

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

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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/Semi-Quantitative

For qualitative/semi-quantitative 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	$\pm 15\%$	International Normalized Ratio (INR)	$\pm 15\%$
Automated Differential	± 3 SD	Platelet Count	$\pm 25\%$
Bilirubin, Neonatal (Total)	± 0.4 mg/dL or $20\% *$	Prothrombin Time	$\pm 15\%$
Bilirubin, Direct	± 2 SD	Red Blood Cell Count	$\pm 6\%$
Cytomegalovirus		Rubella	± 3 SD
Fibrinogen	± 3 SD	Sedimentation Rate	± 3 SD
Glucose, Whole Blood	± 6 mg/dL or $\pm 20\%*$	Specific Gravity	± 0.010
Glycohemoglobin	$\pm 5\%$	Toxoplasma	± 3 SD
Hematocrit	$\pm 6\%$	White Blood Cell Count	$\pm 15\%$
Hemoglobin	$\pm 7\%$		

*Whichever is greater

SEDIMENTATION RATE (MM/HR)

<u>Instrument</u>	Specimen ES-1						Specimen ES-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	142	53.7	13.7	25.5	53	12 - 95	142	11.2	4.1	36.2	10	0 - 24
All Automated Methods	27	71.4	15.0	20.9	70	26 - 117	27	12.5	4.4	34.9	11	0 - 26
All Diesse Methods	11	73.9	16.4	22.1	72	24 - 123	11	13.3	5.1	38.4	11	0 - 29
All Manual Methods	108	50.7	9.9	19.5	50	21 - 81	107	11.3	3.9	34.3	10	0 - 23
All Vital Diagnostics Methods	12	68.1	14.0	20.6	65	25 - 111	12	9.8	2.5	25.9	11	2 - 18
Ves-Matic Easy Diesse	5	76.2	8.0	10.5	72	52 - 101	5	11.4	1.5	13.3	11	6 - 16
Vital Diagnostics Excyte M/10	7	66.6	16.5	24.8	62	17 - 117	7	10.1	2.3	22.4	10	3 - 17
Westergren - diluted	84	51.6	9.0	17.4	51	24 - 79	83	10.3	3.3	31.7	10	0 - 21
Westergren - undiluted	21	45.7	11.6	25.4	47	10 - 81	21	13.9	3.9	28.3	13	2 - 26

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

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	2.70	0.40	14.8	2.6	2.2 - 3.2	17	19.24	1.65	8.6	18.8	16.3 - 22.2
All Abbott Cell-Dyn Instruments	7	3.00	0.34	11.2	3.0	2.5 - 3.5	7	20.50	1.28	6.2	21.0	17.4 - 23.6
Abbott Cell-Dyn Ruby	5	3.00	0.34	11.2	3.0	2.5 - 3.5	5	20.50	1.28	6.2	21.0	17.4 - 23.6
Orphee Mythic 22	8	2.40	0.14	5.9	2.5	2.0 - 2.8	8	18.18	1.33	7.3	18.4	15.4 - 21.0

<u>Instrument</u>	Specimen CL-3						Specimen CL-4					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	6.93	0.80	11.6	6.6	5.8 - 8.0	17	19.29	1.67	8.7	18.7	16.3 - 22.2
All Abbott Cell-Dyn Instruments	7	7.65	0.58	7.6	7.9	6.5 - 8.8	7	20.60	1.28	6.2	21.1	17.5 - 23.7
Abbott Cell-Dyn Ruby	5	7.65	0.58	7.6	7.9	6.5 - 8.8	5	20.60	1.28	6.2	21.1	17.5 - 23.7
Orphee Mythic 22	8	6.38	0.39	6.1	6.6	5.4 - 7.4	8	18.13	1.26	7.0	18.5	15.4 - 20.9

<u>Instrument</u>	Specimen CL-5					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	6.96	0.77	11.1	6.7	5.9 - 8.0
All Abbott Cell-Dyn Instruments	7	7.60	0.62	8.1	7.9	6.4 - 8.8
Abbott Cell-Dyn Ruby	5	7.60	0.62	8.1	7.9	6.4 - 8.8
Orphee Mythic 22	8	6.45	0.45	7.0	6.6	5.4 - 7.5

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

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	2.199	0.090	4.1	2.19	2.06 - 2.34	17	5.335	0.149	2.8	5.35	5.01 - 5.66
All Abbott Cell-Dyn Instruments	7	2.263	0.085	3.8	2.23	2.12 - 2.40	7	5.487	0.051	0.9	5.50	5.15 - 5.82
Abbott Cell-Dyn Ruby	5	2.263	0.085	3.8	2.23	2.12 - 2.40	5	5.487	0.051	0.9	5.50	5.15 - 5.82
Orphee Mythic 22	8	2.158	0.086	4.0	2.16	2.02 - 2.29	8	5.275	0.082	1.6	5.28	4.95 - 5.60
	Specimen CL-3						Specimen CL-4					
All Method	17	4.696	0.142	3.0	4.75	4.41 - 4.98	17	5.321	0.234	4.4	5.30	5.00 - 5.65
All Abbott Cell-Dyn Instruments	7	4.807	0.060	1.3	4.80	4.51 - 5.10	7	5.540	0.106	1.9	5.50	5.20 - 5.88
Abbott Cell-Dyn Ruby	5	4.807	0.060	1.3	4.80	4.51 - 5.10	5	5.540	0.106	1.9	5.50	5.20 - 5.88
Orphee Mythic 22	8	4.657	0.114	2.4	4.69	4.37 - 4.94	8	5.180	0.159	3.1	5.24	4.86 - 5.50
	Specimen CL-5											
All Method	17	4.674	0.159	3.4	4.66	4.39 - 4.96						
All Abbott Cell-Dyn Instruments	7	4.830	0.062	1.3	4.81	4.54 - 5.12						
Abbott Cell-Dyn Ruby	5	4.830	0.062	1.3	4.81	4.54 - 5.12						
Orphee Mythic 22	8	4.573	0.085	1.9	4.57	4.29 - 4.85						

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

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	5.33	0.50	9.3	5.3	4.9 - 5.7	17	16.30	1.05	6.4	15.9	15.1 - 17.5
All Abbott Cell-Dyn Instruments	7	5.78	0.17	3.0	5.8	5.3 - 6.2	7	17.33	0.54	3.1	17.3	16.1 - 18.6
Abbott Cell-Dyn Ruby	5	5.78	0.17	3.0	5.8	5.3 - 6.2	5	17.33	0.54	3.1	17.3	16.1 - 18.6
Orphee Mythic 22	8	4.88	0.10	2.0	4.9	4.5 - 5.3	8	15.38	0.25	1.6	15.4	14.2 - 16.5
	Specimen CL-3						Specimen CL-4					
All Method	17	12.41	1.19	9.6	12.2	11.5 - 13.3	17	16.19	0.95	5.9	15.8	15.0 - 17.4
All Abbott Cell-Dyn Instruments	7	13.48	0.54	4.0	13.6	12.5 - 14.5	7	17.13	0.50	2.9	17.1	15.9 - 18.4
Abbott Cell-Dyn Ruby	5	13.48	0.54	4.0	13.6	12.5 - 14.5	5	17.13	0.50	2.9	17.1	15.9 - 18.4
Orphee Mythic 22	8	11.35	0.13	1.1	11.4	10.5 - 12.2	8	15.35	0.13	0.8	15.4	14.2 - 16.5
	Specimen CL-5											
All Method	17	12.43	1.14	9.1	12.4	11.5 - 13.3						
All Abbott Cell-Dyn Instruments	7	13.48	0.21	1.5	13.5	12.5 - 14.5						
Abbott Cell-Dyn Ruby	5	13.48	0.21	1.5	13.5	12.5 - 14.5						
Orphee Mythic 22	8	11.38	0.17	1.5	11.4	10.5 - 12.2						

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

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	16.54	0.55	3.3	16.5	15.5 - 17.6	17	47.80	1.14	2.4	47.9	44.9 - 50.7
All Abbott Cell-Dyn Instruments	7	16.17	0.15	0.9	16.2	15.1 - 17.2	7	47.10	1.39	2.9	47.8	44.2 - 50.0
Abbott Cell-Dyn Ruby	5	16.17	0.15	0.9	16.2	15.1 - 17.2	5	47.10	1.39	2.9	47.8	44.2 - 50.0
Orphee Mythic 22	8	16.90	0.69	4.1	16.5	15.8 - 18.0	8	48.35	0.93	1.9	48.2	45.4 - 51.3
	Specimen CL-3						Specimen CL-4					
All Method	17	39.61	1.17	3.0	39.6	37.2 - 42.0	17	47.51	1.26	2.6	47.7	44.6 - 50.4
All Abbott Cell-Dyn Instruments	7	39.27	1.27	3.2	40.0	36.9 - 41.7	7	47.17	1.66	3.5	47.0	44.3 - 50.0
Abbott Cell-Dyn Ruby	5	39.27	1.27	3.2	40.0	36.9 - 41.7	5	47.17	1.66	3.5	47.0	44.3 - 50.0
Orphee Mythic 22	8	40.23	1.18	2.9	39.6	37.8 - 42.7	8	47.80	1.30	2.7	47.8	44.9 - 50.7
	Specimen CL-5											
All Method	17	39.39	0.83	2.1	39.2	37.0 - 41.8						
All Abbott Cell-Dyn Instruments	7	39.23	1.00	2.6	39.6	36.8 - 41.6						
Abbott Cell-Dyn Ruby	5	39.23	1.00	2.6	39.6	36.8 - 41.6						
Orphee Mythic 22	8	39.60	0.96	2.4	39.2	37.2 - 42.0						

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

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	47.74	1.33	2.8	47.5	43.7 - 51.8	17	74.90	1.62	2.2	73.8	70.0 - 79.8
All Abbott Cell-Dyn Instruments	7	49.00	0.54	1.1	49.0	47.3 - 50.7	7	76.55	0.57	0.8	76.5	74.8 - 78.3
Abbott Cell-Dyn Ruby	5	49.00	0.54	1.1	49.0	47.3 - 50.7	5	76.55	0.57	0.8	76.5	74.8 - 78.3
Orphee Mythic 22	8	46.75	0.82	1.8	46.8	44.2 - 49.3	8	73.55	0.30	0.4	73.6	72.6 - 74.5
	Specimen CL-3						Specimen CL-4					
All Method	17	62.13	2.70	4.4	62.1	54.0 - 70.3	17	75.11	1.67	2.2	75.1	70.1 - 80.2
All Abbott Cell-Dyn Instruments	7	64.68	0.74	1.1	64.5	62.4 - 66.9	7	76.63	1.03	1.3	77.0	73.5 - 79.8
Abbott Cell-Dyn Ruby	5	64.68	0.74	1.1	64.5	62.4 - 66.9	5	76.63	1.03	1.3	77.0	73.5 - 79.8
Orphee Mythic 22	8	60.08	1.86	3.1	60.3	54.5 - 65.7	8	74.13	0.73	1.0	74.0	71.9 - 76.4
	Specimen CL-5											
All Method	17	62.50	2.16	3.5	61.8	56.0 - 69.0						
All Abbott Cell-Dyn Instruments	7	64.63	0.59	0.9	64.8	62.8 - 66.4						
Abbott Cell-Dyn Ruby	5	64.63	0.59	0.9	64.8	62.8 - 66.4						
Orphee Mythic 22	8	60.85	1.10	1.8	61.1	57.5 - 64.2						

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

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	29.98	6.72	22.4	29.3	9.8 - 50.2	17	13.61	2.19	16.1	13.1	7.0 - 20.2
All Abbott Cell-Dyn Instruments	7	36.33	1.13	3.1	36.3	32.9 - 39.8	7	14.58	2.84	19.5	13.9	6.0 - 23.1
Abbott Cell-Dyn Ruby	5	36.33	1.13	3.1	36.3	32.9 - 39.8	5	14.58	2.84	19.5	13.9	6.0 - 23.1
Orphee Mythic 22	8	25.45	4.52	17.8	26.2	11.8 - 39.1	8	13.18	1.35	10.2	12.8	9.1 - 17.3
	Specimen CL-3						Specimen CL-4					
All Method	17	20.49	3.97	19.4	22.0	8.5 - 32.4	17	12.63	1.35	10.7	12.9	8.5 - 16.7
All Abbott Cell-Dyn Instruments	7	23.65	0.26	1.1	23.6	22.8 - 24.5	7	13.10	1.55	11.9	13.0	8.4 - 17.8
Abbott Cell-Dyn Ruby	5	23.65	0.26	1.1	23.6	22.8 - 24.5	5	13.10	1.55	11.9	13.0	8.4 - 17.8
Orphee Mythic 22	8	18.23	3.18	17.4	19.6	8.6 - 27.8	8	12.65	1.29	10.2	12.9	8.7 - 16.6
	Specimen CL-5											
All Method	17	21.45	3.29	15.3	22.9	11.5 - 31.4						
All Abbott Cell-Dyn Instruments	7	23.53	0.96	4.1	23.9	20.6 - 26.5						
Abbott Cell-Dyn Ruby	5	23.53	0.96	4.1	23.9	20.6 - 26.5						
Orphee Mythic 22	8	20.80	2.65	12.7	20.2	12.8 - 28.8						

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

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	16.00	8.15	50.9	19.4	0.0 - 40.5	17	7.94	2.82	35.5	9.6	0.0 - 16.4
All Abbott Cell-Dyn Instruments	7	7.65	0.66	8.6	7.6	5.6 - 9.7	7	4.60	0.90	19.6	4.6	1.9 - 7.3
Abbott Cell-Dyn Ruby	5	7.65	0.66	8.6	7.6	5.6 - 9.7	5	4.60	0.90	19.6	4.6	1.9 - 7.3
Orphee Mythic 22	8	22.40	2.95	13.2	22.1	13.5 - 31.3	8	9.95	0.41	4.1	10.0	8.7 - 11.2
	Specimen CL-3						Specimen CL-4					
All Method	17	11.80	5.89	49.9	13.6	0.0 - 29.5	17	7.99	2.92	36.5	9.4	0.0 - 16.8
All Abbott Cell-Dyn Instruments	7	5.90	0.35	5.9	6.0	4.8 - 7.0	7	4.67	1.50	32.2	4.8	0.1 - 9.2
Abbott Cell-Dyn Ruby	5	5.90	0.35	5.9	6.0	4.8 - 7.0	5	4.67	1.50	32.2	4.8	0.1 - 9.2
Orphee Mythic 22	8	16.15	2.82	17.4	15.5	7.7 - 24.6	8	9.73	0.54	5.6	9.6	8.0 - 11.4
	Specimen CL-5											
All Method	17	11.04	5.57	50.4	10.8	0.0 - 27.8						
All Abbott Cell-Dyn Instruments	7	5.60	0.55	9.8	5.6	3.9 - 7.3						
Abbott Cell-Dyn Ruby	5	5.60	0.55	9.8	5.6	3.9 - 7.3						
Orphee Mythic 22	8	15.10	3.27	21.7	15.5	5.2 - 25.0						

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

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	5.47	0.94	17.2	5.8	2.6 - 8.3	17	4.48	0.68	15.1	4.7	2.4 - 6.6
All Abbott Cell-Dyn Instruments	7	5.75	0.53	9.1	5.9	4.1 - 7.4	7	5.00	0.18	3.7	5.0	4.4 - 5.6
Abbott Cell-Dyn Ruby	5	5.75	0.53	9.1	5.9	4.1 - 7.4	5	5.00	0.18	3.7	5.0	4.4 - 5.6
Orphee Mythic 22	8	5.03	1.26	25.1	5.4	1.2 - 8.9	8	3.77	0.50	13.4	3.7	2.2 - 5.3
	Specimen CL-3						Specimen CL-4					
All Method	17	6.19	1.44	23.3	5.6	1.8 - 10.6	17	4.43	0.47	10.5	4.6	3.0 - 5.9
All Abbott Cell-Dyn Instruments	7	5.28	0.35	6.6	5.3	4.2 - 6.4	7	4.70	0.24	5.2	4.7	3.9 - 5.5
Abbott Cell-Dyn Ruby	5	5.28	0.35	6.6	5.3	4.2 - 6.4	5	4.70	0.24	5.2	4.7	3.9 - 5.5
Orphee Mythic 22	8	7.23	1.91	26.5	7.8	1.4 - 13.0	8	3.97	0.40	10.2	4.2	2.7 - 5.2
	Specimen CL-5											
All Method	17	5.33	1.17	21.8	5.3	1.8 - 8.9						
All Abbott Cell-Dyn Instruments	7	5.48	0.46	8.5	5.4	4.0 - 6.9						
Abbott Cell-Dyn Ruby	5	5.48	0.46	8.5	5.4	4.0 - 6.9						
Orphee Mythic 22	8	4.78	1.43	29.9	4.6	0.4 - 9.1						

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

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	0.73	0.41	55.4	0.7	0.0 - 2.0	17	0.33	0.17	52.0	0.4	0.0 - 0.9
All Abbott Cell-Dyn Instruments	7	1.10	0.22	19.6	1.2	0.4 - 1.8	7	0.33	0.22	68.2	0.4	0.0 - 1.0
Abbott Cell-Dyn Ruby	5	1.10	0.22	19.6	1.2	0.4 - 1.8	5	0.33	0.22	68.2	0.4	0.0 - 1.0
Orphee Mythic 22	8	0.38	0.21	55.0	0.4	0.0 - 1.0	8	0.33	0.17	52.5	0.4	0.0 - 0.9
Specimen CL-3												
All Method	17	0.56	0.21	38.3	0.5	0.0 - 1.2	17	0.29	0.27	92.3	0.3	0.0 - 1.1
All Abbott Cell-Dyn Instruments	7	0.53	0.21	39.3	0.6	0.0 - 1.2	7	0.30	0.42	141.4	0.2	0.0 - 1.6
Abbott Cell-Dyn Ruby	5	0.53	0.21	39.3	0.6	0.0 - 1.2	5	0.30	0.42	141.4	0.2	0.0 - 1.6
Orphee Mythic 22	8	0.60	0.27	45.1	0.5	0.0 - 1.5	8	0.30	0.08	27.2	0.3	0.0 - 0.6
Specimen CL-5												
All Method	17	0.59	0.21	36.5	0.5	0.0 - 1.3						
All Abbott Cell-Dyn Instruments	7	0.63	0.26	42.1	0.6	0.0 - 1.5						
Abbott Cell-Dyn Ruby	5	0.63	0.26	42.1	0.6	0.0 - 1.5						
Orphee Mythic 22	8	0.53	0.21	39.3	0.5	0.0 - 1.2						

BLOOD BANK

ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-1	Group A	22	100%	Acceptable
BB-2	Group O	22	100%	Acceptable
BB-3	Group B	22	100%	Acceptable
BB-4	Group A	22	100%	Acceptable
BB-5	Group B	22	100%	Acceptable

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-1	Rh Positive	22	100%	Acceptable
BB-2	Rh Positive	22	100%	Acceptable
BB-3	Rh Positive	22	100%	Acceptable
BB-4	Rh Negative	22	100%	Acceptable
BB-5	Rh Negative	22	100%	Acceptable

UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	Unexpected antibody detected	20	100%	Acceptable
AB-2	No unexpected antibody detected	20	100%	Acceptable
AB-3	Unexpected antibody detected	20	100%	Acceptable
AB-4	No unexpected antibody detected	20	100%	Acceptable
AB-5	No unexpected antibody detected	18	90.00%	Acceptable
	Unexpected antibody detected	2	10.00%	

BLOOD BANK

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	Anti-Fy ^a	12	100%	Acceptable
AB-2	No antibody detected	12	100%	Acceptable
AB-3	Anti-K	12	100%	Acceptable
AB-4	No antibody detected	12	100%	Acceptable
AB-5	No antibody detected	12	100%	Acceptable

COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	Not Compatible	18	100%	Acceptable
AB-2	Compatible	18	100%	Acceptable
AB-3	Compatible	13	72.22%	Acceptable
	Not Compatible	5	27.78%	
AB-4	Compatible	17	94.44%	Acceptable
	Not Compatible	1	5.56%	
AB-5	Compatible	16	88.89%	Acceptable
	Not Compatible	2	11.11%	

Specimens AB-3 and AB-5 were graded by referee group.

Coagulation

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-1						Specimen CG-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	48	34.15	5.35	15.7	34.5	29.0 - 39.3	48	11.73	1.30	11.1	11.4	9.9 - 13.5
Dade Innovin												
Dade Behring BFT II	5	30.00	0.85	2.8	30.0	25.5 - 34.5	5	9.50	0.01	0.0	9.5	8.0 - 11.0
Sysmex CA-500/600 series	12	29.58	0.71	2.4	29.7	25.1 - 34.1	12	10.44	0.21	2.0	10.4	8.8 - 12.1
All Coagulation Instruments	17	29.64	0.71	2.4	29.7	25.1 - 34.1	17	10.39	0.49	4.7	10.4	8.8 - 12.0
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	6	36.48	1.36	3.7	36.4	31.0 - 42.0	6	13.12	0.27	2.1	13.0	11.1 - 15.1
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	10	36.78	1.69	4.6	37.0	31.2 - 42.3	10	13.10	0.37	2.8	13.1	11.1 - 15.1
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	49.77	2.99	6.0	48.4	42.3 - 57.3	5	12.97	0.47	3.6	12.8	11.0 - 15.0
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	35.88	1.68	4.7	36.4	30.4 - 41.3	5	10.88	0.29	2.7	10.8	9.2 - 12.6
<u>Reagent/Instrument</u>	Specimen CG-3						Specimen CG-4					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	48	12.25	1.51	12.4	11.9	10.4 - 14.1	48	21.24	2.84	13.4	21.9	18.0 - 24.5
Dade Innovin												
Dade Behring BFT II	5	9.95	0.07	0.7	10.0	8.4 - 11.5	5	18.55	0.92	5.0	18.6	15.7 - 21.4
Sysmex CA-500/600 series	12	11.05	0.90	8.2	11.0	9.3 - 12.8	12	18.38	0.40	2.2	18.4	15.6 - 21.2
All Coagulation Instruments	17	10.95	0.92	8.4	11.0	9.3 - 12.6	17	18.55	0.72	3.9	18.4	15.7 - 21.4
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	6	13.77	0.48	3.5	13.6	11.7 - 15.9	6	22.73	0.55	2.4	22.6	19.3 - 26.2
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	10	13.63	0.32	2.4	13.6	11.5 - 15.7	10	23.30	1.08	4.7	23.4	19.8 - 26.8
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	13.43	0.40	3.0	13.2	11.4 - 15.5	5	27.07	1.77	6.5	26.2	23.0 - 31.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	10.90	0.25	2.3	10.9	9.2 - 12.6	5	21.42	0.96	4.5	21.5	18.2 - 24.7

PROTHROMBIN TIME (seconds)**Specimen CG-5**

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	48	15.16	1.87	12.3	15.0	12.8 - 17.5
Dade Innovin						
Dade Behring BFT II	5	12.70	0.14	1.1	12.7	10.7 - 14.7
Sysmex CA-500/600 series	12	13.18	0.30	2.3	13.0	11.1 - 15.2
All Coagulation Instruments	17	13.22	0.54	4.1	13.0	11.2 - 15.3
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	6	16.73	0.40	2.4	16.7	14.2 - 19.3
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STart Max	10	16.85	0.46	2.7	16.9	14.3 - 19.4
Diagnostica Stago STA NeoPTimal						
Diagnostica Stago STA Compact / Max	5	18.10	1.21	6.7	17.4	15.3 - 20.9
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	14.68	0.46	3.1	14.8	12.4 - 16.9

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-1						Specimen CG-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	49	3.29	0.45	13.6	3.3	2.7 - 3.8	49	0.98	0.05	5.0	1.0	0.8 - 1.2
Dade Innovin												
Dade Behring BFT II	5	2.80	0.14	5.1	2.8	2.3 - 3.3	5	1.00	0.01	0.0	1.0	0.8 - 1.2
Sysmex CA-500/600 series	12	2.98	0.13	4.2	3.0	2.5 - 3.5	12	0.99	0.05	5.2	1.0	0.8 - 1.2
All Coagulation Instruments	17	2.97	0.14	4.7	3.0	2.5 - 3.5	17	1.00	0.05	5.3	1.0	0.8 - 1.2
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	7	3.54	0.17	4.8	3.5	3.0 - 4.1	7	1.00	0.01	0.0	1.0	0.8 - 1.2
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	9	3.61	0.20	5.6	3.6	3.0 - 4.2	9	0.99	0.03	3.4	1.0	0.8 - 1.2
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	4.07	0.15	3.8	4.1	3.4 - 4.7	5	1.00	0.01	0.0	1.0	0.8 - 1.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	3.16	0.30	9.4	3.2	2.6 - 3.7	5	0.90	0.01	0.0	0.9	0.7 - 1.1
<u>Reagent/Instrument</u>	Specimen CG-3						Specimen CG-4					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	49	1.02	0.08	7.4	1.0	0.8 - 1.2	49	1.91	0.16	8.6	1.9	1.6 - 2.2
Dade Innovin												
Dade Behring BFT II	5	1.10	0.01	0.0	1.1	0.9 - 1.3	5	1.80	0.14	7.9	1.8	1.5 - 2.1
Sysmex CA-500/600 series	12	1.08	0.06	5.6	1.1	0.9 - 1.3	12	1.82	0.06	3.2	1.8	1.5 - 2.1
All Coagulation Instruments	17	1.08	0.06	5.4	1.1	0.9 - 1.3	17	1.82	0.07	3.7	1.8	1.5 - 2.1
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	7	1.03	0.05	4.7	1.0	0.8 - 1.2	7	2.00	0.12	5.8	2.0	1.7 - 2.3
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	9	1.04	0.05	5.0	1.0	0.8 - 1.3	9	2.01	0.11	5.2	2.0	1.7 - 2.4
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	1.00	0.01	0.0	1.0	0.8 - 1.2	5	2.13	0.06	2.7	2.1	1.8 - 2.5
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	0.92	0.04	4.9	0.9	0.7 - 1.1	5	1.88	0.15	7.9	1.9	1.5 - 2.2

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

Specimen CG-5

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	49	1.34	0.06	4.7	1.3	1.1 - 1.6
Dade Innovin						
Dade Behring BFT II	5	1.35	0.07	5.2	1.4	1.1 - 1.6
Sysmex CA-500/600 series	12	1.30	0.04	3.3	1.3	1.1 - 1.5
All Coagulation Instruments	17	1.31	0.05	3.9	1.3	1.1 - 1.6
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	7	1.36	0.05	3.9	1.4	1.1 - 1.6
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STart Max	9	1.36	0.05	3.9	1.4	1.1 - 1.6
Diagnostica Stago STA NeoPTimal						
Diagnostica Stago STA Compact / Max	5	1.40	0.01	0.0	1.4	1.1 - 1.7
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	1.28	0.08	6.5	1.3	1.0 - 1.5

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

Specimen CG-1							Specimen CG-2					
<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	27	61.6	11.2	18.2	64	52 - 71	27	27.9	2.1	7.7	28	23 - 33
Dade Actin FSL												
Sysmex CA-500/600 series	7	49.1	2.8	5.7	50	41 - 57	7	26.1	2.3	9.0	25	22 - 31
All Coagulation Instruments	8	50.4	4.3	8.6	51	42 - 58	8	26.3	2.2	8.3	26	22 - 31
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	5	68.7	1.2	1.7	68	58 - 79	5	30.0	1.0	3.3	30	25 - 35
HemosIL APTT-SP												
IL ACL, all models	5	67.0	4.4	6.5	69	56 - 78	5	28.3	1.2	4.1	29	24 - 33
IL TEST APTT-SP												
IL ACL, all models	5	66.5	0.7	1.1	67	56 - 77	5	29.0	0.1	0.0	29	24 - 34
Specimen CG-3							Specimen CG-4					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	27	28.2	3.3	11.6	29	23 - 33	27	37.2	5.9	15.7	37	31 - 43
Dade Actin FSL												
Sysmex CA-500/600 series	7	24.9	0.7	2.8	25	21 - 29	7	31.7	1.8	5.7	32	26 - 37
All Coagulation Instruments	8	25.1	1.0	3.9	25	21 - 29	8	32.1	2.0	6.3	33	27 - 37
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	5	31.7	1.2	3.6	31	26 - 37	5	44.0	2.6	6.0	43	37 - 51
HemosIL APTT-SP												
IL ACL, all models	5	29.5	0.7	2.4	30	25 - 34	5	41.3	2.9	7.0	43	35 - 48
IL TEST APTT-SP												
IL ACL, all models	5	30.5	0.7	2.3	31	25 - 36	5	41.0	1.4	3.4	41	34 - 48
Specimen CG-5												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	27	31.8	4.8	15.1	32	27 - 37						
Dade Actin FSL												
Sysmex CA-500/600 series	7	32.7	11.7	35.8	28	27 - 38						
All Coagulation Instruments	8	32.5	10.9	33.4	28	27 - 38						
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	5	36.7	1.2	3.1	36	31 - 43						
HemosIL APTT-SP												
IL ACL, all models	5	35.3	3.1	8.6	36	30 - 41						
IL TEST APTT-SP												
IL ACL, all models	5	37.0	0.1	0.0	37	31 - 43						

FIBRINOGEN (mg/dL)

Specimen CG-1							Specimen CG-2					
<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	12	248.6	17.2	6.9	255	198 - 299	12	261.1	26.9	10.3	263	208 - 314
IL Fibrinogen-C												
IL ACL, all models	5	251.7	5.8	2.3	255	201 - 303	5	275.3	11.0	4.0	279	220 - 331

Specimen CG-3							Specimen CG-4					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	12	439.3	41.1	9.4	463	351 - 528	12	243.9	19.7	8.1	249	195 - 293
IL Fibrinogen-C												
IL ACL, all models	5	455.3	26.3	5.8	470	364 - 547	5	250.7	8.6	3.4	249	200 - 301

Specimen CG-5						
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	12	158.7	16.8	10.6	163	126 - 191
IL Fibrinogen-C						
IL ACL, all models	5	167.7	8.1	4.8	163	134 - 202

PROTHROMBIN TIME (seconds) – XS Samples

<u>Reagent/Instrument</u>	Specimen XS-1						Specimen XS-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	25	15.16	0.36	2.3	15.1	12.8 - 17.5	26	32.87	1.18	3.6	33.1	27.9 - 37.9
All Roche CoaguChek XS Plus Instruments	12	14.89	0.25	1.7	14.9	12.6 - 17.2	12	32.31	1.30	4.0	32.4	27.4 - 37.2
Roche CoaguChek Pro II	13	15.42	0.23	1.5	15.5	13.1 - 17.8	14	33.36	0.85	2.5	33.2	28.3 - 38.4
Roche CoaguChek XS Plus - Waived	7	14.91	0.33	2.2	14.8	12.6 - 17.2	7	31.94	1.40	4.4	31.9	27.1 - 36.8
Roche CoaguChek XS Plus	5	14.86	0.11	0.8	14.9	12.6 - 17.1	5	32.82	1.06	3.2	32.9	27.8 - 37.8

<u>Reagent/Instrument</u>	Specimen XS-3						Specimen XS-4					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	5	24.15	0.07	0.3	24.2	20.5 - 27.8	5	15.10	0.14	0.9	15.1	12.8 - 17.4
All Roche CoaguChek XS Plus Instruments	5	24.15	0.07	0.3	24.2	20.5 - 27.8	5	15.10	0.14	0.9	15.1	12.8 - 17.4
Roche CoaguChek XS Plus	5	24.15	0.07	0.3	24.2	20.5 - 27.8	5	15.10	0.14	0.9	15.1	12.8 - 17.4

<u>Reagent/Instrument</u>	Specimen XS-5					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	5	31.75	0.07	0.2	31.8	26.9 - 36.6
All Roche CoaguChek XS Plus Instruments	5	31.75	0.07	0.2	31.8	26.9 - 36.6
Roche CoaguChek XS Plus	5	31.75	0.07	0.2	31.8	26.9 - 36.6

INTERNATIONAL NORMALIZED RATIO (INR)– XS Samples

<u>Reagent/Instrument</u>	Specimen XS-1						Specimen XS-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	55	1.26	0.05	4.1	1.3	1.0 - 1.5	55	2.73	0.11	3.9	2.7	2.3 - 3.2
All Roche CoaguChek XS Plus Instruments	29	1.24	0.05	4.0	1.2	1.0 - 1.5	29	2.69	0.11	4.2	2.7	2.2 - 3.1
Roche CoaguChek Pro II	26	1.29	0.04	3.0	1.3	1.0 - 1.5	26	2.78	0.08	2.8	2.8	2.3 - 3.2
Roche CoaguChek XS Plus - Waived	22	1.25	0.05	4.1	1.2	1.0 - 1.5	22	2.68	0.11	4.0	2.7	2.2 - 3.1
Roche CoaguChek XS Plus	7	1.21	0.04	3.1	1.2	1.0 - 1.4	7	2.71	0.13	5.0	2.7	2.3 - 3.2

<u>Reagent/Instrument</u>	Specimen XS-3						Specimen XS-4					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	16	2.05	0.06	3.1	2.1	1.7 - 2.4	16	1.28	0.04	3.2	1.3	1.0 - 1.5
All Roche CoaguChek XS Plus Instruments	5	2.00	0.08	4.1	2.0	1.7 - 2.3	5	1.30	0.01	0.0	1.3	1.1 - 1.5
Roche CoaguChek Pro II	11	2.06	0.05	2.4	2.1	1.7 - 2.4	11	1.27	0.05	3.7	1.3	1.0 - 1.5
Roche CoaguChek XS Plus - Waived	3	-	-	-	2.0	1.7 - 2.3	3	-	-	-	1.3	1.1 - 1.5
Roche CoaguChek XS Plus	2	-	-	-	2.0	1.7 - 2.3	2	-	-	-	1.3	1.1 - 1.5

<u>Reagent/Instrument</u>	Specimen XS-5					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	16	2.75	0.09	3.3	2.8	2.3 - 3.2
All Roche CoaguChek XS Plus Instruments	5	2.65	0.10	3.8	2.6	2.2 - 3.1
Roche CoaguChek Pro II	11	2.78	0.06	2.2	2.8	2.3 - 3.2
Roche CoaguChek XS Plus - Waived	3	-	-	-	2.7	2.2 - 3.2
Roche CoaguChek XS Plus	2	-	-	-	2.6	2.2 - 3.0

URINALYSIS DIPSTICK–SPECIFIC GRAVITY

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	122	1.0192	0.0077	0.8	1.020	1.009 - 1.030
All Iris Diagnostics Methods	7	1.0273	0.0006	0.1	1.027	1.017 - 1.038
All Refractive Index Methods	10	1.0271	0.0026	0.3	1.027	1.017 - 1.038
All Roche Methods	36	1.0159	0.0085	0.8	1.010	1.005 - 1.026
All Siemens Methods	34	1.0196	0.0022	0.2	1.020	1.009 - 1.030
77 Elektronika LabUMat/2	19	1.0269	0.0071	0.7	1.030	1.016 - 1.037
Acon Laboratories	6	1.0142	0.0021	0.2	1.015	1.004 - 1.025
Roche Chemstrips / Combur	9	1.0106	0.0016	0.2	1.010	1.000 - 1.021
Roche cobas u 411	15	1.0117	0.0025	0.2	1.010	1.001 - 1.022
Roche cobas u 601 / 701	7	1.0314	0.0010	0.1	1.032	1.021 - 1.042
Roche Urisys	13	1.0115	0.0023	0.2	1.010	1.001 - 1.022
Siemens Clinitek Advantus	14	1.0182	0.0024	0.2	1.020	1.008 - 1.029
Siemens Clinitek Status / Status+	18	1.0200	0.0001	0.0	1.020	1.010 - 1.030

URINALYSIS DIPSTICK-pH

Specimen UA-1

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	149	-	-	-	-	-	1	-	42	25	73	8	-
77 Elektronika LabUMat/2	19	-	-	-	-	-	1	-	14	3	1	-	-
Acon Laboratories	7	-	-	-	-	-	-	-	-	-	7	-	-
Arkray Aution AU-4050	2	-	-	-	-	-	-	-	-	-	2	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	1	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	-	1	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	-	-	-	-	-	4	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	-	-	-	-	-	-	-	-	2	1	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	1	-	-	-
Other Dipstick Method	2	-	-	-	-	-	-	-	-	-	2	-	-
Roche Chemstrips / Combur	22	-	-	-	-	-	-	-	6	2	14	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	-	-	1	-	-
Roche cobas u 411	15	-	-	-	-	-	-	-	12	-	3	-	-
Roche cobas u 601 / 701	7	-	-	-	-	-	-	-	3	-	4	-	-
Roche Urisys	15	-	-	-	-	-	-	-	7	-	8	-	-
SD UroColor Reagent Strips	1	-	-	-	-	-	-	-	-	1	-	-	-
Siemens Clinitek Advantus	14	-	-	-	-	-	-	-	-	2	12	-	-
Siemens Clinitek Status / Status+	20	-	-	-	-	-	-	-	-	6	6	8	-
Siemens Reagent Strips	12	-	-	-	-	-	-	-	-	-	12	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	-	1	-	-	-
UriScan Pro/II	1	-	-	-	-	-	-	-	-	1	-	-	-

URINALYSIS DIPSTICK–PROTEIN QUALITATIVE

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Participant Results</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	149	-	-	4	82	32	-	-	-	1	28	2	-
77 Elektronika LabUMat/2	19	-	-	-	13	1	-	-	-	-	5	-	-
Acon Laboratories	7	-	-	2	4	1	-	-	-	-	-	-	-
Arkray Aution AU-4050	2	-	-	-	2	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	1	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	3	-	-	-	-	-	1	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	-	-	-	3	-	-	-	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	1	-	-
Other Dipstick Method	2	-	-	-	2	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	-	-	1	20	1	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	1	-	-	-	-	-	-	-
Roche cobas u 411	15	-	-	-	3	5	-	-	-	1	6	-	-
Roche cobas u 601 / 701	7	-	-	-	-	-	-	-	-	-	7	-	-
Roche Urisys	15	-	-	-	1	7	-	-	-	-	7	-	-
SD UroColor Reagent Strips	1	-	-	-	1	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	14	-	-	-	14	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	20	-	-	-	3	16	-	-	-	-	-	1	-
Siemens Reagent Strips	12	-	-	-	12	-	-	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	1	-	-	-	-	-	-	-	-
UriScan Pro/II	1	-	-	-	-	-	-	-	-	-	-	1	-

URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Negative or Normal</u>	<u>Trace</u>	<u>(1+)</u>	<u>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	149	149	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	19	19	-	-	-	-	-	-	-	-	-
Acon Laboratories	7	7	-	-	-	-	-	-	-	-	-
Arkray Aution AU-4050	2	2	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	3	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-	-	-	-	-	-
Other Dipstick Method	1	1	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	22	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-
Roche cobas u 411	15	15	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	7	7	-	-	-	-	-	-	-	-	-
Roche Urisys	15	15	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	1	1	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	14	14	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	20	20	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	12	12	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-
UriScan Pro/II	1	1	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–KETONES

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Participant Results</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 - 10</u> <u>mg/dL</u>	<u>15 - 25</u> <u>mg/dL</u>	<u>40 - 60</u> <u>mg/dL</u>	<u>≥80 - 100</u> <u>mg/dL</u>	<u>≥150</u> <u>mg/dL</u>
ALL METHODS	149	1	-	-	-	-	-	-	67	50	-	-	-	4	27
77 Elektronika LabUMat/2	19	-	-	-	-	-	-	-	12	1	-	-	-	-	6
Acon Laboratories	7	-	-	-	-	-	-	-	7	-	-	-	-	-	-
Arkray Aution AU-4050	2	-	-	-	-	-	-	-	-	2	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	-	-	1	-	
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	-	-	-	-	-	3	-	-	-	-	1
Iris Ichem VELOCITY Urine Chemistry System	3	-	-	-	-	-	-	-	-	3	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	-	-	1	-	
Other Dipstick Method	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Roche Chemstrips / Combur	22	-	-	-	-	-	-	-	22	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Roche cobas u 411	16	-	-	-	-	-	-	-	1	7	-	-	-	-	8
Roche cobas u 601 / 701	6	1	-	-	-	-	-	-	-	-	-	-	-	-	5
Roche Urisys	15	-	-	-	-	-	-	-	7	1	-	-	-	-	7
SD UroColor Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Siemens Clinitek Advantus	14	-	-	-	-	-	-	-	14	-	-	-	-	-	-
Siemens Clinitek Status / Status+	20	-	-	-	-	-	-	-	1	18	-	-	-	1	-
Siemens Reagent Strips	12	-	-	-	-	-	-	-	1	11	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-
UriScan Pro/II	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Positive (Ictotest ONLY)</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Participant Results</u>								
							<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>0.5 - 1.0 mg/dL</u>	<u>2.0 - 4.0 mg/dL</u>	<u>6.0 - 10.0 mg/dL</u>	<u>>10.0 mg/dL</u>
ALL METHODS	125	23	-	-	1	1	-	43	28	-	-	27	2	-	-
77 Elektronika LabUMat/2	19	-	-	-	-	-	-	12	-	-	-	7	-	-	-
Acon Laboratories	7	7	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution AU-4050	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Other Dipstick Method	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	9	5	-	-	-	-	-	2	2	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Roche cobas u 411	15	-	-	-	-	-	-	8	2	-	-	5	-	-	-
Roche cobas u 601 / 701	7	-	-	-	-	-	-	-	-	-	-	7	-	-	-
Roche Urisys	15	1	-	-	-	-	-	7	-	-	-	6	1	-	-
SD UroColor Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	14	-	-	-	-	-	-	4	10	-	-	-	-	-	-
Siemens Clinitek Status / Status+	20	-	-	-	1	1	-	9	9	-	-	-	-	-	-
Siemens Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	1	-	-	-	-	-	-	-	-	-	-	1	-	-	-

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>				
		<u>Normal or 0.0 - 0.2 mg/dL or <3.2 µmol/L</u>	<u>1.0 or <2.0 mg/dL or 16 or 17 µmol/L</u>	<u>2.0/3.0 mg/dL or 34 or 35 µmol/L</u>	<u>4.0 or 4.0/6.0 mg/dL or 70 µmol/L</u>	<u>≥8.0 or ≥12.0 mg/dL or ≥140 or 200 µmol/L</u>
ALL METHODS	125	38	24	12	33	18
77 Elektronika LabUMat/2	20	-	-	1	8	11
Acon Laboratories	7	7	-	-	-	-
Arkray Aution AU-4050	1	-	-	1	-	-
DIRUI H-800 Urine Analyzer	1	-	1	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	1	-	-	-
Iris Diagnostics iChem Velocity Strips	4	1	1	1	1	-
Iris Ichem VELOCITY Urine Chemistry System	3	-	1	-	2	-
Other Analyzer Method	1	-	1	-	-	-
Other Dipstick Method	1	1	-	-	-	-
Roche Chemstrips / Combur	9	8	1	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-
Roche cobas u 411	15	4	11	-	-	-
Roche cobas u 601 / 701	7	3	4	-	-	-
Roche Urisys	15	12	3	-	-	-
SD UroColor Reagent Strips	1	-	-	-	1	-
Siemens Clinitek Advantus	14	-	-	8	6	-
Siemens Clinitek Status / Status+	20	-	-	-	15	5
Siemens Reagent Strips	1	-	-	-	-	1
Sysmex UN Series	1	-	-	1	-	-
UriScan Pro/II	1	-	-	-	-	1

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Participant Results</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>200 -</u> <u>300</u> <u>Ery/μL</u>	<u>\pm0.03</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>\geq 1.0</u> <u>mg/</u> <u>dL</u>
ALL METHODS	148	-	-	-	1	1	6	28	36	38	8	2	-	28	-	-	-	-
77 Elektronika LabUMat/2	18	-	-	-	-	-	-	4	8	-	-	-	-	6	-	-	-	-
Acon Laboratories	7	-	-	-	-	-	-	-	-	7	-	-	-	-	-	-	-	-
Arkray Aution AU-4050	2	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	3	-	-	-	-	-	1	1	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	-	-	-	-	-	3	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Other Dipstick Method	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	21	-	-	-	-	-	-	-	2	19	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Roche cobas u 411	16	-	-	-	-	-	-	-	-	2	6	1	-	7	-	-	-	-
Roche cobas u 601 / 701	6	-	-	-	-	-	-	-	-	-	-	1	-	5	-	-	-	-
Roche Mditron Junior/II	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Roche Urisys	15	-	-	-	-	-	-	-	-	6	1	-	-	8	-	-	-	-
SD UroColor Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	14	-	-	-	-	-	-	8	6	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	20	-	-	-	1	1	-	13	5	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	12	-	-	-	-	-	-	-	12	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
UriScan Pro/II	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>15 or 25 µL</u>	<u>75 or 100 µL</u>	<u>250 or 500 µL</u>
ALL METHODS	136	135	1	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	18	18	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	7	7	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution AU-4050	2	2	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	1	1	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	22	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	16	16	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	6	6	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	15	15	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	14	14	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	20	20	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	1	1	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–NITRITE

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	138	-	138
77 Elektronika LabUMat/2	19	-	19
Acon Laboratories	7	-	7
Arkray Aution AU-4050	2	-	2
DIRUI H-800 Urine Analyzer	1	-	1
Iris Diagnostics Aution Max AX-4280	1	-	1
Iris Diagnostics iChem Velocity Strips	4	-	4
Iris Ichem VELOCITY Urine Chemistry System	3	-	3
Other Analyzer Method	1	-	1
Other Dipstick Method	1	-	1
Roche Chemstrips / Combur	22	-	22
Roche cobas 6500 / u 601	1	-	1
Roche cobas u 411	16	-	16
Roche cobas u 601 / 701	6	-	6
Roche Urisys	15	-	15
SD UroColor Reagent Strips	1	-	1
Siemens Clinitek Advantus	14	-	14
Siemens Clinitek Status / Status+	20	-	20
Siemens Reagent Strips	1	-	1
Sysmex UN Series	1	-	1
UriScan Pro/II	1	-	1

URINALYSIS –MICROALBUMIN (dipstick only)

Specimen UA-1

<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	7	-	-	-	-	-	-	-	1	1	-	5
Other Dipstick Method	2	-	-	-	-	-	-	-	-	-	-	2
Roche Micral - 1 minute	2	-	-	-	-	-	-	-	1	-	-	1

URINALYSIS –URINE hCG

Specimen UA-1

<u>Method</u>	<i>Participant Results</i>		
	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	84	84	-
77 Elektronika LabUMat/2	1	1	-
Abon (Alere) Biopharm	2	2	-
Acon Laboratories	5	5	-
Alere Clearview hCG Cassette	1	1	-
Alere hCG Combo Cassette	2	2	-
Biosynex	4	4	-
JusChek	4	4	-
Ms. Tellme hCG Rapid Test Cassette	20	20	-
Other Dipstick Method	1	1	-
SD Bioline hCG	3	3	-
Siemens Clinitek Status / Status+	15	15	-

MISCELLANEOUS CULTURES

Specimen BA-1 – Eye Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Serratia marcescens	100	69.44%	Acceptable
Serratia sp.	7	4.86%	Acceptable
Gram negative bacilli	1	0.69%	Acceptable
Staphylococcus epidermidis	23	15.97%	Acceptable
Staphylococcus sp.	1	0.69%	Acceptable
Staph – coagulase negative	3	2.08%	Acceptable

Organism(s) present: *Serratia marcescens* and *Staphylococcus epidermidis*

Specimen BA-2 – Stool Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Shigella boydii	15	8.52%	Acceptable
Shigella sp.	77	43.75%	Acceptable
Escherichia coli	75	42.61%	Acceptable
Gram negative bacilli	2	1.14%	Acceptable

Organism(s) present: *Shigella boydii* and *Escherichia coli*

Specimen BA-3 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Eikenella corrodens	68	61.82%	Acceptable
Eikenella sp.	8	7.27%	Acceptable
Gram negative bacilli	5	4.55%	Acceptable
Gram negative coccobacilli	3	2.73%	Acceptable
Growth, referred for identification	1	0.91%	Acceptable

Organism(s) present: *Eikenella corrodens*

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Specimen UC-1, CC-1 (SUS-1) Organism(s) present: *Escherichia coli*

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>
	<i>Interpretative category data</i>				<i>Interpretative category data</i>				
	<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	19	19	-	-	110	110	-	-	100.00%
Amoxicillin/Clavulanate	25	20	1	4	42	39	1	2	88.06%
Ampicillin	20	-	-	20	86	3	3	80	94.34%
Ampicillin/Sulbactam	9	2	6	1	96	1	50	45	97.14%
Aztreonam	5	5	-	-	23	22	1	-	96.43%
Cefaclor	1	1	-	-	-	-	-	-	100.00%
Cefamandole	-	-	-	-	1	-	1	-	100.00%
Cefazolin	9	9	-	-	84	81	3	-	96.77%
Cefdinir	1	1	-	-	-	-	-	-	100.00%
Cefepime	17	17	-	-	108	107	-	1	99.20%
Cefixime	9	9	-	-	6	6	-	-	100.00%
Cefoperazone	7	7	-	-	-	-	-	-	100.00%
Cefotaxime	15	15	-	-	36	35	1	-	98.04%
Cefoxitin	7	7	-	-	30	30	-	-	100.00%
Cefpodoxime	3	3	-	-	1	1	-	-	100.00%
Ceftaroline	-	-	-	-	1	1	-	-	100.00%
Ceftazidime	19	17	2	-	99	99	-	-	98.31%
Ceftizoxime	-	-	-	-	2	2	-	-	100.00%
Ceftolozane/Tazobactam	1	1	-	-	8	8	-	-	100.00%
Ceftriaxone	16	16	-	-	101	98	-	3	97.44%
Cefuroxime	23	22	1	-	58	56	2	-	96.30%
Ciprofloxacin	22	22	-	-	144	142	-	2	98.80%
Colistin	-	-	-	-	1	1	-	-	100.00%
Daptomycin	-	-	-	-	1	1	-	-	Inappropriate drug ¹
Doripenem	-	-	-	-	2	2	-	-	100.00%
Doxycycline	2	2	-	-	-	-	-	-	100.00%
Ertapenem	12	12	-	-	92	92	-	-	100.00%

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

ANTIMICROBIAL SUSCEPTIBILITY TESTING (continued)

Specimen UC-1, CC-1 (SUS-1) Organism(s) present *Enterococcus faecalis* – Vancomycin resistant.

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<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>	
Fosfomycin	13	12	-	1	58	58	-	-	98.59%
Gentamicin	21	21	-	-	128	127	-	1	99.33%
Imipenem	17	17	-	-	55	55	-	-	100.00%
Levofloxacin	12	12	-	-	40	39	-	1	98.08%
Linezolid	-	-	-	-	2	2	-	-	Inappropriate drug ¹
Meropenem	17	17	-	-	93	92	1	-	99.09%
Minocycline	1	1	-	-	1	1	-	-	100.00%
Moxifloxacin	-	-	-	-	2	2	-	-	Inappropriate drug ¹
Nalidixic Acid	3	3	-	-	10	9	-	1	92.31%
Netilmicin	2	2	-	-	1	1	-	-	100.00%
Nitrofurantoin	26	25	1	-	130	130	-	-	99.36%
Norfloxacin	6	6	-	-	54	54	-	-	100.00%
Ofloxacin	3	3	-	-	1	1	-	-	100.00%
Oxacillin	-	-	-	-	1	-	-	1	Inappropriate drug ¹
Penicillin	-	-	-	-	1	-	-	1	Inappropriate drug ¹
Piperacillin	-	-	-	-	2	2	-	-	100.00%
Piperacillin/Tazobactam	15	15	-	-	58	58	-	-	100.00%
Polymyxin B	1	1	-	-	-	-	-	-	Inappropriate method ²
Rifampin	-	-	-	-	1	1	-	-	Inappropriate drug ¹
Streptomycin	-	-	-	-	1	-	1	-	100.00%
Tetracycline	6	6	-	-	5	4	-	1	90.91%
Ticarcillin/Clavulanate	-	-	-	-	2	2	-	-	100.00%
Tobramycin	3	3	-	-	13	13	-	-	100.00%
Trimethoprim	2	2	-	-	1	1	-	-	100.00%
Trimethoprim/Sulfamethoxazole	25	24	-	1	132	131	-	1	98.73%
Vancomycin	-	-	-	-	1	1	-	-	Inappropriate drug ¹

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

² Inappropriate method for drug tested

PARASITOLOGY

Specimen FP-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Schistosoma mansoni eggs	212	66.46%	Acceptable
Schistosoma sp. eggs	42	13.17%	Acceptable
Parasite egg or larva seen – no ID	1	0.31%	Acceptable
Blastocystis hominis	19	5.96%	
Schistosoma haematobium eggs	10	3.13%	
Endolimax nana	9	2.82%	
No parasite seen	7	2.19%	
Fasciola hepatica eggs	6	1.88%	

Parasite(s) present: *Schistosoma mansoni* eggs

Specimen FP-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	264	91.99%	Acceptable
Blastocystis hominis	5	1.74%	
Endolimax nana	4	1.39%	
Taenia sp. eggs	4	1.39%	
Giardia lamblia	3	1.05%	
Hookworm	3	1.05%	

Parasite(s) present: Negative for parasites

PARASITOLOGY (continued)

Specimen FP-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hymenolepis nana eggs	217	58.33%	Acceptable
Trichuris trichiura eggs	17	4.57%	Acceptable
Parasite egg or larva seen – no ID	1	0.27%	Acceptable
Hymenolepis diminuta eggs	35	9.41%	
Entamoeba histolytica	32	8.60%	
Endolimax nana	16	4.30%	
Entamoeba coli	14	3.76%	
Ascaris lumbricoides eggs	11	2.96%	
Taenia sp. eggs	11	2.96%	
Blastocystis hominis	10	2.69%	
No parasite seen	5	1.34%	

Parasite(s) present: *Hymenolepis nana* eggs and *Trichuris trichiura* eggs. This challenge was graded by referee consensus.

Specimen FP-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Diphyllobothrium latum	206	57.87%	Acceptable
Parasite egg or larva seen – no ID	2	0.56%	Acceptable
Hookworm	39	10.96%	
Endolimax nana	33	9.27%	
Paragonimus westermani eggs	15	4.21%	
Entamoeba histolytica	13	3.65%	
Fasciola hepatica eggs	11	3.09%	
Ascaris lumbricoides eggs	9	2.53%	
Blastocystis hominis	9	2.53%	
Entamoeba coli	6	1.69%	

Parasite(s) present: *Diphyllobothrium latum*. This challenge was graded by referee consensus.

PARASITOLOGY (continued)

Specimen FP-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	252	90.97%	Acceptable
Plasmodium sp.	13	4.69%	
Plasmodium falciparum	3	1.08%	
Plasmodium vivax	3	1.08%	

Parasite(s) present: Negative for parasites

Antinuclear Antibody (ANA) - Qualitative

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

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

Antinuclear Antibody (ANA)—Semi-Quantitative (Titer)

<u>Specimen/Method</u>	<u>N/A</u> <u>(Neg)</u>	<u>8/</u> <u>10</u>	<u>16/</u> <u>20</u>	<u>32/</u> <u>40</u>	<u>64/</u> <u>80</u>	<u>128/</u> <u>160</u>	<u>256/</u> <u>320</u>	<u>512/</u> <u>640</u>	<u>>640</u>	<u>1024/</u> <u>1280</u>	<u>2048/</u> <u>2560</u>	<u>≥2560</u>
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Specimen AE-1

ALL METHODS	1	-	-	1	4	2	3	3	-	-	-	-
Bio-Rad	-	-	-	-	-	-	1	-	-	-	-	-
BioSystems	-	-	-	-	-	-	1	1	-	-	-	-
Immuno Concepts	-	-	-	1	2	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	2	1	-	1	-	-	-	-
Kallestad	-	-	-	-	-	1	-	-	-	-	-	-

Antinuclear Antibody (ANA)—Semi-Quantitative (Titer)

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

ALL METHODS	12	-	-	1	-	1	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
BioSystems	1	-	-	-	-	1	-	-	-	-	-	-
Immuno Concepts	2	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	5	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

Specimen AE-3

ALL METHODS	1	-	-	1	-	2	-	3	-	4	1	2
Bio-Rad	-	-	-	-	-	-	-	-	-	1	-	-
BioSystems	1	-	-	-	-	-	-	-	-	1	-	-
Immuno Concepts	-	-	-	1	-	-	-	-	-	2	-	-
INOVA Diagnostics	-	-	-	-	-	2	-	1	-	-	1	1
Kallestad	-	-	-	-	-	-	-	1	-	-	-	-

Specimen AE-4

ALL METHODS	12	-	-	1	-	-	1	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
BioSystems	1	-	-	-	-	-	1	-	-	-	-	-
Immuno Concepts	2	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	5	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

Specimen AE-5

ALL METHODS	13	-	-	1	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
BioSystems	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	5	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

Anti-dsDNA

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	1	-	17	2	15
Bio-Rad	1	-	-	1	-	1
BioSystems	2	-	-	2	-	2
Human	-	1	-	1	-	1
INOVA Diagnostics	7	-	-	7	1	6

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	17	-	17
Bio-Rad	-	1	-	1
BioSystems	-	2	-	2
Human	-	1	-	1
INOVA Diagnostics	-	7	-	7

Anti-RNP

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	11	-	14	11	2
BioSystems	-	1	-	1	-	1
INOVA Diagnostics	2	6	-	8	8	-

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	14	-	14
BioSystems	-	1	-	1
INOVA Diagnostics	-	8	-	8

Anti-RNP/Sm

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

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	-	5
BioSystems	-	1	-	1
INOVA Diagnostics	-	1	-	1

Anti-SSA

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

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	-	18
BioSystems	-	2	-	2
INOVA Diagnostics	-	8	-	8

Anti-SSB

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	-	19	15	3
BioSystems	-	2	-	2	1	1
INOVA Diagnostics	-	9	-	9	8	1

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	19	-	19
BioSystems	-	2	-	2
INOVA Diagnostics	-	9	-	9

Anti-SSA/SSB

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

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

Anti-Sm

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	-	19	3	15
BioSystems	-	2	-	2	-	2
INOVA Diagnostics	-	9	-	9	3	6

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	19	-	19
BioSystems	-	2	-	2
INOVA Diagnostics	-	9	-	9

Rubella—Qualitative

<u>Method</u>	Specimen RU-1		Specimen RU-2		Specimen RU-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	-	-	17	17	-
Abbott Architect	13	-	-	13	13	-
DiaSorin	1	-	-	1	1	-
Roche cobas 6000 / e 601	1	-	-	1	1	-
Roche cobas e 411	1	-	-	1	1	-
Siemens Atellica	1	-	-	1	1	-

<u>Method</u>	Specimen RU-4		Specimen RU-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	-	-	17
Abbott Architect	13	-	-	13
DiaSorin	1	-	-	1
Roche cobas 6000 / e 601	1	-	-	1
Roche cobas e 411	1	-	-	1
Siemens Atellica	1	-	-	1

Rubella—Quantitative (IU/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen RU-1						
All Method	19	18.69	10.99	58.8	12.5	0.0 - 51.7
All Roche Methods	5	36.42	2.46	6.8	36.5	29.0 - 43.9
Abbott Architect	13	12.37	1.18	9.5	12.1	8.8 - 15.9
Specimen RU-2						
All Method	19	0.13	0.22	170.0	0.0	0.0 - 0.9
All Roche Methods	5	0.48	0.13	27.2	0.4	0.0 - 0.9
Abbott Architect	12	0.00	0.01	0.0	0.0	0.0 - 0.1
Specimen RU-3						
All Method	19	39.66	19.31	48.7	28.5	0.0 - 97.6
All Roche Methods	5	70.70	3.13	4.4	70.8	61.3 - 80.1
Abbott Architect	13	28.59	3.31	11.6	27.4	18.6 - 38.6
Specimen RU-4						
All Method	19	50.43	23.53	46.7	38.4	0.0 - 121.1
All Roche Methods	5	88.24	3.33	3.8	86.8	78.2 - 98.3
Abbott Architect	13	36.88	4.28	11.6	37.1	24.0 - 49.8
Specimen RU-5						
All Method	19	0.13	0.20	154.2	0.0	0.0 - 0.8
All Roche Methods	5	0.44	0.11	25.9	0.4	0.0 - 0.8
Abbott Architect	13	0.02	0.06	259.6	0.0	0.0 - 0.3

Syphilis Serology—Qualitative: VDRL Slide

<u>Method</u>	Specimen SY-1			Specimen SY-2			Specimen SY-3		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	34	-	5	34	1	4	34	1	4
Acon Laboratories	1	-	-	1	-	-	1	-	-
Human	-	-	1	1	-	-	1	-	-
Lorne Laboratories	1	-	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	1	-	-	1	-	-	1	-	-
Rodelg Laboratories	1	-	-	1	-	-	1	-	-
SPINREACT	1	-	-	1	-	-	1	-	-
Wiener Lab	26	-	3	25	1	3	25	1	3

<u>Method</u>	Specimen SY-4			Specimen SY-5		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	-	39	-	-	39
Acon Laboratories	-	-	1	-	-	1
Human	-	-	1	-	-	1
Lorne Laboratories	-	-	1	-	-	1
Roche cobas 6000 / e 601	-	-	1	-	-	1
Rodelg Laboratories	-	-	1	-	-	1
SPINREACT	-	-	1	-	-	1
Wiener Lab	-	-	29	-	-	29

Syphilis Serology—Semi-Quantitative: VDRL Slide Titer

<u>Specimen/Method</u>	<u>N/A (Neg)</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-1									
ALL METHODS	4	-	1	13	9	6	1	-	2
Lorne Laboratories	-	-	-	-	-	1	-	-	-
Wiener Lab	3	-	1	11	7	5	1	-	2
Specimen SY-2									
ALL METHODS	3	-	2	12	12	7	-	-	-
Lorne Laboratories	-	-	-	-	-	1	-	-	-
Wiener Lab	2	-	2	10	10	6	-	-	-
Specimen SY-3									
ALL METHODS	3	-	4	12	11	2	2	1	1
Lorne Laboratories	-	-	-	-	-	1	-	-	-
Wiener Lab	2	-	4	9	10	1	2	1	1
Specimen SY-4									
ALL METHODS	36	-	-	-	-	-	-	-	-
Lorne Laboratories	1	-	-	-	-	-	-	-	-
Wiener Lab	30	-	-	-	-	-	-	-	-
Specimen SY-5									
ALL METHODS	36	-	-	-	-	-	-	-	-
Lorne Laboratories	1	-	-	-	-	-	-	-	-
Wiener Lab	30	-	-	-	-	-	-	-	-

Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	7	1	7	1	7	1
Abbott Architect	1	-	1	-	1	-
Atlas Medical	1	-	1	-	1	-
Plasmatec	1	-	1	-	1	-
Serodia	1	-	1	-	1	-
Standard Diagnostics	1	-	1	-	1	-

	Specimen SY-4		Specimen SY-5	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	8	-	8
Abbott Architect	-	1	-	1
Atlas Medical	-	1	-	1
Plasmatec	-	1	-	1
Serodia	-	1	-	1
Standard Diagnostics	-	1	-	1

Syphilis Serology—Qualitative : *Treponema pallidum* Antibodies

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	47	2	47	2	47	2
Abbott Alinity	3	1	3	1	3	1
Abbott Architect	10	-	10	-	10	-
Abon (Alere) Biopharm	1	-	1	-	1	-
DiaSorin	2	-	2	-	2	-
Human	1	-	1	-	1	-
Roche cobas 6000 / c 501	1	-	1	-	1	-
Roche cobas 8000/e801	2	-	2	-	2	-
Roche cobas e 411	1	-	1	-	1	-
SD Bioline	3	-	3	-	3	-
Serodia	9	-	9	-	9	-
Siemens Immulite 2000	1	-	1	-	1	-
Standard Diagnostics	6	-	6	-	6	-
Zeus	1	-	1	-	1	-

	Specimen SY-4		Specimen SY-5	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	49	-	49
Abbott Alinity	-	4	-	4
Abbott Architect	-	10	-	10
Abon (Alere) Biopharm	-	1	-	1
DiaSorin	-	2	-	2
Human	-	1	-	1
Roche cobas 6000 / c 501	-	1	-	1
Roche cobas 8000/e801	-	2	-	2
Roche cobas e 411	-	1	-	1
SD Bioline	-	3	-	3
Serodia	-	9	-	9
Siemens Immulite 2000	-	1	-	1
Standard Diagnostics	-	6	-	6
Zeus	-	1	-	1

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	46	1	46	1	46	1
Atlas Medical	1	-	1	-	1	-
Becton Dickinson	5	-	5	-	5	-
BioSystems	7	-	7	-	7	-
Human	6	-	6	-	6	-
Lorne Laboratories	3	-	3	-	3	-
Omega Diagnostics	2	-	2	-	2	-
Plasmatec	3	-	3	-	3	-
Pulse Scientific	1	-	1	-	1	-
Rodelg Laboratories	1	-	1	-	1	-
SPINREACT	11	-	11	-	11	-

	Specimen SY-4		Specimen SY-5	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	47	-	47
Atlas Medical	-	1	-	1
Becton Dickinson	-	5	-	5
bioMerieux	-	7	-	7
BioSystems	-	6	-	6
Human	-	3	-	3
Lorne Laboratories	-	2	-	2
Omega Diagnostics	-	3	-	3
Plasmatec	-	1	-	1
Pulse Scientific	-	1	-	1
SPINREACT	-	11	-	11

Syphilis Serology—Semi-Quantitative : RPR (Titer)

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>
Specimen SY-1									
ALL METHODS	1	-	15	18	8	1	-	-	2
Atlas Medical	-	-	-	1	-	-	-	-	-
Becton Dickinson	-	-	-	4	1	-	-	-	-
BioSystems	-	-	2	4	1	-	-	-	1
Human	-	-	4	1	-	-	-	-	1
Lorne Laboratories	-	-	-	2	1	-	-	-	-
Omega Diagnostics	-	-	-	1	1	-	-	-	-
Plasmatec	-	-	2	1	-	-	-	-	-
Pulse Scientific	-	-	-	-	1	-	-	-	-
SPINREACT	-	-	5	3	2	1	-	-	-
Specimen SY-2									
ALL METHODS	1	1	13	22	7	-	-	-	1
Atlas Medical	-	-	-	1	-	-	-	-	-
Becton Dickinson	-	-	-	3	2	-	-	-	-
BioSystems	-	-	-	7	1	-	-	-	-
Human	-	-	4	1	-	-	-	-	1
Lorne Laboratories	-	-	1	2	-	-	-	-	-
Omega Diagnostics	-	-	-	1	1	-	-	-	-
Plasmatec	-	-	3	-	-	-	-	-	-
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	1	1	6	3	-	-	-	-

Syphilis Serology—Semi-Quantitative : RPR (Titer) (continued)

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>
Specimen SY-3									
ALL METHODS	1	1	10	25	6	1	-	-	1
Atlas Medical	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	4	1	-	-	-	-
BioSystems	-	-	-	7	-	1	-	-	-
Human	-	-	2	2	1	-	-	-	1
Lorne Laboratories	-	-	1	1	1	-	-	-	-
Omega Diagnostics	-	-	-	1	1	-	-	-	-
Plasmatec	-	-	2	1	-	-	-	-	-
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	1	3	5	2	-	-	-	-
Specimen SY-4									
ALL METHODS	45	-	-	-	-	-	-	-	-
Atlas Medical	1	-	-	-	-	-	-	-	-
Becton Dickinson	5	-	-	-	-	-	-	-	-
BioSystems	8	-	-	-	-	-	-	-	-
Human	6	-	-	-	-	-	-	-	-
Lorne Laboratories	3	-	-	-	-	-	-	-	-
Omega Diagnostics	2	-	-	-	-	-	-	-	-
Plasmatec	3	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	11	-	-	-	-	-	-	-	-

Syphilis Serology—Semi-Quantitative : RPR (Titer) (continued)

<u>Specimen/Method</u>	<u>N/A</u> <u>(Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>
Specimen SY-5									
ALL METHODS	45	-	-	-	-	-	-	-	-
Atlas Medical	1	-	-	-	-	-	-	-	-
Becton Dickinson	5	-	-	-	-	-	-	-	-
BioSystems	8	-	-	-	-	-	-	-	-
Human	6	-	-	-	-	-	-	-	-
Lorne Laboratories	3	-	-	-	-	-	-	-	-
Omega Diagnostics	2	-	-	-	-	-	-	-	-
Plasmatec	3	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	11	-	-	-	-	-	-	-	-

Viral Markers – Anti-HBc (IgM)

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	42	-	1	42	-	3	40	-
Abbott Alinity	-	3	-	-	3	-	-	3	-
Abbott Architect	-	20	-	-	20	-	1	19	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	7	-	-	7	-	-	7	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
Roche cobas e 411	1	-	-	1	-	-	1	-	-
Siemens ADVIA	-	2	-	-	2	-	-	2	-
Siemens Atellica	-	1	-	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-	-	4	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	41	-	2	41	-
Abbott Alinity	-	3	-	-	3	-
Abbott Architect	1	19	-	1	19	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	7	-	-	7	-
Roche cobas 8000/e801	-	4	-	-	4	-
Roche cobas e 411	-	1	-	-	1	-
Siemens ADVIA	-	2	-	-	2	-
Siemens Atellica	1	-	-	1	-	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-

Viral Markers – Anti-HBc (Total / IgG)

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	59	-	-	59	-	59	-	-
Abbott Alinity	-	8	-	-	8	-	8	-	-
Abbott Architect	-	28	-	-	28	-	28	-	-
DiaSorin	-	2	-	-	2	-	2	-	-
Roche cobas 6000 / e 601	-	7	-	-	7	-	7	-	-
Roche cobas 8000/e801	-	4	-	-	4	-	4	-	-
Roche cobas e 411	-	2	-	-	2	-	2	-	-
Siemens ADVIA	-	2	-	-	2	-	2	-	-
Siemens Atellica	-	1	-	-	1	-	1	-	-
Siemens Immulite 2000	-	1	-	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-	4	-	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	59	-	-	58	1	-
Abbott Alinity	8	-	-	8	-	-
Abbott Architect	28	-	-	28	-	-
DiaSorin	2	-	-	2	-	-
Roche cobas 6000 / e 601	7	-	-	6	1	-
Roche cobas 8000/e801	4	-	-	4	-	-
Roche cobas e 411	2	-	-	2	-	-
Siemens ADVIA	2	-	-	2	-	-
Siemens Atellica	1	-	-	1	-	-
Siemens Immulite 2000	1	-	-	1	-	-
VITROS 3600/4600/5600/7600	4	-	-	4	-	-

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	128	-	127	1	-	1	127	-
Abbott Alinity	-	10	-	10	-	-	-	10	-
Abbott Architect	-	52	-	52	-	-	1	51	-
Acon Laboratories	-	1	-	1	-	-	-	1	-
Alere Determine - moderate	-	3	-	3	-	-	-	3	-
Alere Determine - waived	-	2	-	2	-	-	-	2	-
Beckman ACCESS / 2 / Dxl	-	1	-	1	-	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	3	-	3	-	-	-	3	-
Clearview HIV1/2 STAT-PAK	-	2	-	2	-	-	-	2	-
DiaSorin	-	1	-	1	-	-	-	1	-
Human	-	3	-	3	-	-	-	3	-
Roche cobas 6000 / e 601	-	12	-	11	1	-	-	12	-
Roche cobas 8000/e801	-	7	-	7	-	-	-	7	-
Roche cobas e 411	-	8	-	8	-	-	-	8	-
SD Bioline	-	4	-	4	-	-	-	4	-
Siemens ADVIA	-	5	-	5	-	-	-	5	-
Siemens Atellica	-	1	-	1	-	-	-	1	-
Standard Diagnostics	-	2	-	2	-	-	-	2	-
VITROS	-								
3600/4600/5600/7600	-	4	-	4	-	-	-	4	-

Viral Markers – Anti-HIV- (continued)

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	128	-	-	128	-
Abbott Alinity	-	10	-	-	10	-
Abbott Architect	-	52	-	-	52	-
Acon Laboratories	-	1	-	-	1	-
Alere Determine - moderate	-	3	-	-	3	-
Alere Determine - waived	-	2	-	-	2	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-
Clearview HIV1/2 STAT-PAK	-	2	-	-	2	-
DiaSorin	-	1	-	-	1	-
Human	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	12	-	-	12	-
Roche cobas 8000/e801	-	7	-	-	7	-
Roche cobas e 411	-	8	-	-	8	-
SD Bioline	-	4	-	-	4	-
Siemens ADVIA	-	5	-	-	5	-
Siemens Atellica	-	1	-	-	1	-
Standard Diagnostics	-	2	-	-	2	-
VITROS	-			-		
3600/4600/5600/7600	-	4	-	-	4	-

Viral Markers – Anti-HAV (IgM)

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	51	-	-	51	-	-	51	-
Abbott Alinity	-	2	-	-	2	-	-	2	-
Abbott Architect	-	26	-	-	26	-	-	26	-
bioMerieux Vidas, Mini									
Vidas	-	3	-	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	10	-	-	10	-	-	10	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
SD Bioline	-	1	-	-	1	-	-	1	-
Siemens ADVIA	-	2	-	-	2	-	-	2	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
Standard Diagnostics	-	2	-	-	2	-	-	2	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	51	-	-	51	-
Abbott Alinity	-	2	-	-	2	-
Abbott Architect	-	26	-	-	26	-
bioMerieux Vidas, Mini						
Vidas	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	10	-	-	10	-
Roche cobas 8000/e801	-	4	-	-	4	-
SD Bioline	-	1	-	-	1	-
Siemens ADVIA	-	2	-	-	2	-
Siemens Atellica	-	1	-	-	1	-

Viral Markers – Anti-HAV (Total/IgG)

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	35	1	-	35	1	-	1	35	-
Abbott Alinity	2	-	-	2	-	-	-	2	-
Abbott Architect	20	-	-	20	-	-	-	20	-
Beckman ACCESS / 2 / Dxl	1	-	-	1	-	-	-	1	-
bioMerieux Vidas, Mini Vidas	1	-	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	2	1	-	2	1	-	-	3	-
Roche cobas 8000/e801	3	-	-	3	-	-	-	3	-
Roche cobas e 411	2	-	-	2	-	-	-	2	-
Siemens ADVIA	2	-	-	2	-	-	1	1	-
Siemens Atellica	1	-	-	1	-	-	-	1	-
VITROS 3600/4600/5600/7600	1	-	-	1	-	-	-	1	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	35	-	1	35	-
Abbott Alinity	-	2	-	-	2	-
Abbott Architect	-	20	-	-	20	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	3	-	-	3	-
Roche cobas 8000/e801	-	3	-	-	3	-
Roche cobas e 411	-	2	-	-	2	-
Siemens ADVIA	1	1	-	1	1	-
Siemens Atellica	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	-	1	-	-	1	-

Viral Markers – HBeAg

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	31	-	-	31	-	31	-	-
Abbott Alinity	-	2	-	-	2	-	2	-	-
Abbott Architect	-	13	-	-	13	-	13	-	-
Roche cobas 6000 / e 601	-	8	-	-	8	-	8	-	-
Roche cobas 8000/e801	-	5	-	-	5	-	5	-	-
Siemens ADVIA	-	1	-	-	1	-	1	-	-
Siemens Atellica	-	1	-	-	1	-	1	-	-
VITROS									
3600/4600/5600/7600	-	1	-	-	1	-	1	-	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	31	-	-	31	-
Abbott Alinity	-	2	-	-	2	-
Abbott Architect	-	13	-	-	13	-
Roche cobas 6000 / e 601	-	8	-	-	8	-
Roche cobas 8000/e801	-	5	-	-	5	-
Siemens ADVIA	-	1	-	-	1	-
Siemens Atellica	-	1	-	-	1	-
VITROS						
3600/4600/5600/7600	-	1	-	-	1	-

Viral Markers – Anti-HBs

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	70	3	-	70	3	-	38	35	-
Abbott Alinity	7	-	-	7	-	-	1	6	-
Abbott Architect	34	-	-	34	-	-	10	24	-
Beckman ACCESS / 2 / Dxl	1	-	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	6	1	-	6	1	-	6	1	-
Roche cobas 8000/e801	7	-	-	7	-	-	7	-	-
Roche cobas e 411	5	-	-	5	-	-	5	-	-
SD Bioline	-	1	-	-	1	-	-	1	-
Siemens ADVIA	5	-	-	5	-	-	3	2	-
Siemens Atellica	1	-	-	1	-	-	1	-	-
VITROS									
3600/4600/5600/7600	3	-	-	3	-	-	3	-	-
VITROS Eci	1	-	-	1	-	-	1	-	-

Viral Markers – Anti-HBs

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	73	-	2	71	-
Abbott Alinity	-	7	-	-	7	-
Abbott Architect	-	34	-	-	34	-
Beckman ACCESS / 2 / DxI	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	7	-	-	7	-
Roche cobas 8000/e801	-	7	-	-	7	-
Roche cobas e 411	-	5	-	-	5	-
SD Bioline	-	1	-	1	-	-
Siemens ADVIA	-	5	-	-	5	-
Siemens Atellica	-	1	-	-	1	-
VITROS						
3600/4600/5600/7600	-	3	-	-	3	-
VITROS Eci	-	1	-	-	1	-

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	6	119	-	-	125	-	104	21	-
Abbott Alinity	-	12	-	-	12	-	11	1	-
Abbott Architect	2	48	-	-	50	-	50	-	-
Abbott IMx	-	4	-	-	4	-	-	4	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	1	-	-
CTK Biotech	-	2	-	-	2	-	2	-	-
DiaSorin	-	1	-	-	1	-	-	1	-
DiaSorin	-	2	-	-	2	-	2	-	-
Roche cobas 6000 / e 601	-	14	-	-	14	-	13	1	-
Roche cobas 8000/e801	-	6	-	-	6	-	6	-	-
Roche cobas e 411	-	7	-	-	7	-	7	-	-
SD Biotec	-	9	-	-	9	-	-	9	-
Siemens ADVIA	-	6	-	-	6	-	6	-	-
Siemens Atellica	-	1	-	-	1	-	1	-	-
Standard Diagnostics	-	2	-	-	2	-	1	1	-
VITROS 3600/4600/5600/7600	4	-	-	-	4	-	4	-	-

Viral Markers – HBsAg (continued)

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	125	-	123	2	-
Abbott Alinity	-	12	-	12	-	-
Abbott Architect	-	50	-	50	-	-
Abbott IMx	-	4	-	4	-	-
Beckman ACCESS / 2 / Dxl	-	1	-	1	-	-
bioMerieux Vidas, Mini						
Vidas	-	2	-	2	-	-
CTK Biotech	-	1	-	1	-	-
DiaSorin	-	2	-	2	-	-
Roche cobas 6000 / e 601	-	14	-	13	1	-
Roche cobas 8000/e801	-	6	-	6	-	-
Roche cobas e 411	-	7	-	7	-	-
SD Bioline	-	9	-	9	-	-
Siemens ADVIA	-	6	-	6	-	-
Siemens Atellica	-	1	-	1	-	-
Standard Diagnostics	-	2	-	1	1	-
VITROS						
3600/4600/5600/7600	-	4	-	4	-	-

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	109	-	-	109	-	1	108	-
Abbott Alinity	-	12	-	-	12	-	-	12	-
Abbott Architect	-	48	-	-	48	-	-	48	-
Abbott IMx	-	2	-	-	2	-	-	2	-
Abon (Alere) Biopharm	-	1	-	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-	-	1	-
DiaSorin	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	9	-	-	9	-	-	9	-
Roche cobas 8000/e801	-	5	-	-	5	-	-	5	-
Roche cobas e 411	-	7	-	-	7	-	-	7	-
SD Biotline	-	4	-	-	4	-	-	4	-
Siemens ADVIA	-	4	-	-	4	-	-	4	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
Standard Diagnostics	-	4	-	-	4	-	1	3	-
VITROS									
3600/4600/5600/7600	-	4	-	-	4	-	-	4	-
VITROS ECI	-	1	-	-	1	-	-	1	-
Wantai BioPharm	-	1	-	-	1	-	-	1	-

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	109	-	-	108	-
Abbott Alinity	-	12	-	-	12	-
Abbott Architect	-	48	-	-	47	-
Abbott IMx	-	2	-	-	2	-
Abon (Alere) Biopharm	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-
DiaSorin	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	9	-	-	9	-
Roche cobas 8000/e801	-	5	-	-	5	-
Roche cobas e 411	-	7	-	-	7	-
SD Bioline	-	4	-	-	4	-
Siemens ADVIA	-	4	-	-	4	-
Siemens Atellica	-	1	-	-	1	-
Standard Diagnostics	-	4	-	-	4	-
VITROS						
3600/4600/5600/7600	-	4	-	-	4	-
VITROS ECI	-	1	-	-	1	-
Wantai BioPharm	-	1	-	-	1	-

Toxoplasma gondii Antibody (IgG) - Qualitative

<u>Method</u>	Specimen TOX-1			Specimen TOX-2		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	21	-	-	-	21	-
Abbott Architect	13	-	-	-	13	-
bioMerieux Vidas, Mini Vidas	2	-	-	-	2	-
DiaSorin	1	-	-	-	1	-
Roche cobas e 411	3	-	-	-	3	-
VITROS 3600/4600/5600/7600	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-1						
All Method	26	83.108	38.980	46.9	65.45	0.00 - 200.05
All Roche Instruments	6	153.400	17.053	11.1	155.00	102.24 - 204.56
Abbott Architect	15	60.613	7.807	12.9	61.20	37.19 - 84.04
Roche cobas e 411	5	156.933	19.008	12.1	167.20	99.91 - 213.96
Specimen TOX-2						
All Method	26	0.580	0.422	72.8	0.70	0.00 - 1.85
All Roche Instruments	6	0.130	0.001	0.0	0.13	0.12 - 0.14
Abbott Architect	15	0.780	0.281	36.0	0.80	0.00 - 1.63
Roche cobas 6000 / e 601	5	0.130	0.001	0.0	0.13	0.12 - 0.14

Toxoplasma gondii Antibody (IgM) - Qualitative

<u>Method</u>	Specimen TOX-1			Specimen TOX-2		
	<u>Positiv e</u>	<u>Negati ve</u>	<u>Equivoc al</u>	<u>Positiv e</u>	<u>Negativ e</u>	<u>Equivoc al</u>
ALL METHODS	22	1	-	1	22	-
Abbott Architect	14	-	-	-	14	-
bioMerieux Vidas, Mini Vidas	2	-	-	-	2	-
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
Roche cobas e 411	3	-	-	-	3	-
VITROS 3600/4600/5600/7600	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-1						
All Method	26	16.497	8.363	50.7	12.29	0.00 - 41.59
All Roche Instruments	6	30.682	0.922	3.0	30.46	27.91 - 33.45
Abbott Architect	15	11.968	1.000	8.4	11.78	8.96 - 14.97
Roche cobas e 411	5	30.553	1.143	3.7	30.46	27.12 - 33.99
Specimen TOX-2						
All Method	26	0.134	0.069	51.1	0.11	0.00 - 0.35
All Roche Instruments	6	0.232	0.032	13.8	0.23	0.13 - 0.33
Abbott Architect	15	0.089	0.026	29.0	0.10	0.01 - 0.17
Roche cobas e 411	5	0.215	0.013	6.0	0.22	0.17 - 0.26

Cytomegalovirus (CMV) Antibodies (IgG) - Qualitative

<u>Method</u>	Specimen CMV-1			Specimen CMV-2		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	17	-	17	-	-
Abbott Architect	-	14	-	14	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	-	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-1						
All Method	19	1.316	0.727	55.3	1.60	0.00 - 3.50
Abbott Architect	16	1.544	0.532	34.4	1.65	0.00 - 3.14
Specimen CMV-2						
All Method	14	70.814	9.083	12.8	69.10	43.56 - 98.07
Abbott Architect	14	70.814	9.083	12.8	69.10	43.56 - 98.07

Cytomegalovirus (CMV) Antibodies (IgM) - Qualitative

<u>Method</u>	Specimen CMV-1			Specimen CMV-2		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	21	-	21	-	-
Abbott Architect	-	18	-	18	-	-
Roche cobas 6000 / e 601	-	2	-	2	-	-
VITROS 3600/4600/5600/7600	-	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-1						
All Method	17	0.211	0.060	28.3	0.21	0.03 - 0.40
Abbott Architect	15	0.217	0.059	27.1	0.21	0.04 - 0.40
Specimen CMV-2						
All Method	17	5.552	1.496	27.0	5.55	1.06 - 10.05
Abbott Architect	15	5.350	1.076	20.1	5.55	2.12 - 8.58

Neonatal Bilirubin, Total (mg/dL)

<u>Method</u>	Specimen NB-1						Specimen NB-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	41	11.46	0.38	3.3	11.6	9.1 - 13.8	42	16.10	0.52	3.3	16.2	12.8 - 19.4
No Reagent Required												
Bilirubinometer / Reichart UNISTAT	35	11.53	0.36	3.1	11.6	9.2 - 13.9	35	16.19	0.48	2.9	16.3	12.9 - 19.5
All Chemistry Instruments	39	11.49	0.36	3.1	11.6	9.1 - 13.8	39	16.15	0.48	3.0	16.2	12.9 - 19.4
<u>Method</u>	Specimen NB-3						Specimen NB-4					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	42	5.86	0.33	5.7	5.9	4.6 - 7.1	43	17.97	0.78	4.3	18.1	14.3 - 21.6
No Reagent Required												
Bilirubinometer / Unistat	35	5.77	0.28	4.9	5.8	4.6 - 7.0	36	18.11	0.74	4.1	18.4	14.4 - 21.8
All Chemistry Instruments	39	5.82	0.31	5.4	5.8	4.6 - 7.0	40	17.98	0.81	4.5	18.3	14.3 - 21.6
<u>Method</u>	Specimen NB-5											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	39	0.01	0.04	460.5	0.0	0.0 - 0.5						
No Reagent Required												
Bilirubinometer / Unistat	36	0.00	0.01	0.0	0.0	0.0 - 0.4						
All Chemistry Instruments	36	0.00	0.01	0.0	0.0	0.0 - 0.4						

Bilirubin, Direct (mg/dL)

<u>Method</u>	Specimen NB-1						Specimen NB-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	10	4.73	0.76	16.1	4.6	3.1 - 6.3	10	5.64	0.73	12.9	5.4	4.1 - 7.1
<u>Method</u>	Specimen NB-3						Specimen NB-4					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	10	1.23	0.35	28.2	1.1	0.5 - 2.0	10	3.83	0.64	16.8	3.6	2.5 - 5.2
<u>Method</u>	Specimen NB-5											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	10	0.08	0.14	185.2	0.0	0.0 - 0.4						

Glycohemoglobin (percent)

<u>Method</u>	Specimen GH-1						Specimen GH-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	102	10.40	0.37	3.6	10.4	9.8 - 11.0	101	6.14	0.17	2.8	6.2	5.8 - 6.5
All Bio-Rad Methods	4	10.35	0.24	2.3	10.3	9.8 - 10.9	3	6.40	0.20	3.1	6.4	6.0 - 6.8
All Enzymatic A1c Methods	6	9.90	0.41	4.2	10.0	9.4 - 10.4	6	5.60	0.18	3.2	5.7	5.3 - 5.9
All Hemoglobin A1c Methods	97	10.42	0.37	3.6	10.4	9.8 - 11.0	98	6.15	0.16	2.5	6.2	5.8 - 6.5
All Roche Methods	7	10.26	0.28	2.7	10.3	9.7 - 10.8	8	6.00	0.17	2.8	6.0	5.7 - 6.3
All TOSOH Methods	14	10.07	0.11	1.1	10.1	9.5 - 10.6	14	6.07	0.11	1.8	6.1	5.7 - 6.4
Beckman AU A1c	6	9.87	0.37	3.7	10.1	9.3 - 10.4	6	6.07	0.08	1.3	6.1	5.7 - 6.4
Bio-Rad D-10 HbA1C	4	10.35	0.24	2.3	10.3	9.8 - 10.9	3	6.40	0.20	3.1	6.4	6.0 - 6.8
Roche cobas c501 HbA1c	4	10.13	0.29	2.8	10.3	9.6 - 10.7	4	5.98	0.21	3.5	6.0	5.6 - 6.3
Roche Integra A1C	3	10.43	0.15	1.5	10.4	9.9 - 11.0	4	6.03	0.15	2.5	6.0	5.7 - 6.4
Siemens DCA Vantage	49	10.69	0.24	2.3	10.7	10.1 - 11.3	50	6.19	0.14	2.3	6.2	5.8 - 6.6
Siemens Dimension HA1C	9	10.10	0.25	2.5	10.0	9.5 - 10.7	9	6.11	0.15	2.5	6.1	5.8 - 6.5
Siemens Dimension HB1C	4	10.23	0.10	0.9	10.3	9.7 - 10.8	4	6.23	0.13	2.0	6.2	5.9 - 6.6
TOSOH G8	14	10.07	0.11	1.1	10.1	9.5 - 10.6	14	6.07	0.11	1.8	6.1	5.7 - 6.4

Whole Blood Glucose (mg/dL)

<u>Method</u>	Specimen WBG-1						Specimen WBG-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	875	322.1	23.0	7.1	328	257 - 387	879	213.1	17.1	8.0	218	170 - 256
All Abbott Methods	55	305.1	33.2	10.9	303	244 - 367	55	197.7	19.3	9.8	197	158 - 238
All Bayer Methods	19	261.0	18.6	7.1	261	208 - 314	19	171.7	9.0	5.3	172	137 - 207
All Hemocue Methods	47	328.1	7.8	2.4	329	262 - 394	47	222.4	5.8	2.6	223	177 - 267
All Lifescan Methods	8	337.9	13.3	3.9	336	270 - 406	8	226.1	12.0	5.3	226	180 - 272
All Roche Methods	541	328.1	7.5	2.3	329	262 - 394	543	217.9	5.0	2.3	218	174 - 262
Abbott FreeStyle Freedom	10	300.8	28.3	9.4	296	240 - 361	10	194.2	9.4	4.9	196	155 - 234
Abbott FreeStyle Lite/Freedom Lite	6	316.5	3.5	1.1	318	253 - 380	6	206.2	4.6	2.2	206	164 - 248
Abbott FreeStyle Precision Pro	23	283.1	24.8	8.8	279	226 - 340	23	184.0	15.0	8.2	182	147 - 221
Abbott PreciS. Xtra/Optium	10	352.4	15.0	4.3	358	281 - 423	10	226.1	5.1	2.3	225	180 - 272
Abbott Precision XceedPro	6	306.3	20.9	6.8	301	245 - 368	6	199.7	14.6	7.3	198	159 - 240
Acon On Call	10	277.3	8.6	3.1	278	221 - 333	10	186.6	5.9	3.1	188	149 - 224
Arkray Platinum	19	331.9	8.2	2.5	330	265 - 399	19	224.5	3.7	1.6	222	179 - 270
Bayer Contour / Plus	21	259.9	15.9	6.1	261	207 - 312	21	172.0	8.9	5.2	172	137 - 207
CareSens	15	362.4	15.4	4.2	366	289 - 435	15	265.4	9.6	3.6	266	212 - 319
HemoCue Glucose 201	51	328.4	7.7	2.4	329	262 - 395	51	222.8	6.0	2.7	223	178 - 268
Home Diagnostics True Balance / TrueTrack	9	565.9	41.2	7.3	589	452 - 680	11	477.5	16.8	3.5	480	381 - 573
Lifescan One Touch Ultra	26	359.0	16.4	4.6	368	287 - 431	26	239.8	12.0	5.0	247	191 - 288
Medline EvenCare G2 / G3	16	300.3	42.7	14.2	294	240 - 361	18	207.4	23.9	11.5	208	165 - 249
NOVA Biomedical StatStrip	32	274.8	12.4	4.5	275	219 - 330	32	178.7	6.6	3.7	179	142 - 215
Quintet / AC	29	339.9	15.1	4.4	339	271 - 408	29	221.6	9.2	4.2	221	177 - 266
Roche Accu-Chek Inform	10	328.1	6.0	1.8	330	262 - 394	10	217.4	6.8	3.1	218	173 - 261
Roche Accu-Chek Inform II	358	328.0	7.3	2.2	328	262 - 394	358	217.7	5.0	2.3	218	174 - 262
Roche Accu-Chek Performa	170	328.6	7.7	2.3	329	262 - 395	169	218.8	4.3	2.0	220	175 - 263
True Metrix Pro	43	291.2	17.9	6.1	288	232 - 350	42	186.7	7.9	4.2	187	149 - 225

Whole Blood Glucose (mg/dL) (continued)

<u>Method</u>	<u>Specimen WBG-3</u>						<u>Specimen WBG-4</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	141	330.2	37.8	11.4	330	264 - 397	141	172.5	18.6	10.8	174	137 - 207
All Abbott Methods	10	307.8	12.1	3.9	307	246 - 370	10	151.1	5.9	3.9	150	120 - 182
All Lifescan Methods	3	-	-	-	366	293 - 441	3	-	-	-	182	145 - 219
All Roche Methods	77	329.9	11.8	3.6	331	263 - 396	75	175.1	4.2	2.4	175	140 - 211
Abbott FreeStyle Freedom	10	307.8	12.1	3.9	307	246 - 370	10	151.1	5.9	3.9	150	120 - 182
Acon On Call	10	264.1	5.5	2.1	265	211 - 317	10	150.3	5.5	3.6	148	120 - 181
CareSens	5	402.8	11.5	2.9	398	322 - 484	5	214.2	5.1	2.4	212	171 - 258
Lifescan One Touch Ultra	21	386.2	13.0	3.4	392	308 - 464	21	194.0	7.1	3.7	194	155 - 233
NOVA Biomedical StatStrip	10	290.9	6.3	2.2	292	232 - 350	10	146.1	3.1	2.1	147	116 - 176
Roche Accu-Chek Inform	10	339.9	12.2	3.6	337	271 - 408	10	176.8	4.4	2.5	177	141 - 213
Roche Accu-Chek Inform II	60	330.2	6.6	2.0	331	264 - 397	59	174.6	3.5	2.0	174	139 - 210
Roche Accu-Chek Performa	12	295.9	28.0	9.5	283	236 - 356	12	157.1	16.3	10.4	147	125 - 189
True Metrix Pro	2	-	-	-	322	257 - 387	2	-	-	-	169	134 - 203

<u>Method</u>	<u>Specimen WBG-5</u>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	141	103.0	11.1	10.8	106	82 - 124
All Abbott Methods	10	86.9	4.9	5.7	86	69 - 105
All Lifescan Methods	3	-	-	-	105	84 - 127
All Roche Methods	75	106.3	2.3	2.2	106	85 - 128
Abbott FreeStyle Freedom	10	86.9	4.9	5.7	86	69 - 105
Acon On Call	10	90.6	2.8	3.1	90	72 - 109
CareSens	5	129.8	4.0	3.1	128	103 - 156
Lifescan One Touch Ultra	21	111.3	4.3	3.9	111	89 - 134
NOVA Biomedical StatStrip	10	86.4	3.4	4.0	87	69 - 104
Roche Accu-Chek Inform	10	106.8	1.9	1.8	107	85 - 129
Roche Accu-Chek Inform II	60	106.3	2.2	2.1	106	85 - 128
Roche Accu-Chek Performa	12	94.9	10.8	11.4	92	75 - 114
True Metrix Pro	2	-	-	-	92	73 - 110

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