

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

International Data Supplement
2018 MLE-M3



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Table of Contents

Evaluation Criteria	4
Hematology	
Hematology with 5-part Automated Differential (CL Samples – Module 223).....	5
White Blood Cell Count.....	5
Red Blood Cell Count	6
Hemoglobin.....	7
Hematocrit	8
Platelet Count	9
Automated Differential	10
Blood Bank	
ABO Group	15
Rh Factor (D Type).....	15
Unexpected Antibody Detection.....	16
Antibody Identification	16
Compatibility Testing.....	17
Coagulation	
Prothrombin Time	18
International Normalized Ratio (INR)	21
Activated Partial Thromboplastin Time.....	24
Fibrinogen	26
Urinalysis	
Urinalysis Dipstick.....	27
Specific Gravity	27
pH	28
Protein	29
Glucose.....	30
Ketones.....	31
Bilirubin	32
Urobilinogen.....	33
Blood or Hemoglobin	34
Leukocyte Esterase	35
Nitrite	36
Microalbumin (Dipstick Only)	37
Urine hCG	37
Microbiology	
Miscellaneous Cultures	38
Antimicrobial Susceptibility Testing	40
Parasitology (PA Specimens)	42
Parasitology (FP Specimens).....	44

Table of Contents (cont'd)

Immunology

Antinuclear Antibody.....	49
Qualitative.....	49
Semi-Quantitative	49
Anti-dsDNA.....	51
Anti-RNP	51
Anti-RNP/Sm.....	52
Anti-SSA	52
Anti-SSB	53
Anti-SSA/SSB.....	53
Anti-Sm	54
Rubella.....	55
Qualitative.....	55
Quantitative.....	56
Syphilis Serology.....	57
VDRL Slide	57
VDRL Slide (Titer).....	58
MHA-TP	60
TPA.....	61
RPR	62
RPR (Titer).....	63
Viral Markers	66
Anti-HBc (IgM)	66
Anti-HBc (Total/IgG).....	67
Anti-HIV	68
Anti-HAV (IgM).....	70
Anti-HAV (Total/IgG).....	71
HBeAg	72
Anti-HBs	73
HBsAg	74
Anti-HCV.....	75
Toxoplasma gondii	76
Qualitative (IgG).....	76
Quantitative (IgG)	76
Qualitative (IgM)	77
Quantitative (IgM)	77
Cytomegalovirus (CMV)	78
Qualitative (IgG).....	78
Quantitative (IgG)	78
Qualitative (IgM)	79
Quantitative (IgM)	79
Chemistry	
Glycohemoglobin (GH Specimens).....	79
CK-MB	80

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	$\pm 15\%$
Automated Differential	± 3 SD
CK-MB (U/L)	± 3 SD
Cytomegalovirus	± 2 SD
Fibrinogen	$\pm 20\%$
Glycohemoglobin	$\pm 6\%$
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)

<u>Instrument</u>	Specimen CL-11						Specimen CL-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	44	18.92	1.66	8.8	18.6	16.0 - 21.8	42	6.81	0.63	9.3	6.6	5.7 - 7.9
All Abbott Cell-Dyn Instruments	16	20.50	0.47	2.3	20.5	17.4 - 23.6	16	7.54	0.25	3.3	7.5	6.4 - 8.7
Abbott Cell-Dyn Ruby	13	20.57	0.43	2.1	20.6	17.4 - 23.7	13	7.56	0.26	3.5	7.5	6.4 - 8.7
Orphee Mythic 22	26	17.86	0.77	4.3	17.9	15.1 - 20.6	24	6.34	0.21	3.3	6.4	5.3 - 7.3
Specimen CL-13							Specimen CL-14					
All Method	43	2.77	0.42	15.1	2.6	2.3 - 3.2	43	18.84	1.69	9.0	18.4	16.0 - 21.7
All Abbott Cell-Dyn Instruments	16	3.26	0.14	4.3	3.3	2.7 - 3.8	16	20.49	0.52	2.5	20.5	17.4 - 23.6
Abbott Cell-Dyn Ruby	13	3.27	0.15	4.6	3.3	2.7 - 3.8	13	20.57	0.51	2.5	20.7	17.4 - 23.7
Orphee Mythic 22	26	2.48	0.18	7.2	2.4	2.1 - 2.9	25	17.69	0.81	4.6	17.8	15.0 - 20.4
Specimen CL-15												
All Method	43	2.80	0.48	17.0	2.6	2.3 - 3.3						
All Abbott Cell-Dyn Instruments	16	3.38	0.18	5.4	3.4	2.8 - 3.9						
Abbott Cell-Dyn Ruby	13	3.39	0.19	5.7	3.4	2.8 - 4.0						
Orphee Mythic 22	26	2.47	0.15	6.3	2.5	2.0 - 2.9						

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

<i>Instrument</i>	Specimen CL-11						Specimen CL-12					
	<i>Labs</i>	<i>Mean</i>	<i>SD</i>	<i>CV</i>	<i>Median</i>	<i>Range</i>	<i>Labs</i>	<i>Mean</i>	<i>SD</i>	<i>CV</i>	<i>Median</i>	<i>Range</i>
All Method	45	5.136	0.162	3.2	5.09	4.82 - 5.45	44	4.498	0.133	3.0	4.48	4.22 - 4.77
All Abbott Cell-Dyn Instruments	16	5.243	0.129	2.5	5.25	4.92 - 5.56	16	4.606	0.083	1.8	4.62	4.32 - 4.89
Abbott Cell-Dyn Ruby	13	5.249	0.144	2.7	5.26	4.93 - 5.57	13	4.604	0.089	1.9	4.61	4.32 - 4.89
Orpheo Mythic 22	25	5.042	0.080	1.6	5.04	4.73 - 5.35	25	4.436	0.076	1.7	4.43	4.17 - 4.71
Specimen CL-13							Specimen CL-14					
All Method	44	1.983	0.059	3.0	1.97	1.86 - 2.11	45	5.115	0.161	3.1	5.07	4.80 - 5.43
All Abbott Cell-Dyn Instruments	16	2.019	0.043	2.1	2.03	1.89 - 2.15	16	5.237	0.105	2.0	5.26	4.92 - 5.56
Abbott Cell-Dyn Ruby	13	2.018	0.047	2.3	2.02	1.89 - 2.14	13	5.249	0.113	2.2	5.27	4.93 - 5.57
Orpheo Mythic 22	26	1.957	0.046	2.4	1.96	1.83 - 2.08	26	5.018	0.086	1.7	5.02	4.71 - 5.32
Specimen CL-15												
All Method	44	1.982	0.057	2.9	1.98	1.86 - 2.11						
All Abbott Cell-Dyn Instruments	16	2.026	0.032	1.6	2.04	1.90 - 2.15						
Abbott Cell-Dyn Ruby	13	2.022	0.035	1.7	2.02	1.90 - 2.15						
Orpheo Mythic 22	26	1.950	0.041	2.1	1.96	1.83 - 2.07						

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

<u>Instrument</u>	Specimen CL-11						Specimen CL-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	45	15.72	0.72	4.6	15.4	14.6 - 16.9	44	12.44	0.82	6.6	12.1	11.5 - 13.4
All Abbott Cell-Dyn Instruments	16	16.51	0.42	2.5	16.5	15.3 - 17.7	16	13.42	0.29	2.1	13.4	12.4 - 14.4
Abbott Cell-Dyn Ruby	13	16.56	0.45	2.7	16.7	15.4 - 17.8	13	13.40	0.28	2.1	13.4	12.4 - 14.4
Orphee Mythic 22	27	15.22	0.30	2.0	15.3	14.1 - 16.3	26	11.89	0.32	2.7	11.9	11.0 - 12.8
Specimen CL-13							Specimen CL-14					
All Method	45	5.13	0.42	8.2	5.0	4.7 - 5.5	45	15.64	0.75	4.8	15.4	14.5 - 16.8
All Abbott Cell-Dyn Instruments	16	5.59	0.11	2.0	5.6	5.2 - 6.0	16	16.46	0.38	2.3	16.6	15.3 - 17.7
Abbott Cell-Dyn Ruby	13	5.57	0.10	1.9	5.5	5.1 - 6.0	13	16.48	0.41	2.5	16.6	15.3 - 17.7
Orphee Mythic 22	27	4.82	0.12	2.6	4.8	4.4 - 5.2	27	15.13	0.39	2.6	15.1	14.0 - 16.2
Specimen CL-15												
All Method	45	5.11	0.44	8.5	4.9	4.7 - 5.5						
All Abbott Cell-Dyn Instruments	16	5.59	0.18	3.2	5.6	5.2 - 6.0						
Abbott Cell-Dyn Ruby	13	5.55	0.15	2.7	5.6	5.1 - 6.0						
Orphee Mythic 22	27	4.79	0.13	2.6	4.8	4.4 - 5.2						

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

<i>Instrument</i>	Specimen CL-11						Specimen CL-12					
	<i>Labs</i>	<i>Mean</i>	<i>SD</i>	<i>CV</i>	<i>Median</i>	<i>Range</i>	<i>Labs</i>	<i>Mean</i>	<i>SD</i>	<i>CV</i>	<i>Median</i>	<i>Range</i>
All Method	44	45.16	1.98	4.4	45.2	42.4 - 47.9	43	38.45	1.38	3.6	38.8	36.1 - 40.8
All Abbott Cell-Dyn Instruments	16	43.72	2.17	5.0	43.7	41.0 - 46.4	15	37.35	1.06	2.8	37.6	35.1 - 39.6
Abbott Cell-Dyn Ruby	13	43.21	1.44	3.3	43.3	40.6 - 45.9	13	37.32	1.14	3.1	37.6	35.0 - 39.6
Orpheo Mythic 22	27	46.07	1.24	2.7	46.0	43.3 - 48.9	26	39.14	1.13	2.9	39.0	36.7 - 41.5
Specimen CL-13							Specimen CL-14					
All Method	44	15.75	0.83	5.3	15.7	14.8 - 16.7	43	44.83	1.76	3.9	44.9	42.1 - 47.6
All Abbott Cell-Dyn Instruments	15	14.93	0.35	2.4	15.0	14.0 - 15.9	15	43.29	1.12	2.6	43.9	40.6 - 45.9
Abbott Cell-Dyn Ruby	13	14.90	0.36	2.4	15.0	14.0 - 15.8	13	43.32	1.21	2.8	44.0	40.7 - 46.0
Orpheo Mythic 22	27	16.17	0.60	3.7	16.3	15.1 - 17.2	26	45.54	1.15	2.5	45.5	42.8 - 48.3
Specimen CL-15												
All Method	44	15.75	0.76	4.8	15.7	14.8 - 16.7						
All Abbott Cell-Dyn Instruments	15	14.97	0.33	2.2	15.0	14.0 - 15.9						
Abbott Cell-Dyn Ruby	13	14.93	0.34	2.3	15.0	14.0 - 15.9						
Orpheo Mythic 22	27	16.11	0.51	3.1	15.9	15.1 - 17.1						

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

<u>Instrument</u>	Specimen CL-11						Specimen CL-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	45	516.2	37.2	7.2	513	387 - 646	44	278.3	24.9	9.0	271	208 - 348
All Abbott Cell-Dyn Instruments	16	484.8	20.3	4.2	481	363 - 607	16	257.6	10.5	4.1	259	193 - 323
Abbott Cell-Dyn Ruby	13	483.5	21.1	4.4	479	362 - 605	13	256.8	11.4	4.4	256	192 - 321
Orphee Mythic 22	27	533.5	33.1	6.2	535	400 - 667	26	289.6	22.8	7.9	295	217 - 363
Specimen CL-13						Specimen CL-14						
All Method	44	97.1	14.4	14.8	100	72 - 122	43	514.7	39.8	7.7	507	386 - 644
All Abbott Cell-Dyn Instruments	16	82.3	5.0	6.0	83	61 - 103	15	483.9	19.1	3.9	484	362 - 605
Abbott Cell-Dyn Ruby	13	82.0	5.0	6.1	82	61 - 103	12	485.3	20.3	4.2	487	363 - 607
Orphee Mythic 22	26	105.7	10.8	10.2	105	79 - 133	26	530.3	38.5	7.3	530	397 - 663
Specimen CL-15												
All Method	45	97.6	15.2	15.5	101	73 - 123						
All Abbott Cell-Dyn Instruments	16	80.8	5.4	6.7	81	60 - 102						
Abbott Cell-Dyn Ruby	13	80.2	5.6	7.0	79	60 - 101						
Orphee Mythic 22	27	107.1	10.0	9.4	107	80 - 134						

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

<u>Instrument</u>	Specimen CL-11						Specimen CL-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	43	75.33	3.14	4.2	75.1	65.9 - 84.8	42	65.85	2.33	3.5	65.6	58.8 - 72.9
All Abbott Cell-Dyn Instruments	16	78.74	0.70	0.9	78.7	76.6 - 80.9	16	68.24	0.59	0.9	68.2	66.4 - 70.1
Abbott Cell-Dyn Ruby	13	78.93	0.59	0.7	78.9	77.1 - 80.7	13	68.34	0.59	0.9	68.2	66.5 - 70.2
Orphee Mythic 22	26	73.37	2.09	2.8	74.0	67.1 - 79.7	25	64.37	1.70	2.6	64.5	59.2 - 69.5
Specimen CL-13							Specimen CL-14					
All Method	44	50.99	2.07	4.1	51.3	44.7 - 57.2	43	75.20	3.24	4.3	75.2	65.4 - 85.0
All Abbott Cell-Dyn Instruments	16	52.82	1.12	2.1	52.9	49.4 - 56.2	15	78.67	1.03	1.3	78.6	75.5 - 81.8
Abbott Cell-Dyn Ruby	13	52.85	1.03	2.0	52.8	49.7 - 56.0	13	78.72	1.10	1.4	79.2	75.4 - 82.1
Orphee Mythic 22	27	50.02	1.70	3.4	50.2	44.9 - 55.2	26	73.52	2.32	3.2	74.3	66.5 - 80.5
Specimen CL-15												
All Method	44	51.20	2.55	5.0	51.0	43.5 - 58.9						
All Abbott Cell-Dyn Instruments	16	53.66	1.69	3.1	53.5	48.5 - 58.8						
Abbott Cell-Dyn Ruby	13	53.66	1.77	3.3	53.5	48.3 - 59.0						
Orphee Mythic 22	26	50.12	1.31	2.6	50.2	46.1 - 54.1						

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

Instrument	Specimen CL-11						Specimen CL-12					
	Labs	Mean	SD	CV	Median	Range	Labs	Mean	SD	CV	Median	Range
All Method	44	13.63	2.48	18.2	14.0	6.1 - 21.1	44	19.17	4.91	25.6	20.8	4.4 - 33.9
All Abbott Cell-Dyn Instruments	16	14.61	0.69	4.7	14.8	12.5 - 16.7	16	23.10	1.03	4.5	23.4	20.0 - 26.2
Abbott Cell-Dyn Ruby	13	14.47	0.63	4.4	14.7	12.5 - 16.4	13	23.13	1.07	4.6	23.3	19.9 - 26.4
Orphee Mythic 22	27	13.56	3.58	26.4	13.5	2.8 - 24.3	26	17.03	5.00	29.4	17.2	2.0 - 32.1
Specimen CL-13												
All Method	45	31.11	6.52	20.9	32.0	11.5 - 50.7	44	13.61	2.63	19.3	13.7	5.7 - 21.6
All Abbott Cell-Dyn Instruments	16	37.21	2.02	5.4	37.9	31.1 - 43.3	16	14.58	1.22	8.3	14.5	10.9 - 18.3
Abbott Cell-Dyn Ruby	13	37.35	1.63	4.4	37.8	32.4 - 42.3	13	14.52	1.32	9.1	14.6	10.5 - 18.5
Orphee Mythic 22	27	28.21	5.34	18.9	29.5	12.1 - 44.3	27	13.57	3.75	27.6	13.3	2.3 - 24.9
Specimen CL-15												
All Method	45	30.68	6.49	21.1	31.3	11.2 - 50.2						
All Abbott Cell-Dyn Instruments	16	36.01	2.41	6.7	36.4	28.7 - 43.3						
Abbott Cell-Dyn Ruby	13	35.90	2.61	7.3	36.1	28.0 - 43.8						
Orphee Mythic 22	27	28.16	5.98	21.2	29.6	10.2 - 46.1						

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

<u>Instrument</u>	Specimen CL-11						Specimen CL-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	44	7.08	3.93	55.5	8.1	0.0 - 18.9	43	10.29	5.36	52.1	11.2	0.0 - 26.4
All Abbott Cell-Dyn Instruments	16	2.32	0.27	11.6	2.3	1.5 - 3.2	15	3.73	0.58	15.7	3.8	1.9 - 5.5
Abbott Cell-Dyn Ruby	13	2.27	0.26	11.3	2.2	1.5 - 3.1	12	3.58	0.54	15.1	3.7	1.9 - 5.3
Orpheo Mythic 22	27	9.70	1.84	18.9	9.5	4.1 - 15.3	27	13.76	2.83	20.6	13.2	5.2 - 22.3
Specimen CL-13							Specimen CL-14					
All Method	44	14.65	6.68	45.6	16.0	0.0 - 34.7	44	6.89	3.86	56.1	8.1	0.0 - 18.5
All Abbott Cell-Dyn Instruments	16	7.19	1.36	18.9	7.2	3.1 - 11.3	16	2.48	0.43	17.4	2.4	1.1 - 3.8
Abbott Cell-Dyn Ruby	13	6.88	0.92	13.4	7.1	4.1 - 9.7	13	2.52	0.46	18.2	2.4	1.1 - 4.0
Orpheo Mythic 22	27	18.77	4.29	22.8	17.7	5.9 - 31.7	26	9.60	1.83	19.1	9.2	4.1 - 15.1
Specimen CL-15												
All Method	43	15.14	6.77	44.8	15.6	0.0 - 35.5						
All Abbott Cell-Dyn Instruments	15	7.52	0.80	10.6	7.3	5.1 - 10.0						
Abbott Cell-Dyn Ruby	12	7.55	0.88	11.7	7.4	4.8 - 10.3						
Orpheo Mythic 22	27	19.08	4.67	24.5	18.8	5.0 - 33.1						

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

Instrument	Specimen CL-11						Specimen CL-12					
	Labs	Mean	SD	CV	Median	Range	Labs	Mean	SD	CV	Median	Range
All Method	44	3.28	1.16	35.3	3.7	0.0 - 6.8	43	4.50	1.26	28.0	4.5	0.7 - 8.3
All Abbott Cell-Dyn Instruments	17	4.03	0.24	5.9	4.0	3.3 - 4.8	17	4.59	0.42	9.1	4.5	3.3 - 5.9
Abbott Cell-Dyn Ruby	13	4.03	0.22	5.5	4.0	3.3 - 4.7	13	4.62	0.26	5.5	4.5	3.8 - 5.4
Orpheo Mythic 22	26	2.82	1.28	45.4	2.7	0.0 - 6.7	25	4.44	1.63	36.7	4.6	0.0 - 9.4
Specimen CL-13							Specimen CL-14					
All Method	44	2.35	0.56	24.0	2.4	0.6 - 4.1	44	3.35	1.17	34.8	3.8	0.0 - 6.9
All Abbott Cell-Dyn Instruments	17	2.26	0.37	16.3	2.3	1.1 - 3.4	17	4.03	0.34	8.4	4.0	3.0 - 5.1
Abbott Cell-Dyn Ruby	13	2.38	0.30	12.6	2.4	1.4 - 3.3	13	4.02	0.33	8.3	4.0	3.0 - 5.1
Orpheo Mythic 22	26	2.40	0.67	28.0	2.4	0.3 - 4.5	26	2.94	1.32	44.7	3.1	0.0 - 6.9
Specimen CL-15												
All Method	43	2.27	0.65	28.8	2.4	0.3 - 4.3						
All Abbott Cell-Dyn Instruments	17	2.39	0.38	15.7	2.4	1.2 - 3.6						
Abbott Cell-Dyn Ruby	13	2.48	0.33	13.2	2.4	1.4 - 3.5						
Orpheo Mythic 22	26	2.28	0.92	40.5	2.4	0.0 - 5.1						

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

Instrument	Specimen CL-11						Specimen CL-12					
	Labs	Mean	SD	CV	Median	Range	Labs	Mean	SD	CV	Median	Range
All Method	42	0.46	0.41	89.1	0.3	0.0 - 1.8	44	0.35	0.26	75.0	0.3	0.0 - 1.2
All Abbott Cell-Dyn Instruments	16	0.16	0.07	46.6	0.2	0.0 - 0.4	16	0.14	0.15	107.7	0.1	0.0 - 0.7
Abbott Cell-Dyn Ruby	13	0.15	0.07	45.2	0.2	0.0 - 0.4	13	0.15	0.17	111.4	0.1	0.0 - 0.7
Orpheo Mythic 22	27	0.86	0.69	80.5	0.7	0.0 - 3.0	26	0.48	0.23	46.9	0.5	0.0 - 1.2
Specimen CL-13						Specimen CL-14						
All Method	44	0.40	0.34	85.3	0.3	0.0 - 1.5	43	0.54	0.50	92.7	0.4	0.0 - 2.1
All Abbott Cell-Dyn Instruments	16	0.11	0.11	100.0	0.1	0.0 - 0.5	15	0.12	0.08	64.5	0.1	0.0 - 0.4
Abbott Cell-Dyn Ruby	13	0.09	0.08	82.3	0.1	0.0 - 0.4	12	0.13	0.08	58.4	0.1	0.0 - 0.4
Orpheo Mythic 22	26	0.57	0.32	55.1	0.5	0.0 - 1.6	27	0.93	0.68	73.3	0.9	0.0 - 3.0
Specimen CL-15												
All Method	44	0.38	0.30	78.5	0.3	0.0 - 1.3						
All Abbott Cell-Dyn Instruments	16	0.15	0.20	133.3	0.1	0.0 - 0.8						
Abbott Cell-Dyn Ruby	13	0.14	0.22	157.5	0.0	0.0 - 0.8						
Orpheo Mythic 22	26	0.53	0.27	50.5	0.5	0.0 - 1.4						

BLOOD BANK

ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Group O	40	100%	Acceptable
BB-12	Group AB	40	100%	Acceptable
BB-13	Group B	40	100%	Acceptable
BB-14	Group A	40	100%	Acceptable
BB-15	Group O	40	100%	Acceptable

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Rh Positive	40	100%	Acceptable
BB-12	Rh Positive	40	100%	Acceptable
BB-13	Rh Negative	40	100%	Acceptable
BB-14	Rh Positive	40	100%	Acceptable
BB-15	Rh Positive	40	100%	Acceptable

BLOOD BANK

UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	No unexpected antibody detected	22	95.65%	Acceptable
	Unexpected antibody detected	1	4.35%	
AB-12	Unexpected antibody detected	22	95.65%	Acceptable
	No unexpected antibody detected	1	4.35%	
AB-13	Unexpected antibody detected	23	100%	Acceptable
AB-14	No unexpected antibody detected	22	95.65%	Acceptable
	Unexpected antibody detected	1	4.35%	
AB-15	No unexpected antibody detected	22	95.65%	Acceptable
	Unexpected antibody detected	1	4.35%	

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	No antibody detected	13	100%	Acceptable
AB-12	Anti-Fy ^a	13	100%	Acceptable
AB-13	Anti-Jk ^a	13	100%	Acceptable
AB-14	No antibody detected	13	100%	Acceptable
AB-15	No antibody detected	13	100%	Acceptable

BLOOD BANK

COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	Compatible	24	96.00%	Acceptable
	Not Compatible	1	4.00%	
AB-12	Not Compatible	23	92.00%	Acceptable
	Compatible	2	8.00%	
AB-13	Compatible	22	88.00%	Acceptable
	Not Compatible	3	12.00%	
AB-14	Compatible	23	92.00%	Acceptable
	Not Compatible	2	8.00%	
AB-15	Compatible	24	96.00%	Acceptable
	Not Compatible	1	4.00%	

Coagulation

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	80	13.33	1.47	11.0	13.5	11.3 - 15.4	77	12.29	1.28	10.4	12.3	10.4 - 14.2
Dade Innovin												
Dade Behring BFT II	5	11.18	0.88	7.8	11.1	9.4 - 12.9	5	10.10	0.14	1.4	10.2	8.5 - 11.7
Sysmex CA-500/600 series	19	11.84	0.58	4.9	11.7	10.0 - 13.7	18	11.09	0.27	2.4	11.2	9.4 - 12.8
All Coagulation Instruments	26	11.76	0.69	5.8	11.7	9.9 - 13.6	25	10.99	0.50	4.6	11.1	9.3 - 12.7
Dade Thromborel S												
All Coagulation Instruments	5	16.40	1.70	10.3	16.4	13.9 - 18.9	4	-	-	-	10.9	9.2 - 12.6
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STA Compact	5	14.45	0.49	3.4	14.5	12.2 - 16.7	5	13.55	0.21	1.6	13.6	11.5 - 15.6
Diagnostica Stago STart 4/8	6	14.28	0.80	5.6	14.2	12.1 - 16.5	6	13.08	0.48	3.7	13.2	11.1 - 15.1
RAL Clot-SP	19	14.62	0.59	4.1	14.5	12.4 - 16.9	19	13.71	0.49	3.6	13.6	11.6 - 15.8
All Coagulation Instruments	32	14.52	0.61	4.2	14.4	12.3 - 16.8	32	13.58	0.51	3.8	13.5	11.5 - 15.7
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	14.20	0.14	1.0	14.2	12.0 - 16.4	5	13.20	0.14	1.1	13.2	11.2 - 15.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	12.90	0.85	6.6	12.7	10.9 - 14.9	6	11.33	0.35	3.1	11.5	9.6 - 13.1
IL TEST PT Fibrinogen												
IL ACL, all models	6	13.25	0.23	1.7	13.3	11.2 - 15.3	6	12.35	0.31	2.5	12.3	10.4 - 14.3
IL TEST PT-FIB HS PLUS												
IL ACL, all models	5	15.05	0.92	6.1	15.1	12.7 - 17.4	5	13.45	0.21	1.6	13.5	11.4 - 15.5
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	13.65	0.49	3.6	13.7	11.6 - 15.7	5	12.45	1.48	11.9	12.5	10.5 - 14.4

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-13						Specimen CG-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	51	32.96	5.13	15.6	34.0	28.0 - 38.0	79	29.01	4.36	15.0	30.0	24.6 - 33.4
Dade Innovin												
Dade Behring BFT II	5	25.05	2.67	10.7	25.6	21.2 - 28.9	5	27.35	1.30	4.7	27.4	23.2 - 31.5
Sysmex CA-500/600 series	1	-	-	-	20.6	17.5 - 23.7	19	25.92	0.90	3.5	25.7	22.0 - 29.9
All Coagulation Instruments	6	24.16	3.05	12.6	24.1	20.5 - 27.8	32	26.25	1.09	4.1	26.0	22.3 - 30.2
Diag Stago STA Neoplastine Cl+												
Diagnostica Stago STA Compact	4	-	-	-	28.8	24.4 - 33.2	5	31.05	1.34	4.3	31.1	26.3 - 35.8
Diagnostica Stago STart 4/8												
RAL Clot-SP	5	33.75	3.89	11.5	33.8	28.6 - 38.9	5	34.70	0.57	1.6	34.7	29.4 - 40.0
All Coagulation Instruments	6	35.00	0.91	2.6	35.2	29.7 - 40.3	6	33.43	1.96	5.9	32.3	28.4 - 38.5
Diagnostica Stago Neoplastine CI Plus	19	35.42	3.18	9.0	35.7	30.1 - 40.8	19	33.11	1.75	5.3	32.9	28.1 - 38.1
Diagnostica Stago STA Compact	25	35.70	2.33	6.5	35.7	30.3 - 41.1	25	33.43	1.83	5.5	33.3	28.4 - 38.5
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	37.45	0.21	0.6	37.5	31.8 - 43.1	5	32.80	0.42	1.3	32.8	27.8 - 37.8
IL TEST PT Fibrinogen												
IL ACL, all models	6	29.25	2.17	7.4	29.3	24.8 - 33.7	6	32.80	0.94	2.9	32.9	27.8 - 37.8
IL TEST PT-FIB HS PLUS												
IL ACL, all models	5	28.90	1.71	5.9	28.4	24.5 - 33.3	5	21.78	0.69	3.1	21.6	18.5 - 25.1
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	40.10	0.71	1.8	40.1	34.0 - 46.2	5	31.55	0.21	0.7	31.6	26.8 - 36.3
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	25.25	2.47	9.8	25.3	21.4 - 29.1	5	20.05	1.63	8.1	20.1	17.0 - 23.1

PROTHROMBIN TIME (seconds)

Specimen CG-15

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	49	32.52	6.57	20.2	31.8	27.6 - 37.4
Dade Innovin						
Dade Behring BFT II	5	27.47	1.86	6.8	26.6	23.3 - 31.6
Sysmex CA-500/600 series	6	20.27	1.57	7.7	20.8	17.2 - 23.4
All Coagulation Instruments	13	23.67	3.90	16.5	22.5	20.1 - 27.3
Diag Stago STA Neoplastine Cl+						
Diagnostica Stago STA Compact	5	42.10	1.98	4.7	42.1	35.7 - 48.5
Diagnostica Stago STArt 4/8	6	36.63	2.66	7.2	35.1	31.1 - 42.2
RAL Clot-SP	16	37.55	3.08	8.2	38.1	31.9 - 43.2
All Coagulation Instruments	32	37.49	3.54	9.5	38.1	31.8 - 43.2
Diagnostica Stago Neoplastine Cl Plus						
Diagnostica Stago STA Compact	5	28.75	0.07	0.2	28.8	24.4 - 33.1
HemosIL RecombiPlasTin 2G						
IL ACL, all models	6	30.90	1.60	5.2	30.2	26.2 - 35.6
IL TEST PT Fibrinogen						
IL ACL, all models	6	25.63	2.93	11.4	25.4	21.7 - 29.5
IL TEST PT-FIB HS PLUS						
IL ACL, all models	4	-	-	-	27.5	27.6 - 37.4
PH/CMS Thromboplastin-D						
All Coagulation Instruments	5	30.75	0.07	0.2	30.8	26.1 - 35.4

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	76	1.15	0.10	8.8	1.2	0.9 - 1.4	74	1.05	0.08	7.9	1.0	0.8 - 1.3
Dade Innovin												
Dade Behring BFT II	5	1.20	0.08	6.8	1.2	0.9 - 1.5	5	1.10	0.01	0.0	1.1	0.8 - 1.4
Sysmex CA-500/600 series	19	1.16	0.08	6.5	1.2	0.9 - 1.4	18	1.10	0.05	4.4	1.1	0.8 - 1.4
All Coagulation Instruments	26	1.17	0.07	6.4	1.2	0.9 - 1.4	25	1.10	0.05	4.1	1.1	0.8 - 1.4
Dade Thromborel S												
All Coagulation Instruments	5	1.30	0.14	10.9	1.3	1.0 - 1.6	5	1.10	0.28	25.7	1.1	0.8 - 1.4
Diag Stago STA Neoplastine Cl+												
Diagnostica Stago STA Compact	5	1.10	0.14	12.9	1.1	0.8 - 1.4	5	1.05	0.07	6.7	1.1	0.8 - 1.3
Diagnostica Stago STart 4/8	6	1.27	0.06	4.6	1.3	1.0 - 1.6	6	1.13	0.12	10.2	1.2	0.9 - 1.4
RAL Clot-SP	17	1.15	0.06	5.4	1.1	0.9 - 1.4	17	1.04	0.06	5.9	1.0	0.8 - 1.3
All Coagulation Instruments	32	1.16	0.08	6.9	1.2	0.9 - 1.4	32	1.05	0.07	7.0	1.0	0.8 - 1.3
Diagnostica Stago Neoplastine Cl Plus												
Diagnostica Stago STA Compact	5	1.10	0.01	0.0	1.1	0.8 - 1.4	5	1.00	0.01	0.0	1.0	0.8 - 1.2
All Coagulation Instruments	6	1.10	0.01	0.0	1.1	0.8 - 1.4	6	1.00	0.01	0.0	1.0	0.8 - 1.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	1.08	0.13	11.7	1.1	0.8 - 1.3	5	0.98	0.05	5.1	1.0	0.7 - 1.2
IL TEST PT Fibrinogen												
IL ACL, all models	6	1.23	0.05	4.2	1.2	0.9 - 1.5	6	1.07	0.08	7.7	1.1	0.8 - 1.3
IL TEST PT-FIB HS PLUS												
IL ACL, all models	5	1.15	0.07	6.1	1.2	0.9 - 1.4	5	0.95	0.07	7.4	1.0	0.7 - 1.2
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	1.45	0.07	4.9	1.5	1.1 - 1.8	5	1.25	0.21	17.0	1.3	1.0 - 1.5

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-13						Specimen CG-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	48	3.38	0.85	25.1	3.4	2.7 - 4.1	76	2.84	0.45	15.7	2.8	2.2 - 3.5
Dade Innovin												
Dade Behring BFT II	5	2.50	0.29	11.8	2.5	2.0 - 3.0	5	2.68	0.13	4.7	2.7	2.1 - 3.3
Sysmex CA-500/600 series	1	-	-	-	1.9	1.5 - 2.3	18	2.61	0.15	5.8	2.6	2.0 - 3.2
All Coagulation Instruments	7	2.38	0.37	15.6	2.3	1.9 - 2.9	26	2.61	0.14	5.3	2.6	2.0 - 3.2
Dade Thromborel S												
All Coagulation Instruments	4	-	-	-	2.6	2.0 - 3.2	5	2.65	0.35	13.3	2.7	2.1 - 3.2
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STA Compact	4	-	-	-	3.8	2.9 - 4.4	5	3.10	0.57	18.2	3.1	2.4 - 3.8
Diagnostica Stago STArt 4/8	6	3.93	0.23	5.9	3.8	3.1 - 4.8	6	3.67	0.35	9.6	3.7	2.9 - 4.5
RAL Clot-SP	17	3.59	0.45	12.4	3.7	2.8 - 4.4	17	3.27	0.30	9.0	3.3	2.6 - 4.0
All Coagulation Instruments	30	3.65	0.42	11.6	3.7	2.9 - 4.4	31	3.31	0.34	10.3	3.3	2.6 - 4.0
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	3.70	0.01	0.0	3.7	2.9 - 4.5	5	3.20	0.14	4.4	3.2	2.5 - 3.9
All Coagulation Instruments	6	3.67	0.06	1.6	3.7	2.9 - 4.5	6	3.17	0.12	3.6	3.1	2.5 - 3.9
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	2.55	0.34	13.4	2.6	2.0 - 3.1	5	2.90	0.36	12.3	3.0	2.3 - 3.5
IL TEST PT Fibrinogen												
IL ACL, all models	6	4.93	0.59	11.9	4.7	3.9 - 6.0	6	2.93	0.20	6.7	2.9	2.3 - 3.6
IL TEST PT-FIB HS PLUS												
IL ACL, all models	5	3.25	0.07	2.2	3.3	2.6 - 3.9	5	2.50	0.01	0.0	2.5	2.0 - 3.0
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	4.90	0.57	11.5	4.9	3.9 - 5.9	5	3.15	0.35	11.2	3.2	2.5 - 3.8

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

Specimen CG-15

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	48	3.23	0.81	25.1	3.1	2.5 - 3.9
Dade Innovin						
Dade Behring BFT II	5	2.55	0.30	11.8	2.7	2.0 - 3.1
Sysmex CA-500/600 series	6	1.97	0.12	5.9	1.9	1.5 - 2.4
All Coagulation Instruments	12	2.28	0.36	15.9	2.1	1.8 - 2.8
Diag Stago STA Neoplastine Cl+						
Diagnostica Stago STA Compact	5	3.95	1.20	30.4	4.0	3.1 - 4.8
Diagnostica Stago STart 4/8	6	4.10	0.20	4.9	4.1	3.2 - 5.0
RAL Clot-SP	16	3.84	0.56	14.6	3.9	3.0 - 4.7
All Coagulation Instruments	23	3.89	0.57	14.6	3.9	3.1 - 4.7
Diagnostica Stago Neoplastine Cl Plus						
Diagnostica Stago STA Compact	5	2.70	0.01	0.0	2.7	2.1 - 3.3
All Coagulation Instruments	6	2.83	0.23	8.2	2.7	2.2 - 3.4
HemosIL RecombiPlasTin 2G						
IL ACL, all models	6	2.73	0.39	14.2	2.8	2.1 - 3.3
IL TEST PT Fibrinogen						
IL ACL, all models	5	3.63	0.59	16.1	3.4	2.9 - 4.4
IL TEST PT-FIB HS PLUS						
IL ACL, all models	5	2.90	0.42	14.6	2.9	2.3 - 3.5
PH/CMS Thromboplastin-D						
All Coagulation Instruments	5	7.10	0.71	10.0	7.1	5.6 - 8.6

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	38	28.9	3.7	12.7	29	24 - 34	37	29.4	5.2	17.6	30	24 - 34
Dade Actin FSL												
Sysmex CA-500/600 series	11	25.6	0.9	3.6	26	21 - 30	11	24.3	0.6	2.7	24	20 - 28
All Coagulation Instruments	13	25.8	1.0	3.8	26	21 - 30	13	24.5	1.0	4.0	24	20 - 29
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	5	31.5	0.7	2.2	32	26 - 37	5	32.0	0.1	0.0	32	27 - 37
Diagnostica Stago STArt 4/8	5	32.5	2.1	6.5	33	27 - 38	5	34.0	2.8	8.3	34	28 - 40
All Coagulation Instruments	12	32.0	1.4	4.4	32	27 - 37	12	33.0	2.0	6.1	32	28 - 38
Diagnostica Stago STA-PTT												
Diagnostica Stago STA Compact	5	32.0	0.1	0.0	32	27 - 37	5	32.5	0.7	2.2	33	27 - 38
All Coagulation Instruments	6	31.7	0.6	1.8	32	26 - 37	6	32.0	1.0	3.1	32	27 - 37
Hemoliance SynthASil												
IL ACL, all models	5	31.5	3.5	11.2	32	26 - 37	5	40.0	0.1	0.0	40	34 - 46
IL TEST APTT-SP												
IL ACL, all models	6	32.0	2.4	7.4	33	27 - 37	6	31.2	1.3	4.3	31	26 - 36

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

<u>Reagent/Instrument</u>	Specimen CG-13						Specimen CG-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	32	70.7	12.6	17.8	70	60 - 82	37	43.5	4.8	11.0	43	37 - 51
Dade Actin FSL												
Sysmex CA-500/600 series	11	64.5	7.8	12.1	65	54 - 75	11	39.3	1.7	4.4	39	33 - 46
All Coagulation Instruments	13	63.9	7.3	11.4	65	54 - 74	13	39.6	1.8	4.6	40	33 - 46
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	5	89.0	1.4	1.6	89	75 - 103	5	46.0	0.1	0.0	46	39 - 53
Diagnostica Stago STArt 4/8	5	77.5	2.1	2.7	78	65 - 90	5	47.0	5.7	12.0	47	39 - 55
All Coagulation Instruments	12	83.3	6.8	8.2	84	70 - 96	12	46.5	3.3	7.1	46	39 - 54
Diagnostica Stago STA-PTT												
Diagnostica Stago STA Compact	5	76.0	9.9	13.0	76	64 - 88	5	47.5	2.1	4.5	48	40 - 55
All Coagulation Instruments	6	78.7	8.4	10.7	83	66 - 91	6	49.7	4.0	8.1	49	42 - 58
Hemoliance SynthASil												
IL ACL, all models	5	65.5	6.4	9.7	66	55 - 76	5	47.0	1.4	3.0	47	39 - 55
IL TEST APTT-SP												
IL ACL, all models	5	75.8	6.4	8.5	77	64 - 88	6	43.8	1.9	4.4	44	37 - 51
Specimen CG-15												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	31	72.0	14.1	19.6	68	61 - 83						
Dade Actin FSL												
Sysmex CA-500/600 series	10	64.5	7.2	11.2	64	54 - 75						
All Coagulation Instruments	12	65.0	7.4	11.3	64	55 - 75						
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	5	63.5	0.7	1.1	64	53 - 74						
Diagnostica Stago STArt 4/8	5	69.0	15.6	22.5	69	58 - 80						
All Coagulation Instruments	12	66.3	9.5	14.4	64	56 - 77						
Diagnostica Stago STA-PTT												
Diagnostica Stago STA Compact	5	98.0	0.1	0.0	98	83 - 113						
All Coagulation Instruments	6	93.3	8.1	8.7	98	79 - 108						
IL TEST APTT-SP												
IL ACL, all models	5	65.8	11.4	17.3	59	55 - 76						

FIBRINOGEN (mg/dL)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	14	286.8	29.6	10.3	296	229 - 345	14	412.2	62.6	15.2	427	329 - 495
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	5	291.8	6.1	2.1	294	233 - 351	5	449.5	17.0	3.8	453	359 - 540
All Coagulation Instruments	6	283.0	20.3	7.2	292	226 - 340	6	439.4	27.0	6.1	446	351 - 528
Specimen CG-13							Specimen CG-14					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	13	101.5	15.5	15.3	103	81 - 122	14	287.9	38.8	13.5	282	230 - 346
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	5	103.5	3.8	3.7	102	82 - 125	5	281.0	5.5	1.9	281	224 - 338
All Coagulation Instruments	6	96.9	15.1	15.6	101	77 - 117	6	280.6	4.8	1.7	279	224 - 337
Specimen CG-15												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	13	104.4	18.2	17.4	103	83 - 126						
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	5	101.3	4.7	4.7	103	81 - 122						
All Coagulation Instruments	6	95.8	11.8	12.3	100	76 - 115						

URINALYSIS DIPSTICK-SPECIFIC GRAVITY

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	396	1.0179	0.0067	0.7	1.015	1.007 - 1.028
All Arkay Methods	18	1.0283	0.0035	0.3	1.030	1.018 - 1.039
All DIRUI Methods	16	1.0215	0.0042	0.4	1.020	1.011 - 1.032
All Iris Diagnostics Methods	14	1.0253	0.0019	0.2	1.026	1.015 - 1.036
All Refractive Index Methods	48	1.0275	0.0028	0.3	1.028	1.017 - 1.038
All Roche Methods	115	1.0120	0.0027	0.3	1.010	1.001 - 1.022
All Siemens Methods	37	1.0204	0.0037	0.4	1.020	1.010 - 1.031
77 Elektronika LabUMat/2	14	1.0284	0.0029	0.3	1.029	1.018 - 1.039
Acon Laboratories	10	1.0150	0.0024	0.2	1.015	1.005 - 1.025
Arkay Auton Sticks	16	1.0281	0.0036	0.4	1.030	1.018 - 1.039
Combi-Screen Test Strips	11	1.0141	0.0021	0.2	1.015	1.004 - 1.025
DIRUI H-100 / H-500 Urine Analyzer	10	1.0200	0.0001	0.0	1.020	1.010 - 1.030
Other Analyzer Method	14	1.0231	0.0060	0.6	1.023	1.013 - 1.034
Other Dipstick Method	11	1.0150	0.0022	0.2	1.015	1.005 - 1.025
Roche Chemstrips / Combur	12	1.0100	0.0001	0.0	1.010	1.000 - 1.020
Roche cobas 6500 / u 601	12	1.0283	0.0010	0.1	1.028	1.018 - 1.039
Roche cobas u 411	79	1.0124	0.0029	0.3	1.010	1.002 - 1.023
Roche UriSys	42	1.0133	0.0061	0.6	1.010	1.003 - 1.024
SD UroColor Reagent Strips	28	1.0180	0.0034	0.3	1.020	1.008 - 1.029
Siemens Clinitek Advantus	17	1.0185	0.0023	0.2	1.020	1.008 - 1.029
Siemens Clinitek Status / Status+	16	1.0200	0.0001	0.0	1.020	1.010 - 1.030
UriScan Pro/II	12	1.0183	0.0061	0.6	1.018	1.008 - 1.029
UriScan Reagent Strips	30	1.0187	0.0048	0.5	1.020	1.008 - 1.029

URINALYSIS DIPSTICK-pH

Specimen UA-3		Participant Results											
<u>Method</u>	<u>Labs</u>	<u>≤3.5</u>	<u>4.0</u>	<u>4.5</u>	<u>5.0</u>	<u>5.5</u>	<u>6.0</u>	<u>6.5</u>	<u>7.0</u>	<u>7.5</u>	<u>8.0</u>	<u>8.5</u>	<u>≥9.0</u>
ALL METHODS	427	-	-	-	2	-	1	4	249	120	51	-	-
77 Elektronika LabUMat/2	17	-	-	-	-	-	-	-	16	1	-	-	-
Acon Laboratories	12	-	-	-	-	-	-	-	6	5	1	-	-
Analyticon CombiScan 500	5	-	-	-	-	-	-	-	5	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	2	-	-	-	-
Arkray Aution Sticks	16	-	-	-	-	-	-	-	2	12	2	-	-
Arkray PocketChem UA	2	-	-	-	-	-	-	-	-	2	-	-	-
Combi-Screen Test Strips	12	-	-	-	-	-	-	-	11	1	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	10	-	-	-	-	-	-	-	2	4	4	-	-
DIRUI H-800 Urine Analyzer	6	-	-	-	-	-	-	-	1	5	-	-	-
HUMAN Combilyzer	1	-	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	-	-	-	2	-	-	-
Iris Diagnostics iChem Velocity Strips	8	-	-	-	-	-	-	-	7	1	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	6	-	-	-	-	-	1	-	5	-	-	-	-
Other Analyzer Method	15	-	-	-	-	-	-	-	8	6	1	-	-
Other Dipstick Method	11	-	-	-	-	-	-	-	5	5	1	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	-	-	1	-	-	-
Roche Chemstrips / Combur	19	-	-	-	-	-	-	-	16	-	3	-	-
Roche cobas 6500 / u 601	13	-	-	-	-	-	-	-	5	-	8	-	-
Roche cobas u 411	80	-	-	-	1	-	-	-	70	-	9	-	-
Roche Urisys	47	-	-	-	-	-	-	-	32	1	14	-	-
SD UroColor Reagent Strips	30	-	-	-	-	-	-	-	14	13	3	-	-
Siemens Clinitek Advantus	20	-	-	-	-	-	-	-	1	2	17	-	-
Siemens Clinitek Atlas	3	-	-	-	-	-	-	-	-	3	-	-	-
Siemens Clinitek Status / Status+	16	-	-	-	-	-	-	-	-	16	-	-	-
Siemens Multistix Pro	1	-	-	-	-	-	-	-	-	1	-	-	-
Siemens Reagent Strips	14	-	-	-	-	-	-	-	1	13	-	-	-
Urinometer	2	-	-	-	-	-	-	-	2	-	-	-	-
UriScan Pro/II	12	-	-	-	1	-	-	-	1	7	3	-	-
UriScan Reagent Strips	29	-	-	-	-	-	-	-	23	6	-	-	-
URIT Medical Uritest Analyzers	3	-	-	-	-	-	-	-	2	1	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	-	-	-	-	1	-	-
Wiener Lab Urine Strip	7	-	-	-	-	-	-	-	-	-	7	-	-

URINALYSIS DIPSTICK—PROTEIN QUALITATIVE

Specimen UA-3

Participant Results

Method	Labs	Negative	Trace	(1+)	(2+)	(3+)	(4+)	10 - 20 mg/dL	30 - 70 mg/dL	75 mg/dL	100 - 200 mg/dL	≥300 - 600 mg/dL	>600 or ≥1000 mg/dL
ALL METHODS	424	6	-	25	142	37	1	3	10	11	180	9	-
77 Elektronika LabUMat/2	17	1	-	1	9	-	-	-	1	-	4	1	-
Acon Laboratories	12	-	-	1	6	1	-	-	-	-	3	1	-
Analyticon CombiScan 500	4	-	-	-	1	-	-	1	-	-	2	-	-
Arkray Aution Jet	2	1	-	-	-	1	-	-	-	-	-	-	-
Arkray Aution Sticks	16	-	-	-	12	2	-	-	-	-	2	-	-
Arkray PocketChem UA	2	-	-	-	2	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	11	-	-	-	3	-	-	-	1	-	7	-	-
DIRUI H-100 / H-500 Urine Analyzer	11	-	-	2	5	-	-	-	-	-	3	1	-
DIRUI H-800 Urine Analyzer	4	-	-	-	3	-	-	-	-	-	-	1	-
HUMAN Combilyzer	1	-	-	-	-	-	-	-	-	-	1	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	2	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	9	-	-	-	3	-	-	-	1	-	5	-	-
Iris Ichem VELOCITY Urine Chemistry System	6	1	-	1	2	-	-	-	-	-	2	-	-
Other Analyzer Method	16	-	-	1	7	-	1	-	1	-	6	-	-
Other Dipstick Method	10	-	-	1	5	2	-	-	-	-	1	1	-
Plasmatec URIPATH	1	-	-	-	1	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	19	-	-	2	14	1	-	-	-	-	2	-	-
Roche cobas 6500 / u 601	13	-	-	-	-	1	-	-	-	-	12	-	-
Roche cobas u 411	79	1	-	-	1	1	-	-	-	-	7	69	-
Roche Urisys	47	-	-	-	3	8	-	1	1	2	32	-	-
SD UroColor Reagent Strips	30	-	-	7	11	1	-	1	4	-	6	-	-
Siemens Clinitek Advantus	20	-	-	-	8	1	-	-	-	-	10	1	-
Siemens Clinitek Atlas	4	-	-	-	-	-	-	-	-	-	1	3	-
Siemens Clinitek Status / Status+	16	-	-	-	3	12	-	-	-	-	-	1	-
Siemens Reagent Strips	15	-	-	-	12	1	-	-	-	-	2	-	-
Urinometer	2	-	-	2	-	-	-	-	-	-	-	-	-
UriScan Pro/II	12	2	-	-	4	-	-	-	1	-	5	-	-
UriScan Reagent Strips	30	-	-	3	20	4	-	-	-	-	3	-	-
URIT Medical Uritest Analyzers	2	-	-	-	2	-	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	1	-	-	-	-	-	-	-	-
Wiener Lab Urine Strip	7	-	-	4	-	1	-	-	-	1	1	-	-

URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Negative or Normal</u>	<u>Trace</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>Participant Results</u>			
								<u>30 - 100 mg/dL</u>	<u>150 - 300 mg/dL</u>	<u>500 mg/dL</u>	<u>>500 or ≥1000 or ≥2000 mg/dL</u>
ALL METHODS	426	419	1	-	2	1	-	-	1	1	1
77 Elektronika LabUMat/2	17	17	-	-	-	-	-	-	-	-	-
Acon Laboratories	12	12	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	5	5	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	17	17	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	2	2	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	12	12	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	11	11	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	5	5	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	1	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	8	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	5	5	-	-	-	-	-	-	-	-	-
Other Analyzer Method	16	16	-	-	-	-	-	-	-	-	-
Other Dipstick Method	11	10	-	-	1	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	19	19	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	13	13	-	-	-	-	-	-	-	-	-
Roche cobas u 411	80	79	-	-	-	-	-	-	-	-	1
Roche Urisys	47	45	-	-	1	-	-	-	1	-	-
SD UroColor Reagent Strips	30	30	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	20	19	-	-	-	1	-	-	-	-	-
Siemens Clinitek Atlas	3	3	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	16	16	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	15	15	-	-	-	-	-	-	-	-	-
Urinometer	2	2	-	-	-	-	-	-	-	-	-
UriScan Pro/II	12	11	-	-	-	-	-	-	-	1	-
UriScan Reagent Strips	30	29	1	-	-	-	-	-	-	-	-
URIT Medical Uritest Analyzers	2	2	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-	-	-	-	-	-
Wiener Lab Urine Strip	7	7	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK-KETONES

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>Participant Results</u>								
							<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>5 - 10 mg/dL</u>	<u>15 - 25 mg/dL</u>	<u>40 - 60 mg/dL</u>	<u>≥80 - 100 mg/dL</u>	<u>≥150 mg/dL</u>
ALL METHODS	427	8	-	-	-	-	3	82	92	25	3	-	42	38	134
77 Elektronika LabUMat/2	17	-	-	-	-	-	-	8	1	-	-	-	6	-	2
Acon Laboratories	12	2	-	-	-	-	-	2	3	3	-	-	2	-	-
Analyticon CombiScan 500	5	-	-	-	-	-	-	-	1	-	1	-	-	1	2
Arkray Aution Jet	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Arkray Aution Sticks	17	-	-	-	-	-	-	1	12	3	-	-	-	1	-
Arkray PocketChem UA	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-
Combi-Screen Test Strips	12	-	-	-	-	-	-	1	1	-	-	-	1	4	5
DIRUI H-100 / H-500 Urine Analyzer	11	-	-	-	-	-	-	8	-	-	-	-	2	1	-
DIRUI H-800 Urine Analyzer	5	-	-	-	-	-	1	2	1	-	-	-	1	-	-
HUMAN Combilyzer	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	-	1	1	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	-	-	-	-	-	-	1	-	1	-	-	6	-	-
Iris Ichem VELOCITY Urine Chemistry System	5	2	-	-	-	-	-	-	-	-	-	-	3	-	-
Other Analyzer Method	15	1	-	-	-	-	-	3	7	-	-	-	1	2	1
Other Dipstick Method	11	2	-	-	-	-	-	4	2	1	-	-	-	1	1
Plasmatec URIPATH	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Roche Chemstrips / Combur	19	-	-	-	-	-	-	4	14	-	-	-	-	-	1
Roche cobas 6500 / u 601	13	-	-	-	-	-	-	-	-	1	-	-	-	-	12
Roche cobas u 411	80	1	-	-	-	-	-	-	-	1	1	-	1	1	75
Roche UriSys	47	-	-	-	-	-	-	2	7	1	-	-	2	1	34
SD UroColor Reagent Strips	30	-	-	-	-	-	-	11	6	-	-	-	10	2	1
Siemens Clinitek Advantus	20	-	-	-	-	-	1	6	2	-	-	-	1	10	-
Siemens Clinitek Atlas	3	-	-	-	-	-	-	-	-	-	-	-	-	3	-
Siemens Clinitek Status / Status+	17	-	-	-	-	-	-	-	7	9	-	-	-	1	-
Siemens Reagent Strips	15	-	-	-	-	-	-	-	10	3	-	-	-	2	-
Urinometer	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-
UriScan Pro/II	12	-	-	-	-	-	-	2	2	1	1	-	3	3	-
UriScan Reagent Strips	30	-	-	-	-	-	-	19	6	1	-	-	3	1	-
URIT Medical Uritest Analyzers	2	-	-	-	-	-	-	2	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Wiener Lab Urine Strip	7	-	-	-	-	-	-	3	2	-	-	-	-	2	-

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-3

<u>Method</u>	<u>Labs</u>	Participant Results												
		<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	(1+)	(2+)	(3+)	(4+)	0.5 - 1.0 mg/dL	2.0 - 4.0 mg/dL	6.0 - 10.0 mg/dL	>10.0 mg/dL
ALL METHODS	413	74	3	1	8	2	49	94	37	1	44	99	1	-
77 Elektronika LabUMat/2	17	1	-	-	-	-	10	-	-	-	6	-	-	-
Acon Laboratories	12	1	1	-	-	-	4	3	3	-	-	-	-	-
Analyticon CombiScan 500	6	2	-	-	-	-	-	1	-	-	2	1	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	17	1	-	-	-	-	1	13	-	-	-	2	-	-
Arkray PocketChem UA	2	-	-	-	-	-	-	2	-	-	-	-	-	-
Combi-Screen Test Strips	11	2	-	-	-	-	2	2	-	-	1	4	-	-
DIRUI H-100 / H-500 Urine Analyzer	11	-	-	-	-	1	3	3	3	-	-	1	-	-
DIRUI H-800 Urine Analyzer	4	-	-	-	-	-	1	2	1	-	-	-	-	-
HUMAN Combilyzer	1	-	-	-	-	-	1	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	1	-	-	-	-	1	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	9	9	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	5	5	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	16	2	-	-	-	-	3	4	2	1	3	1	-	-
Other Dipstick Method	11	1	-	-	-	-	5	3	1	-	1	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	1	-	-	-	-	-	-
Roche Chemstrips / Combur	17	1	-	-	-	-	1	12	2	-	-	1	-	-
Roche cobas 6500 / u 601	13	-	-	-	-	-	-	1	3	-	1	8	-	-
Roche cobas u 411	80	2	-	-	-	-	3	-	11	-	15	49	-	-
Roche Urisys	47	1	-	-	-	-	4	9	2	-	4	27	-	-
SD UroColor Reagent Strips	30	16	-	-	-	-	4	3	1	-	5	1	-	-
Siemens Clinitek Advantus	21	2	-	1	7	-	-	8	-	-	-	3	-	-
Siemens Clinitek Atlas	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	16	-	-	-	1	1	-	10	4	-	-	-	-	-
Siemens Reagent Strips	4	-	-	-	-	-	-	-	1	2	-	1	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	12	5	-	-	-	-	1	2	-	-	4	-	-	-
UriScan Reagent Strips	30	17	1	-	-	-	4	6	-	-	2	-	-	-
URIT Medical Uritest Analyzers	2	-	-	-	-	-	-	2	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	1	-	-	-	-	-	-	-
Wiener Lab Urine Strip	7	1	-	-	-	-	-	1	3	2	-	-	-	-

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<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	413	95	157	53	74	34
77 Elektronika LabUMat/2	17	-	-	-	5	12
Acon Laboratories	12	6	1	3	2	-
Analyticon CombiScan 500	5	-	1	-	3	1
Arkray Aution Jet	1	1	-	-	-	-
Arkray Aution Sticks	16	5	3	7	1	-
Arkray PocketChem UA	2	1	-	1	-	-
Combi-Screen Test Strips	12	1	1	1	4	5
DIRUI H-100 / H-500 Urine Analyzer	11	4	5	1	1	-
DIRUI H-800 Urine Analyzer	5	3	2	-	-	-
HUMAN Combiblizer	1	-	-	-	1	-
Iris Diagnostics Aution Max AX-4280	2	-	2	-	-	-
Iris Diagnostics iChem Velocity Strips	9	1	-	7	1	-
Iris Ichem VELOCITY Urine Chemistry System	5	1	-	4	-	-
Other Analyzer Method	16	4	3	5	1	3
Other Dipstick Method	11	3	3	3	2	-
Plasmatec URIPATH	1	-	1	-	-	-
Roche Chemstrips / Combur	17	6	7	-	4	-
Roche cobas 6500 / u 601	13	-	12	1	-	-
Roche cobas u 411	80	4	73	-	3	-
Roche Urisys	47	13	23	3	8	-
SD UroColor Reagent Strips	30	23	3	3	-	1
Siemens Clinitek Advantus	20	1	2	6	11	-
Siemens Clinitek Atlas	3	-	-	3	-	-
Siemens Clinitek Status / Status+	16	-	-	1	12	3
Siemens Reagent Strips	4	-	1	1	2	-
Urinometer	2	-	-	-	-	2
UriScan Pro/II	12	4	4	-	4	-
UriScan Reagent Strips	30	8	9	2	6	5
URIT Medical Uritest Analyzers	2	-	1	-	1	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-
Wiener Lab Urine Strip	7	5	-	-	1	1

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>(5+)</u>	<u>5 - 25 Ery/µL</u>	<u>50 - 100 Ery/µL</u>	<u>200 - 250 Ery/µL</u>	<u>±0.03 mg/dL</u>	<u>0.06 - 0.10 mg/dL</u>	<u>0.2 - 0.5 mg/dL</u>	<u>≥ 1.0 mg/dL</u>
ALL METHODS	425	7	-	-	2	3	-	31	149	45	3	-	2	179	-	-	-	4
77 Elektronika LabUMat/2	17	1	-	-	-	-	-	-	9	-	-	-	-	7	-	-	-	-
Acon Laboratories	10	-	-	-	-	-	-	-	4	6	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	5	-	-	-	-	-	-	-	1	1	-	-	-	3	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	17	-	-	-	-	-	-	-	2	13	1	-	-	-	-	-	-	1
Arkray PocketChem UA	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	12	-	-	-	-	-	-	-	4	-	-	-	-	8	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	11	-	-	-	-	-	-	-	8	-	-	-	-	3	-	-	-	-
DIRUI H-800 Urine Analyzer	5	-	-	-	-	-	-	-	4	-	-	-	-	1	-	-	-	-
HUMAN Combilyzer	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	9	-	-	-	-	-	-	3	3	-	-	-	-	-	-	-	-	3
Iris Ichem VELOCITY Urine Chemistry System	5	1	-	-	-	-	-	2	2	-	-	-	-	-	-	-	-	-
Other Analyzer Method	16	-	-	-	-	-	-	2	10	-	-	-	-	4	-	-	-	-
Other Dipstick Method	11	1	-	-	-	-	-	-	7	2	-	-	-	1	-	-	-	-
Plasmatec URI PATH	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	18	-	-	-	-	-	-	-	2	14	-	-	-	2	-	-	-	-
Roche cobas 6500 / u 601	13	-	-	-	-	-	-	-	-	-	1	-	-	12	-	-	-	-
Roche cobas u 411	80	2	-	-	-	-	-	-	-	-	-	-	-	78	-	-	-	-
Roche Miditron Junior/II	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Roche Urisys	47	-	-	-	-	-	-	-	1	7	1	-	-	1	37	-	-	-
SD UroColor Reagent Strips	30	-	-	-	-	-	-	3	16	8	-	-	-	3	-	-	-	-
Siemens Clinitek Advantus	19	-	-	-	1	-	-	1	10	-	-	-	-	7	-	-	-	-
Siemens Clinitek Atlas	3	-	-	-	-	-	-	-	-	-	-	-	-	3	-	-	-	-
Siemens Clinitek Status / Status+	17	-	-	-	1	2	-	-	14	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	16	-	-	-	-	1	-	-	15	-	-	-	-	-	-	-	-	-
Urinometer	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
UriScan Pro/II	12	1	-	-	-	-	-	-	4	1	-	-	-	1	5	-	-	-
UriScan Reagent Strips	30	1	-	-	-	-	-	13	12	1	-	-	-	3	-	-	-	-
URIT Medical Uritest Analyzers	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Wiener Lab Urine Strip	6	-	-	-	-	-	-	-	-	3	1	-	-	2	-	-	-	-

URINALYSIS DIPSTICK-LEUKOCYTE ESTERASE

Specimen UA-3

<u>Method</u>	<i>Participant Results</i>													
	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>15 or 25 µL</u>	<u>75 or 100 µL</u>	<u>250 or 500 µL</u>	
ALL METHODS	411	403	2	-	-	-	3	-	1	-	2	-	-	
77 Elektronika LabUMat/2	17	16	-	-	-	-	-	-	1	-	-	-	-	
Acon Laboratories	12	12	-	-	-	-	-	-	-	-	-	-	-	
Analyticon CombiScan 500	5	5	-	-	-	-	-	-	-	-	-	-	-	
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-	
Arkray Aution Sticks	16	16	-	-	-	-	-	-	-	-	-	-	-	
Arkray PocketChem UA	2	2	-	-	-	-	-	-	-	-	-	-	-	
Combi-Screen Test Strips	12	12	-	-	-	-	-	-	-	-	-	-	-	
DIRUI H-100 / H-500 Urine Analyzer	11	11	-	-	-	-	-	-	-	-	-	-	-	
DIRUI H-800 Urine Analyzer	5	5	-	-	-	-	-	-	-	-	-	-	-	
HUMAN Combilyzer	1	1	-	-	-	-	-	-	-	-	-	-	-	
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-	-	-	-	-	-	-	-	
Iris Diagnostics iChem Velocity Strips	9	9	-	-	-	-	-	-	-	-	-	-	-	
Iris Ichem VELOCITY Urine Chemistry System	5	5	-	-	-	-	-	-	-	-	-	-	-	
Other Analyzer Method	16	16	-	-	-	-	-	-	-	-	-	-	-	
Other Dipstick Method	11	11	-	-	-	-	-	-	-	-	-	-	-	
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-	
Roche Chemstrips / Combur	18	18	-	-	-	-	-	-	-	-	-	-	-	
Roche cobas 6500 / u 601	13	13	-	-	-	-	-	-	-	-	-	-	-	
Roche cobas u 411	81	81	-	-	-	-	-	-	-	-	-	-	-	
Roche UriSys	47	47	-	-	-	-	-	-	-	-	-	-	-	
SD UroColor Reagent Strips	30	30	-	-	-	-	-	-	-	-	-	-	-	
Siemens Clinitek Advantus	20	19	-	-	-	-	1	-	-	-	-	-	-	
Siemens Clinitek Atlas	3	3	-	-	-	-	-	-	-	-	-	-	-	
Siemens Clinitek Status / Status+	16	16	-	-	-	-	-	-	-	-	-	-	-	
Siemens Reagent Strips	4	4	-	-	-	-	-	-	-	-	-	-	-	
Urinometer	2	-	-	-	-	-	2	-	-	-	-	-	-	
UriScan Pro/II	11	10	-	-	-	-	-	-	-	-	1	-	-	
UriScan Reagent Strips	29	28	-	-	-	-	-	-	-	-	1	-	-	
URIT Medical Uritest Analyzers	1	1	-	-	-	-	-	-	-	-	-	-	-	
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	
Wiener Lab Urine Strip	6	5	1	-	-	-	-	-	-	-	-	-	-	

URINALYSIS DIPSTICK–NITRITE

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	416	414	2
77 Elektronika LabUMat/2	17	17	-
Acon Laboratories	12	11	1
Analyticon CombiScan 500	5	5	-
Arkray Aution Jet	1	1	-
Arkray Aution Sticks	17	17	-
Arkray PocketChem UA	2	2	-
Combi-Screen Test Strips	12	12	-
DIRUI H-100 / H-500 Urine Analyzer	11	11	-
DIRUI H-800 Urine Analyzer	5	5	-
HUMAN Combilyzer	1	1	-
Iris Diagnostics Aution Max AX-4280	2	2	-
Iris Diagnostics iChem Velocity Strips	9	9	-
Iris Ichem VELOCITY Urine Chemistry System	5	5	-
Other Analyzer Method	16	16	-
Other Dipstick Method	11	11	-
Plasmatec URIPATH	1	1	-
Roche Chemstrips / Combur	19	19	-
Roche cobas 6500 / u 601	13	13	-
Roche cobas u 411	80	80	-
Roche Urisys	47	47	-
SD UroColor Reagent Strips	30	30	-
Siemens Clinitek Advantus	20	19	1
Siemens Clinitek Atlas	3	3	-
Siemens Clinitek Status / Status+	16	16	-
Siemens Reagent Strips	4	4	-
Urinometer	2	2	-
UriScan Pro/II	12	12	-
UriScan Reagent Strips	30	30	-
URIT Medical Uritest Analyzers	2	2	-
URIT Medical Uritest Reagent Strips	1	1	-
Wiener Lab Urine Strip	7	7	-

URINALYSIS –MICROALBUMIN (dipstick only)

Specimen UA-3

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	4	-	-	-	1	-	-	6	-	7
Beckman Coulter ICON microALB	1	-	-	-	-	-	-	-	-	-	1
DIRUI H-100 / H-500 Urine Analyzer	2	-	-	-	-	-	-	-	1	-	1
NycoCard	1	-	-	-	-	-	-	-	1	-	-
Other Analyzer Method	5	1	-	-	-	-	-	-	1	-	3
Roche Micral - 1 minute	2	-	-	-	-	1	-	-	1	-	-
SD UroColor Reagent Strips	1	1	-	-	-	-	-	-	-	-	-
Siemens Clinitek Microalbumin	1	-	-	-	-	-	-	-	1	-	-
UriScan Reagent Strips	1	1	-	-	-	-	-	-	-	-	-

URINALYSIS –URINE hCG

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	116	1	115
Acon Laboratories	5	-	5
Alere Clearview hCG Cassette	7	-	7
Alere Clearview25 hCG Combo	1	-	1
Alere hCG Cassette	15	-	15
Biotron 1-Step	1	-	1
Immunostics hCG Detector-urine	1	-	1
Medline hCG Test Strip	1	-	1
NDC Pro Advantage	1	-	1
Quidel QuickVue One-Step Combo	19	-	19
SD Bioline hCG	16	1	15
Siemens Clinitek Status / Status+	10	-	10
Stanbio QuStick	1	-	1

MISCELLANEOUS CULTURES

Specimen BA-7 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Moraxella sp.	24	23.53%	Acceptable
Moraxella osloensis	12	11.76%	Acceptable
Growth, referred for identification	2	1.96%	Acceptable
Gram negative coccobacilli	2	1.96%	Acceptable
Neisseria meningitidis	28	27.45%	
Gram positive cocci	5	4.90%	
Acinetobacter sp.	5	4.90%	

Organism(s) present: *Moraxella osloensis*. Specimen BA-7 is graded by 82% referee consensus.

Specimen BA-8 – Sputum Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Streptococcus mitis	62	56.36%	Acceptable
Streptococcus alpha-hemolytic	17	15.45%	Acceptable
Streptococcus viridans group	10	9.09%	Acceptable
Gram positive cocci	2	1.82%	Acceptable
Normal flora	2	1.82%	Acceptable
Gram negative diplococci	2	1.82%	Acceptable
Streptococcus pneumoniae	6	5.45%	

Organism(s) present: *Streptococcus mitis* and *Neisseria sicca*.

MISCELLANEOUS CULTURES

Specimen BA-9 – Eye Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus epidermidis	90	51.72%	Acceptable
Micrococcus luteus	45	25.86%	Acceptable
Micrococcus sp.	24	15.79%	Acceptable
Staph – coagulase negative	7	4.02%	Acceptable
Staphylococcus sp.	4	2.30%	Acceptable
Gram positive cocci	1	0.57%	Acceptable

Organism(s) present: *Micrococcus luteus* and *Staphylococcus epidermidis*.

ANTIMICROBIAL SUSCEPTIBILITY TESTING

<u>Antimicrobial</u>	<u>Disk Diffusion</u>				<u>MIC</u>				<u>Acceptable (%)</u>	
	<u>Interpretative category data</u>				<u>Interpretative category data</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	17	16	-	1	9	8	-	1	92.31%	
Amoxicillin/Clavulanate	23	3	1	19	29	2	-	27	88.89%	
Ampicillin	7	1	-	6	37	3	-	34	91.30%	
Ampicillin/Sulbactam	10	2	-	8	23	5	-	18	80.00%	
Aztreonam	3	1	-	2	-	-	-	-	Inappropriate drug ¹	
Cefaclor	2	1	-	1	-	-	-	-	Ungraded ²	
Cefazolin	8	1	-	7	18	3	-	15	84.62%	
Cefepime	8	2	-	6	8	4	-	4	Referee grading ³	
Cefixime	6	-	1	5	2	1	-	1	Inappropriate drug ¹	
Cefoperazone	1	-	-	1	1	1	-	-	Ungraded ²	
Cefotaxime	12	1	1	10	7	1	-	6	84.21%	
Cefoxitin	27	-	-	27	31	3	-	28	94.83%	
Ceftazidime	6	1	1	4	4	2	-	2	Inappropriate drug ¹	
Ceftriaxone	16	1	2	13	7	3	-	4	76.00% ⁴	
Cefuroxime	16	3	1	12	2	1	-	1	72.22% ⁴	
Cephalexin	5	2	-	3	2	1	-	1	Ungraded ²	
Cephalothin	2	1	-	1	3	1	-	2	Ungraded ²	
Ciprofloxacin	39	2	2	35	117	3	-	114	95.65%	
Clindamycin	4	4	-	-	13	11	-	2	89.47%	
Colistin	-	-	-	-	2	2	-	-	100.00%	
Daptomycin	-	-	-	-	41	41	-	-	100.00%	
Doripenem	1	-	-	1	-	-	-	-	Inappropriate drug ¹	
Doxycycline	6	6	-	-	2	1	-	1	87.50%	
Ertapenem	3	1	-	2	3	2	-	1	50.00% ⁴	
Erythromycin	2	-	-	2	9	-	-	9	Inappropriate drug ¹	
Fosfomycin	7	6	-	1	3	3	-	-	Inappropriate drug ¹	
Gentamicin	34	34	-	-	111	108	-	3	98.00%	
Imipenem	8	4	-	4	3	-	-	3	63.64% ⁴	
Levofloxacin	17	-	2	15	57	2	25	30	62.03% ⁴	
Linezolid	23	23	-	-	92	92	-	-	100.00%	

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

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

³ Drug graded by 80% referee consensus

⁴ Antibiotic should be reported as Resistant.

ANTIMICROBIAL SUSCEPTIBILITY TESTING (cont'd)

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>	
	Interpretative category data				Interpretative category data					
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>		
Meropenem	8	2	-	6	6	2	-	4	Ungraded ²	
Methicillin	2	-	-	2	7	1	-	6	88.89%	
Minocycline	-	-	-	-	26	26	-	-	Inappropriate drug ¹	
Moxifloxacin	5	-	-	5	40	26	8	6	Referee grading ³	
Nalidixic Acid	2	1	-	1	-	-	-	-	Inappropriate drug ¹	
Netilmicin	7	7	-	-	1	1	-	-	Inappropriate drug ¹	
Nitrofurantoin	40	39	-	1	101	100	-	1	98.61%	
Norfloxacin	14	2	1	11	9	2	-	7	78.26%	
Ofloxacin	12	-	1	11	1	-	-	1	92.31%	
Oxacillin	11	-	-	11	121	2	-	119	98.55%	
Penicillin	27	1	-	26	42	-	-	42	98.59%	
Piperacillin	1	-	-	1	-	-	-	-	66.67% ⁴	
Piperacillin/Tazobactam	4	1	-	3	4	4	-	-	Ungraded ²	
Quinupristin/Dalfopristin	-	-	-	-	22	22	-	-	Inappropriate drug ¹	
Rifampin	20	20	-	-	58	57	1	-	98.81%	
Teicoplanin	9	9	-	-	36	36	-	-	100.00%	
Tetracycline	19	19	-	-	66	66	-	-	98.88%	
Ticarcillin	-	-	-	-	1	1	-	-	Inappropriate drug ¹	
Ticarcillin/Clavulanate	-	-	-	-	1	-	-	1	Inappropriate drug ¹	
Tobramycin	2	2	-	-	-	-	-	-	Inappropriate drug ¹	
Trimethoprim	1	1	-	-	5	5	-	-	100.00%	
Trimethoprim/Sulfamethoxazole	36	35	-	1	131	130	-	1	98.84%	
Vancomycin	16	16	-	-	116	116	-	-	100.00%	

Organism(s) present: *Staphylococcus aureus*.

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

PARASITOLOGY (PA Specimens)

Specimen PA-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba hartmanni	3	30.00%	Acceptable
No parasite seen	2	20.00%	
Giardia lamblia	2	20.00%	
Entamoeba histolytica	1	10.00%	
Iodamoeba buetschlii	1	10.00%	
Trichomonas hominis	1	10.00%	

Parasite(s) present: *Entamoeba hartmanni*. This specimen is graded to US statistics.

Specimen PA-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba coli	6	50.00%	Acceptable
No parasite seen	2	16.67%	
Entamoeba histolytica	2	16.67%	
Chilomastix mesnili	1	8.33%	
Dientamoeba fragilis	1	8.33%	

Parasite(s) present: *Entamoeba coli*. This specimen is graded to US statistics.

Specimen PA-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Clonorchis sinensis	17	42.50%	Acceptable
Taenia sp. eggs	13	32.50%	
No parasite seen	4	10.00%	
Ascaris lumbricoides eggs	2	5.00%	
Schistosoma mansoni eggs	2	5.00%	
Hymenolepis nana eggs	1	2.50%	
Paragonimus westermani eggs	1	2.50%	

Parasite(s) present: *Clonorchis sinensis*. This specimen is graded to US statistics

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	27	87.16%	Acceptable
Entamoeba coli	3	9.68%	
Giardia lamblia	1	3.23%	

Parasite(s) present: Hookworm.

Specimen PA-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium vivax	17	70.83%	Acceptable
Plasmodium sp.	3	12.50%	Acceptable
Plasmodium falciparum	2	8.33%	
Plasmodium ovale	1	4.17%	
Babesia sp.	1	4.17%	

Parasite(s) present: *Plasmodium vivax*.

PARASITOLOGY (FP Specimens)

Specimen FP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	101	40.73%	Acceptable
Nematode-like artifact	8	3.23	Acceptable
Root hair artifact	3	1.21%	Acceptable
Strongyloides stercoralis larvae	113	45.56%	
Parasite larva seen but on ID	9	3.63%	
Giardia lamblia	3	1.21%	
Entamoeba histolytica	2	0.81%	
Blastocystis hominis	2	0.81%	
Dientamoeba fragilis	1	0.40%	
Endolimax nana	1	0.40%	
Entamoeba coli	1	0.40%	
Iodamoeba buetschlii	1	0.40%	
Taenia sp. Eggs	1	0.40%	
Parasite egg seen but no ID	1	0.40%	
Cyclospora sp.	1	0.40%	

Parasite(s) present: No parasite seen and Root hair artifact. Specimen FP-11 is graded by 86% referee consensus.

PARASITOLOGY (FP Specimens)

Specimen FP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hymenolepis nana eggs	190	76.00%	Acceptable
Taenia sp. Eggs	19	7.60%	
Hymenolepis diminuta eggs	17	6.80%	
Ascaris lumbricoides eggs	8	3.20%	
Endolimax nana	5	2.00%	
No parasite seen	4	1.60%	
Entamoeba coli	2	0.80%	
Giardia lamblia	2	0.80%	
Blastocystis hominis	2	0.80%	
Iodamoeba buetschlii	1	0.40%	

Parasite(s) present: *Hymenolepis nana* eggs. Specimen FP-12 is graded by 93% referee consensus.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba coli	227	83.46%	Acceptable
Entamoeba histolytica	33	12.13%	
Parasite larva seen but no ID	3	1.10%	
No parasite seen	2	0.74%	
Blastocystis hominis	2	0.74%	
Cyclospora sp.	1	0.37%	
Entamoeba hartmanni	1	0.37%	
Hymenolepis nana eggs	1	0.37%	
Strongyloides stercoralis larvae	1	0.37%	
Parasite egg seen but no ID	1	0.37%	

Parasite(s) present: *Entamoeba coli*.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	207	82.47%	Acceptable
Parasite egg seen but no ID	10	3.98%	Acceptable
Entamoeba coli	8	3.19%	
No parasite seen	7	2.79%	
Nematode-like artifact	4	1.59%	
Trichostrongylus sp. eggs	4	1.59%	
Ascaris lumbricoides eggs	3	1.20%	
Blastocystis hominis	2	0.80%	
Strongyloides stercoralis larvae	2	0.80%	
Other parasite seen but no ID	1	0.40%	
Entamoeba histolytica	1	0.40%	
Enterobius vermicularis eggs	1	0.40%	
Fasciola hepatica eggs	1	0.40%	

Parasite(s) present: *Hookworm*.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium falciparum	163	66.26%	Acceptable
Plasmodium sp.	47	19.11%	Acceptable
Plasmodium vivax	28	11.38%	
No parasite seen	3	1.22%	
Babesia sp.	3	1.22%	
Plasmodium knowlesi	1	0.41%	
Plasmodium malariae	1	0.41%	

Parasite(s) present: *Plasmodium falciparum*.

Antinuclear Antibody (ANA) - Qualitative

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	20	1	16	5
Bio-Rad	-	3	3	-	3	-
BioSystems	-	1	1	-	1	-
Immuno Concepts	-	3	3	-	3	-
INOVA Diagnostics	-	7	6	1	5	2
Zeus	-	1	1	-	1	-
<u>Method</u>	Specimen AE-14		Specimen AE-15			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	-	21	2	19		
Bio-Rad	-	3	-	3		
BioSystems	-	1	1	-		
Immuno Concepts	-	3	-	3		
INOVA Diagnostics	-	7	1	6		
Zeus	-	1	-	1		

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

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>8/ 10</u>	<u>16/ 20</u>	<u>32/ 40</u>	<u>64/ 80</u>	<u>128/ 160</u>	<u>256/ 320</u>	<u>512/ 640</u>	<u>>640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>>2560</u>
Specimen AE-11												
ALL METHODS	13	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	5	-	-	-	-	-	-	-	-	-	-	-
Zeus	1	-	-	-	-	-	-	-	-	-	-	-

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

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>8/ 10</u>	<u>16/ 20</u>	<u>32/ 40</u>	<u>64/ 80</u>	<u>128/ 160</u>	<u>256/ 320</u>	<u>512/ 640</u>	<u>>640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
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Specimen AE-12

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

Specimen AE-13

ALL METHODS	2	-	-	-	1	-	6	2	-	2	-	-
Bio-Rad	-	-	-	-	-	-	1	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	2	-	-	-	-	-
INOVA Diagnostics	2	-	-	-	1	-	1	1	-	-	-	-
Zeus	-	-	-	-	-	-	-	-	-	1	-	-

Specimen AE-14

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

Specimen AE-15

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

Anti-dsDNA

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	17	4	13	1	16
BioSystems	-	1	1	-	-	1
INOVA Diagnostics	-	9	2	7	-	9
Zeus	-	1	-	1	-	1

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	17	-	17
BioSystems	-	1	-	1
INOVA Diagnostics	-	9	-	9
Zeus	-	1	-	1

Anti-RNP

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	14	13	1	-	14
INOVA Diagnostics	-	10	10	-	-	10

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	14	-	14
INOVA Diagnostics	-	10	-	10

Anti-RNP/Sm

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	4	4	-	-	4
<u>Method</u>	Specimen AE-14		Specimen AE-15			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	-	4	-	4		

Anti-SSA

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	17	-	17	-	17
<u>Method</u>	Specimen AE-14		Specimen AE-15			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	-	17	-	17		
INOVA Diagnostics	-	10	-	10		
INOVA Diagnostics	-	10	-	10		

Anti-SSB

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	-	18	-	18
INOVA Diagnostics	-	11	-	11	-	11
<u>Method</u>	Specimen AE-14		Specimen AE-15			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	-	18	-	18		
INOVA Diagnostics	-	11	-	11		

Anti-SSA/SSB

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	-	-	-	-	-
<u>Method</u>	Specimen AE-14		Specimen AE-15			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	-	-	-	-		

Anti-Sm

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	17	17	-	-	17
INOVA Diagnostics	-	11	11	-	-	11
<u>Method</u>	Specimen AE-14		Specimen AE-15			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	-	17	-	17		
INOVA Diagnostics	-	11	-	11		

Rubella—Qualitative

<u>Method</u>	Specimen RU-11		Specimen RU-12		Specimen RU-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	17	1	17	1
Abbott Architect	-	13	12	1	12	1
Roche cobas 6000 / e 601	-	1	1	-	1	-
Roche cobas e 411	-	1	1	-	1	-
Siemens ADVIA Centaur	-	1	1	-	1	-
VITROS ECI	-	2	2	-	2	-

<u>Method</u>	Specimen RU-14		Specimen RU-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	-	18
Abbott Architect	-	13	-	13
Roche cobas 6000 / e 601	-	1	-	1
Roche cobas e 411	-	1	-	1
Siemens ADVIA Centaur	-	1	-	1
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>
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Specimen RU-11

All Method	22	0.07	0.12	177.5	0.0	0.0 - 0.5
Abbott Architect	13	0.00	0.01	0.0	0.0	0.0 - 0.1

Specimen RU-12

All Method	21	44.53	24.63	55.3	30.3	0.0 - 118.5
Abbott Architect	13	28.70	2.06	7.2	28.9	22.5 - 34.9

Specimen RU-13

All Method	22	25.52	15.99	62.6	15.6	0.0 - 73.5
Abbott Architect	13	15.14	0.85	5.6	15.1	12.6 - 17.7

Specimen RU-14

All Method	21	0.05	0.10	187.2	0.0	0.0 - 0.4
Abbott Architect	13	0.00	0.01	0.0	0.0	0.0 - 0.1

Specimen RU-15

All Method	22	0.07	0.12	177.5	0.0	0.0 - 0.5
Abbott Architect	13	0.00	0.01	0.0	0.0	0.0 - 0.1

Syphilis Serology—Qualitative: VDRL Slide

<u>Method</u>	Specimen SY-11			Specimen SY-12			Specimen SY-13		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	-	55	-	-	55	51	2	2
Abbott Architect	-	-	2	-	-	2	2	-	-
Acon Laboratories	-	-	2	-	-	2	1	-	1
Omega Diagnostics	-	-	1	-	-	1	1	-	-
Plasmatec	-	-	4	-	-	4	4	-	-
SPINREACT	-	-	2	-	-	2	2	-	-
Standard Diagnostics	-	-	1	-	-	1	1	-	-
Wiener Lab	-	-	39	-	-	39	36	2	1
<u>Method</u>	Specimen SY-14			Specimen SY-15					
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>			
ALL METHODS	53	1	1	51	1	3			
Abbott Architect	2	-	-	2	-	-			
Acon Laboratories	2	-	-	1	-	1			
Omega Diagnostics	1	-	-	1	-	-			
Plasmatec	4	-	-	4	-	-			
SPINREACT	2	-	-	2	-	-			
Standard Diagnostics	1	-	-	1	-	-			
Wiener Lab	37	1	1	36	1	2			

Syphilis Serology—Semi-Quantitative: VDRL Slide Titer

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>0 dil</u>	<u>1 dil</u>	<u>2 dil</u>	<u>4 dil</u>	<u>8 dil</u>	<u>16 dil</u>	<u>32 dil</u>	<u>>32 dil</u>
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Specimen SY-11

ALL METHODS	48	1	-	-	-	-	-	-	-
Plasmatec	2	-	-	-	-	-	-	-	-
Wiener Lab	41	-	-	-	-	-	-	-	-

Specimen SY-12

ALL METHODS	48	1	-	-	-	-	-	-	-
Plasmatec	2	-	-	-	-	-	-	-	-
Wiener Lab	41	-	-	-	-	-	-	-	-

Specimen SY-13

ALL METHODS	2	-	6	20	19	1	-	-	1
Plasmatec	-	-	-	-	2	-	-	-	-
Wiener Lab	1	-	6	18	15	1	-	-	-

Syphilis Serology—Semi-Quantitative: VDRL Slide Titer

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>0 dil</u>	<u>1 dil</u>	<u>2 dil</u>	<u>4 dil</u>	<u>8 dil</u>	<u>16 dil</u>	<u>32 dil</u>	<u>>32 dil</u>
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Specimen SY-14

ALL METHODS	1	-	2	5	20	16	4	-	1
Plasmatec	-	-	-	-	1	1	-	-	-
Wiener Lab	1	-	1	5	17	14	3	-	-

Specimen SY-15

ALL METHODS	2	1	7	17	19	2	-	-	1
Plasmatec	-	-	-	1	1	-	-	-	-
Wiener Lab	2	1	6	13	17	2	-	-	-

Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	22	-	22	22	-
Abbott Architect	-	3	-	3	3	-
Biokit	-	1	-	1	1	-
DiaSorin	-	1	-	1	1	-
Human	-	1	-	1	1	-
Omega Diagnostics	-	1	-	1	1	-
Plasmatec	-	5	-	5	5	-
Serodia	-	4	-	4	4	-
SPINREACT	-	1	-	1	1	-
Standard Diagnostics	-	1	-	1	1	-
Wiener Lab	-	1	-	1	1	-
Specimen SY-14		Specimen SY-15				
<u>Reactive</u>		<u>Reactive</u>		<u>Non-Reactive</u>		
ALL METHODS	22	-	22	-		
Abbott Architect	3	-	3	-		
Biokit	1	-	1	-		
DiaSorin	1	-	1	-		
Human	1	-	1	-		
Omega Diagnostics	1	-	1	-		
Plasmatec	5	-	5	-		
Serodia	4	-	4	-		
SPINREACT	1	-	1	-		
Standard Diagnostics	1	-	1	-		
Wiener Lab	1	-	1	-		

Syphilis Serology—Qualitative: *Treponema pallidum* Antibodies

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	51	-	51	50	1
Abbott Architect	-	11	-	11	11	-
bioMerieux	-	1	-	1	1	-
Human	-	2	-	2	2	-
Plasmatec	-	6	-	6	5	1
Roche cobas 6000 / c 501	-	2	-	2	2	-
Roche cobas e 411	-	1	-	1	1	-
Serodia	-	8	-	8	8	-
Standard Diagnostics	-	4	-	4	4	-
Specimen SY-14		Specimen SY-15				
<u>Reactive</u>		<u>Reactive</u>		<u>Non-Reactive</u>		
ALL METHODS	51	-	51	-		
Abbott Architect	11	-	11	-		
bioMerieux	1	-	1	-		
Human	2	-	2	-		
Plasmatec	6	-	6	-		
Roche cobas 6000 / c 501	2	-	2	-		
Roche cobas e 411	1	-	1	-		
Serodia	8	-	8	-		
Standard Diagnostics	4	-	4	-		

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13		
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	
ALL METHODS	1	82	-	83	83	-	
Abbott Architect	-	1	-	1	1	-	
Becton Dickinson	-	1	-	1	1	-	
bioMerieux	-	5	-	5	5	-	
BioSystems	-	14	-	14	14	-	
Human	-	5	-	5	5	-	
Omega Diagnostics	-	12	-	12	12	-	
Plasmatec	-	19	-	19	19	-	
Pulse Scientific	-	1	-	1	1	-	
SPINREACT	-	17	-	17	17	-	
Wiener Lab	1	-	-	1	1	-	
Specimen SY-14		Specimen SY-15					
<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>				
ALL METHODS	83	-	81	2			
Abbott Architect	1	-	1	-			
Becton Dickinson	1	-	1	-			
bioMerieux	5	-	5	-			
BioSystems	14	-	14	-			
Human	5	-	5	-			
Omega Diagnostics	12	-	12	-			
Plasmatec	19	-	18	1			
Pulse Scientific	1	-	1	-			
SPINREACT	17	-	17	-			
Wiener Lab	1	-	-	1			

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>
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Specimen SY-11

ALL METHODS	67	1	-	-	-	-	-	-	-
Becton Dickinson	1	-	-	-	-	-	-	-	-
bioMerieux	4	-	-	-	-	-	-	-	-
BioSystems	11	-	-	-	-	-	-	-	-
Human	5	-	-	-	-	-	-	-	-
Omega Diagnostics	10	-	-	-	-	-	-	-	-
Plasmatec	14	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	16	-	-	-	-	-	-	-	-
Wiener Lab	-	1	-	-	-	-	-	-	-

Specimen SY-12

ALL METHODS	68	-	-	-	-	-	-	-	-
Becton Dickinson	1	-	-	-	-	-	-	-	-
bioMerieux	4	-	-	-	-	-	-	-	-
BioSystems	11	-	-	-	-	-	-	-	-
Human	5	-	-	-	-	-	-	-	-
Omega Diagnostics	10	-	-	-	-	-	-	-	-
Plasmatec	14	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	16	-	-	-	-	-	-	-	-
Wiener Lab	1	-	-	-	-	-	-	-	-

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

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>
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Specimen SY-13

ALL METHODS	2	5	36	20	4	1	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-
bioMerieux	-	-	3	1	-	-	-	-	-
BioSystems	-	2	5	4	-	-	-	-	-
Human	-	-	3	2	-	-	-	-	-
Omega Diagnostics	1	-	4	4	-	1	-	-	-
Plasmatec	-	2	6	5	1	-	-	-	-
Pulse Scientific	-	-	-	-	1	-	-	-	-
SPINREACT	-	1	10	3	2	-	-	-	-
Wiener Lab									

Specimen SY-14

ALL METHODS	1	1	4	35	24	3	-	-	-
Becton Dickinson	-	-	-	-	1	-	-	-	-
bioMerieux	-	-	-	3	1	-	-	-	-
BioSystems	-	-	1	8	2	-	-	-	-
Human	-	-	-	3	2	-	-	-	-
Omega Diagnostics	1	-	-	3	5	1	-	-	-
Plasmatec	-	-	2	8	4	-	-	-	-
Pulse Scientific	-	-	-	-	1	-	-	-	-
SPINREACT	-	-	1	7	7	1	-	-	-
Wiener Lab	-	-	-	1	-	-	-	-	-

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

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>
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Specimen SY-15

ALL METHODS	2	5	30	25	4	-	1	1	-
Becton Dickinson	-	-	-	1	-	-	-	-	-
bioMerieux	-	1	2	1	-	-	-	-	-
BioSystems	-	1	5	5	-	-	-	-	-
Human	-	-	2	3	-	-	-	-	-
Omega Diagnostics	1	-	4	3	2	-	-	-	-
Plasmatec	-	1	9	4	-	-	-	-	-
Pulse Scientific	-	-	-	-	1	-	-	-	-
SPINREACT	-	1	6	7	1	-	-	1	-
Wiener Lab	1	-	-	-	-	-	-	-	-

Viral Markers – Anti-HBc (IgM)

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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	49	-	-	50	-	50	-	-
Abbott Architect	1	24	-	-	25	-	25	-	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-	1	-	-
bioMerieux Vidas, Mini									
Vidas	-	1	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	12	-	-	12	-	12	-	-
Roche cobas e 411	-	3	-	-	3	-	3	-	-
Roche Modular Analytics	-	2	-	-	2	-	2	-	-
Siemens ADVIA Centaur	-	2	-	-	2	-	2	-	-
VITROS 3600/4600/5600	-	3	-	-	3	-	3	-	-
Specimen VM-14					Specimen VM-15				
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
	-	50	-		-	50	-		
ALL METHODS	-	50	-	-	25	-			
Abbott Architect	-	25	-	-	25	-			
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-			
bioMerieux Vidas, Mini									
Vidas	-	1	-	-	1	-			
Roche cobas 6000 / e 601	-	12	-	-	12	-			
Roche cobas e 411	-	3	-	-	3	-			
Roche Modular Analytics	-	2	-	-	2	-			
Siemens ADVIA Centaur	-	2	-	-	2	-			
VITROS 3600/4600/5600	-	3	-	-	3	-			

Viral Markers – Anti-HBc (Total / IgG)

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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	73	-	73	2	-	73	2	-
Abbott Architect	1	39	-	40	-	-	39	1	-
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	-	2	-	-
bioMerieux Vidas, Mini									
Vidas	-	1	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	1	14	-	14	1	-	14	1	-
Roche cobas e 411	-	5	-	5	-	-	5	-	-
Roche Modular Analytics	-	1	-	1	-	-	1	-	-
Siemens ADVIA Centaur	-	4	-	4	-	-	4	-	-
VITROS 3600/4600/5600	-	3	-	3	-	-	3	-	-
VITROS ECI	-	2	-	2	-	-	2	-	-
Specimen VM-14					Specimen VM-15				
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	3	71	-	2	73	-			
Abbott Architect	-	40	-	-	40	-			
Beckman ACCESS / 2 / Dxl	1	1	-	-	2	-			
bioMerieux Vidas, Mini									
Vidas	-	1	-	-	1	-			
Roche cobas 6000 / e 601	1	14	-	1	14	-			
Roche cobas e 411	-	5	-	-	5	-			
Roche Modular Analytics	-	1	-	-	1	-			
Siemens ADVIA Centaur	-	3	-	-	4	-			
VITROS 3600/4600/5600	-	3	-	1	2	-			
VITROS ECI	-	2	-	-	2	-			

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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	167	-	1	168	-	1	167	-
Abbott Architect	-	68	-	1	67	-	1	67	-
Acon Laboratories	1	-	-	-	1	-	-	1	-
Alere Clearview HIV1/2									
STAT-PAK	-	1	-	-	1	-	-	1	-
Alere Determine HIV - moderate	-	4	-	-	4	-	-	4	-
Alere Determine HIV - waived	-	1	-	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	3	-	-	3	-	-	3	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	-	1	-
DiASorin	-	1	-	-	1	-	-	1	-
Human	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	35	-	-	35	-	-	35	-
Roche cobas e 411	1	16	-	-	17	-	-	17	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	-	1	-
Roche Modular Analytics	-	3	-	-	3	-	-	3	-
Siemens ADVIA Centaur	-	9	-	-	9	-	-	8	-
Standard Diagnostics	-	2	-	-	2	-	-	2	-
VITROS 3600/4600/5600	-	6	-	-	6	-	-	6	-
VITROS ECI	-	4	-	-	4	-	-	4	-

Viral Markers – Anti-HIV- cont'd

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	167	-	168	1	-
Abbott Architect	1	67	-	68	-	-
Acon Laboratories	-	1	-	1	-	-
Alere Clearview HIV1/2						
STAT-PAK	-	1	-	1	-	-
Alere Determine HIV - moderate	-	4	-	4	-	-
Alere Determine HIV - waived	-	1	-	1	-	-
Beckman ACCESS / 2 / Dxl	-	3	-	3	-	-
bioMerieux Vidas, Mini Vidas	-	1	-	1	-	-
DiASorin	-	1	-	1	-	-
Human	-	1	-	1	-	-
Roche cobas 6000 / e 601	1	34	-	35	-	-
Roche cobas e 411	-	17	-	16	1	-
Roche Elecsys 1010 / 2010	-	1	-	1	-	-
Roche Modular Analytics	-	3	-	3	-	-
Siemens ADVIA Centaur	-	9	-	9	-	-
Standard Diagnostics	-	2	-	2	-	-
VITROS 3600/4600/5600	-	6	-	6	-	-
VITROS ECI	-	4	-	4	-	-

Viral Markers – Anti-HAV (IgM)

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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	67	-	2	66	-	-	68	-
Abbott Architect	-	32	-	1	31	-	-	32	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	17	-	-	17	-	-	17	-
Roche cobas e 411	1	4	-	1	4	-	-	5	-
Roche Modular Analytics	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	5	-	-	5	-	-	5	-
Standard Diagnostics	-	2	-	-	2	-	-	2	-
VITROS 3600/4600/5600	-	1	-	-	1	-	-	1	-
Specimen VM-14			Specimen VM-15						
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>			
	1	67	-	1	67	-			
ALL METHODS	1	67	-	1	67	-			
Abbott Architect	-	32	-	-	32	-			
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-			
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-			
Roche cobas 6000 / e 601	-	17	-	-	17	-			
Roche cobas e 411	1	4	-	1	4	-			
Roche Modular Analytics	-	1	-	-	1	-			
Siemens ADVIA Centaur	-	5	-	-	5	-			
Standard Diagnostics	-	2	-	-	2	-			
VITROS 3600/4600/5600	-	1	-	-	1	-			

Viral Markers – Anti-HAV (Total/IgG)

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13			
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	
ALL METHODS	58	1	-	58	1	-	-	59	-	
Abbott Architect	29	-	-	29	-	-	-	29	-	
bioMerieux Vidas, Mini										
Vidas	4	-	-	4	-	-	-	4	-	
Roche cobas 6000 / e 601	13	-	-	13	-	-	-	13	-	
Roche cobas e 411	3	-	-	3	-	-	-	3	-	
Roche Elecsys 1010 / 2010	1	-	-	1	-	-	-	1	-	
Roche Modular Analytics	2	-	-	2	-	-	-	2	-	
Siemens ADVIA Centaur	4	-	-	4	-	-	-	4	-	
Standard Diagnostics	-	1	-	-	1	-	-	1	-	
VITROS ECi	1	-	-	1	-	-	-	1	-	
Specimen VM-14					Specimen VM-15					
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>			<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>		
	58	1	-			56	3	-		
ALL METHODS	58	1	-			56	3	-		
Abbott Architect	29	-	-			28	1	-		
bioMerieux Vidas, Mini										
Vidas	4	-	-			4	-	-		
Roche cobas 6000 / e 601	13	-	-			13	-	-		
Roche cobas e 411	3	-	-			3	-	-		
Roche Elecsys 1010 / 2010	1	-	-			1	-	-		
Roche Modular Analytics	2	-	-			2	-	-		
Siemens ADVIA Centaur	4	-	-			4	-	-		
Standard Diagnostics	-	1	-			-	1	-		
VITROS ECi	1	-	-			1	-	-		

Viral Markers – HBeAg

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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	-	41	-	-	41	-	1	40	-
Abbott Architect	-	16	-	-	16	-	-	16	-
bioMerieux Vidas, Mini									
Vidas	-	3	-	-	3	-	-	3	-
DiaSorin	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	15	-	-	15	-	-	15	-
Roche cobas e 411	-	2	-	-	2	-	-	2	-
Roche Modular Analytics	-	2	-	-	2	-	-	2	-
Siemens ADVIA Centaur	-	1	-	-	1	-	1	-	-
Specimen VM-14					Specimen VM-15				
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
	-	41	-		-	41	-		
ALL METHODS	-	16	-	-	16	-			
Abbott Architect	-			-					
bioMerieux Vidas, Mini									
Vidas	-	3	-	-	3	-			
DiaSorin	-	1	-	-	1	-			
Roche cobas 6000 / e 601	-	15	-	-	15	-			
Roche cobas e 411	-	2	-	-	2	-			
Roche Modular Analytics	-	2	-	-	2	-			
Siemens ADVIA Centaur	-	1	-	-	1	-			

Viral Markers – Anti-HBs

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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	21	101	-	4	117	1	3	119	-
Abbott Architect	11	38	-	-	49	-	-	49	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-	-	2	-
DiaSorin	1	-	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	6	25	-	1	29	1	1	30	-
Roche cobas e 411	1	11	-	1	11	-	-	12	-
Roche Elecsys 1010 / 2010	1	1	-	-	2	-	-	2	-
Roche Modular Analytics	-	2	-	-	2	-	-	2	-
Siemens ADVIA Centaur	-	8	-	-	8	-	-	8	-
Standard Diagnostics	-	2	-	1	1	-	1	1	-
VITROS 3600/4600/5600	-	6	-	-	6	-	-	6	-
VITROS ECI	-	3	-	-	3	-	-	3	-
Specimen VM-14					Specimen VM-15				
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	119	3	-	119	3	-	119	3	-
Abbott Architect	49	-	-	49	-	-	49	-	-
Beckman ACCESS / 2 / Dxl	2	-	-	2	-	-	2	-	-
DiaSorin	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	31	-	-	31	-	-	31	-	-
Roche cobas e 411	11	1	-	11	1	-	11	1	-
Roche Elecsys 1010 / 2010	2	-	-	2	-	-	2	-	-
Roche Modular Analytics	2	-	-	2	-	-	2	-	-
Siemens ADVIA Centaur	8	-	-	8	-	-	8	-	-
Standard Diagnostics	1	1	-	1	1	-	1	1	-
VITROS 3600/4600/5600	6	-	-	6	-	-	6	-	-
VITROS ECI	3	-	-	3	-	-	3	-	-

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<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	88	68	11	166	2	-	166	1	-
Abbott Architect	57	2	4	64	-	-	64	-	-
Beckman ACCESS / 2 / Dxl	-	3	-	3	-	-	3	-	-
bioMerieux Vidas, Mini									
Vidas	-	2	-	2	-	-	1	-	-
DiaSorin	1	-	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	12	18	6	35	1	-	35	1	-
Roche cobas e 411	8	11	-	18	1	-	19	-	-
Roche Elecsys 1010 / 2010	-	1	-	1	-	-	1	-	-
Roche Modular Analytics	-	2	1	3	-	-	3	-	-
Siemens ADVIA Centaur	-	7	-	7	-	-	7	-	-
Standard Diagnostics	-	8	-	8	-	-	8	-	-
VITROS 3600/4600/5600	5	1	-	6	-	-	6	-	-
VITROS ECi	1	2	-	3	-	-	3	-	-
Specimen VM-14			Specimen VM-15						
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>			
ALL METHODS	2	166	-	-	168	-			
Abbott Architect	1	63	-	-	64	-			
Beckman ACCESS / 2 / Dxl	-	3	-	-	3	-			
bioMerieux Vidas, Mini									
Vidas	-	2	-	-	2	-			
DiaSorin	-	1	-	-	1	-			
Roche cobas 6000 / e 601	-	36	-	-	36	-			
Roche cobas e 411	1	18	-	-	19	-			
Roche Elecsys 1010 / 2010	-	1	-	-	1	-			
Roche Modular Analytics	-	3	-	-	3	-			
Siemens ADVIA Centaur	-	7	-	-	7	-			
Standard Diagnostics	-	8	-	-	8	-			
VITROS 3600/4600/5600	-	6	-	-	6	-			
VITROS ECi	-	3	-	-	3	-			

Viral Markers – Anti-HCV

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	152	4	-	154	2	-	1	154	-
Abbott Architect	62	2	-	64	-	-	1	63	-
Beckman ACCESS / 2 / Dxl	2	-	-	2	-	-	-	2	-
bioMerieux Vidas, Mini Vidas	2	-	-	2	-	-	-	1	-
Human	1	-	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	31	-	-	31	-	-	-	31	-
Roche cobas e 411	15	1	-	15	1	-	-	16	-
Roche Elecsys 1010 / 2010	1	-	-	1	-	-	-	1	-
Roche Modular Analytics	3	-	-	3	-	-	-	3	-
Siemens ADVIA Centaur	8	-	-	8	-	-	-	8	-
Standard Diagnostics	5	-	-	5	-	-	-	5	-
VITROS 3600/4600/5600	6	-	-	6	-	-	-	6	-
VITROS ECI	5	-	-	5	-	-	-	5	-
	Specimen VM-14			Specimen VM-15					
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>			
ALL METHODS	2	154	-	2	154	-			
Abbott Architect	-	64	-	-	64	-			
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-			
bioMerieux Vidas, Mini Vidas	-	2	-	-	2	-			
Human	-	1	-	-	1	-			
Roche cobas 6000 / e 601	-	31	-	-	31	-			
Roche cobas e 411	1	15	-	1	15	-			
Roche Elecsys 1010 / 2010	-	1	-	-	1	-			
Roche Modular Analytics	-	3	-	-	3	-			
Siemens ADVIA Centaur	-	8	-	-	8	-			
Standard Diagnostics	-	5	-	-	5	-			
VITROS 3600/4600/5600	-	6	-	-	6	-			
VITROS ECI	-	5	-	-	5	-			

Toxoplasma gondii Antibody (IgG) - Qualitative

<u>Method</u>	Specimen TOX-5			Specimen TOX-6		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	20	-	-	-	20	-
Abbott Architect	12	-	-	-	12	-
bioMerieux Vidas, Mini						
Vidas	1	-	-	-	1	-
Roche cobas 6000 / e 601	2	-	-	-	2	-
Roche cobas e 411	1	-	-	-	1	-
Siemens ADVIA Centaur	1	-	-	-	1	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen TOX-5						
All Method	21	520.767	276.030	53.0	623.00	0.00 - 1072.83
Abbott Architect	15	453.880	257.336	56.7	455.50	0.00 - 968.56
Roche cobas 6000 / e 601	4	-	-	-	945.95	0.00 - 1072.83
Specimen TOX-6						
All Method	22	0.298	0.172	57.9	0.30	0.00 - 0.65
Abbott Architect	15	0.393	0.110	28.0	0.40	0.17 - 0.62
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-3			Specimen TOX-6		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	22	-	-	-	22	-
Abbott Architect	13	-	-	-	13	-
bioMerieux Vidas, Mini						
Vidas	1	-	-	-	1	-
Roche cobas 6000 / e 601	3	-	-	-	3	-
Roche cobas e 411	2	-	-	-	2	-
Siemens ADVIA Centaur	1	-	-	-	1	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
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Specimen TOX-5

ALL METHODS	18	12.759	9.655	75.7	8.37	0.00 - 32.07
Abbott Architect	12	8.047	0.853	10.6	7.71	6.33 - 9.76

Specimen TOX-6

ALL METHODS	19	0.168	0.044	26.2	0.15	0.08 - 0.26
Abbott Architect	12	0.144	0.024	16.8	0.15	0.09 - 0.20

Cytomegalovirus (CMV) Antibodies (IgG) - Qualitative

<u>Method</u>	Specimen CMV-5			Specimen CMV-6		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	14	-	-	-	14	-
Abbott Architect	12	-	-	-	12	-
Roche cobas 6000 / e 601	2	-	-	-	2	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
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Specimen CMV-5

All Method	17	146.200	25.495	17.4	149.60	95.20 - 197.20
Abbott Architect	13	140.838	25.463	18.1	147.80	89.91 - 191.77

Specimen CMV-6

All Method	17	3.664	1.907	52.1	4.30	0.00 - 7.48
Abbott Architect	13	4.654	0.578	12.4	4.70	3.49 - 5.82

Cytomegalovirus (CMV) Antibodies (IgM) - Qualitative

<u>Method</u>	Specimen CMV-5			Specimen CMV-6		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	18	-	18	-	-
Abbott Architect	-	14	-	14	-	-
Roche cobas 6000 / e 601	-	3	-	3	-	-
Roche cobas e 411	-	1	-	1	-	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
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Specimen CMV-5

All Method	13	0.440	0.104	23.5	0.48	0.23 - 0.65
Abbott Architect	11	0.474	0.069	14.5	0.48	0.33 - 0.62

Specimen CMV-6

All Method	13	2.859	2.583	90.4	1.98	0.00 - 8.03
Abbott Architect	11	1.815	0.224	12.3	1.83	1.36 - 2.27

Glycohemoglobin (percent)

<u>Method</u>	Specimen GH-5						Specimen GH-6					
	<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	197	5.72	0.26	4.5	5.7	5.3 - 6.1	200	11.85	0.79	6.7	11.7	11.1 - 12.6
All Hemoglobin A1c Methods	197	5.72	0.26	4.5	5.7	5.3 - 6.1	200	11.85	0.79	6.7	11.7	11.1 - 12.6
All TOSOH Methods	22	5.81	0.08	1.4	5.8	5.4 - 6.2	23	11.57	0.17	1.5	11.6	10.8 - 12.3
Beckman AU A1c	12	5.53	0.11	2.1	5.5	5.1 - 5.9	12	11.50	0.66	5.7	11.3	10.8 - 12.2
Bio-Rad D-100	12	6.19	0.11	1.8	6.2	5.8 - 6.6	12	11.77	0.35	3.0	11.9	11.0 - 12.5
Roche cobas c 501 HbA1c	11	5.50	0.41	7.5	5.5	5.1 - 5.9	11	10.85	0.59	5.4	11.2	10.2 - 11.6
Siemens DCA Vantage	76	5.73	0.16	2.8	5.7	5.3 - 6.1	77	12.44	0.68	5.5	12.4	11.6 - 13.2
Siemens Dimension HB1C	24	5.68	0.16	2.8	5.7	5.3 - 6.1	24	10.93	0.34	3.1	10.9	10.2 - 11.6
TOSOH G8	22	5.81	0.08	1.4	5.8	5.4 - 6.2	23	11.57	0.17	1.5	11.6	10.8 - 12.3

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>
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Specimen CK-6

All Method	1	-	-	-	21.3	Not graded
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Specimen CK-7

All Method	1	-	-	-	5.9	Not graded
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Specimen CK-8

All Method	1	-	-	-	37.9	Not graded
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Specimen CK-9

All Method	1	-	-	-	14.4	Not graded
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Specimen CK-10

All Method	1	-	-	-	70.6	Not graded
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