	-	-	-	-	14	4	-	-	-
TECO URS Strips	1	-	-	-	-	-	-	1	-	-	-	-	-
Urinometer	2	-	-	-	-	-	-	-	2	-	-	-	-
UriScan Pro/II	8	-	-	-	-	-	1	4	3	-	-	-	-
UriScan Reagent Strips	34	-	-	-	-	-	3	15	16	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-

URINALYSIS DIPSTICK–PROTEIN QUALITATIVE

Specimen UA-3

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</u> <u>mg/dL</u>	<u>30 - 70</u> <u>mg/dL</u>	<u>75</u> <u>mg/dL</u>	<u>100 - 200</u> <u>mg/dL</u>	<u>≥300 - 600</u> <u>mg/dL</u>	<u>>600 or ≥1000</u> <u>mg/dL</u>
ALL METHODS	444	438	-	1	1	1	1	-	-	-	2	-	-
Acon Laboratories	9	8	-	1	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	2	2	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	3	3	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	15	15	-	-	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	3	3	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	14	14	-	-	-	-	-	-	-	-	-	-	-
Diagnostic Test Group Clarity Urocheck	1	1	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	22	22	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	6	6	-	-	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	2	1	-	-	-	-	-	-	-	-	1	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	8	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	17	17	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	9	9	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	2	2	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrip 101	5	5	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	31	30	-	-	1	-	-	-	-	-	-	-	-
Roche cobas u 411	89	88	-	-	-	1	-	-	-	-	-	-	-
Roche Miditron Junior/II	2	2	-	-	-	-	-	-	-	-	-	-	-
Roche Urilux S	2	2	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	48	47	-	-	-	-	-	-	-	-	1	-	-
SD UroColor Reagent Strips	24	24	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 50	1	1	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	2	2	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	30	30	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	6	6	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	12	12	-	-	-	-	-	-	-	-	-	-	-
Siemens Multistix Pro	6	6	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	16	16	-	-	-	-	-	-	-	-	-	-	-
TECO URS Strips	1	1	-	-	-	-	-	-	-	-	-	-	-
Urinometer	2	2	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	8	7	-	-	-	-	1	-	-	-	-	-	-
UriScan Reagent Strips	33	33	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>(1+)</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>
					<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>					
ALL METHODS	447	4	1	9	56	65	76	-	14	53	169	
Acon Laboratories	9	-	-	1	2	1	2	-	2	1	-	
Analyticon CombiScan 500	2	-	-	-	-	-	-	-	-	1	1	
Arkray Aution Jet	3	-	-	-	-	1	2	-	-	-	-	
Arkray Aution Sticks	16	-	-	-	-	-	8	-	-	3	5	
Arkray PocketChem UA	3	-	-	-	-	-	2	-	-	-	1	
Combi-Screen Test Strips	13	-	-	-	-	-	-	-	1	5	7	
Diagnostic Test Group Clarity Urocheck	1	-	-	-	1	-	-	-	-	-	-	
DIRUI H-100 / H-500 Urine Analyzer	22	-	-	1	5	6	1	-	3	6	-	
DIRUI H-800 Urine Analyzer	6	-	-	-	1	1	2	-	1	1	-	
HUMAN Combilyzer	2	1	-	-	-	-	-	-	-	1	-	
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	1	-	-	-	1	
Iris Diagnostics iChem Velocity Strips	8	-	-	-	-	2	-	-	1	5	-	
Other Analyzer Method	17	-	-	-	-	1	6	-	2	1	7	
Other Dipstick Method	9	-	-	-	2	3	-	-	1	2	1	
Plasmatec URIPATH	2	-	-	1	1	-	-	-	-	-	-	
Roche Chemstrip 101	5	-	-	-	-	-	-	-	-	-	5	
Roche Chemstrips / Combur	30	-	-	-	1	2	17	-	-	1	9	
Roche cobas u 411	89	1	-	-	-	2	11	-	1	-	74	
Roche Mditron Junior/II	2	-	-	-	-	-	1	-	-	-	1	
Roche Urilux S	2	-	-	-	-	-	2	-	-	-	-	
Roche Urisys	49	1	-	-	1	1	11	-	1	-	34	
SD UroColor Reagent Strips	24	-	-	-	7	10	2	-	-	1	4	
Serim Blood Leak Strips	1	-	-	-	1	-	-	-	-	-	-	
Siemens Clinitek 50	1	1	-	-	-	-	-	-	-	-	-	
Siemens Clinitek 500	2	-	-	-	-	-	-	-	-	1	1	
Siemens Clinitek Advantus	30	-	-	1	12	6	-	-	-	8	3	
Siemens Clinitek Atlas	6	-	-	-	1	3	-	-	-	1	1	
Siemens Clinitek Status / Status+	12	-	-	-	7	1	-	-	-	3	1	
Siemens Multistix Pro	6	-	-	-	-	2	-	-	-	3	1	
Siemens Reagent Strips	18	-	-	5	1	6	-	-	-	2	4	
Urinometer	2	-	-	-	-	2	-	-	-	-	-	
UriScan Pro/II	8	-	-	-	1	3	-	-	-	-	4	
UriScan Reagent Strips	33	-	-	-	11	10	3	-	1	4	4	
URIT Medical Uritest Analyzers	1	-	-	-	-	1	-	-	-	-	-	
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	-	-	-	1	-	

URINALYSIS DIPSTICK–KETONES

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Participant Results</u>					<u>5 - 10 mg/dL</u>	<u>15 - 20 mg/dL</u>	<u>40 - 60 mg/dL</u>	<u>80 - 100 mg/dL</u>	<u>≥150 mg/dL</u>
						<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>					
ALL METHODS	444	4	-	-	-	11	3	21	129	69	1	1	7	49	149
Acon Laboratories	9	-	-	-	-	-	-	-	3	4	-	-	-	-	2
Analyticon CombiScan 500	2	-	-	-	-	-	-	-	-	-	-	-	-	-	2
Arkray Aution Jet	3	-	-	-	-	-	-	-	-	3	-	-	-	-	-
Arkray Aution Sticks	16	-	-	-	-	-	-	-	1	8	-	-	1	3	3
Arkray PocketChem UA	3	-	-	-	-	-	-	-	-	2	-	-	-	-	1
Combi-Screen Test Strips	13	-	-	-	-	-	-	-	2	-	-	-	-	1	10
Diagnostic Test Group Clarity Urocheck	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	22	-	-	-	-	-	-	-	13	1	1	-	-	6	1
DIRUI H-800 Urine Analyzer	5	-	-	-	-	-	1	-	2	1	-	-	-	1	-
HUMAN Combilyzer	2	1	-	-	-	-	-	-	1	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	-	-	-	1	-	-	-	-	1
Iris Diagnostics iChem Velocity Strips	8	-	-	-	-	-	-	-	-	-	-	-	-	4	4
Other Analyzer Method	18	-	-	-	-	-	1	-	4	3	-	-	1	3	6
Other Dipstick Method	9	-	-	-	-	1	-	1	5	-	-	-	-	1	1
Plasmatec URIPATH	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-
Roche Chemstrip 101	5	-	-	-	-	-	-	1	4	-	-	-	-	-	-
Roche Chemstrips / Combur	29	-	-	-	-	3	-	-	20	2	-	-	-	-	4
Roche cobas u 411	89	1	-	-	-	-	-	-	5	10	-	-	-	1	72
Roche Miditron Junior/II	2	-	-	-	-	-	-	-	-	1	-	-	-	-	1
Roche Urilux S	2	-	-	-	-	-	-	-	1	1	-	-	-	-	-
Roche Urisys	48	1	-	-	-	-	-	1	7	5	-	-	2	-	32
SD UroColor Reagent Strips	24	-	-	-	-	-	-	14	3	2	-	-	2	3	-
Siemens Clinitek 50	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	2	-	-	-	-	-	-	-	-	-	-	-	-	1	1
Siemens Clinitek Advantus	30	-	-	-	-	1	-	-	18	-	-	-	-	9	2
Siemens Clinitek Atlas	6	-	-	-	-	-	-	-	3	1	-	-	-	2	-
Siemens Clinitek Status / Status+	12	-	-	-	-	-	-	-	2	7	-	-	-	1	2
Siemens Multistix Pro	6	-	-	-	-	2	-	-	1	2	-	-	-	1	-
Siemens Reagent Strips	17	-	-	-	-	3	-	-	1	10	-	-	-	-	3
TECO URS Strips	1	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Urinometer	2	-	-	-	-	-	-	1	1	-	-	-	-	-	-
UriScan Pro/II	7	-	-	-	-	-	1	-	4	-	-	-	-	2	-
UriScan Reagent Strips	34	-	-	-	-	-	-	3	19	2	-	-	1	9	-
URIT Medical Uritest Analyzers	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Participant Results</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>	<u>>10.0 mg/dL</u>
						<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>				
ALL METHODS	436	435	-	-	-	-	-	-	1	-	-	-	-	-
Acon Laboratories	9	9	-	-	-	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	16	16	-	-	-	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	12	12	-	-	-	-	-	-	-	-	-	-	-	-
Diagnostic Test Group Clarity Urocheck	1	1	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	22	22	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	5	5	-	-	-	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	8	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	18	18	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	9	9	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrip 101	5	5	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	29	29	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	89	89	-	-	-	-	-	-	-	-	-	-	-	-
Roche Miditron Junior/II	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urilux S	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	49	49	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	24	24	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 50	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	30	30	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	6	6	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	11	11	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Multistix Pro	6	6	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	8	8	-	-	-	-	-	-	-	-	-	-	-	-
TECO URS Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	2	2	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	8	7	-	-	-	-	-	-	1	-	-	-	-	-
UriScan Reagent Strips	34	34	-	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Neg or 0.0 - 0.2 mg/dL</u>	<u>1.0 or <2.0 mg/dL</u>	<u>2.0/3.0 mg/dL</u>	<u>4.0 or 4.0/6.0 mg/dL</u>	<u>≥8.0 or ≥12.0 mg/dL</u>
ALL METHODS	433	423	3	4	2	1
Acon Laboratories	9	9	-	-	-	-
Analyticon CombiScan 500	3	3	-	-	-	-
Arkray Aution Jet	3	3	-	-	-	-
Arkray Aution Sticks	15	15	-	-	-	-
Arkray PocketChem UA	2	2	-	-	-	-
Combi-Screen Test Strips	12	12	-	-	-	-
Diagnostic Test Group Clarity Urocheck	1	1	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	22	21	-	1	-	-
DIRUI H-800 Urine Analyzer	6	5	-	-	1	-
HUMAN Combilyzer	2	2	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	7	1	-	-	-
Other Analyzer Method	17	16	1	-	-	-
Other Dipstick Method	9	8	-	1	-	-
Plasmatec URIPATH	2	2	-	-	-	-
Roche Chemstrip 101	5	5	-	-	-	-
Roche Chemstrips / Combur	29	29	-	-	-	-
Roche cobas u 411	88	88	-	-	-	-
Roche Miditron Junior/II	2	2	-	-	-	-
Roche Urilux S	2	2	-	-	-	-
Roche Urisys	49	48	-	-	1	-
SD UroColor Reagent Strips	24	24	-	-	-	-
Siemens Clinitek 50	1	1	-	-	-	-
Siemens Clinitek 500	2	2	-	-	-	-
Siemens Clinitek Advantus	30	30	-	-	-	-
Siemens Clinitek Atlas	6	5	-	1	-	-
Siemens Clinitek Status / Status+	11	10	-	1	-	-
Siemens Multistix Pro	6	6	-	-	-	-
Siemens Reagent Strips	8	8	-	-	-	-
TECO URS Strips	1	-	1	-	-	-
Urinometer	2	2	-	-	-	-
UriScan Pro/II	8	7	-	-	-	1
UriScan Reagent Strips	34	34	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN
Specimen UA-3

<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>(5+)</u>	<u>5 - 25</u> <u>Ery/μL</u>	<u>50 -</u> <u>100</u> <u>Ery/μL</u>	<u>250</u> <u>Ery/μL</u>	<u>±0.03</u> <u>mg/dL</u>	<u>0.06</u> <u>-</u> <u>0.10</u> <u>mg/</u> <u>dL</u>	<u>0.2 -</u> <u>0.5</u> <u>mg/</u> <u>dL</u>	<u>≥ 1.0</u> <u>mg/</u> <u>dL</u>
ALL METHODS	443	429	4	-	-	-	2	1	2	1	1	1	-	2	-	-	-	-
Acon Laboratories	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	11	11	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Diagnostic Test Group Clarity Urocheck	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	22	22	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	5	5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	2	1	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	18	18	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	9	6	2	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrip 101	5	4	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Roche Chemstrips / Combur	29	28	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Roche cobas u 411	88	84	-	-	-	-	2	-	-	-	1	1	-	-	-	-	-	-
Roche Mditron Junior/II	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urilux S	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	49	48	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	24	23	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 50	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	30	30	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	6	6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	12	12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Multistix Pro	6	6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	17	17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
TECO URS Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	8	7	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	34	34	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-3

<u>Method</u>	<i>Participant Results</i>												
	<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>25 µL</u>	<u>75 or 100 µL</u>	<u>250 or 500 µL</u>
ALL METHODS	427	5	-	2	4	4	6	86	112	2	-	21	185
Acon Laboratories	9	-	-	-	-	-	-	5	2	-	-	2	-
Analyticon CombiScan 500	3	-	-	-	-	-	-	-	-	-	-	-	3
Arkray Aution Jet	2	-	-	-	-	-	-	-	-	-	-	-	2
Arkray Aution Sticks	16	-	-	-	-	-	-	-	-	-	-	-	16
Arkray PocketChem UA	3	-	-	-	-	-	-	-	-	-	-	-	3
Combi-Screen Test Strips	11	-	-	-	-	-	-	-	-	-	-	-	11
Diagnostic Test Group Clarity Urocheck	1	-	-	-	-	-	1	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	23	-	-	-	-	-	-	9	6	-	-	4	4
DIRUI H-800 Urine Analyzer	5	-	-	-	-	-	-	1	3	-	-	-	1
HUMAN Combilyzer	2	1	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	-	-	-	-	-	-	2
Iris Diagnostics iChem Velocity Strips	8	-	-	-	-	-	-	-	4	-	-	-	4
Other Analyzer Method	17	-	-	-	-	-	-	3	5	1	-	1	7
Other Dipstick Method	7	-	-	-	-	-	-	1	2	-	-	-	4
Plasmatec URIPATH	2	-	-	-	-	-	-	-	2	-	-	-	-
Roche Chemstrip 101	6	-	-	-	-	-	-	4	2	-	-	-	-
Roche Chemstrips / Combur	27	-	-	-	-	-	-	9	16	-	-	-	2
Roche cobas u 411	87	1	-	-	-	-	-	1	12	-	-	-	73
Roche Miditron Junior/II	2	-	-	-	-	-	-	-	1	-	-	-	1
Roche Urilux S	2	-	-	-	-	-	-	-	2	-	-	-	-
Roche Urisys	49	1	-	-	-	-	-	1	11	-	-	-	36
SD UroColor Reagent Strips	24	1	-	-	-	-	-	10	8	-	-	2	3
Siemens Clinitek 50	1	1	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	2	-	-	-	-	-	-	1	-	-	-	1	-
Siemens Clinitek Advantus	30	-	-	-	1	-	-	20	1	-	-	6	2
Siemens Clinitek Atlas	6	-	-	-	-	1	-	-	4	-	-	-	1
Siemens Clinitek Status / Status+	11	-	-	2	1	1	3	4	-	-	-	-	-
Siemens Multistix Pro	6	-	-	-	-	-	-	5	-	-	-	1	-
Siemens Reagent Strips	8	-	-	-	2	1	-	3	2	-	-	-	-
TECO URS Strips	1	-	-	-	-	1	-	-	-	-	-	-	-
Urinometer	2	-	-	-	-	-	-	1	1	-	-	-	-
UriScan Pro/II	8	-	-	-	-	-	1	-	5	-	-	-	2
UriScan Reagent Strips	34	-	-	-	-	-	1	5	17	1	-	4	6

URINALYSIS DIPSTICK–NITRITE

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	434	429	5
Acon Laboratories	10	9	1
Analyticon CombiScan 500	3	3	-
Arkray Aution Jet	3	3	-
Arkray Aution Sticks	15	15	-
Arkray PocketChem UA	3	3	-
Combi-Screen Test Strips	12	12	-
Diagnostic Test Group Clarity Urocheck	1	1	-
DIRUI H-100 / H-500 Urine Analyzer	22	22	-
DIRUI H-800 Urine Analyzer	5	5	-
HUMAN Combilyzer	2	1	1
Iris Diagnostics Aution Max AX-4280	2	2	-
Iris Diagnostics iChem Velocity Strips	8	8	-
Other Analyzer Method	18	18	-
Other Dipstick Method	9	9	-
Plasmatec URIPATH	2	2	-
Roche Chemstrip 101	5	5	-
Roche Chemstrips / Combur	29	29	-
Roche cobas u 411	87	86	1
Roche Mditron Junior/II	2	2	-
Roche Urilux S	2	2	-
Roche Urisys	49	48	1
SD UroColor Reagent Strips	25	25	-
Siemens Clinitek 50	1	-	1
Siemens Clinitek 500	2	2	-
Siemens Clinitek Advantus	30	30	-
Siemens Clinitek Atlas	5	5	-
Siemens Clinitek Status / Status+	11	11	-
Siemens Multistix Pro	6	6	-
Siemens Reagent Strips	8	8	-
TECO URS Strips	1	1	-
Urinometer	2	2	-
UriScan Pro/II	8	8	-
UriScan Reagent Strips	34	34	-
URIT Medical Uritest Analyzers	1	1	-
URIT Medical Uritest Reagent Strips	1	1	-

URINALYSIS –MICROALBUMIN (dipstick only)

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>									
		<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	19	2	4	5	2	-	-	-	-	1	-
Beckman Coulter ICON microALB	1	1	-	-	-	-	-	-	-	-	-
HUMAN COMBINA Test Strips	1	-	1	-	-	-	-	-	-	-	-
Roche Micral - 1 minute	5	1	-	4	-	-	-	-	-	-	-
Siemens Clinitek Microalbumin	3	-	3	-	-	-	-	-	-	-	-

URINALYSIS –URINE hCG

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>	
		<u>Positive</u>	<u>Negative</u>
ALL METHODS	124	-	124
Acon Laboratories	12	-	12
Alere Acceava hCG-Urine	1	-	1
Alere Clearview hCG Cassette	6	-	6
Beckman Coulter ICON 25 hCG	2	-	2
Biotron 1-Step	7	-	7
Henry Schein One Step	2	-	2
PEP (Lab Supply) HCG	1	-	1
Quidel QuickVue + One-Step	3	-	3
Quidel QuickVue One-Step Combo	18	-	18
Quidel QuickVue One-Step Urine	9	-	9
RefuAH hCG Dipstick	1	-	1
Stanbio QuStick	1	-	1
Sure-Vue hCG - 25mIU	2	-	2

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen SUS-11

Specimen SUS-11	-----Disk Diffusion-----				-----MIC-----				
	Interpretative category data				Interpretative category data				
<u>Antimicrobial</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Acceptable (%)</u>
Amikacin	50	43	4	3	157	133	5	19	83.33%
Amoxicillin/Clavulanate	35	-	-	35	21	-	-	21	Inappropriate drug ¹
Ampicillin	19	-	-	19	46	1	-	45	Inappropriate drug ¹
Ampicillin/Sulbactam	17	-	-	17	44	1	-	43	Inappropriate drug ¹
Aztreonam	24	22	1	1	72	67	-	5	92.00%
Carbenicillin	2	-	-	2	1	-	-	1	Inappropriate drug ¹
Cefaclor	6	-	-	6	2	-	-	2	Inappropriate drug ¹
Cefazolin	3	-	-	3	22	-	-	22	Inappropriate drug ¹
Cefepime	43	30	4	9	166	144	12	10	83.49%
Cefixime	13	1	-	12	5	-	-	5	Inappropriate drug ¹
Cefoperazone	9	9	-	-	2	1	1	-	Inappropriate drug ¹
Cefotaxime	19	6	3	10	30	2	5	23	Inappropriate drug ¹
Cefotetan	-	-	-	-	1	-	-	1	Inappropriate drug ¹
Cefoxitin	8	-	-	8	32	-	-	32	Inappropriate drug ¹
Cefpodoxime	-	-	-	-	2	-	-	2	Inappropriate drug ¹
Ceftazidime	51	46	-	5	169	156	6	7	91.63%
Ceftizoxime	2	-	-	2	-	-	-	-	Inappropriate drug ¹
Ceftriaxone	36	17	8	11	43	2	2	39	Inappropriate drug ¹
Cefuroxime	22	1	-	21	35	-	1	34	Inappropriate drug ¹
Cephalexin	5	-	-	5	3	-	-	3	Inappropriate drug ¹
Cephalothin	12	-	-	12	18	1	-	17	Inappropriate drug ¹
Ciprofloxacin	69	41	18	10	176	83	86	7	93.33%
Colistin	3	3	-	-	12	12	-	-	100.00%
Doripenem	1	1	-	-	10	10	-	-	100.00%
Doxycycline	4	-	-	4	1	-	-	1	Inappropriate drug ¹
Ertapenem	4	-	-	4	14	9	-	5	Inappropriate drug ¹
Fosfomycin	5	4	-	1	7	-	-	7	Inappropriate drug ¹
Gatifloxacin	2	-	-	2	1	1	-	-	Not graded ²
Gentamicin	58	39	12	7	158	27	96	35	Referee grading ³
Imipenem	44	44	-	-	126	123	2	1	98.29%

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

² This is an ungraded challenge due to lack of comparison group.

³ This specimen was graded by 92% referee consensus.

ANTIMICROBIAL SUSCEPTIBILITY TESTING (cont'd)
Specimen SUS-11

Specimen SUS-11	-----Disk Diffusion-----				-----MIC-----				
	Interpretative category data				Interpretative category data				
<u>Antimicrobial</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Acceptable (%)</u>
Kanamycin	-	-	-	-	1	-	-	1	Inappropriate drug ¹
Levofloxacin	32	11	7	14	57	5	24	28	83.16%
Linezolid	1	-	-	1	-	-	-	-	Inappropriate drug ¹
Lomefloxacin	2	1	-	1	-	-	-	-	Not graded ²
Meropenem	36	36	-	-	152	152	-	-	100.00%
Methicillin	1	-	-	1	1	-	1	-	Inappropriate drug ¹
Minocycline	1	-	-	1	3	-	1	2	Inappropriate drug ¹
Moxifloxacin	8	-	2	6	1	-	-	1	Inappropriate drug ¹
Nalidixic Acid	9	-	-	9	6	-	-	6	Inappropriate drug ¹
Netilmicin	5	5	-	-	10	1	3	6	Not graded ⁴
Nitrofurantoin	33	2	-	31	53	1	-	52	Inappropriate drug ¹
Norfloxacin	30	19	6	5	27	19	4	4	Referee grading ⁵
Ofloxacin	28	4	4	20	1	-	-	1	Referee grading ⁶
Oxacillin	2	-	-	2	1	-	-	1	Not graded ²
Penicillin	3	-	-	3	1	-	-	1	Inappropriate drug ¹
Piperacillin	12	11	-	1	25	22	2	1	87.50%
Piperacillin/Tazobactam	41	41	-	-	133	114	12	7	87.43%
Polymyxin B	4	4	-	-	-	-	-	-	100.00%
Quinupristin/Dalfopristin	-	-	-	-	1	-	-	1	Inappropriate drug ¹
Rifampin	1	-	-	1	-	-	-	-	Inappropriate drug ¹
Sulfisoxazole	-	-	-	-	1	-	-	1	Inappropriate drug ¹
Tetracycline	8	1	-	7	10	-	2	8	Inappropriate drug ¹
Ticarcillin	-	-	-	-	5	5	-	-	100.00%
Ticarcillin/Clavulanate	1	1	-	-	6	6	-	-	100.00%
Tigecycline	1	-	-	1	8	1	-	7	Inappropriate drug ¹
Tobramycin	18	17	-	1	38	36	1	1	95.00%
Trimethoprim	-	-	-	-	1	-	-	1	Inappropriate drug ¹
Trimethoprim/Sulfamethoxazole	31	1	-	30	67	1	1	65	Inappropriate drug ¹
Vancomycin	1	-	-	1	-	-	-	-	Inappropriate drug ¹

Organism present in specimen SUS-11: *Pseudomonas aeruginosa*.

⁴ This is an ungraded challenge due to lack of referee consensus.

⁵ This specimen was graded by 100% referee consensus.

⁶ This specimen was graded by 80% referee consensus.

PARASITOLOGY (PA Specimens)

Specimen PA-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba hartmanni	1	50.00%	Unacceptable
No parasite seen	1	50.00%	Unacceptable

Parasite present in specimen PA-11: *Dientamoeba fragilis*. (Graded by US consensus)

Specimen PA-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	2	100%	Unacceptable

Parasites present in specimen PA-12: *Endolimax nana* and *Blastocystis hominis*. (Graded by US consensus)

Specimen PA-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis larvae	12	92.31%	Acceptable
Hookworm	1	7.69%	

Parasite present in specimen PA-13: *Strongyloides stercoralis* larvae.

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. eggs	12	80.00%	Acceptable
Blastocystis hominis	2	13.33%	
Ascaris lumbricoides eggs	1	6.67%	

Parasite present in specimen PA-14: *Taenia sp. eggs*.

Specimen PA-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium ovale	3	27.27%	Acceptable
Plasmodium sp., NOS	2	18.18%	Acceptable
Plasmodium sp., not falciparum	1	9.09%	Acceptable
Plasmodium vivax	3	27.27%	
No parasite seen	2	18.18%	

Parasite present in specimen PA-15: *Plasmodium ovale*. (Graded by US consensus)

PARASITOLOGY (FP Specimens)

Specimen FP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Balantidium coli	253	82.95%	Acceptable
Parasite egg seen but no ID	3	0.98%	Acceptable
No parasite seen	25	8.20%	
Taenia sp. eggs	4	1.31%	
Schistosoma sp. eggs, NOS	3	0.98%	
Diphyllobothrium latum	3	0.98%	
Endolimax nana	2	0.66%	
Fasciola hepatica eggs	2	0.66%	
Giardia lamblia	2	0.66%	
Hookworm	2	0.66%	
Paragonimus westermani eggs	2	0.66%	
Schistosoma japonicum eggs	2	0.66%	
Enterobius vermicularis	1	0.33%	
Ascaris lumbricoides eggs	1	0.33%	

Parasite present in specimen FP-11: *Balantidium coli*.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis larvae	268	87.87%	Acceptable
Parasite larva seen but no ID	2	0.66%	Acceptable
No parasite seen	21	6.89%	
Endolimax nana	5	1.64%	
Hookworm	3	0.98%	
Paragonimus westermani eggs	1	0.33%	
Entamoeba hartmanni	1	0.33%	
Giardia lamblia	1	0.33%	
Blastocystis hominis	1	0.33%	
Chilomastix mesnili	1	0.33%	
Diphyllobothrium latum	1	0.33%	

Parasite present in specimen FP-12: *Strongyloides stercoralis* larvae.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Paragonimus westermani eggs	170	56.11%	Acceptable
Parasite egg seen but no ID	1	0.33%	Acceptable
Fasciola hepatica eggs	47	15.51%	
Diphylobothrium latum	30	9.90%	
No parasite seen	25	8.25%	
Strongyloides stercoralis larvae	5	1.65%	
Hookworm	5	1.65%	
Chilomastix mesnili	4	1.32%	
Enterobius vermicularis eggs	3	0.99%	
Clonorchis sinensis	3	0.99%	
Ascaris lumbricoides eggs	3	0.99%	
Blastocystis hominis	2	0.66%	
Schistosoma sp. eggs, NOS	2	0.66%	
Trichuris trichiura eggs	1	0.33%	
Giardia lamblia	1	0.33%	
Entamoeba coli	1	0.33%	

Parasite present in specimen FP-13: *Paragonimus westermani* eggs. This challenge was graded by 80% referee consensus.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hymenolepis nana eggs	230	48.02%	Acceptable
Giardia lamblia	173	36.12%	Acceptable
Other parasite seen but no ID	1	0.21%	
Hymenolepis diminuta eggs	32	6.68%	
Taenia sp. eggs	15	3.13%	
Trichuris trichiura eggs	9	1.88%	
Ascaris lumbricoides eggs	8	1.67%	
Endolimax nana	2	0.42%	
Schistosoma japonicum eggs	2	0.42%	
Hookworm	2	0.42%	
Clonorchis sinensis	1	0.21%	
Sarcocystis sp. oocysts	1	0.21%	
No parasite seen	1	0.21%	
Entamoeba histolytica	1	0.21%	
Blastocystis hominis	1	0.21%	

Parasites present in specimen FP-14: *Hymenolepis nana* eggs and *Giardia lamblia*.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	258	90.85%	Acceptable
Trypanosoma sp., NOS	6	2.11%	
Plasmodium vivax	6	2.11%	
Babesia sp.	5	1.76%	
Plasmodium falciparum	4	1.41%	
Plasmodium sp., not falciparum	1	0.35%	
Pneumocystis carinii	1	0.35%	
Toxoplasma gondii	1	0.35%	
Trypanosoma sp., NOS	1	0.35%	
Trypanosoma cruzi	1	0.35%	

Parasite present in specimen FP-15: No parasite present.

Antinuclear Antibody (ANA) - Qualitative

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	-	17	-	1	16
BioSystems	1	-	1	-	-	1
Immuno Concepts	1	-	1	-	-	1
INOVA Diagnostics	7	-	7	-	1	6
Kallestad	2	-	2	-	-	2
Zeus	1	-	1	-	-	1

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	16	15	2
BioSystems	-	1	1	-
Immuno Concepts	-	1	1	-
INOVA Diagnostics	1	6	7	-
Kallestad	-	2	2	-
Zeus	-	1	1	-

Antinuclear Antibody (ANA)—Quantitative (Titer)

This portion is not evaluated. Titers reported are as follows:

<u>Specimen/Method</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-11

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

Specimen AE-12

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

Specimen AE-15

ALL METHODS	-	-	1	1	5	1	2	-	2	-	-
Immuno Concepts	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	1	3	-	-	-	2	-	-
Kallestad	-	-	-	-	1	1	-	-	-	-	-
Zeus	-	-	-	-	-	-	1	-	-	-	-

Anti-dsDNA

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	14	15	-	-	15
BioSystems	-	1	1	-	-	1
Diamedix	-	1	1	-	-	1
INOVA Diagnostics	1	5	6	-	-	6
Zeus	-	1	1	-	-	1

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	15	1	14
BioSystems	-	1	-	1
Diamedix	-	1	-	1
INOVA Diagnostics	-	6	-	6
Zeus	-	1	-	1

Anti-RNP

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	6	2	-	8
INOVA Diagnostics	-	6	5	1	-	6

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	7	-	8
INOVA Diagnostics	1	5	-	6

Specimen AE-12 is graded by 80% referee consensus.

Anti-RNP/Sm

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	1	5	-	6
Diamedix	-	1	-	1	-	1

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	-	6
Diamedix	-	1	-	1

Anti-SSA

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	-	11	1	1	11
Diamedix	1	-	1	-	-	1
INOVA Diagnostics	6	-	5	1	-	6

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	12	3	9
Diamedix	-	1	-	1
INOVA Diagnostics	-	6	2	4

Specimen AE-15 was graded by 82% referee consensus.

Anti-SSB

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	-	1	12	-	13
Diamedix	1	-	-	1	-	1
INOVA Diagnostics	6	-	1	5	-	6

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	13	-	13
Diamedix	-	1	-	1
INOVA Diagnostics	-	6	-	6

Anti-SSA/SSB

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	-	2	-	1	1

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	1	1

Specimens AE-13 and AE-15 are graded by US consensus.

Anti-Sm

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	13	5	8	-	13
Diamedix	-	1	-	1	-	1
INOVA Diagnostics	-	7	5	2	-	7

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	13	-	13
Diamedix	-	1	-	1
INOVA Diagnostics	-	7	-	7

Specimen AE-12 is grade by 81% referee consensus.

Rubella—Qualitative

<u>Method</u>	Specimen RU-11		Specimen RU-12		Specimen RU-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	25	25	-	-	25
Abbott Architect	-	9	9	-	-	9
bioMerieux Vidas, Mini Vidas	-	2	2	-	-	2
DiaSorin	-	1	1	-	-	1
Roche cobas 6000 / e 601	-	2	2	-	-	2
Roche cobas 6000/e601 - IgG	-	1	1	-	-	1
Roche cobas e 411	-	4	4	-	-	4
Siemens ADVIA Centaur	-	1	1	-	-	1
Siemens ADVIA Centaur - IgG	-	3	3	-	-	3
VITROS ECI	-	1	1	-	-	1
VITROS ECI - IgG	-	1	1	-	-	1

<u>Method</u>	Specimen RU-14		Specimen RU-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	-	25	-
Abbott Architect	9	-	9	-
bioMerieux Vidas, Mini Vidas	2	-	2	-
DiaSorin	1	-	1	-
Roche cobas 6000 / e 601	2	-	2	-
Roche cobas 6000/e601 - IgG	1	-	1	-
Roche cobas e 411	4	-	4	-
Siemens ADVIA Centaur	1	-	1	-
Siemens ADVIA Centaur - IgG	3	-	3	-
VITROS ECI	1	-	1	-
VITROS ECI - IgG	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-11						
All Method	34	0.13	0.18	133.8	0.0	0.0 - 0.7
Abbott Architect	12	0.00	0.01	0.0	0.0	0.0 - 0.1
Roche cobas e 411	7	0.30	0.12	38.5	0.3	0.0 - 0.7
Specimen RU-12						
All Method	35	98.75	43.79	44.3	90.0	0.0 - 230.2
Abbott Architect	13	54.94	2.83	5.2	54.0	46.4 - 63.5
Roche cobas e 411	7	140.80	12.69	9.0	137.5	102.7 - 178.9
Specimen RU-13						
All Method	34	0.14	0.20	144.3	0.0	0.0 - 0.8
Abbott Architect	13	0.00	0.01	0.0	0.0	0.0 - 0.1
Roche cobas e 411	7	0.29	0.11	37.4	0.3	0.0 - 0.7
Specimen RU-14						
All Method	34	26.57	11.17	42.0	25.0	0.0 - 60.1
Abbott Architect	13	15.49	0.80	5.1	15.8	13.1 - 17.9
Roche cobas e 411	7	38.60	4.28	11.1	37.7	25.7 - 51.5
Specimen RU-15						
All Method	35	98.63	43.90	44.5	93.0	0.0 - 230.4
Abbott Architect	13	54.64	2.28	4.2	54.2	47.8 - 61.5
Roche cobas e 411	7	143.37	15.54	10.8	143.5	96.7 - 190.0

Syphilis Serology—Qualitative: VDRL Slide

<u>Method</u>	Specimen SY-11			Specimen SY-12			Specimen SY-13		
	<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	29	-	2	30	-	1	31	-	-
Acon Laboratories	1	-	-	1	-	-	1	-	-
Biokit	1	-	-	1	-	-	1	-	-
Omega Diagnostics	1	-	-	1	-	-	1	-	-
Plasmatec	2	-	1	3	-	-	3	-	-
Standard Diagnostics	-	-	1	-	-	1	1	-	-
Wiener Lab	22	-	-	22	-	-	22	-	-

<u>Method</u>	Specimen SY-14			Specimen SY-15		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>
ALL METHODS	-	-	31	1	-	30
Acon Laboratories	-	-	1	-	-	1
Biokit	-	-	1	-	-	1
Omega Diagnostics	-	-	1	-	-	1
Plasmatec	-	-	3	-	-	3
Standard Diagnostics	-	-	1	-	-	1
Wiener Lab	-	-	22	1	-	21

Syphilis Serology—Quantitative: VDRL Slide Titer

<u>Specimen/Method</u>	<u>0 dils</u>	<u>1 dil</u>	<u>2 dils</u>	<u>4 dils</u>	<u>8 dils</u>	<u>16 dils</u>	<u>32 dils</u>	<u>>32 dils</u>
Specimen SY-11								
ALL METHODS	1	5	15	6	-	1	-	-
Omega Diagnostics	-	-	1	-	-	-	-	-
Plasmatec	-	1	-	-	-	1	-	-
Wiener Lab	1	3	13	6	-	-	-	-
Specimen SY-12								
ALL METHODS	1	6	12	8	-	-	1	-
Omega Diagnostics	-	-	-	1	-	-	-	-
Plasmatec	-	1	-	-	-	-	1	-
Wiener Lab	1	4	12	6	-	-	-	-
Specimen SY-13								
ALL METHODS	-	-	5	15	7	1	-	-
Omega Diagnostics	-	-	-	1	-	-	-	-
Plasmatec	-	-	1	-	-	1	-	-
Wiener Lab	-	-	4	12	7	-	-	-

Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	14	-	14	-	14	-
Abbott Architect	4	-	4	-	4	-
Human	1	-	1	-	1	-
Omega Diagnostics	2	-	2	-	2	-
Plasmatec	1	-	1	-	1	-
Serodia	1	-	1	-	1	-

	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	14	-	14
Abbott Architect	-	4	-	4
Human	-	1	-	1
Omega Diagnostics	-	2	-	2
Plasmatec	-	1	-	1
Serodia	-	1	-	1

Syphilis Serology—Qualitative: *Treponema pallidum* Antibodies

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	36	-	35	1	36	-
Abbott Architect	3	-	3	-	3	-
bioMerieux	1	-	1	-	1	-
Human	1	-	1	-	1	-
Omega Diagnostics	4	-	3	1	4	-
Plasmatec	2	-	2	-	2	-
Roche cobas 6000 / c 501	1	-	1	-	1	-
Serodia	13	-	13	-	13	-
SPINREACT	1	-	1	-	1	-

	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	36	-	36
Abbott Architect	-	3	-	3
bioMerieux	-	1	-	1
Human	-	1	-	1
Omega Diagnostics	-	4	-	4
Plasmatec	-	2	-	2
Roche cobas 6000 / c 501	-	1	-	1
Serodia	-	13	-	13
SPINREACT	-	1	-	1

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	104	1	102	3	105	-
ASI	2	-	2	-	2	-
Becton Dickinson	3	-	3	-	3	-
Biokit	2	-	2	-	2	-
bioMerieux	7	-	7	-	7	-
BioSystems	12	-	12	-	12	-
Human	10	-	10	-	10	-
Immunostics Inc.	2	-	2	-	2	-
Omega Diagnostics	17	-	17	-	17	-
Plasmatec	12	-	12	-	12	-
Pulse Scientific	1	-	1	-	1	-
SPINREACT	19	-	19	-	19	-
Standard Diagnostics	1	1	1	1	2	-
Wampole Impact RPR	3	-	3	-	3	-
Wiener Lab	1	-	1	-	1	-

	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	104	-	104
ASI	-	2	-	2
Becton Dickinson	-	3	-	3
Biokit	-	2	-	2
bioMerieux	-	7	-	7
BioSystems	-	11	-	11
Human	-	10	-	10
Immunostics Inc.	-	2	-	2
Omega Diagnostics	-	17	-	17
Plasmatec	-	12	-	12
Pulse Scientific	-	1	-	1
SPINREACT	-	19	-	19
Standard Diagnostics	-	2	-	2
Wampole Impact RPR	-	3	-	3
Wiener Lab	-	1	-	1

Syphilis Serology—Quantitative: RPR (Titer)

<u>Specimen/Method</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>
Specimen SY-11								
ALL METHODS	20	34	12	1	1	1	-	-
Becton Dickinson	-	1	1	-	-	-	-	-
bioMerieux	2	3	-	-	-	-	-	-
BioSystems	2	5	2	-	-	-	-	-
Human	5	1	1	-	-	-	-	-
Immunostics Inc.	1	-	-	-	-	-	-	-
Omega Diagnostics	2	7	2	-	-	1	-	-
Plasmatec	6	2	1	-	1	-	-	-
SPINREACT	-	11	2	1	-	-	-	-
Wampole Impact RPR	-	1	-	-	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-
Specimen SY-12								
ALL METHODS	14	37	14	2	2	1	-	-
Becton Dickinson	-	-	2	-	-	-	-	-
bioMerieux	2	2	1	-	-	-	-	-
BioSystems	1	6	3	-	-	-	-	-
Human	3	3	1	-	-	-	-	-
Immunostics Inc.	1	-	-	-	-	-	-	-
Omega Diagnostics	2	7	1	1	1	-	-	-
Plasmatec	4	4	1	-	-	1	-	-
SPINREACT	-	10	3	-	1	-	-	-
Wampole Impact RPR	-	1	-	-	-	-	-	-
Wiener Lab	-	1	-	-	-	-	-	-

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

<u>Specimen/Method</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>
Specimen SY-13								
ALL METHODS	2	17	34	13	2	1	-	1
Becton Dickinson	-	-	-	2	-	-	-	-
bioMerieux	-	1	3	1	-	-	-	-
BioSystems	-	3	4	3	-	-	-	-
Human	-	4	2	1	-	-	-	-
Immunostics Inc.	-	1	-	-	-	-	-	-
Omega Diagnostics	-	2	7	1	-	1	-	1
Plasmatec	2	3	4	-	1	-	-	-
SPINREACT	-	1	8	4	1	-	-	-
Wampole Impact RPR	-	1	-	-	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-

Viral Markers – Anti-HBc (IgM)

Specimen VM-11				Specimen VM-12			Specimen VM-13		
<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	1	73	-	53	20	1	4	70	-
Abbott Architect	-	30	-	28	1	1	-	30	-
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	-	-	2	-
Bio-Rad Evolis	-	1	-	1	-	-	1	-	-
bioMerieux Vidas, Mini Vidas	-	6	-	6	-	-	-	6	-
Roche cobas 6000 / e 601	1	10	-	2	9	-	2	9	-
Roche cobas e 411	-	3	-	-	3	-	-	3	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	-	1	-
Roche Modular Analytics	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	10	-	10	-	-	-	10	-
VITROS 3600/4600/5600	-	3	-	-	3	-	-	3	-

Specimen VM-14				Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	4	69	1	1	72	-
Abbott Architect	-	30	-	-	30	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-
Bio-Rad Evolis	1	-	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	6	-	-	6	-
Roche cobas 6000 / e 601	2	9	-	-	10	-
Roche cobas e 411	-	3	-	-	3	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-
Roche Modular Analytics	-	1	-	-	1	-
Siemens ADVIA Centaur	-	10	-	-	10	-
VITROS 3600/4600/5600	-	2	1	-	3	-

Viral Markers – Anti-HBc (Total / IgG)

Specimen VM-11				Specimen VM-12			Specimen VM-13		
<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	10	84	-	92	2	-	93	1	-
Abbott Architect	1	40	-	41	-	-	41	-	-
Abbott Architect - Total	-	1	-	1	-	-	1	-	-
Beckman ACCESS / 2 / Dxl	2	-	-	2	-	-	2	-	-
bioMerieux Vidas, Mini									
Vidas	-	5	-	4	1	-	5	-	-
DiaSorin	-	1	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	3	8	-	11	-	-	11	-	-
Roche cobas e 411	4	4	-	8	-	-	8	-	-
Roche Modular Analytics	-	4	-	4	-	-	4	-	-
Siemens ADVIA Centaur	-	14	-	14	-	-	14	-	-
VITROS 3600/4600/5600	-	2	-	2	-	-	2	-	-

Specimen VM-14				Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	89	4	-	3	90	-
Abbott Architect	41	-	-	-	41	-
Abbott Architect - Total	1	-	-	-	1	-
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-
bioMerieux Vidas, Mini						
Vidas	4	1	-	-	5	-
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	10	1	-	-	10	-
Roche cobas e 411	7	1	-	1	7	-
Roche Modular Analytics	4	-	-	-	4	-
Siemens ADVIA Centaur	13	-	-	-	14	-
VITROS 3600/4600/5600	2	-	-	-	2	-

Viral Markers – Anti-HIV

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
<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	2	258	-	-	260	-	260	-	-
Abbott Architect	-	74	-	-	74	-	74	-	-
Abbott Architect - Total	-	1	-	-	1	-	1	-	-
Alere Determine HIV 1/2									
Ag/Ab Combo	-	2	-	-	2	-	2	-	-
Beckman ACCESS / 2 / Dxl	-	10	-	-	10	-	10	-	-
Bio-Rad Evolis	-	1	-	-	1	-	1	-	-
bioMerieux Vidas, Mini									
Vidas	-	12	-	-	12	-	12	-	-
DiaSorin	-	1	-	-	1	-	1	-	-
Human	-	1	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	1	43	-	-	44	-	44	-	-
Roche cobas e 411	1	26	-	-	27	-	27	-	-
Roche Elecsys - Total	-	1	-	-	1	-	1	-	-
Roche Elecsys 1010 / 2010	-	3	-	-	3	-	3	-	-
Roche Modular Analytics	-	7	-	-	7	-	7	-	-
Siemens ADVIA Centaur	-	48	-	-	48	-	48	-	-
Standard Diagnostics	-	3	-	-	3	-	3	-	-
VITROS 3600/4600/5600	-	4	-	-	4	-	4	-	-
VITROS ECI	-	4	-	-	4	-	4	-	-

Viral Markers – Anti-HIV- cont'd

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	5	252	1	76	171	12
Abbott Architect	-	74	-	-	74	-
Abbott Architect - Total	-	1	-	-	1	-
Alere Determine HIV 1/2						
Ag/Ab Combo	-	2	-	-	2	-
Beckman ACCESS / 2 / DxI	1	9	-	2	8	-
Bio-Rad Evolis	-	1	-	-	1	-
bioMerieux Vidas, Mini						
Vidas	-	12	-	8	3	1
DiaSorin	-	1	-	1	-	-
Human	-	1	-	-	1	-
Roche cobas 6000 / e 601	1	43	-	31	10	2
Roche cobas e 411	1	25	1	21	3	3
Roche Elecsys - Total	-	1	-	-	-	1
Roche Elecsys 1010 / 2010	1	2	-	3	-	-
Roche Modular Analytics	-	7	-	6	1	-
Siemens ADVIA Centaur	1	46	-	1	45	2
Standard Diagnostics	-	3	-	-	3	-
VITROS 3600/4600/5600	-	4	-	-	4	-
VITROS Eci	-	4	-	-	4	-

Specimen VM-15 was graded by 83% referee consensus.

Viral Markers – Anti-HAV (IgM)

Specimen VM-11				Specimen VM-12			Specimen VM-13		
<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	96	2	1	1	98	-	1	98	-
Abbott Architect	34	1	1	1	35	-	-	36	-
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-	-	1	-
bioMerieux Vidas, Mini									
Vidas	11	-	-	-	11	-	-	11	-
Roche cobas 6000 / e 601	13	1	-	-	14	-	-	14	-
Roche cobas e 411	8	-	-	-	8	-	1	7	-
Roche Modular Analytics	5	-	-	-	5	-	-	5	-
Siemens ADVIA Centaur	17	-	-	-	17	-	-	17	-
Standard Diagnostics	1	-	-	-	1	-	-	1	-
VITROS 3600/4600/5600	1	-	-	-	1	-	-	1	-
VITROS Eci	1	-	-	-	1	-	-	1	-

Specimen VM-14				Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	3	95	-	2	96	-
Abbott Architect	1	35	-	-	36	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-
bioMerieux Vidas, Mini						
Vidas	-	11	-	-	11	-
Roche cobas 6000 / e 601	1	13	-	1	12	-
Roche cobas e 411	1	7	-	1	7	-
Roche Modular Analytics	-	5	-	-	5	-
Siemens ADVIA Centaur	-	16	-	-	17	-
Standard Diagnostics	-	1	-	-	1	-
VITROS 3600/4600/5600	-	1	-	-	1	-
VITROS Eci	-	1	-	-	1	-

Viral Markers – Anti-HAV (Total/IgG)

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
<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	98	-	-	3	95	-	97	1	-
Abbott Architect	36	-	-	-	36	-	36	-	-
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-	1	-	-
bioMerieux Vidas, Mini									
Vidas	8	-	-	-	8	-	8	-	-
Roche cobas 6000 / e 601	12	-	-	1	11	-	12	-	-
Roche cobas e 411	7	-	-	1	6	-	7	-	-
Roche Elecsys 1010 / 2010	2	-	-	-	2	-	2	-	-
Roche Modular Analytics	2	-	-	-	2	-	2	-	-
Siemens ADVIA Centaur	21	-	-	1	20	-	21	-	-
Standard Diagnostics	1	-	-	-	1	-	-	1	-
VITROS ECI	1	-	-	-	1	-	1	-	-

	Specimen VM-14			Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	96	1	-	65	29	4
Abbott Architect	36	-	-	30	5	1
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-
bioMerieux Vidas, Mini						
Vidas	8	-	-	4	2	2
Roche cobas 6000 / e 601	12	-	-	12	-	-
Roche cobas e 411	7	-	-	7	-	-
Roche Elecsys 1010 / 2010	2	-	-	2	-	-
Roche Modular Analytics	2	-	-	2	-	-
Siemens ADVIA Centaur	20	-	-	3	18	-
Standard Diagnostics	-	1	-	-	1	-
VITROS ECI	1	-	-	1	-	-

Viral Markers – HBeAg

Specimen VM-11				Specimen VM-12			Specimen VM-13		
<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	-	63	-	-	63	-	-	63	-
Abbott Architect	-	23	-	-	23	-	-	23	-
bioMerieux Vidas, Mini Vidas	-	4	-	-	4	-	-	4	-
DiaSorin	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	10	-	-	10	-	-	10	-
Roche cobas e 411	-	4	-	-	4	-	-	4	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	-	1	-
Roche Modular Analytics	-	3	-	-	3	-	-	3	-
Siemens ADVIA Centaur	-	11	-	-	11	-	-	11	-
VITROS ECI	-	1	-	-	1	-	-	1	-

Specimen VM-14				Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	28	34	-	1	62	-
Abbott Architect	-	23	-	-	23	-
bioMerieux Vidas, Mini Vidas	-	4	-	-	4	-
DiaSorin	2	-	-	-	2	-
Roche cobas 6000 / e 601	10	-	-	1	9	-
Roche cobas e 411	2	2	-	-	4	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-
Roche Modular Analytics	2	1	-	-	3	-
Siemens ADVIA Centaur	9	1	-	-	11	-
VITROS ECI	-	1	-	-	1	-

Viral Markers – Anti-HBs

Specimen VM-11				Specimen VM-12			Specimen VM-13		
<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	-	190	-	-	190	-	189	1	-
Abbott Architect	-	60	-	-	60	-	60	-	-
Beckman ACCESS / 2 / Dxl	-	3	-	-	3	-	3	-	-
bioMerieux Vidas, Mini									
Vidas	-	6	-	-	6	-	6	-	-
Roche cobas 6000 / e 601	-	34	-	-	34	-	33	1	-
Roche cobas e 411	-	20	-	-	20	-	20	-	-
Roche Elecsys 1010 / 2010	-	2	-	-	2	-	2	-	-
Roche Modular Analytics	-	6	-	-	6	-	6	-	-
Siemens ADVIA Centaur	-	44	-	-	44	-	44	-	-
VITROS 3600/4600/5600	-	4	-	-	4	-	4	-	-
VITROS ECI	-	2	-	-	2	-	2	-	-

Specimen VM-14				Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	187	-	9	179	2
Abbott Architect	-	60	-	3	57	-
Beckman ACCESS / 2 / Dxl	1	2	-	-	2	1
bioMerieux Vidas, Mini						
Vidas	-	6	-	-	6	-
Roche cobas 6000 / e 601	1	33	-	2	31	1
Roche cobas e 411	-	20	-	1	19	-
Roche Elecsys 1010 / 2010	-	2	-	1	1	-
Roche Modular Analytics	-	6	-	-	6	-
Siemens ADVIA Centaur	-	43	-	-	44	-
VITROS 3600/4600/5600	-	4	-	-	4	-
VITROS ECI	-	2	-	-	2	-

Viral Markers – HBsAg

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
<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	58	197	7	247	14	1	1	261	-
Abbott Architect	-	74	-	74	-	-	1	73	-
Abbott Architect - Total	-	1	-	1	-	-	-	1	-
Beckman ACCESS / 2 / DxI	-	8	-	7	1	-	-	8	-
Bio-Rad Evolis	-	1	-	1	-	-	-	1	-
bioMerieux Vidas, Mini Vidas	1	9	-	9	1	-	-	10	-
DiaSorin	-	1	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	29	6	3	37	1	-	-	38	-
Roche cobas e 411	18	12	3	33	-	-	-	33	-
Roche Elecsys - Total	-	1	-	1	-	-	-	1	-
Roche Elecsys 1010 / 2010	1	3	-	4	-	-	-	4	-
Roche Modular Analytics	5	2	-	7	-	-	-	7	-
Siemens ADVIA Centaur	1	47	-	46	1	1	-	48	-
Standard Diagnostics	-	3	-	-	3	-	-	3	-
VITROS 3600/4600/5600	1	4	-	5	-	-	-	5	-
VITROS ECI	-	6	-	6	-	-	-	6	-

Specimen VM-11 was graded by 91% referee consensus.

	Specimen VM-14			Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	258	1	1	38	213	11
Abbott Architect	73	1	-	2	72	-
Abbott Architect - Total	1	-	-	-	1	-
Beckman ACCESS / 2 / DxI	8	-	-	-	8	-
Bio-Rad Evolis	1	-	-	-	1	-
bioMerieux Vidas, Mini Vidas	10	-	-	1	9	-
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	38	-	-	18	13	7
Roche cobas e 411	33	-	-	10	21	2
Roche Elecsys - Total	1	-	-	-	1	-
Roche Elecsys 1010 / 2010	4	-	-	-	4	-
Roche Modular Analytics	7	-	-	3	3	1
Siemens ADVIA Centaur	46	-	1	2	46	-
Standard Diagnostics	3	-	-	-	3	-
VITROS 3600/4600/5600	5	-	-	-	5	-
VITROS ECI	6	-	-	-	6	-

Viral Markers – Anti-HCV

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
<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	1	226	-	1	226	-	1	226	-
Abbott Architect	1	71	-	-	72	-	-	72	-
Abbott Architect - Total	-	1	-	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	5	-	-	5	-	-	5	-
Bio-Rad Evolis	-	1	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	6	-	-	6	-	-	6	-
DiaSorin	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	30	-	-	30	-	-	30	-
Roche cobas e 411	-	24	-	-	24	-	1	23	-
Roche Elecsys 1010 / 2010	-	3	-	-	3	-	-	3	-
Roche Modular Analytics	-	6	-	-	6	-	-	6	-
Siemens ADVIA Centaur	-	45	-	-	45	-	-	45	-
Standard Diagnostics	-	4	-	-	4	-	-	4	-
VITROS 3600/4600/5600	-	5	-	1	4	-	-	5	-
VITROS ECI	-	6	-	-	6	-	-	6	-

	Specimen VM-14			Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	62	162	1	226	1	-
Abbott Architect	1	71	-	71	1	-
Abbott Architect - Total	-	1	-	1	-	-
Beckman ACCESS / 2 / Dxl	-	5	-	5	-	-
Bio-Rad Evolis	-	1	-	1	-	-
bioMerieux Vidas, Mini Vidas	-	6	-	6	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas 6000 / e 601	28	2	-	30	-	-
Roche cobas e 411	21	3	-	24	-	-
Roche Elecsys 1010 / 2010	3	-	-	3	-	-
Roche Modular Analytics	6	-	-	6	-	-
Siemens ADVIA Centaur	1	43	-	45	-	-
Standard Diagnostics	-	4	-	4	-	-
VITROS 3600/4600/5600	-	5	-	5	-	-
VITROS ECI	-	6	-	6	-	-

Toxoplasma gondii Antibody (IgG) - Qualitative

<u>Method</u>	Specimen TOX-5		Specimen TOX-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	29	-	-	29
Abbott Architect	10	-	-	10
Beckman ACCESS / 2 / Dxl	3	-	-	3
bioMerieux Vidas, Mini Vidas	3	-	-	3
DiaSorin	1	-	-	1
Roche cobas 6000 / e 601	2	-	-	2
Roche cobas e 411	5	-	-	5
Roche Elecsys 1010 / 2010	1	-	-	1
Siemens ADVIA Centaur	3	-	-	3
VITROS ECI	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-5						
All Method	30	490.230	244.723	49.9	462.00	0.78 - 979.68
Abbott Architect	11	435.900	328.311	75.3	200.00	0.00 - 1092.53
Roche cobas e 411	6	553.567	128.562	23.2	619.30	296.44 - 810.70
Specimen TOX-6						
All Method	28	0.095	0.088	92.2	0.10	0.00 - 0.28
Abbott Architect	11	0.100	0.045	44.7	0.10	0.01 - 0.19
Roche cobas e 411	6	0.193	0.103	53.0	0.13	0.00 - 0.40

Toxoplasma gondii Antibody (IgM) - Qualitative

<u>Method</u>	Specimen TOX-5		Specimen TOX-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	28	-	1	27
Abbott Architect	8	-	-	8
Beckman ACCESS / 2 / Dxl	3	-	1	2
bioMerieux Vidas, Mini Vidas	3	-	-	3
DiaSorin	1	-	-	1
Roche cobas 6000 / e 601	4	-	-	4
Roche cobas e 411	4	-	-	4
Roche Elecsys 1010 / 2010	1	-	-	1
Siemens ADVIA Centaur	3	-	-	3
VITROS ECI	1	-	-	1

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>
Specimen TOX-5						
All Method	23	15.382	15.763	102.5	7.23	0.00 - 46.91
Abbott Architect	9	6.516	0.699	10.7	6.60	5.11 - 7.92
Specimen TOX-6						
All Method	23	0.174	0.096	55.0	0.18	0.00 - 0.37
Abbott Architect	9	0.108	0.087	80.9	0.08	0.00 - 0.29

Cytomegalovirus (CMV) Antibodies (IgG) - Qualitative

<u>Method</u>	<u>Specimen CMV-5</u>		<u>Specimen CMV-6</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	20	1	12	9
Abbott Architect	10	-	10	-
Beckman ACCESS / 2 / Dxl	1	-	-	1
bioMerieux Vidas, Mini Vidas	3	-	-	3
DiaSorin	1	-	1	-
Roche cobas 6000 / e 601	1	-	-	1
Roche cobas e 411	3	1	1	3
VITROS ECI	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>
Specimen CMV-5						
All Method	21	99.791	36.081	36.2	96.30	27.62 - 171.96
Abbott Architect	10	118.830	17.143	14.4	123.90	84.54 - 153.12
Specimen CMV-6						
All Method	21	7.714	7.029	91.1	4.00	0.00 - 21.78
Abbott Architect	10	14.470	3.103	21.4	14.15	8.26 - 20.68

Cytomegalovirus (CMV) Antibodies (IgM) - Qualitative

<u>Method</u>	<u>Specimen CMV-5</u>		<u>Specimen CMV-6</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	15	6
Abbott Architect	-	8	8	-
Beckman ACCESS / 2 / DxI	-	1	1	-
bioMerieux Vidas, Mini Vidas	-	3	3	-
DiaSorin	-	1	1	-
DPC Immulite 2000	-	1	1	-
Roche cobas 6000 / e 601	-	2	-	2
Roche cobas e 411	-	4	-	4
VITROS ECI	-	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>
Specimen CMV-5						
All Method	19	0.178	0.146	82.2	0.17	0.00 - 0.48
Abbott Architect	8	0.203	0.103	50.8	0.25	0.00 - 0.41
Specimen CMV-6						
All Method	19	2.249	1.448	64.4	2.53	0.00 - 5.15
Abbott Architect	8	3.559	0.715	20.1	3.47	2.12 - 4.99

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-11						
All Method	12	99.80	29.88	29.9	88.1	10.1 - 189.5
Roche cobas 6000 / c 501	7	87.39	2.34	2.7	87.4	80.3 - 94.5
Specimen CK-12						
All Method	11	17.82	2.08	11.6	17.1	11.5 - 24.1
Roche cobas 6000 / c 501	7	17.44	1.00	5.7	17.1	14.4 - 20.5
Specimen CK-13						
All Method	13	37.51	22.66	60.4	28.0	0.0 - 105.5
Roche cobas 6000 / c 501	7	28.01	1.61	5.8	27.8	23.1 - 32.9
Specimen CK-14						
All Method	12	54.53	17.36	31.8	48.2	2.4 - 106.7
Roche cobas 6000 / c 501	7	47.73	1.58	3.3	48.0	43.0 - 52.5
Specimen CK-15						
All Method	12	8.88	3.38	38.0	7.9	0.0 - 19.1
Roche cobas 6000 / c 501	7	7.83	0.48	6.1	8.0	6.3 - 9.3

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