

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 2 • 2

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

Table of Contents

Evaluation Criteria	4
Hematology	
Sedimentation Rate	5
Hematology with 5-part Automated Differential (CL Samples – Module 223)	5
White Blood Cell Count.....	5
Red Blood Cell Count.....	6
Hemoglobin.....	6
Hematocrit.....	7
Platelet Count.....	7
Automated Differential.....	8
Blood Bank	
ABO Group	11
Rh Factor (D Type)	11
Unexpected Antibody Detection	11
Antibody Identification	12
Compatibility Testing	12
Coagulation	
Prothrombin Time	13
International Normalized Ratio (INR).....	15
Activated Partial Thromboplastin Time	17
Fibrinogen	18
Prothrombin Time (XS Samples)	19
International Normalized Ratio (INR) (XS Samples).....	20
Urinalysis	
Urinalysis Dipstick	21
Specific Gravity.....	21
pH.....	22
Protein.....	23
Glucose.....	24
Ketones.....	25
Bilirubin.....	26
Urobilinogen.....	27
Blood or Hemoglobin.....	28
Leukocyte Esterase.....	29
Nitrite.....	30
Microalbumin (Dipstick Only).....	31
Urine hCG	31
Microbiology	
Miscellaneous Cultures	32
Antimicrobial Susceptibility Testing	33
Parasitology (FP Specimens)	35
Immunology	
Antinuclear Antibody	37
Qualitative.....	37
Semi-Quantitative.....	37

Table of Contents (continued)

Immunology

Anti-dsDNA.....	39
Anti-RNP	39
Anti-RNP/Sm	40
Anti-SSA	40
Anti-SSB	41
Anti-SSA/SSB	41
Anti-Sm	42
Rubella.....	42
Qualitative.....	42
Quantitative.....	43
Syphilis Serology.....	44
VDRL Slide	44
VDRL Slide (Titer).....	45
MHA-TP	47
TPA.....	48
RPR	49
RPR (Titer).....	50
Viral Markers	53
Anti-HBc (IgM)	53
Anti-HBc (Total/IgG)	54
Anti-HIV	55
Anti-HAV (IgM).....	57
Anti-HAV (Total/IgG).....	58
HBeAg	59
Anti-HBs	60
HBsAg	61
Anti-HCV.....	63
Toxoplasma gondii	65
Qualitative (IgG).....	65
Quantitative (IgG)	65
Qualitative (IgM)	66
Quantitative (IgM)	66
Cytomegalovirus (CMV)	67
Qualitative (IgG).....	67
Quantitative (IgG)	67
Qualitative (IgM)	68
Quantitative (IgM)	68

Chemistry

Bilirubin, Neonatal (Total)	69
Bilirubin, Direct (NB Specimens).....	69
Glycohemoglobin (GH Specimens).....	70
Glucose, Whole Blood (WBG Specimens).....	71

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-3						Specimen ES-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	139	14.0	4.6	33.1	13	0 - 28	134	67.5	15.5	22.9	67	21 - 114
All Automated Methods	24	16.7	3.9	23.5	16	4 - 29	25	88.8	19.4	21.8	88	30 - 147
All Diesse Methods	8	16.5	3.7	22.7	17	5 - 28	9	99.8	13.5	13.5	101	59 - 141
All Manual Methods	104	13.6	4.2	31.1	12	0 - 27	102	65.0	12.0	18.4	66	29 - 101
All Vital Diagnostics Methods	12	14.8	2.2	14.9	15	8 - 22	12	77.3	11.9	15.4	76	41 - 113
Vital Diagnostics Excyte M/10	7	14.7	2.7	18.3	14	6 - 23	7	74.9	13.2	17.6	70	35 - 115
Westergren - diluted	82	12.6	3.5	27.8	12	2 - 24	81	65.9	11.7	17.7	66	30 - 101
Westergren - undiluted	20	16.6	4.6	27.9	17	2 - 31	18	63.4	13.1	20.6	66	24 - 103

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	2.74	0.42	15.4	2.8	2.3 - 3.2	15	6.99	0.67	9.6	6.9	5.9 - 8.1
All Abbott Cell-Dyn Instruments	12	3.10	0.18	5.9	3.1	2.6 - 3.6	12	7.55	0.40	5.4	7.7	6.4 - 8.7
Abbott Cell-Dyn Ruby	8	3.10	0.18	5.9	3.1	2.6 - 3.6	8	7.55	0.40	5.4	7.7	6.4 - 8.7
Orphee Mythic 22	6	2.38	0.17	7.2	2.4	2.0 - 2.8	6	6.43	0.21	3.2	6.4	5.4 - 7.4

<u>Instrument</u>	Specimen CL-8						Specimen CL-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	9.05	0.77	8.6	9.0	7.6 - 10.5	15	18.96	1.40	7.4	19.2	16.1 - 21.9
All Abbott Cell-Dyn Instruments	12	9.68	0.48	4.9	9.8	8.2 - 11.2	12	20.20	0.37	1.8	20.2	17.1 - 23.3
Abbott Cell-Dyn Ruby	8	9.68	0.48	4.9	9.8	8.2 - 11.2	8	20.20	0.37	1.8	20.2	17.1 - 23.3
Orphee Mythic 22	6	8.43	0.36	4.3	8.4	7.1 - 9.7	6	17.73	0.58	3.3	17.7	15.0 - 20.4

<u>Instrument</u>	Specimen CL-10					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	2.73	0.38	13.8	2.7	2.3 - 3.2
All Abbott Cell-Dyn Instruments	12	3.05	0.17	5.7	3.0	2.5 - 3.6
Abbott Cell-Dyn Ruby	8	3.05	0.17	5.7	3.0	2.5 - 3.6
Orphee Mythic 22	6	2.40	0.14	5.9	2.5	2.0 - 2.8

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

Specimen CL-6							Specimen CL-7					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	2.193	0.049	2.3	2.19	2.06 - 2.33	15	4.668	0.125	2.7	4.69	4.38 - 4.95
All Abbott Cell-Dyn Instruments	12	2.218	0.039	1.7	2.21	2.08 - 2.36	12	4.768	0.050	1.0	4.78	4.48 - 5.06
Abbott Cell-Dyn Ruby	8	2.218	0.039	1.7	2.21	2.08 - 2.36	8	4.768	0.050	1.0	4.78	4.48 - 5.06
Orphee Mythic 22	6	2.168	0.051	2.3	2.17	2.03 - 2.30	6	4.568	0.087	1.9	4.57	4.29 - 4.85
Specimen CL-8							Specimen CL-9					
All Method	15	6.429	0.338	5.3	6.41	6.04 - 6.82	15	5.176	0.143	2.8	5.23	4.86 - 5.49
All Abbott Cell-Dyn Instruments	12	6.703	0.207	3.1	6.65	6.30 - 7.11	12	5.290	0.037	0.7	5.30	4.97 - 5.61
Abbott Cell-Dyn Ruby	8	6.703	0.207	3.1	6.65	6.30 - 7.11	8	5.290	0.037	0.7	5.30	4.97 - 5.61
Orphee Mythic 22	6	6.155	0.153	2.5	6.19	5.78 - 6.53	6	5.063	0.108	2.1	5.03	4.75 - 5.37
Specimen CL-10												
All Method	15	2.171	0.067	3.1	2.15	2.04 - 2.31						
All Abbott Cell-Dyn Instruments	12	2.220	0.075	3.4	2.21	2.08 - 2.36						
Abbott Cell-Dyn Ruby	8	2.220	0.075	3.4	2.21	2.08 - 2.36						
Orphee Mythic 22	6	2.135	0.031	1.5	2.14	2.00 - 2.27						

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

Specimen CL-6							Specimen CL-7					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	5.23	0.56	10.7	5.2	4.8 - 5.6	15	12.85	1.03	8.0	13.0	11.9 - 13.8
All Abbott Cell-Dyn Instruments	12	5.73	0.17	3.0	5.8	5.3 - 6.2	12	13.78	0.22	1.6	13.8	12.8 - 14.8
Abbott Cell-Dyn Ruby	8	5.73	0.17	3.0	5.8	5.3 - 6.2	8	13.78	0.22	1.6	13.8	12.8 - 14.8
Orphee Mythic 22	6	4.73	0.17	3.6	4.8	4.3 - 5.1	6	11.93	0.37	3.1	11.9	11.0 - 12.8
Specimen CL-8							Specimen CL-9					
All Method	15	18.14	1.09	6.0	18.3	16.8 - 19.5	15	15.98	0.89	5.6	16.1	14.8 - 17.1
All Abbott Cell-Dyn Instruments	12	19.13	0.19	1.0	19.1	17.7 - 20.5	12	16.78	0.17	1.0	16.8	15.6 - 18.0
Abbott Cell-Dyn Ruby	8	19.13	0.19	1.0	19.1	17.7 - 20.5	8	16.78	0.17	1.0	16.8	15.6 - 18.0
Orphee Mythic 22	6	17.15	0.34	2.0	17.1	15.9 - 18.4	6	15.18	0.34	2.2	15.3	14.1 - 16.3
Specimen CL-10												
All Method	15	5.16	0.54	10.6	4.8	4.7 - 5.6						
All Abbott Cell-Dyn Instruments	12	5.73	0.06	1.0	5.7	5.3 - 6.2						
Abbott Cell-Dyn Ruby	8	5.73	0.06	1.0	5.7	5.3 - 6.2						
Orphee Mythic 22	6	4.73	0.10	2.0	4.8	4.3 - 5.1						

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	16.54	0.92	5.5	16.4	15.5 - 17.6	15	39.80	1.59	4.0	39.7	37.4 - 42.2
All Abbott Cell-Dyn Instruments	12	15.75	0.30	1.9	15.8	14.8 - 16.7	12	38.68	1.09	2.8	39.0	36.3 - 41.0
Abbott Cell-Dyn Ruby	8	15.75	0.30	1.9	15.8	14.8 - 16.7	8	38.68	1.09	2.8	39.0	36.3 - 41.0
Orphee Mythic 22	6	17.33	0.46	2.7	17.4	16.2 - 18.4	6	40.93	1.16	2.8	40.9	38.4 - 43.4

<u>Instrument</u>	Specimen CL-8						Specimen CL-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	55.04	1.49	2.7	54.7	51.7 - 58.4	15	46.51	1.94	4.2	46.5	43.7 - 49.4
All Abbott Cell-Dyn Instruments	12	54.70	1.50	2.7	54.8	51.4 - 58.0	12	45.18	1.26	2.8	45.1	42.4 - 47.9
Abbott Cell-Dyn Ruby	8	54.70	1.50	2.7	54.8	51.4 - 58.0	8	45.18	1.26	2.8	45.1	42.4 - 47.9
Orphee Mythic 22	6	55.38	1.63	2.9	54.7	52.0 - 58.7	6	47.85	1.57	3.3	47.5	44.9 - 50.8

<u>Instrument</u>	Specimen CL-10					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	16.51	0.92	5.6	16.4	15.5 - 17.6
All Abbott Cell-Dyn Instruments	12	15.78	0.33	2.1	15.8	14.8 - 16.8
Abbott Cell-Dyn Ruby	8	15.78	0.33	2.1	15.8	14.8 - 16.8
Orphee Mythic 22	6	17.25	0.65	3.7	17.1	16.2 - 18.3

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	92.3	16.0	17.4	88	69 - 116	15	276.8	9.6	3.5	277	207 - 346
All Abbott Cell-Dyn Instruments	12	79.5	5.8	7.3	79	59 - 100	12	278.3	6.2	2.2	277	208 - 348
Abbott Cell-Dyn Ruby	8	79.5	5.8	7.3	79	59 - 100	8	278.3	6.2	2.2	277	208 - 348
Orphee Mythic 22	6	105.0	11.4	10.9	108	78 - 132	6	275.3	13.1	4.8	279	206 - 345

<u>Instrument</u>	Specimen CL-8						Specimen CL-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	109.1	21.1	19.3	100	81 - 137	15	505.0	19.3	3.8	511	378 - 632
All Abbott Cell-Dyn Instruments	12	129.7	12.7	9.8	136	97 - 163	12	495.3	24.3	4.9	486	371 - 620
Abbott Cell-Dyn Ruby	8	129.7	12.7	9.8	136	97 - 163	8	495.3	24.3	4.9	486	371 - 620
Orphee Mythic 22	6	93.8	6.7	7.1	94	70 - 118	6	514.8	5.5	1.1	514	386 - 644

<u>Instrument</u>	Specimen CL-10					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	89.9	16.2	18.0	80	67 - 113
All Abbott Cell-Dyn Instruments	12	78.3	1.7	2.2	79	58 - 98
Abbott Cell-Dyn Ruby	8	78.3	1.7	2.2	79	58 - 98
Orphee Mythic 22	6	105.3	12.3	11.7	102	78 - 132

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	47.74	2.25	4.7	48.0	40.9 - 54.5	15	63.29	5.01	7.9	64.6	48.2 - 78.4
All Abbott Cell-Dyn Instruments	12	49.35	0.93	1.9	49.7	46.5 - 52.2	12	66.98	0.54	0.8	67.2	65.3 - 68.7
Abbott Cell-Dyn Ruby	8	49.35	0.93	1.9	49.7	46.5 - 52.2	8	66.98	0.54	0.8	67.2	65.3 - 68.7
Orphee Mythic 22	6	46.13	2.01	4.4	46.7	40.1 - 52.2	6	59.60	4.68	7.9	61.4	45.5 - 73.7

<u>Instrument</u>	Specimen CL-8						Specimen CL-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	69.65	4.10	5.9	70.5	57.3 - 82.0	15	75.26	2.35	3.1	75.9	68.2 - 82.4
All Abbott Cell-Dyn Instruments	12	72.90	1.32	1.8	73.2	68.9 - 76.9	12	77.35	0.35	0.5	77.4	76.2 - 78.5
Abbott Cell-Dyn Ruby	8	72.90	1.32	1.8	73.2	68.9 - 76.9	8	77.35	0.35	0.5	77.4	76.2 - 78.5
Orphee Mythic 22	6	66.40	3.05	4.6	66.5	57.2 - 75.6	6	73.18	1.07	1.5	72.9	69.9 - 76.4

<u>Instrument</u>	Specimen CL-10					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	47.54	3.39	7.1	48.7	37.3 - 57.8
All Abbott Cell-Dyn Instruments	12	49.70	0.87	1.8	49.5	47.0 - 52.4
Abbott Cell-Dyn Ruby	8	49.70	0.87	1.8	49.5	47.0 - 52.4
Orphee Mythic 22	6	45.38	3.69	8.1	46.6	34.2 - 56.5

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	35.05	4.87	13.9	35.7	20.4 - 49.7	15	22.76	1.55	6.8	22.7	18.1 - 27.5
All Abbott Cell-Dyn Instruments	12	39.35	1.09	2.8	39.5	36.0 - 42.7	12	23.58	1.47	6.2	23.5	19.1 - 28.0
Abbott Cell-Dyn Ruby	8	39.35	1.09	2.8	39.5	36.0 - 42.7	8	23.58	1.47	6.2	23.5	19.1 - 28.0
Orphee Mythic 22	6	30.75	2.18	7.1	30.7	24.2 - 37.3	6	21.67	0.93	4.3	21.4	18.8 - 24.5

<u>Instrument</u>	Specimen CL-8						Specimen CL-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	18.44	1.58	8.6	17.9	13.6 - 23.2	15	14.08	1.33	9.4	14.2	10.0 - 18.1
All Abbott Cell-Dyn Instruments	12	17.65	0.45	2.6	17.8	16.2 - 19.1	12	13.30	1.25	9.4	13.1	9.5 - 17.1
Abbott Cell-Dyn Ruby	8	17.65	0.45	2.6	17.8	16.2 - 19.1	8	13.30	1.25	9.4	13.1	9.5 - 17.1
Orphee Mythic 22	6	19.50	2.07	10.6	19.2	13.3 - 25.7	6	14.85	0.97	6.6	14.7	11.9 - 17.8

<u>Instrument</u>	Specimen CL-10					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	36.81	6.84	18.6	39.7	16.2 - 57.4
All Abbott Cell-Dyn Instruments	12	41.95	3.31	7.9	40.7	32.0 - 51.9
Abbott Cell-Dyn Ruby	8	41.95	3.31	7.9	40.7	32.0 - 51.9
Orphee Mythic 22	6	29.97	1.00	3.3	29.6	26.9 - 33.0

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	14.31	6.56	45.8	14.0	0.0 - 34.0	15	8.71	4.12	47.3	6.3	0.0 - 21.1
All Abbott Cell-Dyn Instruments	12	8.25	0.86	10.4	8.1	5.6 - 10.9	12	5.48	0.68	12.5	5.5	3.4 - 7.6
Abbott Cell-Dyn Ruby	8	8.25	0.86	10.4	8.1	5.6 - 10.9	8	5.48	0.68	12.5	5.5	3.4 - 7.6
Orphee Mythic 22	6	20.38	1.28	6.3	20.5	16.5 - 24.3	6	13.03	1.15	8.8	13.0	9.5 - 16.5
<u>Instrument</u>	Specimen CL-8						Specimen CL-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	6.84	3.07	44.9	5.1	0.0 - 16.1	15	7.48	3.15	42.2	7.2	0.0 - 17.0
All Abbott Cell-Dyn Instruments	12	4.43	0.56	12.6	4.4	2.7 - 6.1	12	4.55	0.17	3.8	4.6	4.0 - 5.1
Abbott Cell-Dyn Ruby	8	4.43	0.56	12.6	4.4	2.7 - 6.1	8	4.55	0.17	3.8	4.6	4.0 - 5.1
Orphee Mythic 22	6	10.07	0.76	7.6	9.9	7.7 - 12.4	6	10.40	0.61	5.8	10.5	8.5 - 12.3
<u>Instrument</u>	Specimen CL-10											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	15	14.11	6.68	47.3	13.7	0.0 - 34.2						
All Abbott Cell-Dyn Instruments	12	7.98	0.64	8.0	7.9	6.0 - 9.9						
Abbott Cell-Dyn Ruby	8	7.98	0.64	8.0	7.9	6.0 - 9.9						
Orphee Mythic 22	6	20.25	1.80	8.9	19.9	14.8 - 25.7						

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	2.43	0.33	13.6	2.5	1.4 - 3.5	15	3.31	0.82	24.6	3.6	0.8 - 5.8
All Abbott Cell-Dyn Instruments	12	2.50	0.23	9.2	2.5	1.8 - 3.2	12	3.60	0.28	7.9	3.7	2.7 - 4.5
Abbott Cell-Dyn Ruby	8	2.50	0.23	9.2	2.5	1.8 - 3.2	8	3.60	0.28	7.9	3.7	2.7 - 4.5
Orphee Mythic 22	6	2.33	0.47	20.3	2.5	0.9 - 3.8	6	2.93	1.22	41.7	3.2	0.0 - 6.6
<u>Instrument</u>	Specimen CL-8						Specimen CL-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	3.43	1.25	36.6	4.0	0.0 - 7.2	15	3.18	2.21	69.5	3.7	0.0 - 9.8
All Abbott Cell-Dyn Instruments	12	4.45	0.10	2.2	4.4	4.1 - 4.8	12	5.10	0.29	5.8	5.1	4.2 - 6.0
Abbott Cell-Dyn Ruby	8	4.45	0.10	2.2	4.4	4.1 - 4.8	8	5.10	0.29	5.8	5.1	4.2 - 6.0
Orphee Mythic 22	6	2.40	0.92	38.3	2.3	0.0 - 5.2	6	1.25	1.18	94.3	1.2	0.0 - 4.8
<u>Instrument</u>	Specimen CL-10											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	15	2.07	0.53	25.3	2.1	0.4 - 3.7						
All Abbott Cell-Dyn Instruments	12	2.15	0.26	12.3	2.2	1.3 - 3.0						
Abbott Cell-Dyn Ruby	8	2.15	0.26	12.3	2.2	1.3 - 3.0						
Orphee Mythic 22	6	1.97	0.83	42.3	1.7	0.0 - 4.5						

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	15	0.64	0.29	45.1	0.5	0.0 - 1.6	15	0.43	0.23	54.5	0.4	0.0 - 1.2
All Abbott Cell-Dyn Instruments	12	0.48	0.05	10.5	0.5	0.3 - 0.7	12	0.30	0.22	72.0	0.4	0.0 - 1.0
Abbott Cell-Dyn Ruby	8	0.48	0.05	10.5	0.5	0.3 - 0.7	8	0.30	0.22	72.0	0.4	0.0 - 1.0
Orphee Mythic 22	6	0.80	0.35	43.3	0.7	0.0 - 1.9	6	0.55	0.19	34.8	0.5	0.0 - 1.2
	Specimen CL-8						Specimen CL-9					
All Method	15	0.25	0.18	70.9	0.3	0.0 - 0.8	15	0.29	0.16	57.1	0.3	0.0 - 0.8
All Abbott Cell-Dyn Instruments	12	0.23	0.22	98.5	0.2	0.0 - 0.9	12	0.25	0.21	83.3	0.3	0.0 - 0.9
Abbott Cell-Dyn Ruby	8	0.23	0.22	98.5	0.2	0.0 - 0.9	8	0.25	0.21	83.3	0.3	0.0 - 0.9
Orphee Mythic 22	6	0.28	0.15	54.5	0.3	0.0 - 0.8	6	0.33	0.13	38.7	0.3	0.0 - 0.8
	Specimen CL-10											
All Method	15	0.39	0.28	72.3	0.4	0.0 - 1.3						
All Abbott Cell-Dyn Instruments	12	0.23	0.21	91.6	0.3	0.0 - 0.9						
Abbott Cell-Dyn Ruby	8	0.23	0.21	91.6	0.3	0.0 - 0.9						
Orphee Mythic 22	6	0.55	0.26	48.1	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-6	Group A	21	95.45%	Acceptable
	Group AB	1	4.55%	
BB-7	Group B	21	95.45%	Acceptable
	Group AB	1	4.55%	
BB-8	Group O	22	100%	Acceptable
BB-9	Group B	22	100%	Acceptable
BB-10	Group O	22	100%	Acceptable

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-6	Rh Negative	21	95.45%	Acceptable
BB-6	Rh Positive	1	4.55%	
BB-7	Rh Positive	22	100%	Acceptable
BB-8	Rh Positive	22	100%	Acceptable
BB-9	Rh Positive	22	100%	Acceptable
BB-10	Rh Negative	22	100%	Acceptable

UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	No unexpected antibody detected	20	100%	Acceptable
AB-7	No unexpected antibody detected	20	100%	Acceptable
AB-8	No unexpected antibody detected	20	100%	Acceptable
AB-9	Unexpected antibody detected	20	100%	Acceptable
AB-10	Unexpected antibody detected	19	95.00%	Acceptable
	No unexpected antibody detected	1	5.00%	

BLOOD BANK

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	No antibody detected	14	100%	Acceptable
AB-7	No antibody detected	14	100%	Acceptable
AB-8	No antibody detected	14	100%	Acceptable
AB-9	Anti-E	13	100%	Acceptable
AB-10	Anti-D	13	100%	Acceptable

COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	Compatible	14	93.33%	Acceptable
	Not Compatible	1	6.67%	
AB-7	Compatible	14	93.33%	Acceptable
	Not Compatible	1	6.67%	
AB-8	Compatible	14	93.33%	Acceptable
	Not Compatible	1	6.67%	
AB-9	Compatible	14	93.33%	Acceptable
	Not Compatible	1	6.67%	
AB-10	Compatible	15	100%	Acceptable

Coagulation

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-6						Specimen CG-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	47	12.58	1.73	13.7	11.6	10.6 - 14.5	47	23.67	3.73	15.7	23.5	20.1 - 27.3
Dade Innovin												
Dade Behring BFT II	5	11.20	0.57	5.1	11.2	9.5 - 12.9	5	20.80	0.01	0.0	20.8	17.6 - 24.0
Sysmex CA-500/600 series	12	10.92	0.26	2.4	11.0	9.2 - 12.6	12	19.61	0.82	4.2	19.6	16.6 - 22.6
All Coagulation Instruments	18	10.95	0.29	2.7	11.0	9.3 - 12.6	18	19.71	0.88	4.5	19.7	16.7 - 22.7
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	6	14.53	0.53	3.6	14.5	12.3 - 16.8	6	27.50	1.20	4.4	27.2	23.3 - 31.7
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	10	14.49	0.43	3.0	14.4	12.3 - 16.7	10	26.83	0.90	3.4	27.1	22.8 - 30.9
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	14.05	0.07	0.5	14.1	11.9 - 16.2	5	30.00	0.28	0.9	30.0	25.5 - 34.5
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	11.35	0.21	1.8	11.4	9.6 - 13.1	6	23.42	1.03	4.4	23.4	19.9 - 27.0
<u>Reagent/Instrument</u>	Specimen CG-8						Specimen CG-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	47	33.06	5.67	17.1	34.2	28.0 - 38.1	47	13.37	1.54	11.5	12.7	11.3 - 15.4
Dade Innovin												
Dade Behring BFT II	5	29.10	1.84	6.3	29.1	24.7 - 33.5	5	11.65	0.21	1.8	11.7	9.9 - 13.4
Sysmex CA-500/600 series	12	26.59	1.03	3.9	26.6	22.6 - 30.6	12	12.00	0.36	3.0	12.1	10.2 - 13.8
All Coagulation Instruments	18	26.87	1.40	5.2	26.7	22.8 - 30.9	18	11.97	0.35	2.9	12.1	10.1 - 13.8
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	6	37.97	1.53	4.0	38.0	32.2 - 43.7	6	15.25	0.67	4.4	15.1	12.9 - 17.6
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	10	37.64	1.84	4.9	37.6	31.9 - 43.3	10	14.67	0.72	4.9	14.8	12.4 - 16.9
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	43.25	0.21	0.5	43.3	36.7 - 49.8	5	15.30	0.57	3.7	15.3	13.0 - 17.6
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	33.88	1.77	5.2	33.3	28.7 - 39.0	6	12.54	0.45	3.6	12.5	10.6 - 14.5

PROTHROMBIN TIME (seconds)**Specimen CG-10**

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	47	12.24	1.62	13.2	11.5	10.4 - 14.1
Dade Innovin						
Dade Behring BFT II	5	10.25	0.07	0.7	10.3	8.7 - 11.8
Sysmex CA-500/600 series	12	10.86	0.34	3.1	10.9	9.2 - 12.5
All Coagulation Instruments	18	10.79	0.37	3.5	10.8	9.1 - 12.5
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	6	14.17	0.54	3.8	14.2	12.0 - 16.3
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STart Max	10	13.88	0.66	4.8	14.0	11.7 - 16.0
Diagnostica Stago STA NeoPTimal						
Diagnostica Stago STA Compact / Max	5	13.65	0.21	1.6	13.7	11.6 - 15.7
HemosIL RecombiPlasTin 2G						
IL ACL, all models	6	11.12	0.29	2.6	11.1	9.4 - 12.8

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-6						Specimen CG-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	47	1.08	0.08	7.4	1.1	0.9 - 1.3	47	2.17	0.27	12.6	2.1	1.8 - 2.5
Dade Innovin												
Dade Behring BFT II	5	1.15	0.07	6.1	1.2	0.9 - 1.4	5	2.05	0.07	3.4	2.1	1.7 - 2.4
Sysmex CA-500/600 series	12	1.08	0.05	4.2	1.1	0.9 - 1.3	12	1.96	0.12	5.9	2.0	1.6 - 2.3
All Coagulation Instruments	18	1.07	0.07	6.6	1.1	0.9 - 1.3	18	1.95	0.13	6.7	2.0	1.6 - 2.3
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	6	1.11	0.04	3.4	1.1	0.9 - 1.3	6	2.46	0.10	4.0	2.4	2.0 - 2.9
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	10	1.13	0.05	4.4	1.1	0.9 - 1.4	10	2.41	0.14	5.7	2.5	2.0 - 2.8
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	1.10	0.01	0.0	1.1	0.9 - 1.3	5	2.45	0.07	2.9	2.5	2.0 - 2.9
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	0.98	0.08	7.7	1.0	0.8 - 1.2	6	2.03	0.20	9.7	2.0	1.7 - 2.4
<u>Reagent/Instrument</u>	Specimen CG-8						Specimen CG-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	47	3.16	0.52	16.4	2.9	2.6 - 3.7	47	1.15	0.08	7.1	1.2	0.9 - 1.4
Dade Innovin												
Dade Behring BFT II	5	2.75	0.21	7.7	2.8	2.3 - 3.2	5	1.20	0.01	0.0	1.2	1.0 - 1.4
Sysmex CA-500/600 series	12	2.70	0.16	5.9	2.7	2.2 - 3.2	12	1.17	0.07	5.6	1.2	0.9 - 1.4
All Coagulation Instruments	18	2.68	0.19	6.9	2.7	2.2 - 3.1	18	1.17	0.06	5.3	1.2	0.9 - 1.4
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	6	3.70	0.14	3.8	3.7	3.1 - 4.3	6	1.20	0.08	6.8	1.2	1.0 - 1.4
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	10	3.68	0.26	7.2	3.7	3.1 - 4.3	10	1.13	0.07	6.2	1.1	0.9 - 1.4
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	3.60	0.01	0.0	3.6	3.0 - 4.2	5	1.20	0.01	0.0	1.2	1.0 - 1.4
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	2.98	0.24	8.0	2.9	2.5 - 3.5	6	1.08	0.08	7.7	1.1	0.9 - 1.3

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

Specimen CG-10

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	47	1.05	0.08	7.7	1.1	0.8 - 1.3
Dade Innovin						
Dade Behring BFT II	5	1.15	0.07	6.1	1.2	0.9 - 1.4
Sysmex CA-500/600 series	12	1.08	0.05	4.2	1.1	0.9 - 1.3
All Coagulation Instruments	18	1.08	0.06	5.2	1.1	0.9 - 1.3
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	6	1.10	0.06	5.2	1.1	0.9 - 1.3
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STart Max	10	1.04	0.07	7.0	1.1	0.8 - 1.3
Diagnostica Stago STA NeoPTimal						
Diagnostica Stago STA Compact / Max	5	1.05	0.07	6.7	1.1	0.8 - 1.3
HemosIL RecombiPlasTin 2G						
IL ACL, all models	6	0.95	0.08	8.8	0.9	0.8 - 1.1

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

Specimen CG-6							Specimen CG-7					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	24	27.5	5.1	18.4	25	23 - 32	24	35.6	2.3	6.4	36	30 - 41
Dade Actin FSL												
Sysmex CA-500/600 series	7	23.9	0.9	3.8	24	20 - 28	7	34.7	2.1	5.9	35	29 - 40
All Coagulation Instruments	8	23.9	0.8	3.5	24	20 - 28	8	34.6	1.9	5.6	35	29 - 40
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	5	29.0	0.1	0.0	29	24 - 34	5	38.0	0.1	0.0	38	32 - 44
HemosIL APTT-SP												
IL ACL, all models	5	34.5	7.8	22.5	35	29 - 40	5	36.0	1.4	3.9	36	30 - 42
IL TEST APTT-SP												
IL ACL, all models	5	34.0	1.4	4.2	34	28 - 40	5	38.0	2.8	7.4	38	32 - 44
Specimen CG-8							Specimen CG-9					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	24	40.5	3.9	9.6	42	34 - 47	24	28.3	4.1	14.5	27	24 - 33
Dade Actin FSL												
Sysmex CA-500/600 series	7	40.1	2.5	6.2	39	34 - 47	7	25.3	2.1	8.5	25	21 - 30
All Coagulation Instruments	8	40.1	2.3	5.7	40	34 - 47	8	25.3	2.0	7.8	25	21 - 30
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	5	43.5	0.7	1.6	44	36 - 51	5	32.5	0.7	2.2	33	27 - 38
HemosIL APTT-SP												
IL ACL, all models	5	37.5	9.2	24.5	38	31 - 44	5	33.0	4.2	12.9	33	28 - 38
IL TEST APTT-SP												
IL ACL, all models	5	44.0	2.8	6.4	44	37 - 51	5	32.5	0.7	2.2	33	27 - 38
Specimen CG-10												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	24	25.7	2.9	11.4	25	21 - 30						
Dade Actin FSL												
Sysmex CA-500/600 series	7	23.3	1.3	5.4	23	19 - 27						
All Coagulation Instruments	8	23.3	1.2	5.0	23	19 - 27						
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	5	28.5	0.7	2.5	29	24 - 33						
HemosIL APTT-SP												
IL ACL, all models	5	29.0	0.1	0.0	29	24 - 34						
IL TEST APTT-SP												
IL ACL, all models	5	29.0	1.4	4.9	29	24 - 34						

FIBRINOGEN (mg/dL)

Specimen CG-6							Specimen CG-7					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	11	440.1	35.4	8.0	429	352 - 529	11	237.3	15.7	6.6	234	189 - 285
IL Fibrinogen-C												
IL ACL, all models	6	419.8	20.0	4.8	418	335 - 504	6	234.0	15.9	6.8	239	187 - 281
Specimen CG-8							Specimen CG-9					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	11	239.3	22.3	9.3	245	191 - 288	11	155.4	10.6	6.8	152	124 - 187
IL Fibrinogen-C												
IL ACL, all models	6	237.5	24.3	10.2	246	190 - 285	6	152.0	6.2	4.1	152	121 - 183
Specimen CG-10												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	11	197.0	6.7	3.4	195	157 - 237						
IL Fibrinogen-C												
IL ACL, all models	6	198.0	6.1	3.1	195	158 - 238						

PROTHROMBIN TIME (seconds) – XS Samples

<u>Reagent/Instrument</u>	Specimen XS-6						Specimen XS-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	28	22.68	1.07	4.7	22.9	19.2 - 26.1	28	15.22	0.45	3.0	15.2	12.9 - 17.6
All Roche CoaguChek XS Plus Instruments	14	22.81	0.87	3.8	22.5	19.3 - 26.3	14	15.28	0.50	3.3	15.3	12.9 - 17.6
Roche CoaguChek Pro II	14	22.56	1.26	5.6	23.0	19.1 - 26.0	14	15.16	0.41	2.7	15.1	12.8 - 17.5
Roche CoaguChek XS Plus - Waived	9	22.78	0.68	3.0	22.5	19.3 - 26.2	9	15.11	0.42	2.8	15.1	12.8 - 17.4
Roche CoaguChek XS Plus	5	22.86	1.22	5.3	22.5	19.4 - 26.3	5	15.58	0.53	3.4	15.6	13.2 - 18.0

<u>Reagent/Instrument</u>	Specimen XS-8						Specimen XS-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	10	15.08	0.58	3.8	15.2	12.8 - 17.4	10	22.83	2.55	11.2	23.3	19.4 - 26.3
All Roche CoaguChek XS Plus Instruments	10	15.08	0.58	3.8	15.2	12.8 - 17.4	10	22.83	2.55	11.2	23.3	19.4 - 26.3
Roche CoaguChek XS Plus - Waived	5	14.75	0.64	4.3	14.8	12.5 - 17.0	5	20.85	1.91	9.2	20.9	17.7 - 24.0
Roche CoaguChek XS Plus	5	15.40	0.42	2.8	15.4	13.0 - 17.8	5	24.80	0.57	2.3	24.8	21.0 - 28.6

<u>Reagent/Instrument</u>	Specimen XS-10					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	10	31.70	1.34	4.2	31.3	26.9 - 36.5
All Roche CoaguChek XS Plus Instruments	10	31.70	1.34	4.2	31.3	26.9 - 36.5
Roche CoaguChek XS Plus - Waived	5	30.75	0.07	0.2	30.8	26.1 - 35.4
Roche CoaguChek XS Plus	5	32.65	1.34	4.1	32.7	27.7 - 37.6

INTERNATIONAL NORMALIZED RATIO (INR)– XS Samples

Specimen XS-6							Specimen XS-7						
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	
All Method	54	1.90	0.07	3.9	1.9	1.6 - 2.2	56	1.27	0.05	4.2	1.3	1.0 - 1.5	
All Roche CoaguChek XS Plus Instruments	29	1.90	0.07	3.8	1.9	1.6 - 2.2	30	1.26	0.06	4.5	1.3	1.0 - 1.5	
Roche CoaguChek Pro II	25	1.90	0.08	4.0	1.9	1.6 - 2.2	26	1.28	0.05	3.8	1.3	1.0 - 1.5	
Roche CoaguChek XS Plus - Waived	23	1.90	0.06	3.0	1.9	1.6 - 2.2	24	1.25	0.05	4.1	1.3	1.0 - 1.5	
Roche CoaguChek XS Plus	6	1.93	0.12	6.3	2.0	1.6 - 2.3	6	1.30	0.06	4.9	1.3	1.1 - 1.5	

Specimen XS-8							Specimen XS-9						
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	
All Method	20	1.28	0.04	3.4	1.3	1.0 - 1.5	20	1.99	0.08	3.9	2.0	1.6 - 2.3	
All Roche CoaguChek XS Plus Instruments	9	1.27	0.05	4.1	1.3	1.0 - 1.5	9	1.88	0.17	9.1	1.9	1.6 - 2.2	
Roche CoaguChek Pro II	11	1.28	0.04	3.2	1.3	1.0 - 1.5	11	2.02	0.04	2.0	2.0	1.7 - 2.4	
Roche CoaguChek XS Plus - Waived	5	1.25	0.06	4.6	1.3	1.0 - 1.5	5	1.80	0.14	7.9	1.9	1.5 - 2.1	
Roche CoaguChek XS Plus	4	-	-	-	1.3	1.1 - 1.5	4	-	-	-	2.1	1.7 - 2.4	

Specimen XS-10						
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	20	2.69	0.08	2.9	2.7	2.2 - 3.1
All Roche CoaguChek XS Plus Instruments	9	2.63	0.08	3.1	2.6	2.2 - 3.1
Roche CoaguChek Pro II	11	2.72	0.06	2.2	2.7	2.3 - 3.2
Roche CoaguChek XS Plus - Waived	5	2.60	0.01	0.0	2.6	2.2 - 3.0
Roche CoaguChek XS Plus	4	-	-	-	2.7	2.2 - 3.2

URINALYSIS DIPSTICK–SPECIFIC GRAVITY

Specimen UA-2

<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	114	1.0238	0.0056	0.6	1.025	1.013 - 1.034
All Iris Diagnostics Methods	7	1.0270	0.0014	0.1	1.028	1.017 - 1.037
All Refractive Index Methods	10	1.0269	0.0034	0.3	1.028	1.016 - 1.037
All Roche Methods	30	1.0211	0.0065	0.6	1.020	1.011 - 1.032
All Siemens Methods	35	1.0227	0.0025	0.2	1.025	1.012 - 1.033
77 Elektronika LabUMat/2	14	1.0321	0.0017	0.2	1.032	1.022 - 1.043
Acon Laboratories	9	1.0250	0.0035	0.3	1.025	1.015 - 1.035
Roche Chemstrips / Combur	8	1.0181	0.0046	0.5	1.020	1.008 - 1.029
Roche cobas u 411	9	1.0189	0.0022	0.2	1.020	1.008 - 1.029
Roche cobas u 601 / 701	6	1.0313	0.0057	0.6	1.034	1.021 - 1.042
Roche Urisys	15	1.0183	0.0041	0.4	1.020	1.008 - 1.029
Siemens Clinitek Advantus	14	1.0236	0.0024	0.2	1.025	1.013 - 1.034
Siemens Clinitek Status / Status+	20	1.0220	0.0025	0.2	1.020	1.012 - 1.032

URINALYSIS DIPSTICK-pH

Specimen UA-2

Participant Results

<u>Method</u>	<u>Labs</u>	<u>≤3.5</u>	<u>4.0</u>	<u>4.5</u>	<u>5.0</u>	<u>5.5</u>	<u>6.0</u>	<u>6.5</u>	<u>7.0</u>	<u>7.5</u>	<u>8.0</u>	<u>8.5</u>	<u>≥9.0</u>
ALL METHODS	138	-	-	-	90	26	22	-	-	-	-	-	-
77 Elektronika LabUMat/2	14	-	-	-	14	-	-	-	-	-	-	-	-
Acon Laboratories	9	-	-	-	1	-	8	-	-	-	-	-	-
Arkray Aution AU-4050	2	-	-	-	1	1	-	-	-	-	-	-	-
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	-	-	-	1	-	1	-	-	-	-	-	-
Roche Chemstrips / Combur	21	-	-	-	21	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	1	-	-	-	-	-	-	-	-
Roche cobas u 411	9	-	-	-	9	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	6	-	-	-	6	-	-	-	-	-	-	-	-
Roche Urisys	15	-	-	-	15	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	1	-	-	-	-	1	-	-	-	-	-	-	-
Siemens Clinitek Advantus	14	-	-	-	-	13	1	-	-	-	-	-	-
Siemens Clinitek Status / Status+	20	-	-	-	11	8	1	-	-	-	-	-	-
Siemens Reagent Strips	12	-	-	-	-	1	11	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	1	-	-	-	-	-	-	-	-
UriScan Pro/II	1	-	-	-	1	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–PROTEIN QUALITATIVE

Specimen UA-2

<u>Method</u>	Participant Results												
	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>10 - 20 mg/dL</u>	<u>30 - 70 mg/dL</u>	<u>75 mg/dL</u>	<u>100 - 200 mg/dL</u>	<u>≥300 - 600 mg/dL</u>	<u>>600 or ≥1000 mg/dL</u>
ALL METHODS	138	137	-	-	-	-	-	-	-	-	-	-	1
77 Elektronika LabUMat/2	14	14	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	9	9	-	-	-	-	-	-	-	-	-	-	-
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	2	2	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	21	21	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	9	9	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	6	5	-	-	-	-	-	-	-	-	-	-	1
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–GLUCOSE

Specimen UA-2

<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	138	7	16	23	1	5	58	-	3	1	24
77 Elektronika LabUMat/2	14	-	-	-	-	-	9	-	-	-	5
Acon Laboratories	9	-	-	1	-	-	8	-	-	-	-
Arkray Aution AU-4050	2	-	-	-	-	-	1	-	-	-	1
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	1
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	-	2	1	-	-	-	1
Iris Ichem VELOCITY Urine Chemistry System	3	-	-	-	-	3	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	1	-
Other Dipstick Method	1	-	-	-	-	-	1	-	-	-	-
Roche Chemstrips / Combur	21	-	-	-	-	-	21	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	1	-	-	-	-
Roche cobas u 411	9	-	-	-	-	-	3	-	-	-	6
Roche cobas u 601 / 701	6	-	-	-	-	-	-	-	-	-	6
Roche Urisys	15	-	-	-	-	-	11	-	1	-	3
SD UroColor Reagent Strips	1	-	-	1	-	-	-	-	-	-	-
Siemens Clinitek Advantus	14	-	4	9	-	-	-	-	1	-	-
Siemens Clinitek Status / Status+	20	-	8	11	-	-	-	-	1	-	-
Siemens Reagent Strips	12	7	4	1	-	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	-	-	1
UriScan Pro/II	1	-	-	-	1	-	-	-	-	-	-

URINALYSIS DIPSTICK–KETONES

Specimen UA-2

<u>Method</u>	<u>Labs</u>	<u>Participant Results</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>
		<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>						
ALL METHODS	137	4	1	-	-	-	11	84	9	2	-	2	21	-	3	
77 Elektronika LabUMat/2	14	-	-	-	-	-	2	7	-	-	-	-	5	-	-	
Acon Laboratories	8	2	-	-	-	-	3	2	1	-	-	-	-	-	-	
Arkray Aution AU-4050	2	-	-	-	-	-	-	1	-	-	-	-	1	-	-	
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	21	-	1	-	-	-	1	18	1	-	-	-	-	-	-	
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	
Roche cobas u 411	9	-	-	-	-	-	-	-	2	1	-	-	3	-	3	
Roche cobas u 601 / 701	6	-	-	-	-	-	-	-	-	-	-	-	6	-	-	
Roche Urisys	15	-	-	-	-	-	1	8	3	-	-	-	3	-	-	
SD UroColor Reagent Strips	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	
Siemens Clinitek Advantus	14	-	-	-	-	-	4	9	-	-	-	-	1	-	-	
Siemens Clinitek Status / Status+	20	-	-	-	-	-	-	17	2	-	-	-	1	-	-	
Siemens Reagent Strips	12	-	-	-	-	-	-	12	-	-	-	-	-	-	-	
Sysmex UN Series	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	
UriScan Pro/II	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-2

<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	114	114	-	-	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	14	14	-	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-
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	8	8	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-
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–UROBILINOGEN

Specimen UA-2

<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>\geq8.0 or \geq12.0 mg/dL or \geq140 or 200 μmol/L</u>
ALL METHODS	114	114	-	-	-	-
77 Elektronika LabUMat/2	14	14	-	-	-	-
Acon Laboratories	9	9	-	-	-	-
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	8	8	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-
Roche cobas u 411	9	9	-	-	-	-
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–BLOOD/HEMOGLOBIN

Specimen UA-2

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>(5+)</u>	<u>5 - 25</u> <u>Ery/μL</u>	<u>50 -</u> <u>100</u> <u>Ery/μL</u>	<u>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	138	138	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	14	14	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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	20	20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	6	6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Mditron Junior/II	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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–LEUKOCYTE ESTERASE

Specimen UA-2

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>15 or 25 µL</u>	<u>75 or 100 µL</u>	<u>250 or 500 µL</u>
ALL METHODS	126	-	2	1	-	-	31	17	45	2	1	-	27
77 Elektronika LabUMat/2	14	-	-	-	-	-	-	-	9	-	-	-	5
Acon Laboratories	9	-	-	-	-	-	2	7	-	-	-	-	-
Arkray Aution AU-4050	2	-	-	-	-	-	-	-	-	1	-	-	1
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	-	-	1
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	-	-	-	-	2	-	-	-	2
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	-	-	-	1	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	-	-	-	-	2	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	-	-	1
Other Dipstick Method	1	-	-	-	-	-	-	1	-	-	-	-	-
Roche Chemstrips / Combur	21	-	-	-	-	-	2	-	19	-	-	-	-
Roche cobas u 411	9	-	-	-	-	-	-	-	2	1	-	-	6
Roche cobas u 601 / 701	6	-	-	-	-	-	-	-	-	-	-	-	6
Roche Urisys	15	-	-	-	-	-	-	1	10	-	-	-	4
SD UroColor Reagent Strips	1	-	-	-	-	-	-	1	-	-	-	-	-
Siemens Clinitek Advantus	14	-	1	-	-	-	12	-	-	-	1	-	-
Siemens Clinitek Status / Status+	20	-	1	1	-	-	15	3	-	-	-	-	-
Siemens Reagent Strips	1	-	-	-	-	-	-	1	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	-	-	-	-	1
UriScan Pro/II	1	-	-	-	-	-	-	1	-	-	-	-	-

URINALYSIS DIPSTICK–NITRITE**Specimen UA-2*****Participant Results***

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	127	117	10
77 Elektronika LabUMat/2	14	14	-
Acon Laboratories	9	8	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	4	-
Iris Ichem VELOCITY Urine Chemistry System	3	3	-
Other Analyzer Method	1	1	-
Other Dipstick Method	1	1	-
Roche Chemstrips / Combur	21	21	-
Roche cobas 6500 / u 601	1	1	-
Roche cobas u 411	9	4	5
Roche cobas u 601 / 701	6	4	2
Roche Urisys	15	15	-
SD UroColor Reagent Strips	1	1	-
Siemens Clinitek Advantus	14	13	1
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-2

<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	4	2	-	-	-	-	-	-	-
Roche Micral - 1 minute	2	1	-	1	-	-	-	-	-	-	-

URINALYSIS –URINE hCG

Specimen UA-2

<u>Method</u>	<i>Participant Results</i>		
	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	81	22	59
77 Elektronika LabUMat/2	1	1	-
Acon Laboratories	5	3	2
Alere hCG Combo Cassette	2	-	2
Biosynex	4	3	1
JusChek	5	1	4
Ms. Tellme hCG Rapid Test Cassette	20	-	20
SD Bioline hCG	2	1	1
Siemens Clinitek Status / Status+	15	-	15

This challenge is ungraded due to lack of referee consensus. The sample was negative on the Beckman Access but questionable on most rapid tests. Another analyte in the sample caused a degradation of the hCG.

MISCELLANEOUS CULTURES

Specimen BA-4 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Klebsiella aerogenes	65	38.41%	Acceptable
Cutibacterium acnes	25	15.24%	Acceptable
Anaerobic cultures not performed	9	5.49%	Acceptable
Anaerobe present – would refer	8	4.88%	Acceptable
Gram positive bacilli	3	1.83%	Acceptable
Anaerobe present – no ID	3	1.83%	Acceptable
Gram negative bacilli	1	0.66%	Acceptable
Klebsiella sp.	1	0.61%	Acceptable
Enterobacter sp.	44	26.83%	

Organism(s) present: *Klebsiella aerogenes* and *Cutibacterium acnes*. This challenge was graded by referee consensus.

Technical note: In 2019, *Enterobacter aerogenes* was re-classified as *Klebsiella aerogenes* owing to its higher genotypic similarity with the genus *Klebsiella*. It has been demonstrated that patients with *Klebsiella aerogenes* bloodstream infections have a much poorer clinical outcome than those with *Enterobacter sp.*, thus making it clinically relevant to distinguish between these two genera of organisms. See <https://journals.asm.org/doi/full/10.1128/JCM.00582-20> for more details regarding the significance of this differentiation.

Specimen BA-5 – Sputum Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Streptococcus pneumoniae	96	82.76%	Acceptable
Gram positive cocci	3	2.59%	Acceptable
Streptococcus viridans group	1	0.86%	Acceptable
Streptococcus alpha-hemolytic	1	0.86%	Acceptable
No growth (sterile)	7	6.03%	

Organism(s) present: *Streptococcus pneumoniae*

Specimen BA-6 – CSF (Spinal Fluid) Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pantoea sp.	74	61.67%	Acceptable
Pantoea agglomerans	26	21.67%	Acceptable
Gram negative bacilli	4	3.33%	Acceptable
Enterobacter sp.	5	4.17%	

Organism(s) present: *Pantoea agglomerans*

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Specimen UC-6, CC-6 (SUS-6) Organism(s) present: *Staphylococcus aureus*

<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>	
Amikacin	4	4	-	-	8	7	-	1	Inappropriate drug ¹
Amoxicillin/Clavulanate	12	12	-	-	14	13	-	1	96.15%
Ampicillin	7	3	-	4	23	1	-	22	Inappropriate drug ¹
Ampicillin/Sulbactam	4	4	-	-	16	13	-	3	85.00%
Aztreonam	-	-	-	-	1	1	-	-	Intrinsically Resistant ²
Cefaclor	2	2	-	-	-	-	-	-	100.00%
Cefazolin	3	3	-	-	11	9	-	2	85.71%
Cefdinir	1	1	-	-	-	-	-	-	100.00%
Cefepime	2	2	-	-	7	7	-	-	100.00%
Cefixime	5	2	-	3	-	-	-	-	Inappropriate drug ¹
Cefoperazone	-	-	-	-	1	1	-	-	100.00%
Cefotaxime	5	5	-	-	3	3	-	-	100.00%
Cefoxitin	16	15	-	1	13	11	-	2	89.66%
Cefpodoxime	4	4	-	-	-	-	-	-	100.00%
Ceftaroline	1	1	-	-	36	36	-	-	100.00%
Ceftazidime	1	-	-	1	2	2	-	-	Inappropriate drug ¹
Ceftazidime	19	17	2	-	99	99	-	-	98.31%
Ceftolozane/Tazobactam	1	1	-	-	1	1	-	-	Inappropriate drug ¹
Ceftriaxone	8	8	-	-	8	6	1	1	87.50%
Cefuroxime	12	12	-	-	3	3	-	-	100.00%
Ciprofloxacin	21	20	1	-	138	136	1	1	98.11%
Colistin	-	-	-	-	1	-	1	-	Intrinsically Resistant ²
Daptomycin	-	-	-	-	47	47	-	-	100.00%
Doripenem	-	-	-	-	1	1	-	-	100.00%
Doxycycline	5	5	-	-	1	1	-	-	100.00%
Ertapenem	1	1	-	-	2	2	-	-	100.00%
Fosfomycin	3	3	-	-	2	2	-	-	Inappropriate drug ¹

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

² This drug is intrinsically resistant to organism.

ANTIMICROBIAL SUSCEPTIBILITY TESTING (continued)

Specimen UC-6, CC-6 (SUS-6) Organism(s) present: *Staphylococcus aureus*

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<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>	
Gatifloxacin	-	-	-	-	1	1	-	-	100.00%
Gentamicin	22	21	-	1	73	73	-	-	98.95%
Imipenem	1	1	-	-	4	4	-	-	100.00%
Levofloxacin	15	15	-	-	90	89	-	1	99.05%
Linezolid	14	14	-	-	87	87	-	-	100.00%
Meropenem	3	3	-	-	5	5	-	-	100.00%
Minocycline	-	-	-	-	15	15	-	-	100.00%
Moxifloxacin	3	3	-	-	26	25	1	-	96.55%
Nalidixic Acid	1	-	-	1	-	-	-	-	100.00%
Netilmicin	-	-	-	-	1	1	-	-	Inappropriate drug ¹
Nitrofurantoin	27	26	1	-	133	133	-	-	99.38%
Norfloxacin	5	5	-	-	9	8	-	1	92.86%
Ofloxacin	5	5	-	-	1	-	-	1	83.33%
Oxacillin	15	15	-	-	120	117	-	3	97.78%
Penicillin	21	-	-	21	51	1	-	50	98.61%
Piperacillin/Tazobactam	2	2	-	-	2	2	-	-	100.00%
Quinupristin/Dalfopristin	-	-	-	-	13	13	-	-	100.00%
Rifampin	14	14	-	-	65	64	-	1	98.73%
Teicoplanin	1	1	-	-	20	20	-	-	100.00%
Tetracycline	10	10	-	-	77	77	-	-	100.00%
Tobramycin	1	1	-	-	-	-	-	-	Inappropriate ¹
Trimethoprim	1	1	-	-	6	6	-	-	100.00%
Trimethoprim/Sulfamethoxazole	25	25	-	-	149	149	-	-	100.00%
Vancomycin	7	7	-	-	117	117	-	-	100.00%

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

Specimen FP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	271	61.31%	Acceptable
Trichuris trichiura eggs	146	33.03%	Acceptable
Parasite egg or larva seen – no ID	1	0.33%	Acceptable
Taenia sp. eggs	9	2.04%	
Blastocystis hominis	5	1.15%	
Endolimax nana	4	0.90%	

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

Specimen FP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	259	49.24%	Acceptable
Blastocystis hominis	149	28.33%	Acceptable
Protozoan cyst or trophozoite seen	1	0.19%	Acceptable
Entamoeba coli	65	11.98%	
Endolimax nana	23	4.37%	
Entamoeba histolytica	13	2.47%	
Strongyloides stercoralis larva	5	0.95%	
No parasite seen	5	0.95%	

Parasite(s) present: *Giardia lamblia* and *Blastocystis hominis*

PARASITOLOGY (continued)

Specimen FP-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	265	93.93%	Acceptable
Endolimax nana	5	1.79%	

Parasite(s) present: Negative for parasites

Specimen FP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba coli	229	47.44%	Acceptable
Schistosoma mansoni eggs	160	33.13%	Acceptable
Parasite egg or larva seen – no ID	1	0.21%	Acceptable
Entamoeba histolytica	20	4.14%	
Blastocystis hominis	10	2.07%	
Fasciola hepatica eggs	4	0.83%	

Parasite(s) present: *Entamoeba coli* and *Schistosoma mansoni* eggs

Specimen FP-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Trypanosoma sp.	148	55.24%	Acceptable
Trypanosoma brucei sp.	28	10.07%	Acceptable
Trypanosoma brucei gambiense	4	1.44%	Acceptable
Trypanosoma cruzi	91	32.73%	

Parasite(s) present: *Trypanosoma brucei gambiense*. This challenge was graded by referee consensus.

Antinuclear Antibody (ANA) - Qualitative

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	22	-	-	22	1	21
Bio-Rad	1	-	-	1	-	1
BioSystems	2	-	-	2	-	2
Human	1	-	-	1	-	1
Immuno Concepts	3	-	-	3	-	3
INOVA Diagnostics	10	-	-	10	1	9
Kallestad	1	-	-	1	-	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	21	1	-	22
Bio-Rad	1	-	-	1
BioSystems	2	-	-	2
Human	1	-	-	1
Immuno Concepts	3	-	-	3
INOVA Diagnostics	9	1	-	10
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>
------------------------	----------------------------	------------------------	-------------------------	-------------------------	-------------------------	---------------------------	---------------------------	---------------------------	----------------	-----------------------------	-----------------------------	--------------

Specimen AE-6

ALL METHODS	-	-	1	1	-	-	2	6	1	4	2	1
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
BioSystems	-	-	-	-	-	-	-	-	-	1	-	1
Immuno Concepts	-	-	-	1	-	-	-	2	-	-	-	-
INOVA Diagnostics	-	-	1	-	-	-	2	2	1	2	1	-
Kallestad	-	-	-	-	-	-	-	-	-	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>
------------------------	----------------------------	------------------------	-------------------------	-------------------------	-------------------------	---------------------------	---------------------------	---------------------------	----------------	-----------------------------	-----------------------------	--------------

Specimen AE-7

ALL METHODS	17	-	-	1	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
BioSystems	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	9	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

Specimen AE-8

ALL METHODS	16	-	-	2	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
BioSystems	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	8	-	-	1	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

Specimen AE-9

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

Specimen AE-10

ALL METHODS	17	-	-	1	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
BioSystems	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	9	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

Anti-dsDNA

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	21	-	22	-	22
Bio-Rad	-	1	-	1	-	1
BioSystems	-	2	-	2	-	2
Human	-	1	-	1	-	1
INOVA Diagnostics	-	11	-	11	-	11

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	19	-	22
Bio-Rad	-	1	-	1
BioSystems	1	1	-	2
Human	-	1	-	1
INOVA Diagnostics	2	9	-	11

Anti-RNP

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	10	2	-	13	-	13
BioSystems	-	1	-	1	-	1
INOVA Diagnostics	8	-	-	8	-	8

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	12	-	13
BioSystems	-	1	-	1
INOVA Diagnostics	-	8	-	8

Anti-RNP/Sm

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	-	7	1	6
Alegria by ORGENTEC	3	-	-	3	-	3
INOVA Diagnostics	1	-	-	1	-	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7
BioSystems	-	3	-	3
INOVA Diagnostics	-	1	-	1

Anti-SSA

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	17	-	20	-	20
Alegria by ORGENTEC	-	3	-	3	-	3
BioSystems	-	1	-	1	-	1
INOVA Diagnostics	-	8	-	8	-	8

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	1	2	18
Alegria by ORGENTEC	3	-	-	3
BioSystems	1	-	-	1
INOVA Diagnostics	8	-	-	8

Anti-SSB

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	18	-	21	-	21
Alegria by ORGENTEC	-	3	-	3	-	3
BioSystems	-	1	-	1	-	1
INOVA Diagnostics	-	9	-	9	-	9

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	20	-	-	21
Alegria by ORGENTEC	3	-	-	3
BioSystems	1	-	-	1
INOVA Diagnostics	9	-	-	9

Anti-SSA/SSB

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

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

Anti-Sm

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	19	-	-	20	-	20
Alegria by ORGENTEC	3	-	-	3	-	3
BioSystems	1	-	-	1	-	1
INOVA Diagnostics	9	-	-	9	-	9

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	19	-	20
Alegria by ORGENTEC	-	3	-	3
BioSystems	-	1	-	1
INOVA Diagnostics	-	9	-	9

Rubella—Qualitative

<u>Method</u>	Specimen RU-6		Specimen RU-7		Specimen RU-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	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-9		Specimen RU-10	
	<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-6						
All Method	18	0.17	0.28	161.6	0.0	0.0 - 1.0
All Roche Methods	5	0.45	0.13	28.7	0.5	0.0 - 0.9
Abbott Architect	11	0.00	0.01	0.0	0.0	0.0 - 0.1
Specimen RU-7						
All Method	18	49.73	27.43	55.2	34.8	0.0 - 132.1
All Roche Methods	5	92.02	4.85	5.3	92.2	77.4 - 106.6
Abbott Architect	13	33.47	5.15	15.4	34.0	18.0 - 49.0
Specimen RU-8						
All Method	18	0.16	0.25	162.4	0.0	0.0 - 1.0
All Roche Methods	5	0.54	0.11	21.1	0.5	0.1 - 0.9
Abbott Architect	12	0.00	0.01	0.0	0.0	0.0 - 0.1
Specimen RU-9						
All Method	18	49.53	28.37	57.3	34.6	0.0 - 134.7
All Roche Methods	5	93.34	6.01	6.4	92.7	75.3 - 111.4
Abbott Architect	13	32.68	4.61	14.1	33.5	18.8 - 46.6
Specimen RU-10						
All Method	18	66.33	33.97	51.2	49.8	0.0 - 168.3
All Roche Methods	5	124.43	4.69	3.8	124.2	110.3 - 138.6
Abbott Architect	13	48.45	7.87	16.3	49.1	24.8 - 72.1

Syphilis Serology—Qualitative: VDRL Slide

<u>Method</u>	Specimen SY-6			Specimen SY-7			Specimen SY-8		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>
ALL METHODS	-	-	37	-	-	37	28	2	7
Acon Laboratories	-	-	1	-	-	1	1	-	-
CTK Biotech	-	-	1	-	-	1	1	-	-
Lorne Laboratories	-	-	1	-	-	1	1	-	-
Plasmatec	-	-	6	-	-	6	3	1	2
Roche cobas 6000 / e 601	-	-	1	-	-	1	1	-	-
Standard Diagnostics	-	-	1	-	-	1	-	1	-
Wiener Lab	-	-	21	-	-	21	17	-	4

<u>Method</u>	Specimen SY-9			Specimen SY-10		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>
ALL METHODS	37	-	-	31	-	6
Acon Laboratories	1	-	-	1	-	-
CTK Biotech	1	-	-	1	-	-
Lorne Laboratories	1	-	-	1	-	-
Plasmatec	6	-	-	3	-	3
Roche cobas 6000 / e 601	1	-	-	1	-	-
Standard Diagnostics	1	-	-	-	-	1
Wiener Lab	21	-	-	20	-	1

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-6									
ALL METHODS	34	-	-	-	-	-	-	-	-
Alere Determine - moderate	1	-	-	-	-	-	-	-	-
Lorne Laboratories	2	-	-	-	-	-	-	-	-
Plasmatec	4	-	-	-	-	-	-	-	-
Wiener Lab	21	-	-	-	-	-	-	-	-
Specimen SY-7									
ALL METHODS	34	-	-	-	-	-	-	-	-
Alere Determine - moderate	1	-	-	-	-	-	-	-	-
Lorne Laboratories	2	-	-	-	-	-	-	-	-
Plasmatec	4	-	-	-	-	-	-	-	-
Wiener Lab	21	-	-	-	-	-	-	-	-
Specimen SY-8									
ALL METHODS	6	3	6	14	4	1	-	-	-
Alere Determine - moderate	-	1	-	-	-	-	-	-	-
Lorne Laboratories	1	-	-	-	-	1	-	-	-
Plasmatec	-	-	3	1	-	-	-	-	-
Wiener Lab	4	1	1	11	4	-	-	-	-

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

Specimen SY-9

ALL METHODS	-	1	5	7	13	8	-	-	-
Alere Determine - moderate	-	-	1	-	-	-	-	-	-
Lorne Laboratories	-	-	1	-	-	1	-	-	-
Plasmatec	-	-	-	2	1	1	-	-	-
Wiener Lab	-	1	2	3	9	6	-	-	-

Specimen SY-10

ALL METHODS	34	4	3	7	15	3	2	-	-
Alere Determine - moderate	1	-	1	-	-	-	-	-	-
Lorne Laboratories	2	1	-	-	-	-	1	-	-
Plasmatec	4	-	-	2	1	1	-	-	-
Wiener Lab	21	2	2	4	11	2	-	-	-

Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	9	-	9	9	-
Abbott Architect	-	1	-	1	1	-
Atlas Medical	-	1	-	1	1	-
Plasmatec	-	3	-	3	3	-
Serodia	-	1	-	1	1	-
SPINREACT	-	1	-	1	1	-
Standard Diagnostics	-	1	-	1	1	-

	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	9	-	9	-
Abbott Architect	1	-	1	-
Atlas Medical	1	-	1	-
Plasmatec	3	-	3	-
Serodia	1	-	1	-
SPINREACT	1	-	1	-
Standard Diagnostics	1	-	1	-

Syphilis Serology—Qualitative : *Treponema pallidum* Antibodies

<u>Method</u>	<u>Specimen SY-6</u>		<u>Specimen SY-7</u>		<u>Specimen SY-8</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	45	1	45	45	1
Abbott Alinity	-	4	-	4	4	-
Abbott Architect	-	11	-	11	11	-
DiaSorin	-	2	-	2	2	-
Human	-	1	-	1	1	-
Plasmatec	-	1	-	1	1	-
Roche cobas 6000 / c 501	-	1	-	1	1	-
Roche cobas 8000 / e801	-	1	-	1	1	-
Roche cobas e 411	-	1	-	1	1	-
SD Bioline	-	6	-	6	6	-
Serodia	-	8	-	8	7	1
Siemens Immulite 2000	-	1	-	1	1	-
Standard Diagnostics	-	3	-	3	3	-
Zeus	1	-	1	-	1	-

	<u>Specimen SY-9</u>		<u>Specimen SY-10</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	46	-	46	-
Abbott Alinity	4	-	4	-
Abbott Architect	11	-	11	-
DiaSorin	2	-	2	-
Human	1	-	1	-
Plasmatec	1	-	1	-
Roche cobas 6000 / c 501	1	-	1	-
Roche cobas 8000 / e801	1	-	1	-
Roche cobas e 411	1	-	1	-
SD Bioline	6	-	6	-
Serodia	8	-	8	-
Siemens Immulite 2000	1	-	1	-
Standard Diagnostics	3	-	3	-
Zeus	1	-	1	-

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	66	1	66	56	11
Atlas Medical	-	1	-	1	1	-
Becton Dickinson	1	4	1	4	5	-
BioSystems	-	8	-	8	8	-
Human	-	3	-	3	3	-
Lorne Laboratories	-	5	-	5	4	1
Omega Diagnostics	-	2	-	2	2	-
Plasmatec	-	27	-	27	21	6
Pulse Scientific	-	1	-	1	-	1
SPINREACT	-	10	-	10	8	2

	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	67	-	61	6
Atlas Medical	1	-	1	-
Becton Dickinson	5	-	5	-
BioSystems	8	-	8	-
Human	3	-	3	-
Lorne Laboratories	5	-	5	-
Omega Diagnostics	2	-	2	-
Plasmatec	27	-	24	3
Pulse Scientific	1	-	-	1
SPINREACT	10	-	9	1

Syphilis Serology—Semi-Quantitative : RPR (Titer)

<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-6									
ALL METHODS	57	-	-	-	-	-	1	-	-
Atlas Medical	1	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	1	-	-
BioSystems	7	-	-	-	-	-	-	-	-
Human	4	-	-	-	-	-	-	-	-
Lorne Laboratories	5	-	-	-	-	-	-	-	-
Omega Diagnostics	3	-	-	-	-	-	-	-	-
Plasmatec	20	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	10	-	-	-	-	-	-	-	-
Specimen SY-7									
ALL METHODS	57	-	-	-	-	-	1	-	-
Atlas Medical	1	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	1	-	-
BioSystems	7	-	-	-	-	-	-	-	-
Human	4	-	-	-	-	-	-	-	-
Lorne Laboratories	5	-	-	-	-	-	-	-	-
Omega Diagnostics	3	-	-	-	-	-	-	-	-
Plasmatec	20	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	10	-	-	-	-	-	-	-	-

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-8									
ALL METHODS	10	16	27	3	1	-	-	-	1
Atlas Medical	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	1	3	-	-	-	-	-	1
BioSystems	-	2	4	1	-	-	-	-	-
Human	-	2	1	1	-	-	-	-	-
Lorne Laboratories	2	1	1	1	-	-	-	-	-
Omega Diagnostics	-	1	1	-	1	-	-	-	-
Plasmatec	5	6	9	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	2	2	6	-	-	-	-	-	-
Specimen SY-9									
ALL METHODS	-	3	17	30	5	2	-	-	1
Atlas Medical	-	-	-	1	-	-	-	-	-
Becton Dickinson	-	-	1	3	-	-	-	-	1
BioSystems	-	-	2	4	-	1	-	-	-
Human	-	-	2	-	2	-	-	-	-
Lorne Laboratories	-	-	1	3	-	1	-	-	-
Omega Diagnostics	-	-	-	2	1	-	-	-	-
Plasmatec	-	2	7	9	2	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	-	3	7	-	-	-	-	-

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-10									
ALL METHODS	6	13	28	5	3	-	-	2	1
Atlas Medical	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	2	1	1	-	-	-	-	1
BioSystems	-	1	3	1	2	-	-	-	-
Human	-	1	2	-	-	-	-	1	-
Lorne Laboratories	1	-	3	-	-	-	-	1	-
Omega Diagnostics	-	-	1	1	1	-	-	-	-
Plasmatec	3	7	8	2	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	1	1	8	-	-	-	-	-	-

Viral Markers – Anti-HBc (IgM)

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<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	-	3	38	-
Abbott Alinity	-	3	-	-	3	-	-	3	-
Abbott Architect	-	18	-	-	18	-	2	16	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	6	-	-	6	-	-	6	-
Roche cobas 8000 / e602	-	1	-	-	1	-	-	1	-
Roche cobas 8000 / e801	-	4	-	-	4	-	1	3	-
Roche cobas e 411	-	1	-	-	1	-	-	1	-
Siemens ADVIA	-	2	-	-	2	-	-	2	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-	-	4	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	41	-	-	41	-
Abbott Alinity	-	3	-	-	3	-
Abbott Architect	-	18	-	-	18	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	6	-	-	6	-
Roche cobas 8000 / e602	-	1	-	-	1	-
Roche cobas 8000 / e801	-	4	-	-	4	-
Roche cobas e 411	-	1	-	-	1	-
Siemens ADVIA	-	2	-	-	2	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-

Viral Markers – Anti-HBc (Total / IgG)

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<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	57	-	1	57	-	57	1	-
Abbott Alinity	-	9	-	-	9	-	9	-	-
Abbott Architect	-	23	-	-	23	-	23	-	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-	2	-	-
DiaSorin	-	1	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	8	-	-	8	-	8	-	-
Roche cobas 8000 / e801	-	4	-	-	4	-	4	-	-
Roche cobas e 411	1	2	-	1	2	-	2	1	-
Siemens ADVIA	-	3	-	-	3	-	3	-	-
Siemens Atellica	-	1	-	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-	4	-	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	56	-	2	56	-
Abbott Alinity	-	9	-	-	9	-
Abbott Architect	-	23	-	-	23	-
DiaSorin	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	1	-	-	1	-
Roche cobas 8000/e801	-	8	-	-	8	-
Roche cobas e 411	-	4	-	-	4	-
Siemens ADVIA	1	2	-	1	2	-
Siemens Atellica	1	2	-	1	2	-
Siemens Immulite 2000	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<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	-	-	37	110	5	2	150	-
Abbott Alinity	12	-	-	-	12	-	-	12	-
Abbott Architect	56	-	-	-	56	-	-	56	-
Acon Laboratories	1	-	-	-	1	-	1	-	-
ad-bio Rapid Test	1	-	-	-	1	-	-	1	-
Alere Determine - moderate	5	-	-	-	5	-	-	5	-
Alere Determine - waived	2	-	-	-	2	-	-	2	-
Beckman ACCESS / 2 / Dxl	4	-	-	1	3	-	1	3	-
bioMerieux Vidas, Mini Vidas	3	-	-	3	-	-	-	3	-
Clearview HIV1/2 STAT-PAK	1	-	-	-	1	-	-	1	-
DiaSorin	1	-	-	1	-	-	-	1	-
Human	2	-	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	26	-	-	19	3	4	-	26	-
Roche cobas 8000 / e801	7	-	-	2	5	-	-	7	-
Roche cobas e 411	13	-	-	7	5	1	-	13	-
SD Bioline	4	-	-	-	4	-	-	4	-
Siemens ADVIA	5	-	-	3	2	-	-	5	-
Siemens Atellica	1	-	-	1	-	-	-	1	-
VITROS 3600/4600/5600/7600	4	-	-	-	4	-	-	4	-
VITROS Eci	1	-	-	-	1	-	-	1	-

Viral Markers – Anti-HIV- (continued)

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	152	-	-	152	-
Abbott Alinity	-	12	-	-	12	-
Abbott Architect	-	56	-	-	56	-
Acon Laboratories	-	1	-	-	1	-
ad-bio Rapid Test	-	1	-	-	1	-
Alere Determine - moderate	-	5	-	-	5	-
Alere Determine - waived	-	2	-	-	2	-
Beckman ACCESS / 2 / DxI	-	4	-	-	4	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-
Clearview HIV1/2 STAT-PAK	-	1	-	-	1	-
DiaSorin	-	1	-	-	1	-
Human	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	26	-	-	26	-
Roche cobas 8000 / e801	-	7	-	-	7	-
Roche cobas e 411	-	13	-	-	13	-
SD Bioline	-	4	-	-	4	-
Siemens ADVIA	-	5	-	-	5	-
Siemens Atellica	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-
VITROS ECI	-	1	-	-	1	-

Viral Markers – Anti-HAV (IgM)

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<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	-	4	-	-	4	-	-	4	-
Abbott Architect	-	26	-	-	26	-	-	26	-
bioMerieux Vidas, Mini Vidas	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	8	-	-	8	-	-	8	-
Roche cobas 8000 / e801	-	4	-	-	4	-	-	4	-
Roche cobas e 411	-	1	-	-	1	-	-	1	-
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-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	48	3	-	1	50	-
Abbott Alinity	4	-	-	-	4	-
Abbott Architect	24	2	-	1	25	-
bioMerieux Vidas, Mini Vidas	2	-	-	-	2	-
Roche cobas 6000 / e 601	8	-	-	-	8	-
Roche cobas 8000 / e801	4	-	-	-	4	-
Roche cobas e 411	1	-	-	-	1	-
SD Bioline	1	-	-	-	1	-
Siemens ADVIA	2	-	-	-	2	-
Siemens Atellica	1	-	-	-	1	-

Viral Markers – Anti-HAV (Total/IgG)

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<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	54	2	-	2	54	-	-	56	-
Abbott Alinity	3	-	-	-	3	-	-	3	-
Abbott Architect	25	-	-	1	24	-	-	25	-
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	1	-	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	10	1	-	-	11	-	-	11	-
Roche cobas 8000 / e602	1	-	-	-	1	-	-	1	-
Roche cobas 8000 / e801	3	-	-	-	3	-	-	3	-
Roche cobas e 411	5	-	-	-	5	-	-	5	-
SD Bioline	-	1	-	-	1	-	-	1	-
Siemens ADVIA	3	-	-	1	2	-	-	3	-
Siemens Atellica	1	-	-	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	1	-	-	-	1	-	-	1	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	54	2	-	53	3	-
Abbott Alinity	3	-	-	3	-	-
Abbott Architect	25	-	-	25	-	-
Beckman ACCESS / 2 / Dxl	1	-	-	1	-	-
bioMerieux Vidas, Mini Vidas	1	-	-	1	-	-
Roche cobas 6000 / e 601	11	-	-	10	1	-
Roche cobas 8000 / e602	1	-	-	1	-	-
Roche cobas 8000 / e801	3	-	-	3	-	-
Roche cobas e 411	5	-	-	5	-	-
SD Bioline	-	1	-	-	1	-
Siemens ADVIA	2	1	-	2	1	-
Siemens Atellica	1	-	-	1	-	-
VITROS 3600/4600/5600/7600	1	-	-	1	-	-

Viral Markers – HBeAg

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<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	-	32	-	-	32	-	-	32	-
Abbott Alinity	-	3	-	-	3	-	-	3	-
Abbott Architect	-	14	-	-	14	-	-	14	-
Roche cobas 6000 / e 601	-	6	-	-	6	-	-	6	-
Roche cobas 8000 / e602	-	1	-	-	1	-	-	1	-
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-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	32	-	-	32	-
Abbott Alinity	-	3	-	-	3	-
Abbott Architect	-	14	-	-	14	-
Roche cobas 6000 / e 601	-	6	-	-	6	-
Roche cobas 8000 / e602	-	1	-	-	1	-
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-6			Specimen VM-7			Specimen VM-8		
	<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	100	2	-	101	1	-	8	92	2
Abbott Alinity	8	-	-	8	-	-	-	8	-
Abbott Architect	38	1	-	39	-	-	1	38	-
Beckman ACCESS / 2 / Dxl	3	-	-	3	-	-	-	3	-
Roche cobas 6000 / e 601	22	1	-	22	1	-	5	18	-
Roche cobas 8000 / e801	7	-	-	7	-	-	-	7	-
Roche cobas e 411	11	-	-	11	-	-	1	8	2
Siemens ADVIA	6	-	-	6	-	-	1	5	-
Siemens Atellica	1	-	-	1	-	-	-	1	-
VITROS 3600/4600/5600/7600	3	-	-	3	-	-	-	3	-
VITROS Eci	1	-	-	1	-	-	-	1	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	98	2	98	4	-
Abbott Alinity	-	8	-	8	-	-
Abbott Architect	-	39	-	39	-	-
Beckman ACCESS / 2 / Dxl	-	3	-	3	-	-
Roche cobas 6000 / e 601	1	22	-	22	1	-
Roche cobas 8000 / e801	-	7	-	7	-	-
Roche cobas e 411	1	8	2	10	1	-
Siemens ADVIA	-	6	-	5	1	-
Siemens Atellica	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	-	3	-	2	1	-
VITROS Eci	-	1	-	1	-	-

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<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	-	1	150	1	2	150	-
Abbott Alinity	-	13	-	-	13	-	-	13	-
Abbott Architect	-	54	-	-	54	-	-	54	-
Abbott IMx	-	2	-	-	2	-	-	2	-
ad-bio Rapid Test	-	1	-	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	4	-	-	4	-	-	4	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-	-	3	-
CTK Biotech	-	1	-	-	1	-	-	1	-
DiaSorin	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	30	-	-	29	1	-	30	-
Roche cobas 8000 / e801	-	6	-	-	6	-	-	6	-
Roche cobas e 411	-	13	-	1	12	-	1	12	-
SD Bioline	-	10	-	-	10	-	-	10	-
Siemens ADVIA	-	5	-	-	5	-	1	4	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
Standard Diagnostics	-	1	-	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-	-	4	-

Viral Markers – HBsAg (continued)

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	151	-	3	149	-
Abbott Alinity	-	13	-	-	13	-
Abbott Architect	-	54	-	-	54	-
Abbott IMx	-	2	-	-	2	-
ad-bio Rapid Test	-	1	-	-	1	-
Beckman ACCESS / 2 / DxI	-	4	-	-	4	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-
CTK Biotech	-	1	-	-	1	-
DiaSorin	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	30	-	-	30	-
Roche cobas 8000 / e801	-	6	-	-	6	-
Roche cobas e 411	1	12	-	2	11	-
SD Bioline	-	10	-	-	10	-
Siemens ADVIA	-	5	-	1	4	-
Siemens Atellica	-	1	-	-	1	-
Standard Diagnostics	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<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	-	133	-	129	3	1	30	96	7
Abbott Alinity	-	13	-	12	1	-	-	13	-
Abbott Architect	-	52	-	52	-	-	1	51	-
Abbott IMx	-	3	-	3	-	-	-	3	-
Abon (Alere) Biopharm	-	1	-	1	-	-	-	1	-
ad-bio Rapid Test	-	3	-	3	-	-	-	3	-
Beckman ACCESS / 2 / Dxl	-	3	-	3	-	-	-	3	-
DiaSorin	-	2	-	2	-	-	-	2	-
Roche cobas 6000 / e 601	-	24	-	24	-	-	17	1	6
Roche cobas 8000 / e801	-	5	-	5	-	-	5	-	-
Roche cobas e 411	-	10	-	9	-	1	6	3	1
SD Bioline	-	3	-	3	-	-	-	3	-
Siemens ADVIA	-	5	-	3	2	-	-	5	-
Siemens Atellica	-	1	-	1	-	-	-	1	-
Standard Diagnostics	-	2	-	2	-	-	-	2	-
VITROS 3600/4600/5600/7600	-	4	-	4	-	-	-	4	-
VITROS ECI	-	1	-	1	-	-	-	1	-

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	133	-	1	132	-
Abbott Alinity	-	13	-	-	13	-
Abbott Architect	-	52	-	-	52	-
Abbott IMx	-	3	-	-	3	-
Abon (Alere) Biopharm	-	1	-	-	1	-
ad-bio Rapid Test	-	3	-	-	3	-
Beckman ACCESS / 2 / Dxl	-	3	-	-	3	-
DiaSorin	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	24	-	-	24	-
Roche cobas 8000 / e801	-	5	-	-	5	-
Roche cobas e 411	-	10	-	-	10	-
SD Bioline	-	3	-	-	3	-
Siemens ADVIA	-	5	-	-	5	-
Siemens Atellica	-	1	-	-	1	-
Standard Diagnostics	-	2	-	-	2	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-
VITROS ECI	-	1	-	-	1	-

Toxoplasma gondii Antibody (IgG) - Qualitative

<u>Method</u>	Specimen TOX-3			Specimen TOX-4		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	19	-	19	-	-
Abbott Architect	-	13	-	13	-	-
bioMerieux Vidas, Mini Vidas	-	1	-	1	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
Roche cobas e 411	-	2	-	2	-	-
VITROS 3600/4600/5600/7600	-	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-3						
All Method	23	0.495	0.335	67.7	0.60	0.00 - 1.51
All Roche Instruments	10	0.130	0.001	0.0	0.13	0.12 - 0.14
Abbott Architect	14	0.664	0.101	15.2	0.70	0.36 - 0.97
Roche cobas 6000 / e 601	5	0.130	0.001	0.0	0.13	0.12 - 0.14
Roche cobas e 411	5	0.130	0.001	0.0	0.13	0.12 - 0.14
Specimen TOX-4						
All Method	23	88.361	37.860	42.8	68.80	0.00 - 201.95
All Roche Instruments	10	145.350	20.963	14.4	154.05	82.45 - 208.25
Abbott Architect	14	66.114	6.042	9.1	65.65	47.98 - 84.25
Roche cobas 6000 / e 601	5	158.567	8.268	5.2	159.20	133.76 - 183.38
Roche cobas e 411	5	132.133	22.500	17.0	119.90	64.63 - 199.64

Toxoplasma gondii Antibody (IgM) - Qualitative

<u>Method</u>	Specimen TOX-3			Specimen TOX-4		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	20	-	20	-	-
Abbott Architect	-	13	-	13	-	-
bioMerieux Vidas, Mini Vidas	-	1	-	1	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	2	-	2	-	-
Roche cobas e 411	-	2	-	2	-	-
VITROS 3600/4600/5600/7600	-	1	-	1	-	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen TOX-3						
All Method	22	0.178	0.050	28.0	0.17	0.02 - 0.33
All Roche Instruments	7	0.228	0.039	17.2	0.22	0.11 - 0.35
Abbott Architect	13	0.165	0.041	24.5	0.16	0.04 - 0.29
Roche cobas e 411	5	0.208	0.015	7.2	0.21	0.16 - 0.26
Specimen TOX-4						
All Method	22	16.769	8.777	52.3	12.97	0.00 - 43.11
All Roche Instruments	7	30.238	2.589	8.6	30.63	22.47 - 38.01
Abbott Architect	13	11.759	1.863	15.8	11.20	6.16 - 17.35
Roche cobas e 411	5	31.385	1.387	4.4	31.19	27.22 - 35.55

Cytomegalovirus (CMV) Antibodies (IgG) - Qualitative

<u>Method</u>	Specimen CMV-3			Specimen CMV-4		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	16	-	15	-	1
Abbott Architect	-	14	-	13	-	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-3						
All Method	18	1.208	0.520	43.1	1.25	0.00 - 2.77
Abbott Architect	15	1.380	0.326	23.6	1.30	0.40 - 2.36
Specimen CMV-4						
All Method	17	345.959	152.488	44.1	250.00	0.00 - 803.43
Abbott Architect	14	326.086	150.553	46.2	250.00	0.00 - 777.75

Cytomegalovirus (CMV) Antibodies (IgM) - Qualitative

<u>Method</u>	Specimen CMV-3			Specimen CMV-4		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	17	3	-	6	11	3
Abbott Architect	17	-	-	6	8	3
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-3						
All Method	16	2.202	0.567	25.7	2.28	0.50 - 3.91
Abbott Architect	14	2.371	0.353	14.9	2.34	1.31 - 3.44
Specimen CMV-4						
All Method	16	0.869	0.410	47.1	0.90	0.00 - 2.10
Abbott Architect	14	0.945	0.373	39.5	0.92	0.00 - 2.07

Neonatal Bilirubin, Total (mg/dL)

<u>Method</u>	Specimen NB-6						Specimen NB-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	39	0.01	0.02	435.6	0.0	0.0 - 0.5	43	18.28	0.65	3.6	18.4	14.6 - 22.0
No Reagent Required												
Bilirubinometer / Reichart UNISTAT	37	0.00	0.01	0.0	0.0	0.0 - 0.4	37	18.32	0.64	3.5	18.4	14.6 - 22.0
All Chemistry Instruments	37	0.00	0.01	0.0	0.0	0.0 - 0.4	40	18.26	0.67	3.7	18.4	14.6 - 22.0
<u>Method</u>	Specimen NB-8						Specimen NB-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	43	10.90	0.43	4.0	11.0	8.7 - 13.1	42	15.80	0.43	2.7	15.8	12.6 - 19.0
No Reagent Required												
Bilirubinometer / Reichart UNISTAT	36	10.96	0.40	3.7	11.1	8.7 - 13.2	35	15.88	0.42	2.6	15.9	12.7 - 19.1
All Chemistry Instruments	40	10.94	0.41	3.8	11.0	8.7 - 13.2	39	15.83	0.43	2.7	15.8	12.6 - 19.0
<u>Method</u>	Specimen NB-10											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	44	5.77	0.34	5.9	5.8	4.6 - 7.0						
No Reagent Required												
Bilirubinometer / Reichart UNISTAT	35	5.73	0.22	3.8	5.8	4.5 - 6.9						
All Chemistry Instruments	41	5.73	0.32	5.5	5.8	4.5 - 6.9						

Bilirubin, Direct (mg/dL)

<u>Method</u>	Specimen NB-6						Specimen NB-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	10	0.09	0.15	170.8	0.0	0.0 - 0.4	10	3.53	0.70	19.9	3.4	2.1 - 5.0
<u>Method</u>	Specimen NB-8						Specimen NB-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	10	4.34	0.63	14.4	4.1	3.0 - 5.6	10	5.21	0.72	13.9	5.1	3.7 - 6.7
<u>Method</u>	Specimen NB-10											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	10	1.08	0.36	33.6	0.9	0.3 - 1.8						

Glycohemoglobin (percent)

<u>Method</u>	Specimen GH-3						Specimen GH-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	114	6.85	0.23	3.3	6.8	6.5 - 7.2	112	10.58	0.31	2.9	10.5	10.0 - 11.2
All Bio-Rad Methods	5	6.87	0.21	3.0	6.8	6.5 - 7.3	4	-	-	-	10.8	10.2 - 11.3
All Enzymatic A1c Methods	8	6.51	0.34	5.2	6.6	6.1 - 6.9	7	10.23	0.81	7.9	10.5	9.7 - 10.8
All Hemoglobin A1c Methods	95	6.87	0.23	3.3	6.9	6.5 - 7.3	92	10.58	0.32	3.0	10.5	10.0 - 11.2
All Roche Methods	7	6.61	0.22	3.3	6.6	6.2 - 7.0	7	10.81	0.30	2.8	10.9	10.2 - 11.4
All TOSOH Methods	14	6.76	0.09	1.4	6.8	6.4 - 7.2	14	10.31	0.10	1.0	10.3	9.7 - 10.9
Abbott Architect Hb A1C	5	6.63	0.06	0.9	6.6	6.3 - 7.0	5	10.53	0.06	0.5	10.5	10.0 - 11.1
Beckman AU A1c	6	6.68	0.15	2.2	6.7	6.3 - 7.1	6	10.63	0.36	3.4	10.6	10.1 - 11.2
Bio-Rad D-10 HbA1C	5	6.87	0.21	3.0	6.8	6.5 - 7.3	4	-	-	-	10.8	10.2 - 11.3
Roche cobas c501 HbA1c	5	6.53	0.23	3.5	6.4	6.2 - 6.9	5	10.63	0.38	3.6	10.8	10.1 - 11.2
Roche Integra A1C	5	6.68	0.22	3.3	6.6	6.3 - 7.1	5	10.95	0.17	1.6	10.9	10.4 - 11.5
Siemens DCA Vantage	47	6.96	0.20	2.9	7.0	6.6 - 7.4	46	10.65	0.30	2.9	10.7	10.1 - 11.2
Siemens Dimension HA1C	9	6.97	0.26	3.7	6.9	6.6 - 7.4	9	10.47	0.19	1.9	10.5	9.9 - 11.0
Siemens Dimension HB1C	5	6.83	0.13	1.8	6.8	6.4 - 7.2	5	10.25	0.24	2.3	10.4	9.7 - 10.8
TOSOH G8	14	6.76	0.09	1.4	6.8	6.4 - 7.2	14	10.31	0.10	1.0	10.3	9.7 - 10.9

Whole Blood Glucose (mg/dL)

<u>Method</u>	Specimen WBG-6						Specimen WBG-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	964	208.4	17.5	8.4	212	166 - 251	972	111.2	11.9	10.7	113	88 - 134
All Abbott Methods	56	192.4	15.9	8.3	192	153 - 231	55	96.9	7.6	7.8	96	77 - 117
All Arkray Methods	5	247.8	36.1	14.6	233	198 - 298	5	134.0	9.5	7.1	133	107 - 161
All Bayer Methods	17	167.2	16.2	9.7	164	133 - 201	17	85.4	5.6	6.6	83	68 - 103
All Hemocue Methods	52	219.3	6.8	3.1	219	175 - 264	52	131.9	7.3	5.6	133	105 - 159
All Lifescan Methods	9	225.9	10.6	4.7	225	180 - 272	9	112.7	5.0	4.4	113	90 - 136
All Roche Methods	548	213.4	5.3	2.5	212	170 - 257	551	113.4	3.0	2.6	113	90 - 137
Abbott FreeStyle Freedom	10	191.3	11.9	6.2	193	153 - 230	10	97.6	7.4	7.5	96	78 - 118
Abbott FreeStyle Lite/Freedom Lite	6	203.7	7.1	3.5	203	162 - 245	6	105.5	4.8	4.5	104	84 - 127
Abbott FreeStyle Precision Pro	24	189.7	21.0	11.1	184	151 - 228	24	94.7	8.7	9.2	92	75 - 114
Abbott PreciS. Xtra/Optium	10	196.2	8.0	4.1	199	156 - 236	10	96.6	3.6	3.7	98	77 - 116
Abbott Precision XceedPro	6	187.7	8.9	4.7	186	150 - 226	5	96.6	4.0	4.2	96	77 - 116
Acon On Call	10	176.6	8.2	4.7	179	141 - 212	10	95.0	2.7	2.8	95	76 - 114
Arkray Platinum	21	220.4	9.2	4.2	221	176 - 265	22	128.4	3.3	2.6	129	102 - 155
Bayer Contour / Plus	16	165.9	5.7	3.4	165	132 - 200	18	84.2	3.7	4.4	83	67 - 102
CareSens	27	256.2	18.7	7.3	259	204 - 308	27	133.9	8.9	6.7	134	107 - 161
GluNEO Lite	5	235.6	8.8	3.7	231	188 - 283	5	110.6	3.8	3.4	110	88 - 133
HemoCue Glucose 201	54	218.9	7.1	3.2	219	175 - 263	54	131.0	8.0	6.1	133	104 - 158
Home Diagnostics True Balance / TrueTrack	8	471.6	19.6	4.2	471	377 - 566	8	281.1	9.6	3.4	282	224 - 338
Lifescan One Touch Ultra	35	219.7	12.7	5.8	219	175 - 264	35	110.1	6.4	5.8	111	88 - 133
Medline EvenCare G2 / G3	18	213.9	22.4	10.5	214	171 - 257	18	118.6	5.6	4.7	118	94 - 143
NOVA Biomedical StatStrip	66	180.6	11.4	6.3	178	144 - 217	64	95.6	7.5	7.9	94	76 - 115
Quintet / AC	27	218.4	9.8	4.5	218	174 - 263	26	109.0	6.6	6.1	110	87 - 131
Roche Accu-Chek Inform	10	212.5	4.3	2.0	212	170 - 255	10	114.4	2.7	2.3	115	91 - 138
Roche Accu-Chek Inform II	407	212.6	4.8	2.3	212	170 - 256	407	113.0	2.8	2.5	113	90 - 136
Roche Accu-Chek Instant / Plus	5	185.0	2.5	1.4	185	148 - 222	5	98.0	2.6	2.7	97	78 - 118
Roche Accu-Chek Performa	138	214.9	7.5	3.5	214	171 - 258	138	114.1	4.0	3.5	115	91 - 137
True Metrix Pro	49	182.6	9.9	5.4	185	146 - 220	47	93.6	4.7	5.0	94	74 - 113

Whole Blood Glucose (mg/dL) (continued)

<u>Method</u>	Specimen WBG-8						Specimen WBG-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	210	168.3	18.1	10.7	172	134 - 202	209	100.8	10.4	10.3	104	80 - 121
All Abbott Methods	10	151.4	7.7	5.1	153	121 - 182	10	91.0	5.7	6.2	90	72 - 110
All Lifescan Methods	4	-	-	-	184	147 - 222	4	-	-	-	106	84 - 127
All Roche Methods	98	173.9	4.4	2.5	174	139 - 209	95	105.9	2.4	2.3	106	84 - 128
Abbott FreeStyle Freedom	10	151.4	7.7	5.1	153	121 - 182	10	91.0	5.7	6.2	90	72 - 110
Acon On Call	9	144.6	5.8	4.0	145	115 - 174	10	88.1	2.5	2.9	89	70 - 106
CareSens	17	208.2	14.2	6.8	210	166 - 250	17	122.6	11.8	9.6	124	98 - 148
Lifescan One Touch Ultra	28	174.5	8.0	4.6	177	139 - 210	28	100.8	4.5	4.5	100	80 - 121
NOVA Biomedical StatStrip	40	147.5	12.0	8.1	145	117 - 177	39	88.4	7.0	8.0	87	70 - 107
Roche Accu-Chek Inform	10	173.3	4.3	2.5	173	138 - 208	10	107.2	4.0	3.8	106	85 - 129
Roche Accu-Chek Inform II	81	174.1	4.3	2.5	174	139 - 209	81	105.9	2.5	2.4	106	84 - 128
Roche Accu-Chek Performa	15	163.2	14.1	8.6	171	130 - 196	15	98.2	8.8	9.0	103	78 - 118

<u>Method</u>	Specimen WBG-10					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	209	313.1	27.6	8.8	321	250 - 376
All Abbott Methods	10	300.7	13.1	4.3	294	240 - 361
All Lifescan Methods	4	-	-	-	342	274 - 411
All Roche Methods	99	324.9	9.2	2.8	325	259 - 390
Abbott FreeStyle Freedom	10	300.7	13.1	4.3	294	240 - 361
Acon On Call	10	276.0	12.0	4.3	278	220 - 332
CareSens	17	343.8	30.6	8.9	351	275 - 413
Lifescan One Touch Ultra	28	324.4	11.1	3.4	327	259 - 390
NOVA Biomedical StatStrip	36	270.6	13.2	4.9	271	216 - 325
Roche Accu-Chek Inform	10	324.1	6.1	1.9	325	259 - 389
Roche Accu-Chek Inform II	80	325.6	8.2	2.5	325	260 - 391
Roche Accu-Chek Performa	15	315.2	25.7	8.1	315	252 - 379

Medical Laboratory Evaluation
 1300 L St NW Ste 201
 Washington, DC 20005-4676
 800-338-2746 • 202-261-4510 • Fax: 202-835-0440
www.aab-mle.org