

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-M2**



Total Commitment to Education and Service
Provided by ACP, Inc.

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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-6							Specimen CL-7					
<i><u>Instrument</u></i>	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>
All Method	79	7.85	0.61	7.7	8.0	6.6 - 9.1	79	2.98	0.35	11.8	3.1	2.5 - 3.5
All Abbott Cell-Dyn Instruments	63	8.10	0.24	3.0	8.1	6.8 - 9.4	63	3.13	0.13	4.1	3.1	2.6 - 3.6
Abbott Cell-Dyn 3200	10	8.06	0.20	2.4	8.1	6.8 - 9.3	10	3.10	0.16	5.3	3.1	2.6 - 3.6
Abbott Cell-Dyn Ruby	46	8.13	0.22	2.8	8.1	6.9 - 9.4	45	3.15	0.11	3.6	3.1	2.6 - 3.7
Orphee Mythic 22	13	6.62	0.27	4.0	6.6	5.6 - 7.7	14	2.29	0.08	3.6	2.3	1.9 - 2.7
Specimen CL-8							Specimen CL-9					
All Method	79	20.33	1.40	6.9	20.7	17.2 - 23.4	79	20.43	1.51	7.4	20.9	17.3 - 23.5
All Abbott Cell-Dyn Instruments	64	20.87	0.61	2.9	20.8	17.7 - 24.0	62	21.02	0.60	2.8	21.1	17.8 - 24.2
Abbott Cell-Dyn 3200	10	20.68	0.66	3.2	20.5	17.5 - 23.8	10	20.83	1.02	4.9	20.5	17.7 - 24.0
Abbott Cell-Dyn Ruby	46	20.98	0.53	2.5	21.0	17.8 - 24.2	46	21.14	0.53	2.5	21.1	17.9 - 24.4
Orphee Mythic 22	13	17.48	0.41	2.3	17.5	14.8 - 20.2	14	17.59	0.86	4.9	17.3	14.9 - 20.3
Specimen CL-10												
All Method	79	3.04	0.42	13.8	3.1	2.5 - 3.5						
All Abbott Cell-Dyn Instruments	62	3.19	0.17	5.4	3.2	2.7 - 3.7						
Abbott Cell-Dyn 3200	10	3.09	0.17	5.4	3.1	2.6 - 3.6						
Abbott Cell-Dyn Ruby	44	3.23	0.16	4.9	3.2	2.7 - 3.8						
Orphee Mythic 22	14	2.25	0.09	3.8	2.3	1.9 - 2.6						

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

Specimen CL-6							Specimen CL-7					
<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	4.614	0.130	2.8	4.64	4.33 - 4.90	79	2.128	0.064	3.0	2.13	2.00 - 2.26
All Abbott Cell-Dyn Instruments	64	4.649	0.106	2.3	4.66	4.37 - 4.93	64	2.145	0.052	2.4	2.14	2.01 - 2.28
Abbott Cell-Dyn 3200	10	4.557	0.128	2.8	4.53	4.28 - 4.84	10	2.127	0.042	2.0	2.11	1.99 - 2.26
Abbott Cell-Dyn Ruby	46	4.678	0.083	1.8	4.68	4.39 - 4.96	46	2.153	0.049	2.3	2.15	2.02 - 2.29
Orphee Mythic 22	13	4.455	0.109	2.5	4.47	4.18 - 4.73	14	2.055	0.057	2.8	2.05	1.93 - 2.18
Specimen CL-8							Specimen CL-9					
All Method	78	5.186	0.161	3.1	5.20	4.87 - 5.50	78	5.184	0.155	3.0	5.21	4.87 - 5.50
All Abbott Cell-Dyn Instruments	64	5.226	0.145	2.8	5.25	4.91 - 5.54	64	5.222	0.137	2.6	5.24	4.90 - 5.54
Abbott Cell-Dyn 3200	10	5.113	0.119	2.3	5.16	4.80 - 5.42	10	5.110	0.147	2.9	5.12	4.80 - 5.42
Abbott Cell-Dyn Ruby	46	5.276	0.106	2.0	5.30	4.95 - 5.60	46	5.262	0.102	1.9	5.27	4.94 - 5.58
Orphee Mythic 22	13	4.994	0.082	1.6	5.01	4.69 - 5.30	13	5.011	0.125	2.5	5.00	4.71 - 5.32
Specimen CL-10												
All Method	78	2.125	0.055	2.6	2.12	1.99 - 2.26						
All Abbott Cell-Dyn Instruments	64	2.141	0.045	2.1	2.13	2.01 - 2.27						
Abbott Cell-Dyn 3200	10	2.144	0.037	1.7	2.14	2.01 - 2.28						
Abbott Cell-Dyn Ruby	46	2.142	0.046	2.2	2.13	2.01 - 2.28						
Orphee Mythic 22	14	2.039	0.075	3.7	2.06	1.91 - 2.17						

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

Specimen CL-6							Specimen CL-7					
<i><u>Instrument</u></i>	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>
All Method	79	13.41	0.76	5.6	13.6	12.4 - 14.4	78	5.33	0.35	6.5	5.4	4.9 - 5.8
All Abbott Cell-Dyn Instruments	64	13.71	0.29	2.1	13.7	12.7 - 14.7	64	5.47	0.12	2.3	5.5	5.0 - 5.9
Abbott Cell-Dyn 3200	10	13.61	0.37	2.7	13.5	12.6 - 14.6	10	5.52	0.12	2.2	5.5	5.1 - 6.0
Abbott Cell-Dyn Ruby	46	13.75	0.26	1.9	13.7	12.7 - 14.8	46	5.45	0.12	2.2	5.5	5.0 - 5.9
Orphee Mythic 22	13	11.86	0.22	1.8	11.8	11.0 - 12.7	13	4.60	0.07	1.5	4.6	4.2 - 5.0
Specimen CL-8							Specimen CL-9					
All Method	79	16.21	0.73	4.5	16.4	15.0 - 17.4	78	16.20	0.69	4.3	16.4	15.0 - 17.4
All Abbott Cell-Dyn Instruments	64	16.45	0.36	2.2	16.5	15.3 - 17.7	63	16.44	0.34	2.1	16.5	15.2 - 17.6
Abbott Cell-Dyn 3200	10	16.31	0.25	1.5	16.3	15.1 - 17.5	10	16.27	0.42	2.6	16.3	15.1 - 17.5
Abbott Cell-Dyn Ruby	45	16.52	0.25	1.5	16.5	15.3 - 17.7	45	16.53	0.29	1.8	16.5	15.3 - 17.7
Orphee Mythic 22	13	14.84	0.25	1.7	14.8	13.7 - 15.9	13	14.88	0.22	1.5	14.9	13.8 - 16.0
Specimen CL-10												
All Method	77	5.33	0.35	6.5	5.4	4.9 - 5.8						
All Abbott Cell-Dyn Instruments	64	5.47	0.13	2.5	5.4	5.0 - 5.9						
Abbott Cell-Dyn 3200	10	5.51	0.14	2.5	5.5	5.1 - 5.9						
Abbott Cell-Dyn Ruby	46	5.44	0.12	2.2	5.4	5.0 - 5.9						
Orphee Mythic 22	13	4.55	0.14	3.1	4.6	4.2 - 4.9						

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

Specimen CL-6							Specimen CL-7					
<i><u>Instrument</u></i>	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>
All Method	78	38.61	1.82	4.7	38.5	36.2 - 41.0	78	15.41	0.74	4.8	15.3	14.4 - 16.4
All Abbott Cell-Dyn Instruments	56	37.78	1.13	3.0	37.5	35.5 - 40.1	56	15.09	0.45	3.0	15.0	14.1 - 16.0
Abbott Cell-Dyn 3200	10	37.13	0.86	2.3	37.1	34.9 - 39.4	10	15.03	0.33	2.2	15.1	14.1 - 16.0
Abbott Cell-Dyn Ruby	46	37.92	1.14	3.0	37.7	35.6 - 40.2	46	15.11	0.47	3.1	15.0	14.2 - 16.1
Orphee Mythic 22	13	39.93	1.02	2.6	40.0	37.5 - 42.4	13	15.80	0.50	3.2	15.7	14.8 - 16.8
Specimen CL-8							Specimen CL-9					
All Method	78	44.43	2.08	4.7	44.0	41.7 - 47.2	78	44.43	2.21	5.0	43.8	41.7 - 47.1
All Abbott Cell-Dyn Instruments	56	43.45	1.23	2.8	43.4	40.8 - 46.1	56	43.35	1.27	2.9	43.4	40.7 - 46.0
Abbott Cell-Dyn 3200	10	42.41	1.12	2.6	42.4	39.8 - 45.0	10	42.36	1.25	2.9	42.0	39.8 - 45.0
Abbott Cell-Dyn Ruby	46	43.68	1.14	2.6	43.6	41.0 - 46.3	46	43.57	1.18	2.7	43.5	40.9 - 46.2
Orphee Mythic 22	13	46.14	1.21	2.6	46.2	43.3 - 49.0	13	46.32	1.16	2.5	46.4	43.5 - 49.2
Specimen CL-10												
All Method	77	15.35	0.72	4.7	15.2	14.4 - 16.3						
All Abbott Cell-Dyn Instruments	56	15.09	0.46	3.0	15.0	14.1 - 16.0						
Abbott Cell-Dyn 3200	10	15.18	0.39	2.6	15.2	14.2 - 16.1						
Abbott Cell-Dyn Ruby	46	15.07	0.47	3.1	15.0	14.1 - 16.0						
Orphee Mythic 22	13	15.65	0.64	4.1	15.6	14.7 - 16.6						

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

Specimen CL-6							Specimen CL-7					
<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	269.3	14.6	5.4	271	202 - 337	76	74.4	6.7	9.1	74	55 - 94
All Abbott Cell-Dyn Instruments	60	268.1	11.4	4.3	270	201 - 336	63	73.2	5.5	7.5	73	54 - 92
Abbott Cell-Dyn 3200	8	-	-	-	269	201 - 336	10	73.6	4.7	6.3	75	55 - 92
Abbott Cell-Dyn Ruby	44	268.5	11.5	4.3	270	201 - 336	46	72.8	5.6	7.7	73	54 - 91
Orphee Mythic 22	14	279.1	25.8	9.2	279	209 - 349	14	88.4	13.4	15.2	86	66 - 111
Specimen CL-8							Specimen CL-9					
All Method	76	495.0	24.5	4.9	494	371 - 619	79	491.9	24.2	4.9	491	368 - 615
All Abbott Cell-Dyn Instruments	59	491.6	18.3	3.7	492	368 - 615	64	488.1	20.7	4.3	490	366 - 611
Abbott Cell-Dyn 3200	9	-	-	-	491	368 - 615	10	482.9	21.9	4.5	486	362 - 604
Abbott Cell-Dyn Ruby	43	491.9	18.3	3.7	493	368 - 615	46	489.6	19.5	4.0	491	367 - 612
Orphee Mythic 22	14	512.4	29.7	5.8	507	384 - 641	14	512.2	28.0	5.5	510	384 - 641
Specimen CL-10												
All Method	78	74.6	7.0	9.4	73	55 - 94						
All Abbott Cell-Dyn Instruments	63	72.4	5.0	7.0	72	54 - 91						
Abbott Cell-Dyn 3200	10	71.0	3.8	5.4	70	53 - 89						
Abbott Cell-Dyn Ruby	45	72.9	5.2	7.1	72	54 - 92						
Orphee Mythic 22	13	84.2	5.5	6.5	84	63 - 106						

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

Specimen CL-6							Specimen CL-7					
<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	62.74	1.46	2.3	63.0	58.3 - 67.2	77	50.57	1.54	3.1	50.6	45.9 - 55.3
All Abbott Cell-Dyn Instruments	62	63.21	1.06	1.7	63.3	60.0 - 66.4	63	50.92	1.26	2.5	51.0	47.1 - 54.8
Abbott Cell-Dyn 3200	10	63.04	0.75	1.2	63.0	60.7 - 65.3	10	50.04	1.35	2.7	49.8	45.9 - 54.1
Abbott Cell-Dyn Ruby	43	63.39	0.86	1.4	63.3	60.8 - 66.0	45	51.01	1.24	2.4	51.0	47.3 - 54.8
Orphee Mythic 22	14	60.48	1.44	2.4	60.8	56.1 - 64.9	14	48.53	1.75	3.6	48.5	43.2 - 53.8
Specimen CL-8							Specimen CL-9					
All Method	78	71.78	1.28	1.8	72.0	67.9 - 75.7	75	71.90	1.18	1.6	72.0	68.3 - 75.5
All Abbott Cell-Dyn Instruments	62	72.25	0.84	1.2	72.3	69.7 - 74.8	62	72.29	0.78	1.1	72.4	69.9 - 74.7
Abbott Cell-Dyn 3200	10	71.73	1.54	2.1	72.1	67.1 - 76.4	10	71.51	2.54	3.6	72.5	63.8 - 79.2
Abbott Cell-Dyn Ruby	44	72.37	0.68	0.9	72.4	70.3 - 74.5	45	72.37	0.66	0.9	72.4	70.4 - 74.4
Orphee Mythic 22	14	69.91	0.74	1.1	70.1	67.7 - 72.2	13	69.71	0.81	1.2	69.9	67.2 - 72.2
Specimen CL-10												
All Method	75	51.21	1.51	3.0	51.4	46.6 - 55.8						
All Abbott Cell-Dyn Instruments	60	51.56	1.14	2.2	51.5	48.1 - 55.0						
Abbott Cell-Dyn 3200	10	51.13	1.25	2.4	51.1	47.3 - 54.9						
Abbott Cell-Dyn Ruby	44	51.87	1.23	2.4	51.8	48.1 - 55.6						
Orphee Mythic 22	14	49.09	1.55	3.2	48.9	44.4 - 53.8						

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

Specimen CL-6							Specimen CL-7					
<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	72	25.77	2.53	9.8	26.3	18.1 - 33.4	71	38.19	2.74	7.2	38.7	29.9 - 46.5
All Abbott Cell-Dyn Instruments	61	26.41	1.35	5.1	26.4	22.3 - 30.5	63	38.76	1.80	4.6	38.9	33.3 - 44.2
Abbott Cell-Dyn 3200	10	26.90	1.01	3.8	27.0	23.8 - 30.0	10	40.03	1.89	4.7	39.7	34.3 - 45.8
Abbott Cell-Dyn Ruby	44	26.34	1.42	5.4	26.3	22.0 - 30.6	45	38.56	1.70	4.4	38.6	33.4 - 43.7
Orphee Mythic 22	11	19.55	3.49	17.8	20.6	9.0 - 30.1	11	29.75	6.30	21.2	30.3	10.8 - 48.7
Specimen CL-8							Specimen CL-9					
All Method	68	17.17	0.93	5.4	17.1	14.3 - 20.0	69	17.12	1.04	6.1	17.2	14.0 - 20.3
All Abbott Cell-Dyn Instruments	60	17.25	0.90	5.2	17.2	14.5 - 20.0	60	17.17	0.77	4.5	17.2	14.8 - 19.5
Abbott Cell-Dyn 3200	9	-	-	-	17.9	14.5 - 20.0	10	18.01	2.93	16.3	17.2	9.2 - 26.9
Abbott Cell-Dyn Ruby	43	17.12	0.87	5.1	17.1	14.5 - 19.8	43	17.07	0.82	4.8	17.2	14.6 - 19.6
Orphee Mythic 22	11	14.84	2.51	16.9	16.0	7.3 - 22.4	11	14.45	3.25	22.5	15.5	4.7 - 24.2
Specimen CL-10												
All Method	71	37.49	2.67	7.1	37.9	29.4 - 45.6						
All Abbott Cell-Dyn Instruments	63	37.88	2.10	5.5	38.0	31.5 - 44.2						
Abbott Cell-Dyn 3200	10	38.97	2.14	5.5	39.7	32.5 - 45.5						
Abbott Cell-Dyn Ruby	42	37.82	1.22	3.2	37.9	34.1 - 41.5						
Orphee Mythic 22	10	30.77	6.27	20.4	31.0	11.9 - 49.6						

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

Specimen CL-6							Specimen CL-7					
<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	8.24	4.50	54.6	6.4	0.0 - 21.8	69	7.64	3.32	43.5	6.7	0.0 - 17.7
All Abbott Cell-Dyn Instruments	61	6.34	0.69	11.0	6.3	4.2 - 8.5	62	6.68	0.84	12.6	6.6	4.1 - 9.3
Abbott Cell-Dyn Ruby	43	6.29	0.54	8.5	6.3	4.6 - 7.9	45	6.70	0.80	11.9	6.6	4.2 - 9.1
Orphee Mythic 22	12	18.03	2.94	16.3	18.0	9.1 - 26.9	12	22.59	5.41	23.9	22.3	6.3 - 38.9
Specimen CL-8							Specimen CL-9					
All Method	75	5.89	3.05	51.8	4.7	0.0 - 15.1	69	5.07	1.58	31.2	4.6	0.3 - 9.9
All Abbott Cell-Dyn Instruments	58	4.59	0.39	8.5	4.6	3.4 - 5.8	58	4.57	0.39	8.6	4.5	3.3 - 5.8
Abbott Cell-Dyn Ruby	44	4.60	0.38	8.3	4.6	3.4 - 5.8	43	4.56	0.39	8.5	4.5	3.3 - 5.8
Orphee Mythic 22	13	12.06	2.18	18.0	11.4	5.5 - 18.6	11	10.85	2.56	23.6	10.4	3.1 - 18.6
Specimen CL-10												
All Method	68	7.33	2.96	40.4	6.5	0.0 - 16.3						
All Abbott Cell-Dyn Instruments	61	6.52	1.17	18.0	6.4	3.0 - 10.1						
Abbott Cell-Dyn Ruby	43	6.66	0.90	13.6	6.6	3.9 - 9.4						
Orphee Mythic 22	11	21.29	4.87	22.9	22.0	6.6 - 36.0						

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

Specimen CL-6							Specimen CL-7					
<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	73	3.56	0.43	11.9	3.6	2.2 - 4.9	77	3.15	0.45	14.3	3.1	1.8 - 4.6
All Abbott Cell-Dyn Instruments	63	3.58	0.27	7.6	3.6	2.7 - 4.5	62	3.21	0.33	10.4	3.1	2.2 - 4.3
Abbott Cell-Dyn 3200	10	3.62	0.29	8.0	3.6	2.7 - 4.5	10	3.25	0.20	6.0	3.2	2.6 - 3.9
Abbott Cell-Dyn Ruby	45	3.55	0.28	8.0	3.6	2.7 - 4.5	45	3.22	0.40	12.5	3.1	2.0 - 4.5
Orphee Mythic 22	13	4.13	1.39	33.5	4.2	0.0 - 8.3	14	2.95	0.83	28.1	2.9	0.4 - 5.5
Specimen CL-8							Specimen CL-9					
All Method	71	5.25	0.32	6.1	5.2	4.2 - 6.3	71	5.24	0.34	6.5	5.3	4.2 - 6.3
All Abbott Cell-Dyn Instruments	61	5.25	0.26	4.9	5.2	4.4 - 6.1	63	5.26	0.29	5.5	5.3	4.3 - 6.2
Abbott Cell-Dyn 3200	10	5.45	1.12	20.5	5.2	2.0 - 8.9	10	5.20	0.32	6.2	5.3	4.2 - 6.2
Abbott Cell-Dyn Ruby	45	5.27	0.25	4.8	5.3	4.5 - 6.1	45	5.26	0.29	5.5	5.3	4.3 - 6.2
Orphee Mythic 22	12	4.28	1.34	31.4	4.8	0.2 - 8.4	12	3.95	1.48	37.5	4.3	0.0 - 8.4
Specimen CL-10												
All Method	76	3.24	0.47	14.4	3.2	1.8 - 4.7						
All Abbott Cell-Dyn Instruments	63	3.21	0.42	13.1	3.2	1.9 - 4.5						
Abbott Cell-Dyn 3200	10	3.02	0.41	13.7	3.1	1.7 - 4.3						
Abbott Cell-Dyn Ruby	45	3.26	0.44	13.6	3.2	1.9 - 4.6						
Orphee Mythic 22	12	3.38	0.68	20.1	3.6	1.3 - 5.5						

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

Specimen CL-6							Specimen CL-7					
<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	0.30	0.19	64.0	0.3	0.0 - 0.9	75	0.51	0.28	55.7	0.5	0.0 - 1.4
All Abbott Cell-Dyn Instruments	62	0.29	0.18	64.3	0.3	0.0 - 0.9	60	0.50	0.24	48.2	0.5	0.0 - 1.3
Abbott Cell-Dyn 3200	10	0.33	0.21	64.0	0.4	0.0 - 1.0	10	0.63	0.32	51.3	0.6	0.0 - 1.7
Abbott Cell-Dyn Ruby	44	0.25	0.16	64.3	0.3	0.0 - 0.8	44	0.52	0.25	47.3	0.5	0.0 - 1.3
Orphee Mythic 22	13	0.35	0.22	62.8	0.3	0.0 - 1.1	14	0.54	0.53	97.1	0.4	0.0 - 2.2
Specimen CL-8							Specimen CL-9					
All Method	78	0.53	0.27	50.0	0.5	0.0 - 1.4	77	0.53	0.27	50.6	0.6	0.0 - 1.4
All Abbott Cell-Dyn Instruments	63	0.55	0.26	46.7	0.5	0.0 - 1.4	62	0.55	0.26	46.3	0.6	0.0 - 1.4
Abbott Cell-Dyn 3200	10	0.62	0.30	48.6	0.6	0.0 - 1.6	10	0.76	0.37	48.5	0.7	0.0 - 1.9
Abbott Cell-Dyn Ruby	45	0.57	0.25	43.4	0.6	0.0 - 1.4	45	0.54	0.24	44.2	0.6	0.0 - 1.3
Orphee Mythic 22	14	0.41	0.25	61.3	0.4	0.0 - 1.2	14	0.42	0.31	74.0	0.4	0.0 - 1.4
Specimen CL-10												
All Method	73	0.43	0.27	62.6	0.4	0.0 - 1.3						
All Abbott Cell-Dyn Instruments	61	0.45	0.27	61.6	0.4	0.0 - 1.3						
Abbott Cell-Dyn 3200	10	0.57	0.37	65.7	0.6	0.0 - 1.7						
Abbott Cell-Dyn Ruby	44	0.46	0.25	53.7	0.4	0.0 - 1.2						
Orphee Mythic 22	14	0.53	0.55	104.0	0.4	0.0 - 2.2						

BLOOD BANK
ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-6	Group A	142	99.30%	Acceptable
	Group B	1	0.70%	
BB-7	Group O	142	99.30%	Acceptable
	Group A	1	0.70%	
BB-8	Group B	142	99.30%	Acceptable
	Group O	1	0.70%	
BB-9	Group O	142	99.30%	Acceptable
	Group A	1	0.70%	
BB-10	Group A	140	97.90%	Acceptable
	Group AB	2	1.40%	
	Group O	1	0.70%	

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-6	Rh Positive	144	100%	Acceptable
BB-7	Rh Positive	144	100%	Acceptable
BB-8	Rh Negative	142	98.61%	Acceptable
	Rh Positive	2	1.39%	
BB-9	Rh Negative	143	99.31%	Acceptable
	Rh Positive	1	0.69%	
BB-10	Rh Positive	143	99.31%	Acceptable
	Rh Negative	1	0.69%	

BLOOD BANK

UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	Unexpected antibody detected	96	96.97%	Acceptable
	No unexpected antibody detected	3	3.03%	
AB-7	No unexpected antibody detected	98	98.99%	Acceptable
	Unexpected antibody detected	1	1.01%	
AB-8	No unexpected antibody detected	98	98.99%	Acceptable
	Unexpected antibody detected	1	1.01%	
AB-9	Unexpected antibody detected	94	94.95%	Acceptable
	No unexpected antibody detected	5	5.05%	
AB-10	No unexpected antibody detected	94	94.95%	Acceptable
	Unexpected antibody detected	1	1.01%	

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	Anti-K	44	95.65%	Acceptable
	Other antibody not listed	1	2.17%	
	Anti-C	1	2.17%	
AB-7	No antibody detected	46	100%	Acceptable
AB-8	No antibody detected	46	100%	Acceptable
AB-9	Anti-Fy(a)	43	93.48%	Acceptable
	Anti-Fy(b)	1	2.17%	
	Anti-E	1	2.17%	
AB-10	No antibody detected	46	100%	Acceptable

BLOOD BANK

COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	Not Compatible	101	96.19%	Acceptable
	Compatible	4	3.81%	
AB-7	Compatible	104	99.05%	Acceptable
	Not Compatible	1	0.95%	
AB-8	Compatible	104	99.05%	Acceptable
	Not Compatible	1	0.95%	
AB-9	Compatible	102	97.14%	Acceptable
	Not Compatible	3	2.86%	
AB-10	Compatible	100	95.24%	Acceptable
	Not Compatible	5	4.76%	

Coagulation

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-6						Specimen CG-7					
	<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	136	48.87	9.51	19.5	50.9	41.5 - 56.3	141	11.91	1.46	12.2	12.2	10.1 - 13.7
Dade Innovin												
Dade Behring BFT II	5	46.60	5.26	11.3	46.1	39.6 - 53.6	5	9.16	0.29	3.1	9.2	7.7 - 10.6
Sysmex CA-500/600 series	27	43.72	2.25	5.1	43.8	37.1 - 50.3	28	10.35	0.23	2.2	10.4	8.8 - 12.0
All Coagulation Instruments	36	44.11	2.97	6.7	43.9	37.4 - 50.8	37	10.11	0.62	6.2	10.3	8.5 - 11.7
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	5	61.24	5.41	8.8	60.5	52.0 - 70.5	5	12.52	0.31	2.5	12.6	10.6 - 14.4
Diagnostica Stago STart 4/8	10	55.42	6.71	12.1	56.3	47.1 - 63.8	10	12.65	0.69	5.5	12.5	10.7 - 14.6
RAL Clot-SP	18	56.06	2.77	4.9	56.1	47.6 - 64.5	18	13.54	0.55	4.1	13.5	11.5 - 15.6
All Coagulation Instruments	39	56.71	3.83	6.8	56.4	48.1 - 65.3	43	13.07	0.69	5.3	13.1	11.1 - 15.1
Diagon Dia-PT												
Coalyzer-410	6	41.02	6.96	17.0	43.8	34.8 - 47.2	7	12.13	0.64	5.3	12.2	10.3 - 14.0
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	51.48	3.33	6.5	51.9	43.7 - 59.3	6	11.45	0.19	1.6	11.5	9.7 - 13.2
IL TEST PT Fibrinogen												
IL ACL, all models	8	30.53	1.85	6.1	30.9	25.9 - 35.2	9	11.07	0.40	3.6	11.0	9.4 - 12.8
IL TEST PT-FIB HS PLUS												
IL ACL, all models	15	53.35	7.77	14.6	56.0	45.3 - 61.4	16	13.17	0.57	4.3	13.2	11.1 - 15.2
IL TEST PT-FIB Recombinant												
IL ACL, all models	7	56.03	4.97	8.9	56.7	47.6 - 64.5	7	12.31	0.62	5.0	12.4	10.4 - 14.2

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-8						Specimen CG-9					
	<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	139	13.51	1.20	8.9	13.5	11.4 - 15.6	141	11.97	1.41	11.8	12.2	10.1 - 13.8
Dade Innovin												
Dade Behring BFT II	5	12.02	0.41	3.4	12.1	10.2 - 13.9	5	9.42	0.41	4.4	9.5	8.0 - 10.9
Sysmex CA-500/600 series	27	12.52	0.33	2.6	12.5	10.6 - 14.5	28	10.43	0.26	2.5	10.4	8.8 - 12.0
All Coagulation Instruments	37	12.45	0.53	4.3	12.5	10.5 - 14.4	37	10.21	0.57	5.6	10.4	8.6 - 11.8
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	5	13.62	0.55	4.1	13.5	11.5 - 15.7	5	12.38	0.34	2.8	12.3	10.5 - 14.3
Diagnostica Stago STart 4/8	10	13.67	0.57	4.2	13.6	11.6 - 15.8	10	12.42	0.55	4.4	12.4	10.5 - 14.3
RAL Clot-SP	18	14.87	0.72	4.8	14.9	12.6 - 17.2	18	13.43	0.47	3.5	13.6	11.4 - 15.5
All Coagulation Instruments	42	14.24	0.83	5.9	14.2	12.1 - 16.4	43	12.94	0.63	4.9	12.9	11.0 - 14.9
Diagon Dia-PT												
Coalyzer-410	7	13.56	1.03	7.6	13.7	11.5 - 15.6	7	12.70	1.40	11.0	12.2	10.7 - 14.7
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	12.07	0.18	1.5	12.1	10.2 - 13.9	6	11.25	0.31	2.7	11.2	9.5 - 13.0
IL TEST PT Fibrinogen												
IL ACL, all models	9	13.21	0.35	2.7	13.2	11.2 - 15.2	9	11.58	0.38	3.3	11.5	9.8 - 13.4
IL TEST PT-FIB HS PLUS												
IL ACL, all models	16	14.69	0.49	3.4	14.7	12.4 - 16.9	16	13.33	0.54	4.1	13.5	11.3 - 15.4
IL TEST PT-FIB Recombinant												
IL ACL, all models	7	14.04	1.19	8.5	14.5	11.9 - 16.2	7	12.64	1.02	8.1	12.7	10.7 - 14.6

PROTHROMBIN TIME (seconds)

Specimen CG-10						
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	138	29.11	4.42	15.2	29.9	24.7 - 33.5
Dade Innovin						
Dade Behring BFT II	5	26.60	2.40	9.0	27.3	22.6 - 30.6
Sysmex CA-500/600 series	27	25.67	1.12	4.4	25.8	21.8 - 29.6
All Coagulation Instruments	36	25.75	1.43	5.6	25.8	21.8 - 29.7
Diag Stago STA Neoplastine CI+						
bioMerieux Thrombolyzer Compact X/XR	5	33.98	1.53	4.5	33.5	28.8 - 39.1
Diagnostica Stago STart 4/8	10	31.35	3.09	9.9	31.4	26.6 - 36.1
RAL Clot-SP	18	33.09	1.13	3.4	33.2	28.1 - 38.1
All Coagulation Instruments	42	32.79	1.71	5.2	33.0	27.8 - 37.8
Diagon Dia-PT						
Coalyzer-410	7	28.01	3.04	10.8	28.4	23.8 - 32.3
HemosIL RecombiPlasTin 2G						
IL ACL, all models	6	29.42	2.00	6.8	29.2	25.0 - 33.9
IL TEST PT Fibrinogen						
IL ACL, all models	9	22.18	4.05	18.3	20.6	18.8 - 25.6
IL TEST PT-FIB HS PLUS						
IL ACL, all models	14	32.54	1.96	6.0	33.3	27.6 - 37.5
IL TEST PT-FIB Recombinant						
IL ACL, all models	7	31.84	2.37	7.4	32.1	27.0 - 36.7

PROTHROMBIN TIME-INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-6						Specimen CG-7					
	<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	130	5.25	1.35	25.8	4.7	4.1 - 6.3	139	0.97	0.08	7.8	1.0	0.7 - 1.2
Dade Innovin												
Dade Behring BFT II	5	4.10	0.47	11.4	4.3	3.2 - 5.0	5	1.02	0.08	8.2	1.0	0.8 - 1.3
Sysmex CA-500/600 series	26	4.18	0.15	3.5	4.2	3.3 - 5.1	28	1.00	0.04	4.3	1.0	0.7 - 1.2
All Coagulation Instruments	37	4.15	0.29	6.9	4.2	3.3 - 5.0	38	1.00	0.05	5.5	1.0	0.7 - 1.2
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	4	-	-	-	6.9	5.4 - 8.2	5	0.96	0.09	9.3	1.0	0.7 - 1.2
Diagnostica Stago STart 4/8	8	6.98	0.62	8.9	6.9	5.5 - 8.4	9	0.94	0.07	7.7	0.9	0.7 - 1.2
RAL Clot-SP	17	6.72	0.53	7.8	6.7	5.3 - 8.1	17	1.02	0.08	7.4	1.0	0.8 - 1.3
All Coagulation Instruments	35	6.89	0.64	9.3	6.9	5.5 - 8.3	40	0.99	0.08	7.9	1.0	0.7 - 1.2
Diagon Dia-PT												
Coalyzer-410	6	3.85	0.80	20.7	4.2	3.0 - 4.7	6	0.92	0.08	8.2	0.9	0.7 - 1.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	7	4.79	0.23	4.7	4.8	3.8 - 5.8	7	1.03	0.08	7.3	1.0	0.8 - 1.3
IL TEST PT Fibrinogen												
IL ACL, all models	9	5.99	0.85	14.2	6.0	4.7 - 7.2	9	0.91	0.06	6.6	0.9	0.7 - 1.1
IL TEST PT-FIB HS PLUS												
IL ACL, all models	13	4.85	0.56	11.5	4.6	3.8 - 5.9	17	0.93	0.08	8.3	0.9	0.7 - 1.2
IL TEST PT-FIB Recombinant												
IL ACL, all models	6	4.62	0.77	16.6	4.8	3.6 - 5.6	7	0.90	0.06	6.4	0.9	0.7 - 1.1
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	8.02	1.01	12.6	7.5	6.4 - 9.7	5	0.96	0.05	5.7	1.0	0.7 - 1.2

PROTHROMBIN TIME-INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-8						Specimen CG-9					
	<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	139	1.13	0.11	10.2	1.1	0.9 - 1.4	139	0.98	0.08	8.0	1.0	0.7 - 1.2
Dade Innovin												
Dade Behring BFT II	5	1.28	0.04	3.5	1.3	1.0 - 1.6	5	1.06	0.05	5.2	1.1	0.8 - 1.3
Sysmex CA-500/600 series	27	1.20	0.05	4.3	1.2	0.9 - 1.5	28	1.01	0.06	5.8	1.0	0.8 - 1.3
All Coagulation Instruments	38	1.22	0.06	5.1	1.2	0.9 - 1.5	38	1.02	0.06	6.3	1.0	0.8 - 1.3
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	5	1.08	0.11	10.1	1.1	0.8 - 1.3	5	0.94	0.09	9.5	1.0	0.7 - 1.2
Diagnostica Stago STart 4/8	9	1.04	0.07	7.0	1.0	0.8 - 1.3	9	0.93	0.05	5.4	0.9	0.7 - 1.2
RAL Clot-SP	17	1.14	0.09	7.6	1.1	0.9 - 1.4	17	0.99	0.07	7.5	1.0	0.7 - 1.2
All Coagulation Instruments	39	1.10	0.09	7.9	1.1	0.8 - 1.4	40	0.98	0.07	7.5	1.0	0.7 - 1.2
Diagon Dia-PT												
Coalyzer-410	6	1.05	0.10	10.0	1.1	0.8 - 1.3	6	0.95	0.14	14.5	0.9	0.7 - 1.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	7	1.09	0.04	3.5	1.1	0.8 - 1.4	7	1.01	0.07	6.8	1.0	0.8 - 1.3
IL TEST PT Fibrinogen												
IL ACL, all models	9	1.26	0.14	11.3	1.3	1.0 - 1.6	9	0.99	0.08	7.9	1.0	0.7 - 1.2
IL TEST PT-FIB HS PLUS												
IL ACL, all models	17	1.06	0.09	8.9	1.1	0.8 - 1.3	17	0.95	0.09	9.9	1.0	0.7 - 1.2
IL TEST PT-FIB Recombinant												
IL ACL, all models	7	1.01	0.07	6.8	1.0	0.8 - 1.3	7	0.90	0.06	6.4	0.9	0.7 - 1.1
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	1.14	0.13	11.8	1.2	0.9 - 1.4	5	1.00	0.07	7.1	1.0	0.8 - 1.2

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

Specimen CG-10

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	137	2.83	0.48	16.9	2.7	2.2 - 3.4
Dade Innovin						
Dade Behring BFT II	5	2.54	0.24	9.5	2.6	2.0 - 3.1
Sysmex CA-500/600 series	26	2.47	0.09	3.7	2.5	1.9 - 3.0
All Coagulation Instruments	37	2.47	0.15	6.0	2.5	1.9 - 3.0
Diag Stago STA Neoplastine CI+						
bioMerieux Thrombolyzer Compact X/XR	5	3.48	0.48	13.8	3.5	2.7 - 4.2
Diagnostica Stago STart 4/8	9	3.17	0.46	14.6	3.1	2.5 - 3.9
RAL Clot-SP	17	3.31	0.20	5.9	3.3	2.6 - 4.0
All Coagulation Instruments	40	3.28	0.39	12.0	3.3	2.6 - 4.0
Diagon Dia-PT						
Coalyzer-410	6	2.48	0.26	10.6	2.5	1.9 - 3.0
HemosIL RecombiPlasTin 2G						
IL ACL, all models	7	2.71	0.16	5.8	2.7	2.1 - 3.3
IL TEST PT Fibrinogen						
IL ACL, all models	9	2.97	0.39	13.3	2.8	2.3 - 3.6
IL TEST PT-FIB HS PLUS						
IL ACL, all models	14	2.69	0.24	9.0	2.7	2.1 - 3.3
IL TEST PT-FIB Recombinant						
IL ACL, all models	7	2.59	0.31	12.1	2.6	2.0 - 3.2
PH/CMS Thromboplastin-D						
All Coagulation Instruments	5	3.36	0.55	16.4	3.4	2.6 - 4.1

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

<u>Reagent/Instrument</u>	Specimen CG-6						Specimen CG-7					
	<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	73.3	11.9	16.3	71	62 - 85	82	29.7	2.8	9.6	29	25 - 35
Dade Actin												
All Coagulation Instruments	5	111.0	20.7	18.7	122	94 - 128	5	30.2	2.9	9.5	30	25 - 35
Dade Actin FSL												
Sysmex CA-500/600 series	14	68.2	2.6	3.9	68	57 - 79	14	28.2	1.2	4.2	28	23 - 33
All Coagulation Instruments	16	69.3	4.1	6.0	69	58 - 80	16	28.1	1.3	4.5	28	23 - 33
Diagnostica Stago STA C.K. Prest												
bioMerieux Thrombolyzer Compact X/XR	4	74.5	1.3	1.7	75	63 - 86	4	33.3	0.5	1.5	33	28 - 39
Diagnostica Stago STart 4/8	5	77.0	3.3	4.3	78	65 - 89	5	32.8	0.8	2.6	33	27 - 38
All Coagulation Instruments	14	74.0	4.5	6.0	74	62 - 86	14	31.7	3.3	10.4	33	26 - 37
Diagnostica Stago STA-PTT												
All Coagulation Instruments	3	-	-	-	80	68 - 93	3	-	-	-	35	29 - 40
Diagon Dia-PTT												
Coalyzer-410	2	-	-	-	45	62 - 85	3	-	-	-	34	25 - 35
Hemoliance SynthASil												
IL ACL, all models	5	91.0	12.1	13.3	90	77 - 105	5	29.0	0.7	2.4	29	24 - 34
IL TEST APTT-SP												
IL ACL, all models	26	67.7	4.9	7.2	69	57 - 78	27	28.3	1.5	5.2	28	24 - 33

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

Specimen CG-8							Specimen CG-9					
<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	84	35.3	5.5	15.6	35	30 - 41	84	27.3	3.1	11.2	27	23 - 32
Dade Actin												
All Coagulation Instruments	5	31.2	0.8	2.7	31	26 - 36	5	27.6	2.5	9.1	27	23 - 32
Dade Actin FSL												
Sysmex CA-500/600 series	14	28.6	0.5	1.8	29	24 - 33	14	24.6	0.9	3.8	25	20 - 29
All Coagulation Instruments	15	28.7	0.6	2.2	29	24 - 33	16	24.7	0.9	3.8	25	20 - 29
Diagnostica Stago STA C.K. Prest												
bioMerieux Thrombolyzer Compact X/XR	4	41.8	1.0	2.3	42	35 - 49	4	28.8	3.3	11.5	30	24 - 34
Diagnostica Stago STart 4/8	5	39.0	1.6	4.1	39	33 - 45	5	30.6	0.9	2.9	30	26 - 36
All Coagulation Instruments	14	39.6	2.2	5.7	40	33 - 46	14	29.4	3.1	10.5	30	24 - 34
Diagnostica Stago STA-PTT												
All Coagulation Instruments	3	-	-	-	40	35 - 49	3	-	-	-	31	26 - 36
Diagon Dia-PTT												
Coalyzer-410	3	-	-	-	37	30 - 41	4	32.0	3.7	11.4	32	27 - 37
Hemoliance SynthASil												
IL ACL, all models	5	45.0	2.9	6.5	46	38 - 52	5	31.0	1.2	4.0	31	26 - 36
IL TEST APTT-SP												
IL ACL, all models	26	35.2	1.4	4.1	35	29 - 41	27	25.8	1.2	4.6	26	21 - 30
Specimen CG-10												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	76	50.8	8.3	16.4	49	43 - 59						
Dade Actin												
All Coagulation Instruments	4	74.3	5.4	7.2	75	63 - 86						
Dade Actin FSL												
Sysmex CA-500/600 series	14	46.6	1.6	3.4	47	39 - 54						
All Coagulation Instruments	16	47.3	2.6	5.5	47	40 - 55						
Diagnostica Stago STA C.K. Prest												
bioMerieux Thrombolyzer Compact X/XR	4	50.8	1.3	2.5	51	43 - 59						
Diagnostica Stago STart 4/8	5	52.0	4.3	8.3	50	44 - 60						
All Coagulation Instruments	14	49.6	4.4	8.8	50	42 - 58						
Diagnostica Stago STA-PTT												
All Coagulation Instruments	4	51.3	5.0	9.7	51	43 - 59						
Diagon Dia-PTT												
Coalyzer-410	4	113.8	13.2	11.6	115	96 - 131						
Hemoliance SynthASil												
IL ACL, all models	4	60.3	5.9	9.7	61	51 - 70						
IL TEST APTT-SP												
IL ACL, all models	25	46.6	3.5	7.5	46	39 - 54						

FIBRINOGEN (mg/dL)

Specimen CG-6							Specimen CG-7					
<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	335.7	59.3	17.7	333	268 - 403	38	528.7	102.3	19.3	544	422 - 635
Diagnostica Stago STA Fibrinogen												
All Coagulation Instruments	8	275.6	32.2	11.7	277	220 - 331	8	510.3	118.4	23.2	526	408 - 613
IL TEST PT-FIB HS PLUS												
IL ACL, all models	12	385.2	42.5	11.0	398	308 - 463	14	556.9	58.3	10.5	570	445 - 669
IL TEST PT-FIB Recombinant												
IL ACL, all models	5	364.8	40.6	11.1	381	291 - 438	6	545.8	36.8	6.7	548	436 - 655
Specimen CG-8							Specimen CG-9					
<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	34	152.0	25.5	16.8	155	121 - 183	38	362.8	44.4	12.2	357	290 - 436
Diagnostica Stago STA Fibrinogen												
All Coagulation Instruments	7	137.1	24.6	17.9	154	109 - 165	8	341.6	35.3	10.3	350	273 - 410
IL TEST PT-FIB HS PLUS												
IL ACL, all models	12	155.5	22.1	14.2	159	124 - 187	14	385.9	48.0	12.4	379	308 - 464
IL TEST PT-FIB Recombinant												
IL ACL, all models	5	138.4	19.2	13.9	142	110 - 167	6	364.7	16.7	4.6	362	291 - 438
Specimen CG-10												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	36	342.9	56.1	16.4	335	274 - 412						
Diagnostica Stago STA Fibrinogen												
All Coagulation Instruments	8	287.0	16.2	5.7	290	229 - 345						
IL TEST PT-FIB HS PLUS												
IL ACL, all models	12	382.8	46.9	12.2	370	306 - 460						
IL TEST PT-FIB Recombinant												
IL ACL, all models	6	379.8	50.6	13.3	382	303 - 456						

URINALYSIS DIPSTICK–SPECIFIC GRAVITY

Specimen UA-2

<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	405	1.0152	0.0043	0.4	1.015	1.005 - 1.026
All Roche Methods	142	1.0125	0.0032	0.3	1.010	1.002 - 1.023
All Siemens Methods	50	1.0187	0.0032	0.3	1.020	1.008 - 1.029
Arkray Aution Sticks	16	1.0227	0.0066	0.6	1.022	1.012 - 1.033
Combi-Screen Test Strips	11	1.0127	0.0025	0.3	1.015	1.002 - 1.023
DIRUI H-100 / H-500 Urine Analyzer	19	1.0155	0.0022	0.2	1.015	1.005 - 1.026
Other Analyzer Method	15	1.0173	0.0053	0.5	1.019	1.007 - 1.028
Roche Chemstrips / Combur	18	1.0117	0.0024	0.2	1.010	1.001 - 1.022
Roche cobas u 411	84	1.0118	0.0024	0.2	1.010	1.001 - 1.022
Roche Urisys	53	1.0135	0.0039	0.4	1.015	1.003 - 1.024
SD UroColor Reagent Strips	31	1.0190	0.0033	0.3	1.020	1.009 - 1.030
Siemens Clinitek Advantus	29	1.0183	0.0030	0.3	1.020	1.008 - 1.029
UriScan Reagent Strips	39	1.0163	0.0041	0.4	1.015	1.006 - 1.027

URINALYSIS DIPSTICK-pH

Specimen UA-2

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	435	-	-	-	1	-	5	16	346	64	2	-	1
Acon Laboratories	5	-	-	-	-	-	-	-	5	-	-	-	-
Analyticon CombiScan 500	3	-	-	-	-	-	1	-	2	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	2	-	-	-	-
Arkray Aution Sticks	17	-	-	-	-	-	-	-	17	-	-	-	-
Arkray PocketChem UA	3	-	-	-	-	-	-	-	3	-	-	-	-
Combi-Screen Test Strips	12	-	-	-	-	-	-	-	11	-	1	-	-
CYBOW Urine Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	20	-	-	-	-	-	3	5	4	8	-	-	-
DIRUI H-800 Urine Analyzer	7	-	-	-	-	-	-	1	5	1	-	-	-
HUMAN Combilyzer	2	-	-	-	-	-	-	-	2	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	-	-	2	-	-	-	-
Iris Diagnostics iChem Velocity Strips	9	-	-	-	-	-	-	-	8	1	-	-	-
Other Analyzer Method	21	-	-	-	-	-	1	1	18	1	-	-	-
Other Dipstick Method	9	-	-	-	-	-	-	-	7	2	-	-	-
Plasmatec URIPATH	3	-	-	-	-	-	-	2	1	-	-	-	-
Roche Chemstrips / Combur	19	-	-	-	1	-	-	-	16	2	-	-	-
Roche cobas u 411	86	-	-	-	-	-	-	1	85	-	-	-	-
Roche Mditron Junior/II	4	-	-	-	-	-	-	-	4	-	-	-	-
Roche Urilux S	2	-	-	-	-	-	-	-	2	-	-	-	-
Roche Urisys	56	-	-	-	-	-	-	-	55	-	1	-	-
SD UroColor Reagent Strips	31	-	-	-	-	-	-	-	24	6	-	-	1
Siemens Clinitek 50	3	-	-	-	-	-	-	-	3	-	-	-	-
Siemens Clinitek 500	3	-	-	-	-	-	-	1	2	-	-	-	-
Siemens Clinitek Advantus	30	-	-	-	-	-	-	-	9	21	-	-	-
Siemens Clinitek Atlas	6	-	-	-	-	-	-	-	6	-	-	-	-
Siemens Clinitek Status / Status+	9	-	-	-	-	-	-	-	7	2	-	-	-
Siemens Multistix Pro	2	-	-	-	-	-	-	-	1	1	-	-	-
Siemens Reagent Strips	14	-	-	-	-	-	-	-	1	13	-	-	-
Urinometer	5	-	-	-	-	-	-	-	1	4	-	-	-
UriScan Pro/II	7	-	-	-	-	-	-	2	5	-	-	-	-
UriScan Reagent Strips	39	-	-	-	-	-	-	3	34	2	-	-	-

URINALYSIS DIPSTICK–PROTEIN QUALITATIVE

Specimen UA-2

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	436	4	1	16	162	43	1	-	13	20	162	14	-
Acon Laboratories	5	-	-	1	2	-	-	-	-	-	1	1	-
Analyticon CombiScan 500	3	-	-	-	-	-	-	-	-	-	3	-	-
Arkray Aution Jet	2	-	-	-	1	-	-	-	-	-	1	-	-
Arkray Aution Sticks	17	-	-	-	8	-	-	-	1	-	8	-	-
Arkray PocketChem UA	3	-	-	-	2	-	-	-	-	-	1	-	-
Combi-Screen Test Strips	12	1	-	1	3	-	-	-	-	-	5	2	-
CYBOW Urine Reagent Strips	1	-	-	-	1	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	21	-	-	-	11	2	-	-	-	-	6	2	-
DIRUI H-800 Urine Analyzer	6	-	1	1	2	2	-	-	-	-	-	-	-
HUMAN Combilyzer	2	-	-	-	-	-	-	-	1	-	1	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	1	-	-	-	-	-	1	-	-
Iris Diagnostics iChem Velocity Strips	9	1	-	4	1	-	-	-	3	-	-	-	-
Other Analyzer Method	22	-	-	1	14	-	-	-	1	-	5	1	-
Other Dipstick Method	9	-	-	-	5	-	-	-	1	-	2	1	-
Plasmatec URIPATH	3	-	-	-	2	1	-	-	-	-	-	-	-
Roche Chemstrips / Combur	20	-	-	-	14	4	-	-	-	-	2	-	-
Roche cobas u 411	88	-	-	1	5	12	-	-	-	15	55	-	-
Roche Mditron Junior/II	4	-	-	-	1	2	-	-	-	-	1	-	-
Roche Urilux S	1	-	-	-	1	-	-	-	-	-	-	-	-
Roche Urisys	56	1	-	-	6	4	1	-	-	5	37	2	-
SD UroColor Reagent Strips	31	1	-	6	16	2	-	-	3	-	3	-	-
Siemens Clinitek 50	3	-	-	-	-	1	-	-	-	-	-	2	-
Siemens Clinitek 500	3	-	-	-	-	-	-	-	-	-	2	1	-
Siemens Clinitek Advantus	29	-	-	-	18	1	-	-	-	-	9	1	-
Siemens Clinitek Atlas	6	-	-	-	4	-	-	-	-	-	2	-	-
Siemens Clinitek Status / Status+	10	-	-	-	3	4	-	-	-	-	3	-	-
Siemens Multistix Pro	2	-	-	-	-	-	-	-	-	-	1	1	-
Siemens Reagent Strips	13	-	-	-	6	6	-	-	-	-	1	-	-
Urinometer	5	-	-	1	4	-	-	-	-	-	-	-	-
UriScan Pro/II	7	-	-	-	1	1	-	-	-	-	5	-	-
UriScan Reagent Strips	39	-	-	-	28	1	-	-	3	-	7	-	-

URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-2

<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	437	432	-	2	-	-	1	-	-	-	2
Acon Laboratories	6	6	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	3	3	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	17	17	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	3	3	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	11	11	-	-	-	-	-	-	-	-	-
CYBOW Urine Reagent Strips	1	1	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	21	21	-	-	-	-	-	-	-	-	-
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	9	9	-	-	-	-	-	-	-	-	-
Other Analyzer Method	21	21	-	-	-	-	-	-	-	-	-
Other Dipstick Method	9	9	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	3	3	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	19	19	-	-	-	-	-	-	-	-	-
Roche cobas u 411	88	87	-	-	-	-	-	-	-	-	1
Roche Mditron Junior/II	4	4	-	-	-	-	-	-	-	-	-
Roche Urilux S	2	2	-	-	-	-	-	-	-	-	-
Roche Urisys	56	54	-	-	-	-	1	-	-	-	1
SD UroColor Reagent Strips	31	31	-	-	-	-	-	-	-	-	-
Siemens Clinitek 50	3	3	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	3	3	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	30	30	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	6	6	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	10	10	-	-	-	-	-	-	-	-	-
Siemens Multistix Pro	2	2	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	14	14	-	-	-	-	-	-	-	-	-
Urinometer	5	5	-	-	-	-	-	-	-	-	-
UriScan Pro/II	7	7	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	38	37	-	1	-	-	-	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–KETONES

Specimen UA-2

<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>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>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>										
ALL METHODS	437	431	1	-	-	-	1	-	-	1	1	-	-	-	-	2				
Acon Laboratories	6	6	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Analyticon CombiScan 500	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Arkray Aution Jet	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Arkray Aution Sticks	17	17	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Arkray PocketChem UA	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Combi-Screen Test Strips	11	11	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
CYBOW Urine Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
DIRUI H-100 / H-500 Urine Analyzer	21	21	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
DIRUI H-800 Urine Analyzer	5	5	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
HUMAN Combilyzer	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Iris Diagnostics iChem Velocity Strips	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Other Analyzer Method	22	22	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Other Dipstick Method	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Plasmatec URIPATH	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Roche Chemstrips / Combur	18	18	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Roche cobas u 411	88	87	-	-	-	-	-	-	-	-	-	-	-	-	-	1				
Roche Mditron Junior/II	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Roche Urilux S	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Roche Urisys	57	55	-	-	-	-	-	-	-	1	-	-	-	-	-	1				
SD UroColor Reagent Strips	31	29	1	-	-	-	-	-	-	-	1	-	-	-	-	-				
Siemens Clinitek 50	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Siemens Clinitek 500	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Siemens Clinitek Advantus	30	30	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Siemens Clinitek Atlas	6	6	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Siemens Clinitek Status / Status+	10	10	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Siemens Multistix Pro	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Siemens Reagent Strips	13	13	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Urinometer	5	5	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
UriScan Pro/II	7	7	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
UriScan Reagent Strips	39	38	-	-	-	-	1	-	-	-	-	-	-	-	-	-				
URIT Medical Uritest Analyzers	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-				

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-2

<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	427	423	-	1	-	-	-	-	1	-	-	-	2	-
Acon Laboratories	6	6	-	-	-	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	17	17	-	-	-	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	11	11	-	-	-	-	-	-	-	-	-	-	-	-
CYBOW Urine Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	21	21	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	5	5	-	-	-	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	9	9	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	22	22	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	9	9	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	3	2	-	1	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	18	18	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	88	87	-	-	-	-	-	-	-	-	-	-	1	-
Roche Miditron Junior/II	4	4	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urilux S	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	57	55	-	-	-	-	-	-	1	-	-	-	1	-
SD UroColor Reagent Strips	31	31	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 50	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	30	30	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	6	6	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	9	9	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Multistix Pro	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	4	4	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	5	5	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	7	7	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	39	39	-	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-2

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	424	414	2	3	2	3
Acon Laboratories	6	6	-	-	-	-
Analyticon CombiScan 500	3	3	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-
Arkray Aution Sticks	15	15	-	-	-	-
Arkray PocketChem UA	3	3	-	-	-	-
Combi-Screen Test Strips	11	11	-	-	-	-
CYBOW Urine Reagent Strips	1	1	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	21	20	-	1	-	-
DIRUI H-800 Urine Analyzer	5	4	-	-	1	-
HUMAN Combilyzer	2	2	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-
Iris Diagnostics iChem Velocity Strips	9	8	1	-	-	-
Other Analyzer Method	22	22	-	-	-	-
Other Dipstick Method	9	9	-	-	-	-
Plasmatec URIPATH	3	3	-	-	-	-
Roche Chemstrips / Combur	18	18	-	-	-	-
Roche cobas u 411	87	85	1	-	-	1
Roche Miditron Junior/II	4	4	-	-	-	-
Roche Urilux S	2	2	-	-	-	-
Roche Urisys	57	55	-	-	1	1
SD UroColor Reagent Strips	31	31	-	-	-	-
Siemens Clinitek 50	3	3	-	-	-	-
Siemens Clinitek 500	3	3	-	-	-	-
Siemens Clinitek Advantus	30	29	-	1	-	-
Siemens Clinitek Atlas	6	6	-	-	-	-
Siemens Clinitek Status / Status+	9	8	-	1	-	-
Siemens Multistix Pro	2	2	-	-	-	-
Siemens Reagent Strips	4	4	-	-	-	-
Urinometer	5	5	-	-	-	-
UriScan Pro/II	7	7	-	-	-	-
UriScan Reagent Strips	39	38	-	-	-	1
URIT Medical Uritest Analyzers	1	1	-	-	-	-

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN

Specimen UA-2

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</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	434	7	-	1	-	12	2	9	180	38	17	-	2	160	-	-	-	6
Acon Laboratories	6	-	-	-	-	-	-	-	5	1	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	17	-	-	-	-	-	-	3	11	-	-	-	-	-	-	-	-	3
Arkray PocketChem UA	3	-	-	-	-	-	-	-	3	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	11	1	-	-	-	-	-	-	6	-	-	-	-	4	-	-	-	-
CYBOW Urine Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	21	-	-	-	-	1	-	-	16	1	-	-	-	3	-	-	-	-
DIRUI H-800 Urine Analyzer	5	-	-	-	-	-	-	-	5	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	2	-	-	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	9	1	-	-	-	-	1	-	4	1	-	-	-	-	-	-	-	2
Other Analyzer Method	22	2	-	-	-	-	-	-	12	1	-	-	1	5	-	-	-	1
Other Dipstick Method	9	-	-	-	-	-	-	-	4	1	-	-	-	4	-	-	-	-
Plasmatec URIPATH	3	-	-	-	-	1	-	-	2	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	18	1	-	-	-	1	-	-	1	11	1	-	-	3	-	-	-	-
Roche cobas u 411	87	1	-	1	-	1	-	-	-	4	10	-	-	70	-	-	-	-
Roche Mditron Junior/II	4	-	-	-	-	-	-	-	-	-	2	-	-	2	-	-	-	-
Roche Urilux S	2	-	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-
Roche Urisys	56	-	-	-	-	-	-	-	1	10	2	-	-	43	-	-	-	-
SD UroColor Reagent Strips	31	-	-	-	-	-	-	-	22	5	-	-	-	4	-	-	-	-
Siemens Clinitek 50	3	-	-	-	-	1	-	-	1	-	-	-	-	1	-	-	-	-
Siemens Clinitek 500	3	1	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	30	-	-	-	-	3	-	-	18	1	1	-	-	7	-	-	-	-
Siemens Clinitek Atlas	6	-	-	-	-	-	-	-	4	-	-	-	-	2	-	-	-	-
Siemens Clinitek Status / Status+	10	-	-	-	-	3	-	-	7	-	-	-	-	-	-	-	-	-
Siemens Multistix Pro	2	-	-	-	-	-	-	-	1	-	-	-	1	-	-	-	-	-
Siemens Reagent Strips	13	-	-	-	-	1	-	-	12	-	-	-	-	-	-	-	-	-
Urinometer	5	-	-	-	-	-	-	-	3	1	-	-	-	1	-	-	-	-
UriScan Pro/II	7	-	-	-	-	-	-	-	3	-	-	-	-	4	-	-	-	-
UriScan Reagent Strips	39	-	-	-	-	-	1	5	28	-	-	-	-	5	-	-	-	-
URIT Medical Uritest Analyzers	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-2

<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	419	409	2	-	-	-	5	-	1	-	-	-	2
Acon Laboratories	6	6	-	-	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	3	3	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	17	17	-	-	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	3	3	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	10	10	-	-	-	-	-	-	-	-	-	-	-
CYBOW Urine Reagent Strips	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	9	9	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	21	21	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	8	8	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	2	2	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	17	17	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	87	86	-	-	-	-	-	-	-	-	-	-	1
Roche Miditron Junior/II	4	4	-	-	-	-	-	-	-	-	-	-	-
Roche Urilux S	2	2	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	57	55	-	-	-	-	-	-	1	-	-	-	1
SD UroColor Reagent Strips	30	27	1	-	-	-	2	-	-	-	-	-	-
Siemens Clinitek 50	3	3	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	3	3	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	30	30	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	6	6	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	9	9	-	-	-	-	-	-	-	-	-	-	-
Siemens Multistix Pro	2	2	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	4	4	-	-	-	-	-	-	-	-	-	-	-
Urinometer	5	4	-	-	-	-	1	-	-	-	-	-	-
UriScan Pro/II	7	7	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	38	35	1	-	-	-	2	-	-	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–NITRITE

Specimen UA-2

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	426	8	418
Acon Laboratories	7	-	7
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
CYBOW Urine Reagent Strips	1	-	1
DIRUI H-100 / H-500 Urine Analyzer	21	-	21
DIRUI H-800 Urine Analyzer	5	-	5
HUMAN Combilyzer	2	-	2
Iris Diagnostics Aution Max AX-4280	2	-	2
Iris Diagnostics iChem Velocity Strips	9	-	9
Other Analyzer Method	22	1	21
Other Dipstick Method	9	1	8
Plasmatec URIPATH	3	-	3
Roche Chemstrips / Combur	18	-	18
Roche cobas u 411	87	2	85
Roche Mditron Junior/II	4	-	4
Roche Urilux S	2	-	2
Roche Urisys	57	2	55
SD UroColor Reagent Strips	32	-	32
Siemens Clinitek 50	3	-	3
Siemens Clinitek 500	3	-	3
Siemens Clinitek Advantus	30	1	29
Siemens Clinitek Atlas	5	-	5
Siemens Clinitek Status / Status+	9	-	9
Siemens Multistix Pro	2	-	2
Siemens Reagent Strips	4	-	4
Urinometer	5	-	5
UriScan Pro/II	7	-	7
UriScan Reagent Strips	39	1	38
URIT Medical Uritest Analyzers	1	-	1

URINALYSIS –MICROALBUMIN (dipstick only)

Specimen UA-2

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	18	3	-	-	1	-	3	-	6	1	4
Arkray Aution Sticks	1	1	-	-	-	-	-	-	-	-	-
Beckman Coulter ICON microALB	1	-	-	-	-	-	-	-	-	-	1
DIRUI H-100 / H-500 Urine Analyzer	2	-	-	-	-	-	-	-	2	-	-
HUMAN COMBINA Test Strips	1	-	-	-	-	-	1	-	-	-	-
Roche Micral - 1 minute	1	1	-	-	-	-	-	-	-	-	-
Siemens Clinitek Microalbumin	3	-	-	-	-	-	-	-	3	-	-

URINALYSIS –URINE hCG

Specimen UA-2

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	98	98	-
Acon Laboratories	11	11	-
Alere Aceava hCG-Urine	1	1	-
Alere Clearview hCG Cassette	4	4	-
Biotron 1-Step	9	9	-
Other Analyzer Method	1	1	-
Quidel QuickVue One-Step Combo	17	17	-
RefuAH hCG Dipstick	1	1	-
Roche cobas u 411	1	1	-
Stanbio QuStick	1	1	-
Sure-Vue hCG - 25mIU	2	2	-

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Specimen SUS-6	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>
<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>	
Amikacin	49	48	1	-	137	136	-	1	98.97%
Amoxicillin/Clavulanate	49	19	6	24	57	9	1	47	66.36% ¹
Ampicillin	25	11	1	13	72	7	-	65	80.20%
Ampicillin/Sulbactam	28	22	-	6	35	20	2	13	Not graded ²
Aztreonam	19	19	-	-	37	34	1	2	93.10%
Cefaclor	10	5	1	4	2	2	-	-	Not graded ²
Cefamandole	-	-	-	-	1	1	-	-	Not graded ³
Cefazolin	8	2	3	3	39	2	-	37	85.42%
Cefepime	30	30	-	-	138	134	1	3	97.71%
Cefixime	26	22	1	3	10	5	-	5	75.68% ⁴
Cefoperazone	12	12	-	-	1	1	-	-	100.00%
Cefotaxime	36	34	2	-	67	61	1	5	91.74%
Cefotetan	-	-	-	-	4	2	1	1	Not graded ³
Cefoxitin	17	6	-	11	71	4	-	67	88.89%
Cefpodoxime	4	4	-	-	4	3	-	1	87.50%
Ceftazidime	43	43	-	-	125	122	2	1	97.71%
Ceftizoxime	2	2	-	-	1	1	-	-	Not graded ³
Ceftriaxone	49	48	-	1	124	117	2	5	95.05%
Cefuroxime	45	43	-	2	70	42	1	27	Not graded ²
Cephalexin	8	1	1	6	3	1	-	2	72.73% ⁵
Cephalothin	8	1	-	7	42	1	-	41	96.30%
Chloramphenicol	4	4	-	-	-	-	-	-	Inappropriate drug ⁶
Ciprofloxacin	58	58	-	-	171	171	-	-	100.00%
Daptomycin	-	-	-	-	2	2	-	-	Not graded ³
Doripenem	-	-	-	-	4	4	-	-	Not graded ³
Doxycycline	5	3	2	-	1	1	-	-	100.00%
Ertapenem	16	16	-	-	128	127	-	1	99.33%
Fosfomycin	12	12	-	-	16	16	-	-	100.00%
Gatifloxacin	1	1	-	-	2	2	-	-	Not graded ³

¹ This specimen was graded by 84% referee consensus.

² This is an ungraded challenge due to less than 80% referee consensus.

³ This is an ungraded challenge due to lack of comparison group.

⁴ This specimen was graded by 86% referee consensus.

⁵ This specimen was graded by 82% referee consensus.

⁶ This is an inappropriate drug for organism and/or source.

ANTIMICROBIAL SUSCEPTIBILITY TESTING (cont'd)
Specimen SUS-6

Specimen SUS-6					-----Disk Diffusion-----					-----MIC-----					
<u>Antimicrobial</u>	<u>Interpretative category data</u>				<u>Interpretative category data</u>				<u>Acceptable (%)</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>							
Gentamicin	53	52	1	-	168	168	-	-	99.57%						
Imipenem	40	40	-	-	90	90	-	-	100.00%						
Kanamycin	2	1	1	-	-	-	-	-	Not graded ³						
Levofloxacin	28	28	-	-	51	50	-	1	98.78%						
Linezolid	-	-	-	-	1	1	-	-	Inappropriate drug ⁶						
Lomefloxacin	3	3	-	-	-	-	-	-	Not graded ³						
Meropenem	29	29	-	-	124	124	-	-	100.00%						
Methicillin	1	-	-	1	-	-	-	-	Inappropriate drug ⁶						
Minocycline	-	-	-	-	1	1	-	-	Not graded ³						
Moxifloxacin	14	14	-	-	1	1	-	-	Inappropriate drug ⁶						
Nalidixic Acid	15	14	1	-	8	8	-	-	95.65%						
Netilmicin	8	8	-	-	3	3	-	-	100.00%						
Nitrofurantoin	50	49	1	-	139	139	-	-	99.49%						
Norfloxacin	29	29	-	-	46	46	-	-	100.00%						
Ofloxacin	26	26	-	-	3	3	-	-	100.00%						
Oxacillin	3	-	-	3	-	-	-	-	Inappropriate drug ⁶						
Penicillin	1	-	1	-	2	2	-	-	Not graded ³						
Piperacillin	5	5	-	-	18	16	1	1	91.67%						
Piperacillin/Tazobactam	28	28	-	-	95	93	1	1	97.64%						
Rifampin	1	1	-	-	1	1	-	-	Inappropriate drug ⁶						
Sulfisoxazole	1	1	-	-	1	1	-	-	Not graded ³						
Teicoplanin	4	1	-	3	-	-	-	-	Inappropriate drug ⁶						
Tetracycline	11	10	1	-	4	4	-	-	93.75%						
Ticarcillin	1	-	-	1	-	-	-	-	Not graded ³						
Ticarcillin/Clavulanate	1	1	-	-	2	2	-	-	Not graded ³						
Tigecycline	-	-	-	-	8	8	-	-	Inappropriate drug ⁶						
Tobramycin	10	9	-	1	40	40	-	-	98.08%						
Trimethoprim	2	2	-	-	2	2	-	-	100.00%						
Trimethoprim/Sulfamethoxazole	45	44	1	-	164	164	-	-	99.54%						
Vancomycin	4	-	-	4	1	1	-	-	Inappropriate drug ⁶						

Organism present in specimen SUS-6: *Citrobacter freundii*.

PARASITOLOGY (PA Specimens)

Specimen PA-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	5	100%	Acceptable

Parasite present in specimen PA-6: *Giardia lamblia*.

Specimen PA-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	4	80%	Acceptable
Isospora belli oocysts	1	20%	

Parasite present in specimen PA-7: No parasite seen.

Specimen PA-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Fasciola hepatica eggs	10	55.56%	Acceptable
Entamoeba coli	3	16.67%	
No parasite seen	2	11.11%	
Hookworm	1	5.56%	
Diphyllobothrium latum	1	5.56%	
Endolimax nana	1	5.56%	

Parasite present in specimen PA-8: *Fasciola hepatica* eggs. (Graded by US consensus)

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Diphyllobothrium latum	12	70.59%	Acceptable
Parasite egg seen but no ID	1	5.88%	Acceptable
Ascaris lumbricoides eggs	2	11.76%	
Endolimax nana	1	5.88%	
Fasciola hepatica eggs	1	5.88%	

Parasite present in specimen PA-9: *Diphyllobothrium latum*. (Graded by US consensus)

Specimen PA-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	15	88.24%	Acceptable
Ascaris lumbricoides eggs	1	5.88%	
Entamoeba coli	1	5.88%	

Parasite present in specimen PA-10: *Hookworm*.

PARASITOLOGY (FP Specimens)

Specimen FP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Diphyllobothrium latum	220	72.13%	Acceptable
Parasite egg seen but no ID	2	0.66%	Acceptable
Fasciola hepatica eggs	23	7.54%	
Paragonimus westermani eggs	16	5.25%	
Ascaris lumbricoides eggs	12	3.93%	
Endolimax nana	8	2.62%	
Entamoeba histolytica	4	1.31%	
Blastocystis hominis	4	1.31%	
Clonorchis sinensis	3	0.98%	
Hookworm	3	0.98%	
Entamoeba coli	2	0.66%	
Trichostrongylus sp. eggs	2	0.66%	
Entamoeba hartmanni	1	0.33%	
Chilomastix mesnili	1	0.33%	
Hymenolepis nana eggs	1	0.33%	
Giardia lamblia	1	0.33%	
Schistosoma japonicum eggs	1	0.33%	
Strongyloides stercoralis larvae	1	0.33%	

Parasite present in specimen FP-6: *Diphyllobothrium latum*. This challenge was graded by 90% referee consensus.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No seen parasite	264	92.96%	Acceptable
Taenia sp. eggs	4	1.41%	
Ascaris lumbricoides eggs	3	1.06%	
Balantidium coli	2	0.70%	
Strongyloides stercoralis larvae	2	0.70%	
Clonorchis sinensis	2	0.70%	
Hymenolepis nana eggs	1	0.35%	
Parasite egg seen but no ID	1	0.35%	
Blastocystis hominis	1	0.35%	
Endolimax nana	1	0.35%	
Entamoeba histolytica	1	0.35%	
Fasciola hepatica eggs	1	0.35%	
Giardia lamblia	1	0.35%	

Parasite present in specimen FP-7: No parasite seen.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	262	73.80%	Acceptable
Entamoeba coli	59	16.62%	
Trichostrongylus sp. eggs	6	1.69%	
Parasite egg seen but no ID	6	1.69%	
Entamoeba histolytica	4	1.13%	
Strongyloides stercoralis larvae	4	1.13%	
Ascaris lumbricoides eggs	3	0.85%	
Blastocystis hominis	2	0.56%	
Schistosoma sp. eggs, NOS	2	0.56%	
No parasite seen	2	0.56%	
Parasite larva seen but no ID	1	0.28%	
Schistosoma mansoni eggs	1	0.28%	
Fasciola hepatica eggs	1	0.28%	
Diphyllobothrium latum	1	0.28%	
Endolimax nana	1	0.28%	

Parasite present in specimen FP-8: *Hookworm*. This challenge was graded by 95% referee consensus.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Clonorchis sinensis	121	41.30%	Acceptable
Parasite egg seen but no ID	5	1.71%	Acceptable
No parasite seen	111	37.88%	
Taenia sp. eggs	19	6.48%	
Giardia lamblia	7	2.39%	
Strongyloides stercoralis larvae	6	2.05%	
Diphyllobothrium latum	6	2.05%	
Schistosoma haematobium egg	3	1.02%	
Endolimax nana	3	1.02%	
Ascaris lumbricoides eggs	2	0.68%	
Blastocystis hominis	1	0.34%	
Enterobius vermicularis eggs	1	0.34%	
Fasciola hepatica eggs	1	0.34%	
Hymenolepis nana eggs	1	0.34%	
Paragonimus westermani eggs	1	0.34%	
Schistosoma sp. eggs, NOS	1	0.34%	
Parasite larva seen but no ID	1	0.34%	
Other parasite seen but no ID	1	0.34%	
Trichuris trichiura eggs	1	0.34%	
Protozoan seen but no ID	1	0.34%	

Parasite present in specimen FP-9: *Clonorchis sinensis*. This challenge was graded by 80% referee consensus.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Leishmania sp.	169	61.68%	Acceptable
Trypanosoma sp., NOS	45	16.42%	
Trypanosoma cruzi	35	12.77%	
Trypanosoma brucei	13	4.74%	
Plasmodium falciparum	4	1.46%	
Babesia sp.	3	1.09%	
No parasite seen	2	0.73%	
Plasmodium sp., NOS	1	0.36%	
Pneumocystis carinii	1	0.36%	
Toxoplasma gondii	1	0.36%	

Parasite present in specimen FP-10: *Leishmania species*. This challenge was graded by 80% referee consensus.

Antinuclear Antibody (ANA) - Qualitative

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	2	-	15	15	-
BioSystems	1	-	-	1	1	-
Immuno Concepts	1	-	-	1	1	-
INOVA Diagnostics	5	-	-	5	5	-
Kallestad	2	-	-	2	2	-
Phadia ELiA	-	1	-	1	1	-
Zeus	1	-	-	1	1	-

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	15	-	-	15
BioSystems	1	-	-	1
Immuno Concepts	1	-	-	1
INOVA Diagnostics	5	-	-	5
Kallestad	2	-	-	2
Phadia ELiA	1	-	-	1
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-6

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

Specimen AE-8

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

Specimen AE-9

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

Anti-dsDNA

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	12	-	13	13	-
BioSystems	-	1	-	1	1	-
INOVA Diagnostics	-	5	-	5	5	-
Zeus	-	1	-	1	1	-

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	-	-	13
BioSystems	1	-	-	1
INOVA Diagnostics	5	-	-	5
Zeus	1	-	-	1

Anti-RNP

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	10	-	10	8	2
INOVA Diagnostics	-	5	-	5	4	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	2	-	10
INOVA Diagnostics	4	1	-	5

Anti-RNP/Sm

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

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	4	-	6

Specimen AE-9 is an ungraded challenge due to less than 80% participant consensus.

Anti-SSA

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	10	-	12	12	-
INOVA Diagnostics	1	4	-	5	5	-

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	-	-	12
INOVA Diagnostics	5	-	-	5

Anti-SSB

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	12	-	12	-	12
INOVA Diagnostics	-	5	-	5	-	5

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	12	-	12
INOVA Diagnostics	-	5	-	5

Anti-SSA/SSB

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	-	5	4	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	1	-	5

Anti-Sm

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	12	-	12	5	7
INOVA Diagnostics	-	6	-	6	5	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	9	-	12
INOVA Diagnostics	3	3	-	6

Specimens AE-8 and AE-9 are ungraded challenges due to less than 80% participant consensus.

Rubella—Qualitative

<u>Method</u>	Specimen RU-6		Specimen RU-7		Specimen RU-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	24	1	-	25	25	-
Abbott Architect	8	-	-	8	8	-
bioMerieux Vidas, Mini Vidas	2	-	-	2	2	-
DiaSorin	1	-	-	1	1	-
Roche cobas 6000 / c 501	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	2	-	-	2	2	-
VITROS ECI	2	-	-	2	2	-

<u>Method</u>	Specimen RU-9		Specimen RU-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	-	-	25
Abbott Architect	8	-	-	8
bioMerieux Vidas, Mini Vidas	2	-	-	2
DiaSorin	1	-	-	1
Roche cobas 6000 / c 501	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	2	-	-	2
VITROS ECI	2	-	-	2

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-6						
All Method	32	50.19	17.60	35.1	54.7	0.0 - 103.1
Abbott Architect	11	31.27	2.15	6.9	30.9	24.8 - 37.8
Roche cobas e 411	7	65.96	4.94	7.5	67.5	51.1 - 80.8
Specimen RU-7						
All Method	33	0.18	0.22	122.5	0.0	0.0 - 0.9
Abbott Architect	11	0.00	0.01	0.0	0.0	0.0 - 0.1
Roche cobas e 411	7	0.31	0.16	50.1	0.2	0.0 - 0.8
Specimen RU-8						
All Method	32	102.91	37.18	36.1	111.9	0.0 - 214.5
Abbott Architect	11	59.15	4.60	7.8	58.7	45.3 - 73.0
Roche cobas e 411	7	140.66	9.16	6.5	141.1	113.1 - 168.2
Specimen RU-9						
All Method	32	26.26	8.84	33.6	26.1	0.0 - 52.8
Abbott Architect	11	16.83	1.13	6.7	16.8	13.4 - 20.3
Roche cobas e 411	7	35.93	3.12	8.7	36.5	26.5 - 45.3
Specimen RU-10						
All Method	33	0.17	0.21	120.5	0.0	0.0 - 0.8
Abbott Architect	11	0.00	0.01	0.0	0.0	0.0 - 0.1
Roche cobas e 411	7	0.30	0.13	43.0	0.2	0.0 - 0.7

Syphilis Serology—Qualitative: VDRL Slide

<u>Method</u>	Specimen SY-6			Specimen SY-7			Specimen SY-8		
	<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	27	-	-	-	-	27	25	1	1
bioMerieux	1	-	-	-	-	1	1	-	-
Omega Diagnostics	1	-	-	-	-	1	1	-	-
Plasmatec	2	-	-	-	-	2	1	1	-
Standard Diagnostics	1	-	-	-	-	1	1	-	-
Wiener Lab	18	-	-	-	-	18	17	-	1

<u>Method</u>	Specimen SY-9			Specimen SY-10		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>
ALL METHODS	-	-	27	26	1	-
bioMerieux	-	-	1	1	-	-
Omega Diagnostics	-	-	1	1	-	-
Plasmatec	-	-	2	1	1	-
Standard Diagnostics	-	-	1	1	-	-
Wiener Lab	-	-	18	18	-	-

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-6								
ALL METHODS	2	1	2	13	4	3	-	-
Omega Diagnostics	-	-	-	1	-	-	-	-
Plasmatec	-	1	-	-	-	-	-	-
Wiener Lab	2	-	1	8	4	3	-	-
Specimen SY-8								
ALL METHODS	-	2	16	5	1	-	-	-
Omega Diagnostics	-	-	1	-	-	-	-	-
Plasmatec	-	-	1	-	-	-	-	-
Wiener Lab	-	1	10	5	1	-	-	-
Specimen SY-10								
ALL METHODS	2	2	14	6	1	-	-	-
Omega Diagnostics	-	-	1	-	-	-	-	-
Plasmatec	-	1	-	-	-	-	-	-
Wiener Lab	1	1	9	6	1	-	-	-

Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	13	-	-	13	13	-
Abbott Architect	4	-	-	4	4	-
Human	2	-	-	2	2	-
Omega Diagnostics	1	-	-	1	1	-
Serodia	1	-	-	1	1	-

	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	13	13	-
Abbott Architect	-	4	4	-
Human	-	2	2	-
Omega Diagnostics	-	1	1	-
Serodia	-	1	1	-

Syphilis Serology—Qualitative: *Treponema pallidum* Antibodies

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	37	-	-	37	36	1
Abbott Architect	3	-	-	3	3	-
Human	2	-	-	2	2	-
Omega Diagnostics	2	-	-	2	1	1
Plasmatec	2	-	-	2	2	-
Roche cobas 6000 / c 501	1	-	-	1	1	-
Serodia	17	-	-	17	17	-

	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	37	36	1
Abbott Architect	-	3	3	-
Human	-	2	2	-
Omega Diagnostics	-	2	1	1
Plasmatec	-	2	2	-
Roche cobas 6000 / c 501	-	1	1	-
Serodia	-	17	17	-

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	88	1	2	87	83	6
Becton Dickinson	2	-	-	2	2	-
bioMerieux	7	1	1	7	7	1
BioSystems	12	-	-	12	12	-
Human	9	-	1	8	8	1
Immunostics Inc.	1	-	-	1	1	-
Omega Diagnostics	18	-	-	18	17	1
Plasmatec	12	-	-	12	11	1
Pulse Scientific	1	-	-	1	-	1
SPINREACT	16	-	-	16	16	-
Standard Diagnostics	1	-	-	1	1	-
Wampole Impact RPR	1	-	-	1	1	-
Wiener Lab	1	-	-	1	1	-

	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	2	87	86	3
Becton Dickinson	-	2	2	-
bioMerieux	1	7	8	-
BioSystems	-	12	12	-
Human	-	9	8	1
Immunostics Inc.	-	1	1	-
Omega Diagnostics	-	18	18	-
Plasmatec	-	12	11	1
Pulse Scientific	-	1	-	1
SPINREACT	-	16	16	-
Standard Diagnostics	-	1	1	-
Wampole Impact RPR	-	1	1	-
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>
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Specimen SY-6

ALL METHODS	1	15	33	15	-	2	-	3
Becton Dickinson	-	-	-	2	-	-	-	-
bioMerieux	-	4	-	1	-	-	-	-
BioSystems	-	-	5	4	-	-	-	-
Human	-	2	3	2	-	-	-	1
Immunostics Inc.	-	-	1	-	-	-	-	-
Omega Diagnostics	1	2	5	3	-	2	-	1
Plasmatec	-	3	5	-	-	-	-	-
SPINREACT	-	1	10	3	-	-	-	-
Wampole Impact RPR	-	1	-	-	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-

Specimen SY-8

ALL METHODS	22	31	9	1	1	-	-	2
Becton Dickinson	-	2	-	-	-	-	-	-
bioMerieux	4	-	1	-	-	-	-	-
BioSystems	2	6	1	-	-	-	-	-
Human	3	2	1	-	-	-	-	1
Immunostics Inc.	-	1	-	-	-	-	-	-
Omega Diagnostics	6	3	2	1	-	-	-	1
Plasmatec	3	5	-	-	-	-	-	-
SPINREACT	3	7	4	-	-	-	-	-
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-10								
ALL METHODS	14	33	14	1	2	-	-	3
Becton Dickinson	-	-	2	-	-	-	-	-
bioMerieux	4	-	1	-	-	-	-	-
BioSystems	-	4	3	1	-	-	-	-
Human	1	4	1	-	-	-	-	1
Immunostics Inc.	-	1	-	-	-	-	-	-
Omega Diagnostics	4	6	1	-	2	-	-	1
Plasmatec	2	6	-	-	-	-	-	-
SPINREACT	1	8	5	-	-	-	-	-
Wampole Impact RPR	-	1	-	-	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-

Viral Markers – Anti-HBc (IgM)

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
<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>
	<u>e</u>								
ALL METHODS	8	54	8	2	69	-	4	67	-
Abbott Architect	-	22	-	-	22	-	-	22	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-	-	2	-
bioMerieux Vidas, Mini									
Vidas	3	2	-	-	5	-	-	5	-
Roche cobas 6000 / e 601	1	12	-	1	13	-	1	13	-
Roche cobas e 411	-	4	-	-	4	-	-	4	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	-	1	-
Roche Modular Analytics	1	1	-	-	2	-	1	1	-
Siemens ADVIA Centaur	-	5	8	-	13	-	-	13	-
VITROS 3600/4600/5600	-	2	-	-	2	-	-	2	-

	Specimen VM-9			Specimen VM-10		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	4	67	-	1	69	-
Abbott Architect	-	22	-	-	22	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-
bioMerieux Vidas, Mini						
Vidas	-	5	-	-	5	-
Roche cobas 6000 / e 601	1	13	-	-	13	-
Roche cobas e 411	-	4	-	-	4	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-
Roche Modular Analytics	1	1	-	-	2	-
Siemens ADVIA Centaur	-	13	-	-	13	-
VITROS 3600/4600/5600	-	2	-	-	2	-

Viral Markers – Anti-HBc (Total / IgG)

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
<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	87	1	-	10	78	-	87	1	-
Abbott Architect	36	-	-	2	34	-	36	-	-
Beckman ACCESS / 2 / Dxl	2	-	-	2	-	-	2	-	-
bioMerieux Vidas, Mini									
Vidas	3	1	-	-	4	-	3	1	-
DiaSorin	1	-	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	13	-	-	1	12	-	13	-	-
Roche cobas e 411	7	-	-	3	4	-	7	-	-
Roche Modular Analytics	3	-	-	-	3	-	3	-	-
Siemens ADVIA Centaur	14	-	-	1	13	-	14	-	-
VITROS 3600/4600/5600	2	-	-	-	2	-	2	-	-

	Specimen VM-9			Specimen VM-10		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	88	-	-	13	73	2
Abbott Architect	36	-	-	-	36	-
Beckman ACCESS / 2 / Dxl	2	-	-	2	-	-
bioMerieux Vidas, Mini						
Vidas	4	-	-	1	2	1
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	13	-	-	1	12	-
Roche cobas e 411	7	-	-	6	-	1
Roche Modular Analytics	3	-	-	1	2	-
Siemens ADVIA Centaur	14	-	-	-	14	-
VITROS 3600/4600/5600	2	-	-	-	2	-

Viral Markers – Anti-HIV

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
<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	260	1	1	259	3	5	255	2
Abbott Architect	-	70	-	-	70	-	-	70	-
Acon Laboratories	-	1	-	-	1	-	-	1	-
Alere Determine HIV 1/2									
Ag/Ab Combo	-	1	-	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	1	7	-	-	8	-	-	8	-
bioMerieux Vidas, Mini									
Vidas	-	12	-	1	11	-	1	11	-
DiaSorin	-	1	-	-	1	-	-	1	-
Human	-	3	-	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	45	-	-	46	-	2	43	-
Roche cobas e 411	-	28	1	-	26	3	1	26	2
Roche Elecsys 1010 / 2010	-	4	-	-	4	-	-	4	-
Roche Modular Analytics	-	5	-	-	5	-	-	5	-
Siemens ADVIA Centaur	-	44	-	-	44	-	-	44	-
Standard Diagnostics	-	4	-	-	4	-	-	4	-
VITROS 3600/4600/5600	-	4	-	-	4	-	-	4	-
VITROS ECI	-	7	-	-	7	-	-	7	-

Viral Markers – Anti-HIV- cont'd

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	262	1	-	235	23	4
Abbott Architect	69	1	-	70	-	-
Acon Laboratories	1	-	-	1	-	-
Alere Determine HIV 1/2						
Ag/Ab Combo	1	-	-	1	-	-
Beckman ACCESS / 2 / Dxl	8	-	-	8	-	-
bioMerieux Vidas, Mini						
Vidas	12	-	-	11	1	-
DiaSorin	1	-	-	1	-	-
Human	3	-	-	2	1	-
Roche cobas 6000 / e 601	46	-	-	43	1	1
Roche cobas e 411	29	-	-	27	2	-
Roche Elecsys 1010 / 2010	4	-	-	4	-	-
Roche Modular Analytics	5	-	-	3	1	1
Siemens ADVIA Centaur	44	-	-	43	1	-
Standard Diagnostics	4	-	-	1	3	-
VITROS 3600/4600/5600	4	-	-	1	2	1
VITROS ECI	7	-	-	3	3	1

Viral Markers – Anti-HAV (IgM)

Specimen VM-6				Specimen VM-7			Specimen VM-8		
<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	-	105	-	-	105	-	3	103	-
Abbott Architect	-	32	-	-	32	-	1	31	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-	-	2	-
bioMerieux Vidas, Mini	-	9	-	-	8	-	-	9	-
Vidas	-	1	-	-	1	-	-	1	-
Human	-	14	-	-	15	-	1	14	-
Roche cobas 6000 / e 601	-	10	-	-	10	-	1	9	-
Roche cobas e 411	-	4	-	-	4	-	-	4	-
Roche Modular Analytics	-	20	-	-	20	-	-	20	-
Siemens ADVIA Centaur	-	1	-	-	1	-	-	1	-
Standard Diagnostics	-	1	-	-	1	-	-	1	-
VITROS 3600/4600/5600	-	1	-	-	1	-	-	1	-
VITROS ECI	-	1	-	-	1	-	-	1	-

Specimen VM-9				Specimen VM-10		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	3	103	-	4	101	-
Abbott Architect	-	32	-	-	32	-
Beckman ACCESS / 2 / Dxl	-	2	-	1	1	-
bioMerieux Vidas, Mini	-	9	-	-	9	-
Vidas	-	1	-	-	1	-
Human	-	14	-	1	13	-
Roche cobas 6000 / e 601	1	9	-	1	9	-
Roche cobas e 411	-	4	-	-	4	-
Roche Modular Analytics	-	20	-	-	20	-
Siemens ADVIA Centaur	-	1	-	-	1	-
Standard Diagnostics	-	1	-	-	1	-
VITROS 3600/4600/5600	-	1	-	-	1	-
VITROS ECI	-	1	-	-	1	-

Viral Markers – Anti-HAV (Total/IgG)

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
<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	9	88	1	2	96	-	90	5	3
Abbott Architect	1	29	-	-	30	-	29	-	1
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-	1	-	-
bioMerieux Vidas, Mini									
Vidas	-	7	-	-	7	-	7	-	-
Roche cobas 6000 / e 601	4	8	-	2	10	-	11	1	-
Roche cobas e 411	1	7	-	-	8	-	8	-	-
Roche Elecsys 1010 / 2010	-	1	1	-	2	-	2	-	-
Roche Modular Analytics	-	2	-	-	2	-	2	-	-
Siemens ADVIA Centaur	3	20	-	-	23	-	23	-	-
VITROS ECI	-	1	-	-	1	-	-	-	1

	Specimen VM-9			Specimen VM-10		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	96	2	-	97	1	-
Abbott Architect	30	-	-	30	-	-
Beckman ACCESS / 2 / Dxl	1	-	-	1	-	-
bioMerieux Vidas, Mini						
Vidas	7	-	-	7	-	-
Roche cobas 6000 / e 601	12	-	-	12	-	-
Roche cobas e 411	8	-	-	8	-	-
Roche Elecsys 1010 / 2010	2	-	-	2	-	-
Roche Modular Analytics	2	-	-	2	-	-
Siemens ADVIA Centaur	23	-	-	23	-	-
VITROS ECI	1	-	-	1	-	-

Viral Markers – HBeAg

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
<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	1	-	3	62	-	-	65	-
Abbott Architect	21	-	-	1	20	-	-	21	-
bioMerieux Vidas, Mini Vidas	3	-	-	-	3	-	-	3	-
DiaSorin	2	-	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	10	-	-	-	11	-	-	11	-
Roche cobas e 411	4	-	-	-	4	-	-	4	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-	-	1	-
Roche Modular Analytics	2	-	-	-	2	-	-	2	-
Siemens ADVIA Centaur	13	-	-	1	12	-	-	13	-
VITROS ECI	1	-	-	-	1	-	-	1	-

	Specimen VM-9			Specimen VM-10		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	65	-	-	63	-
Abbott Architect	-	21	-	-	21	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-
DiaSorin	-	2	-	-	1	-
Roche cobas 6000 / e 601	-	11	-	-	10	-
Roche cobas e 411	-	4	-	-	4	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-
Roche Modular Analytics	-	2	-	-	2	-
Siemens ADVIA Centaur	-	13	-	-	13	-
VITROS ECI	-	1	-	-	1	-

Viral Markers – Anti-HBs

Specimen VM-6				Specimen VM-7			Specimen VM-8		
<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	193	-	1	195	-	2	194	-
Abbott Architect	-	53	-	-	53	-	-	53	-
Beckman ACCESS / 2 / Dxl	-	4	-	-	4	-	-	4	-
bioMerieux Vidas, Mini Vidas	-	5	-	-	5	-	-	5	-
Roche cobas 6000 / e 601	-	37	-	-	38	-	-	38	-
Roche cobas e 411	-	24	-	-	24	-	-	24	-
Roche Elecsys 1010 / 2010	-	2	-	-	2	-	-	2	-
Roche Modular Analytics	-	6	-	-	6	-	-	6	-
Siemens ADVIA Centaur	-	41	-	1	40	-	-	41	-
Standard Diagnostics	1	-	-	-	1	-	-	1	-
VITROS 3600/4600/5600	-	4	-	-	4	-	-	4	-
VITROS ECI	-	3	-	-	3	-	-	3	-

Specimen VM-9				Specimen VM-10		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	194	2	-	191	4	-
Abbott Architect	53	-	-	53	-	-
Beckman ACCESS / 2 / Dxl	4	-	-	4	-	-
bioMerieux Vidas, Mini Vidas	5	-	-	5	-	-
Roche cobas 6000 / e 601	38	-	-	37	-	-
Roche cobas e 411	24	-	-	24	-	-
Roche Elecsys 1010 / 2010	2	-	-	2	-	-
Roche Modular Analytics	6	-	-	6	-	-
Siemens ADVIA Centaur	41	-	-	41	-	-
Standard Diagnostics	-	1	-	-	1	-
VITROS 3600/4600/5600	4	-	-	4	-	-
VITROS ECI	3	-	-	3	-	-

Viral Markers – HBsAg

Specimen VM-6				Specimen VM-7			Specimen VM-8		
<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	261	1	-	17	244	2	30	220	12
Abbott Architect	68	1	-	5	64	-	4	65	-
Beckman ACCESS / 2 / Dxl	7	-	-	1	6	-	1	6	-
bioMerieux Vidas, Mini									
Vidas	11	-	-	1	10	-	-	11	-
DiaSorin	1	-	-	-	1	-	1	-	-
Human	1	-	-	-	-	1	-	1	-
Roche cobas 6000 / e 601	40	-	-	2	39	-	9	24	7
Roche cobas e 411	33	-	-	4	29	-	6	24	3
Roche Elecsys 1010 / 2010	5	-	-	-	5	-	2	3	-
Roche Modular Analytics	5	-	-	-	5	-	1	3	1
Siemens ADVIA Centaur	46	-	-	3	43	-	3	43	-
Standard Diagnostics	2	-	-	-	2	-	-	2	-
VITROS 3600/4600/5600	5	-	-	-	5	-	-	5	-
VITROS ECI	7	-	-	-	7	-	-	7	-

Specimen VM-9				Specimen VM-10		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	6	257	-	8	253	1
Abbott Architect	2	67	-	2	67	-
Beckman ACCESS / 2 / Dxl	2	5	-	-	7	-
bioMerieux Vidas, Mini						
Vidas	-	11	-	-	11	-
DiaSorin	-	1	-	-	1	-
Human	-	1	-	-	1	-
Roche cobas 6000 / e 601	1	40	-	3	37	-
Roche cobas e 411	-	33	-	2	30	1
Roche Elecsys 1010 / 2010	-	5	-	-	5	-
Roche Modular Analytics	-	5	-	-	5	-
Siemens ADVIA Centaur	-	46	-	-	46	-
Standard Diagnostics	-	2	-	-	2	-
VITROS 3600/4600/5600	-	5	-	-	5	-
VITROS ECI	-	7	-	-	7	-

Viral Markers – Anti-HCV

Specimen VM-6				Specimen VM-7			Specimen VM-8		
<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	235	-	236	-	-	61	172	3
Abbott Architect	1	65	-	66	-	-	2	64	-
Beckman ACCESS / 2 / Dxl	-	6	-	6	-	-	-	6	-
bioMerieux Vidas, Mini Vidas	-	11	-	11	-	-	-	11	-
DiaSorin	-	1	-	1	-	-	-	1	-
Human	-	1	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	31	-	31	-	-	28	1	2
Roche cobas e 411	-	26	-	26	-	-	21	4	1
Roche Elecsys 1010 / 2010	-	3	-	3	-	-	3	-	-
Roche Modular Analytics	-	5	-	5	-	-	3	2	-
Siemens ADVIA Centaur	-	43	-	43	-	-	-	43	-
Standard Diagnostics	-	5	-	5	-	-	-	5	-
VITROS 3600/4600/5600	-	5	-	5	-	-	-	5	-
VITROS ECI	-	7	-	7	-	-	-	7	-

Specimen VM-9				Specimen VM-10		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	61	173	2	78	157	1
Abbott Architect	1	65	-	-	66	-
Beckman ACCESS / 2 / Dxl	-	6	-	-	6	-
bioMerieux Vidas, Mini Vidas	-	11	-	1	10	-
DiaSorin	-	1	-	-	1	-
Human	-	1	-	-	1	-
Roche cobas 6000 / e 601	29	1	1	31	-	-
Roche cobas e 411	21	4	1	25	1	-
Roche Elecsys 1010 / 2010	2	1	-	3	-	-
Roche Modular Analytics	3	2	-	5	-	-
Siemens ADVIA Centaur	1	42	-	2	41	-
Standard Diagnostics	-	5	-	1	4	-
VITROS 3600/4600/5600	-	5	-	1	3	1
VITROS ECI	-	7	-	-	7	-

Toxoplasma gondii Antibody (IgG) - Qualitative

<u>Method</u>	Specimen TOX-3		Specimen TOX-4	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	26	26	-
Abbott Architect	-	10	10	-
Beckman ACCESS / 2 / Dxl	-	1	1	-
bioMerieux Vidas, Mini Vidas	-	4	4	-
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	-	2	2	-

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-3						
All Method	26	0.2	0.4	209.9	0	0 - 1
Abbott Architect	9	0.0	0.1	0.0	0	0 - 1
Roche cobas e 411	6	0.5	0.5	109.5	1	0 - 2
Specimen TOX-4						
All Method	26	237.6	167.3	70.4	147	0 - 573
Abbott Architect	8	76.8	7.0	9.1	77	62 - 91
Roche cobas e 411	6	392.2	128.1	32.7	406	135 - 649

Toxoplasma gondii Antibody (IgM) - Qualitative

<u>Method</u>	Specimen TOX-3		Specimen TOX-4	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	27	27	-
Abbott Architect	-	9	9	-
Beckman ACCESS / 2 / Dxl	-	1	1	-
bioMerieux Vidas, Mini Vidas	-	4	4	-
DiaSorin	-	1	1	-
Roche cobas 6000 / e 601	-	4	4	-
Roche cobas e 411	-	5	5	-
Roche Elecsys 1010 / 2010	-	1	1	-
Siemens ADVIA Centaur	-	2	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>
Specimen TOX-3						
All Method	22	0.1	0.4	436.0	0	0 - 1
Abbott Architect	7	0.0	0.1	0.0	0	0 - 1
Roche cobas e 411	5	0.4	0.9	223.6	0	0 - 3
Specimen TOX-4						
All Method	23	9.5	7.1	74.8	10	0 - 24
Abbott Architect	7	4.1	0.4	9.1	4	3 - 5
Roche cobas e 411	5	12.0	2.1	17.7	12	7 - 17

Cytomegalovirus (CMV) Antibodies (IgG) - Qualitative

<u>Method</u>	Specimen CMV-3		Specimen CMV-4	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	10	22	-
Abbott Architect	10	-	10	-
Beckman ACCESS / 2 / Dxl	-	1	1	-
bioMerieux Vidas, Mini Vidas	1	3	4	-
DiaSorin	1	-	1	-
Roche cobas 6000 / e 601	-	1	1	-
Roche cobas e 411	-	5	5	-

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-3						
All Method	21	7.0	7.3	105.4	4	0 - 22
Abbott Architect	7	15.1	1.9	12.3	15	11 - 19
Roche cobas e 411	5	0.4	0.5	136.9	0	0 - 2
Specimen CMV-4						
All Method	20	128.9	36.0	27.9	120	56 - 201
Abbott Architect	7	164.4	20.3	12.3	162	123 - 205
Roche cobas e 411	5	124.6	32.3	25.9	116	59 - 190

Cytomegalovirus (CMV) Antibodies (IgM) - Qualitative

<u>Method</u>	<u>Specimen CMV-3</u>		<u>Specimen CMV-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	15	7	-	22
Abbott Architect	8	-	-	8
Beckman ACCESS / 2 / Dxl	1	-	-	1
bioMerieux Vidas, Mini Vidas	4	-	-	4
DiaSorin	1	-	-	1
DPC Immulite 2000	1	-	-	1
Roche cobas 6000 / e 601	-	2	-	2
Roche cobas e 411	-	5	-	5

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-3						
All Method	18	1.7	1.6	95.1	1	0 - 5
Abbott Architect	5	3.4	0.9	26.3	4	1 - 6
Roche cobas e 411	5	1.0	1.7	173.2	0	0 - 5
Specimen CMV-4						
All Method	17	0.1	0.2	412.3	0	0 - 1
Abbott Architect	5	0.0	0.1	0.0	0	0 - 1
Roche cobas e 411	5	0.4	0.9	223.6	0	0 - 3

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-6						
All Method	12	8.03	1.59	19.8	7.4	3.2 - 12.8
Roche cobas 6000 / c 501	6	7.37	0.48	6.6	7.2	5.9 - 8.9
Specimen CK-7						
All Method	11	29.65	6.05	20.4	27.4	11.4 - 47.9
Roche cobas 6000 / c 501	6	27.15	1.64	6.1	26.7	22.2 - 32.1
Specimen CK-8						
All Method	11	19.31	4.30	22.3	17.1	6.4 - 32.2
Roche cobas 6000 / c 501	6	16.90	0.99	5.9	16.7	13.9 - 19.9
Specimen CK-9						
All Method	11	95.79	20.13	21.0	85.0	35.3 - 156.2
Roche cobas 6000 / c 501	6	85.35	3.66	4.3	84.5	74.3 - 96.4
Specimen CK-10						
All Method	11	52.66	10.96	20.8	47.1	19.7 - 85.6
Roche cobas 6000 / c 501	6	47.12	2.34	5.0	46.6	40.1 - 54.2

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