

MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 2 • 0

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

International Data Supplement
2020 MLE-M3



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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	12
Antibody Identification	12
Compatibility Testing	13
Coagulation	
Prothrombin Time	14
International Normalized Ratio (INR)	16
Activated Partial Thromboplastin Time	17
Fibrinogen	19
Prothrombin Time (XS Samples)	20
International Normalized Ratio (INR) (XS Samples)	21
Urinalysis	
Urinalysis Dipstick	22
Specific Gravity	22
pH	23
Protein	24
Glucose.....	25
Ketones.....	26
Bilirubin	27
Urobilinogen.....	28
Blood or Hemoglobin	29
Leukocyte Esterase	30
Nitrite	31
Microalbumin (Dipstick Only)	32
Urine hCG	32
Microbiology	
Miscellaneous Cultures	33
Antimicrobial Susceptibility Testing	35
Parasitology (PA Specimens)	37
Parasitology (FP Specimens)	39
Immunology	
Antinuclear Antibody	44
Qualitative	44
Semi-Quantitative	44

Table of Contents (cont'd)

Immunology

Anti-dsDNA.....	46
Anti-RNP	46
Anti-RNP/Sm	47
Anti-SSA	47
Anti-SSB	48
Anti-SSA/SSB	48
Anti-Sm	49
Rubella.....	50
Qualitative.....	50
Quantitative.....	51
Syphilis Serology	52
VDRL Slide	52
VDRL Slide (Titer).....	53
MHA-TP	55
TPA.....	56
RPR	57
RPR (Titer).....	59
Viral Markers	62
Anti-HBc (IgM)	62
Anti-HBc (Total/IgG)	63
Anti-HIV	64
Anti-HAV (IgM).....	66
Anti-HAV (Total/IgG).....	67
HBeAg	68
Anti-HBs	69
HBsAg	71
Anti-HCV.....	73
Toxoplasma gondii	75
Qualitative (IgG).....	75
Quantitative (IgG)	75
Qualitative (IgM)	76
Quantitative (IgM)	76
Cytomegalovirus (CMV)	77
Qualitative (IgG).....	77
Quantitative (IgG)	77
Qualitative (IgM)	78
Quantitative (IgM)	78

Chemistry

Bilirubin, Neonatal (Total)	79
Bilirubin, Direct (NB Specimens)	79
Glycohemoglobin (GH Specimens)	80
Glucose, Whole Blood (WBG Specimens)	81
Folate	83
CK-MB	83

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	$\pm 15\%$	Hemoglobin	$\pm 7\%$
Automated Differential	± 3 SD	International Normalized Ratio (INR)	$\pm 20\%$
Bilirubin, Neonatal (Total)	± 0.4 mg/dL or $20\% *$	Platelet Count	$\pm 25\%$
Bilirubin, Direct	± 2 SD	Prothrombin Time	$\pm 15\%$
CK-MB (U/L)	± 3 SD	Red Blood Cell Count	$\pm 6\%$
Cytomegalovirus	± 3 SD	Rubella	± 3 SD
Fibrinogen	$\pm 20\%$	Sedimentation Rate	± 3 SD
Folate	± 1 ng/mL or $\pm 30\%*$	Specific Gravity	± 0.010
Glucose, Whole Blood	± 12 mg/dL or $\pm 20\%*$	Toxoplasma	± 2 SD
Glycohemoglobin	$\pm 6\%$	White Blood Cell Count	$\pm 15\%$
Hematocrit	$\pm 6\%$		

*Whichever is greater

SEDIMENTATION RATE (MM/HR)

<u>Instrument</u>	Specimen ES-5						Specimen ES-6					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	149	40.9	9.7	23.6	39	21 - 61	152	8.8	2.8	31.4	8	3 - 15
All Automated Methods	31	54.2	10.0	18.4	53	34 - 75	32	10.5	3.4	32.3	10	3 - 18
All Diese Methods	10	56.4	9.8	17.3	56	36 - 76	10	12.4	3.8	30.9	11	4 - 21
All Manual Methods	110	37.5	6.8	18.2	37	23 - 52	108	8.4	2.3	27.0	8	3 - 13
All Vital Diagnostics Methods	17	53.2	9.9	18.7	50	33 - 74	17	9.1	2.3	25.1	9	4 - 14
Westergren - diluted	87	36.9	6.6	17.8	36	23 - 51	88	8.0	2.0	25.2	8	3 - 12
Westergren - undiluted	17	38.3	7.6	19.8	37	23 - 54	17	10.2	3.0	29.2	9	4 - 17

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

<u>Instrument</u>	Specimen CL-11						Specimen CL-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	6.56	0.68	10.4	6.4	5.5 - 7.6	22	2.50	0.36	14.3	2.5	2.1 - 2.9
All Abbott Cell-Dyn Instruments	12	7.12	0.82	11.5	7.4	6.0 - 8.2	12	2.74	0.53	19.4	2.9	2.3 - 3.2
Abbott Cell-Dyn Ruby	11	7.12	0.82	11.5	7.4	6.0 - 8.2	11	2.74	0.53	19.4	2.9	2.3 - 3.2
Orphee Mythic 22	10	6.21	0.43	7.0	6.3	5.2 - 7.2	10	2.35	0.15	6.4	2.4	1.9 - 2.8

<u>Instrument</u>	Specimen CL-13						Specimen CL-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	6.57	0.55	8.4	6.5	5.5 - 7.6	22	18.03	1.49	8.3	17.7	15.3 - 20.8
All Abbott Cell-Dyn Instruments	12	7.14	0.27	3.8	7.3	6.0 - 8.3	12	19.50	0.50	2.6	19.5	16.5 - 22.5
Abbott Cell-Dyn Ruby	11	7.14	0.27	3.8	7.3	6.0 - 8.3	11	19.50	0.50	2.6	19.5	16.5 - 22.5
Orphee Mythic 22	10	6.23	0.45	7.2	6.3	5.2 - 7.2	10	17.23	1.40	8.1	17.6	14.6 - 19.9

<u>Instrument</u>	Specimen CL-15					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	2.61	0.33	12.6	2.5	2.2 - 3.0
All Abbott Cell-Dyn Instruments	12	3.00	0.19	6.2	3.0	2.5 - 3.5
Abbott Cell-Dyn Ruby	11	3.00	0.19	6.2	3.0	2.5 - 3.5
Orphee Mythic 22	10	2.39	0.16	6.5	2.4	2.0 - 2.8

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

<i><u>Instrument</u></i>	Specimen CL-11						Specimen CL-12					
	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>
All Method	22	4.660	0.099	2.1	4.65	4.38 - 4.94	22	2.290	0.040	1.8	2.29	2.15 - 2.43
All Abbott Cell-Dyn Instruments	12	4.760	0.078	1.6	4.77	4.47 - 5.05	12	2.260	0.128	5.7	2.30	2.12 - 2.40
Abbott Cell-Dyn Ruby	11	4.760	0.078	1.6	4.77	4.47 - 5.05	11	2.260	0.128	5.7	2.30	2.12 - 2.40
Orphee Mythic 22	10	4.620	0.060	1.3	4.62	4.34 - 4.90	10	2.284	0.040	1.8	2.29	2.14 - 2.43
<i><u>Instrument</u></i>	Specimen CL-13						Specimen CL-14					
	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>
All Method	22	4.643	0.082	1.8	4.64	4.36 - 4.93	22	5.261	0.105	2.0	5.22	4.94 - 5.58
All Abbott Cell-Dyn Instruments	12	4.722	0.056	1.2	4.73	4.43 - 5.01	12	5.360	0.067	1.3	5.37	5.03 - 5.69
Abbott Cell-Dyn Ruby	11	4.722	0.056	1.2	4.73	4.43 - 5.01	11	5.360	0.067	1.3	5.37	5.03 - 5.69
Orphee Mythic 22	10	4.598	0.065	1.4	4.61	4.32 - 4.88	10	5.216	0.095	1.8	5.21	4.90 - 5.53
<i><u>Instrument</u></i>	Specimen CL-15											
	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>						
All Method	22	2.293	0.041	1.8	2.28	2.15 - 2.44						
All Abbott Cell-Dyn Instruments	12	2.314	0.056	2.4	2.33	2.17 - 2.46						
Abbott Cell-Dyn Ruby	11	2.314	0.056	2.4	2.33	2.17 - 2.46						
Orphee Mythic 22	10	2.283	0.030	1.3	2.28	2.14 - 2.42						

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

<i><u>Instrument</u></i>	Specimen CL-11						Specimen CL-12					
	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>
All Method	22	12.51	0.95	7.6	12.1	11.6 - 13.4	22	5.03	0.46	9.2	4.8	4.6 - 5.4
All Abbott Cell-Dyn Instruments	12	13.76	0.38	2.8	13.9	12.7 - 14.8	12	5.60	0.31	5.5	5.6	5.2 - 6.0
Abbott Cell-Dyn Ruby	11	13.76	0.38	2.8	13.9	12.7 - 14.8	11	5.60	0.31	5.5	5.6	5.2 - 6.0
Orphee Mythic 22	10	11.85	0.21	1.8	11.9	11.0 - 12.7	10	4.70	0.12	2.5	4.8	4.3 - 5.1
<i><u>Instrument</u></i>	Specimen CL-13						Specimen CL-14					
	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>
All Method	22	12.38	0.75	6.1	12.1	11.5 - 13.3	22	16.31	0.69	4.2	16.0	15.1 - 17.5
All Abbott Cell-Dyn Instruments	12	13.45	0.37	2.7	13.5	12.5 - 14.4	12	17.16	0.46	2.7	17.3	15.9 - 18.4
Abbott Cell-Dyn Ruby	11	13.45	0.37	2.7	13.5	12.5 - 14.4	11	17.16	0.46	2.7	17.3	15.9 - 18.4
Orphee Mythic 22	10	11.93	0.26	2.2	11.9	11.0 - 12.8	10	15.89	0.21	1.3	15.9	14.7 - 17.0
<i><u>Instrument</u></i>	Specimen CL-15											
	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>						
All Method	22	5.03	0.51	10.1	4.8	4.6 - 5.4						
All Abbott Cell-Dyn Instruments	12	5.70	0.14	2.5	5.8	5.3 - 6.1						
Abbott Cell-Dyn Ruby	11	5.70	0.14	2.5	5.8	5.3 - 6.1						
Orphee Mythic 22	10	4.66	0.13	2.8	4.7	4.3 - 5.0						

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

<u>Instrument</u>	Specimen CL-11						Specimen CL-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	40.44	1.49	3.7	41.1	38.0 - 42.9	22	17.13	1.19	7.0	17.5	16.0 - 18.2
All Abbott Cell-Dyn Instruments	12	38.70	0.53	1.4	38.7	36.3 - 41.1	12	15.80	0.95	6.0	16.2	14.8 - 16.8
Abbott Cell-Dyn Ruby	11	38.70	0.53	1.4	38.7	36.3 - 41.1	11	15.80	0.95	6.0	16.2	14.8 - 16.8
Orphee Mythic 22	10	41.63	0.50	1.2	41.6	39.1 - 44.2	10	18.01	0.36	2.0	18.1	16.9 - 19.1
<u>Instrument</u>	Specimen CL-13						Specimen CL-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	40.22	1.51	3.7	40.8	37.8 - 42.7	22	47.87	1.67	3.5	48.1	45.0 - 50.8
All Abbott Cell-Dyn Instruments	12	38.46	1.00	2.6	38.4	36.1 - 40.8	12	45.88	0.79	1.7	45.7	43.1 - 48.7
Abbott Cell-Dyn Ruby	11	38.46	1.00	2.6	38.4	36.1 - 40.8	11	45.88	0.79	1.7	45.7	43.1 - 48.7
Orphee Mythic 22	10	41.25	0.61	1.5	40.9	38.7 - 43.8	10	48.98	0.89	1.8	48.9	46.0 - 52.0
<u>Instrument</u>	Specimen CL-15											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	22	17.26	0.95	5.5	17.4	16.2 - 18.3						
All Abbott Cell-Dyn Instruments	12	16.20	0.39	2.4	16.3	15.2 - 17.2						
Abbott Cell-Dyn Ruby	11	16.20	0.39	2.4	16.3	15.2 - 17.2						
Orphee Mythic 22	10	17.99	0.48	2.6	18.1	16.9 - 19.1						

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

<u>Instrument</u>	Specimen CL-11						Specimen CL-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	257.3	18.1	7.0	259	192 - 322	22	95.7	18.6	19.5	100	71 - 120
All Abbott Cell-Dyn Instruments	12	242.4	17.4	7.2	245	181 - 303	12	74.0	7.4	10.0	73	55 - 93
Abbott Cell-Dyn Ruby	11	242.4	17.4	7.2	245	181 - 303	11	74.0	7.4	10.0	73	55 - 93
Orphee Mythic 22	10	264.1	14.3	5.4	262	198 - 331	10	105.9	11.3	10.7	105	79 - 133
<u>Instrument</u>	Specimen CL-13						Specimen CL-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	258.3	17.3	6.7	263	193 - 323	22	494.6	30.0	6.1	485	370 - 619
All Abbott Cell-Dyn Instruments	12	250.4	19.4	7.7	241	187 - 313	12	470.8	14.9	3.2	472	353 - 589
Abbott Cell-Dyn Ruby	11	250.4	19.4	7.7	241	187 - 313	11	470.8	14.9	3.2	472	353 - 589
Orphee Mythic 22	10	260.4	16.7	6.4	265	195 - 326	10	506.1	28.9	5.7	506	379 - 633
<u>Instrument</u>	Specimen CL-15											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	22	97.5	17.1	17.5	98	73 - 122						
All Abbott Cell-Dyn Instruments	12	78.0	10.0	12.9	81	58 - 98						
Abbott Cell-Dyn Ruby	11	78.0	10.0	12.9	81	58 - 98						
Orphee Mythic 22	10	105.6	9.2	8.7	106	79 - 133						

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

<u>Instrument</u>	Specimen CL-11						Specimen CL-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	64.19	2.10	3.3	64.4	57.8 - 70.5	22	49.84	2.31	4.6	50.5	42.9 - 56.8
All Abbott Cell-Dyn Instruments	12	66.23	1.15	1.7	65.9	62.7 - 69.7	12	51.23	0.71	1.4	51.5	49.0 - 53.4
Abbott Cell-Dyn Ruby	11	66.23	1.15	1.7	65.9	62.7 - 69.7	11	51.23	0.71	1.4	51.5	49.0 - 53.4
Orphee Mythic 22	10	63.14	1.95	3.1	63.3	57.2 - 69.0	10	49.20	2.74	5.6	50.3	40.9 - 57.5
<u>Instrument</u>	Specimen CL-13						Specimen CL-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	64.35	3.02	4.7	64.0	55.2 - 73.4	22	75.63	1.46	1.9	75.6	71.2 - 80.1
All Abbott Cell-Dyn Instruments	12	67.62	1.47	2.2	67.0	63.2 - 72.1	12	77.22	0.68	0.9	77.1	75.1 - 79.3
Abbott Cell-Dyn Ruby	11	67.62	1.47	2.2	67.0	63.2 - 72.1	11	77.22	0.68	0.9	77.1	75.1 - 79.3
Orphee Mythic 22	10	62.43	2.24	3.6	62.6	55.7 - 69.2	10	74.88	1.08	1.4	74.6	71.6 - 78.2
<u>Instrument</u>	Specimen CL-15											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	22	50.49	2.74	5.4	50.7	42.2 - 58.8						
All Abbott Cell-Dyn Instruments	12	52.20	1.96	3.7	51.4	46.3 - 58.1						
Abbott Cell-Dyn Ruby	11	52.20	1.96	3.7	51.4	46.3 - 58.1						
Orphee Mythic 22	10	49.33	3.02	6.1	50.4	40.2 - 58.4						

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

<u>Instrument</u>	Specimen CL-11						Specimen CL-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	21.16	3.03	14.3	21.6	12.0 - 30.3	22	31.64	5.86	18.5	31.6	14.0 - 49.3
All Abbott Cell-Dyn Instruments	12	23.50	0.81	3.5	23.5	21.0 - 26.0	12	37.60	1.73	4.6	37.0	32.4 - 42.8
Abbott Cell-Dyn Ruby	11	23.50	0.81	3.5	23.5	21.0 - 26.0	11	37.60	1.73	4.6	37.0	32.4 - 42.8
Orphee Mythic 22	10	19.89	3.40	17.1	20.0	9.6 - 30.1	10	28.85	5.72	19.8	28.6	11.6 - 46.1
<u>Instrument</u>	Specimen CL-13						Specimen CL-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	20.95	2.80	13.4	21.7	12.5 - 29.4	22	14.96	1.51	10.1	15.2	10.4 - 19.5
All Abbott Cell-Dyn Instruments	12	23.24	1.19	5.1	23.9	19.6 - 26.9	12	16.16	0.53	3.3	16.2	14.5 - 17.8
Abbott Cell-Dyn Ruby	11	23.24	1.19	5.1	23.9	19.6 - 26.9	11	16.16	0.53	3.3	16.2	14.5 - 17.8
Orphee Mythic 22	10	19.10	2.74	14.3	20.8	10.8 - 27.4	10	13.73	1.10	8.0	13.9	10.4 - 17.1
<u>Instrument</u>	Specimen CL-15											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	22	32.42	5.70	17.6	33.0	15.3 - 49.6						
All Abbott Cell-Dyn Instruments	12	37.72	2.28	6.0	38.5	30.8 - 44.6						
Abbott Cell-Dyn Ruby	11	37.72	2.28	6.0	38.5	30.8 - 44.6						
Orphee Mythic 22	10	29.30	5.51	18.8	29.1	12.7 - 45.9						

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

<u>Instrument</u>	Specimen CL-11						Specimen CL-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	10.73	3.83	35.7	11.5	0.0 - 22.3	22	14.76	5.78	39.2	15.4	0.0 - 32.1
All Abbott Cell-Dyn Instruments	12	5.45	0.86	15.7	5.5	2.8 - 8.1	12	7.05	0.37	5.2	7.1	5.9 - 8.2
Abbott Cell-Dyn Ruby	11	5.45	0.86	15.7	5.5	2.8 - 8.1	11	7.05	0.37	5.2	7.1	5.9 - 8.2
Orphee Mythic 22	10	13.45	1.58	11.7	13.4	8.7 - 18.2	10	18.46	3.50	18.9	18.7	7.9 - 29.0
<u>Instrument</u>	Specimen CL-13						Specimen CL-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	10.47	4.59	43.8	11.4	0.0 - 24.3	22	6.69	2.90	43.4	7.3	0.0 - 15.4
All Abbott Cell-Dyn Instruments	12	4.62	0.77	16.7	4.8	2.3 - 7.0	12	2.96	0.51	17.3	3.1	1.4 - 4.5
Abbott Cell-Dyn Ruby	11	4.62	0.77	16.7	4.8	2.3 - 7.0	11	2.96	0.51	17.3	3.1	1.4 - 4.5
Orphee Mythic 22	10	13.98	1.78	12.7	13.5	8.6 - 19.4	10	8.90	1.06	11.9	9.2	5.7 - 12.1
<u>Instrument</u>	Specimen CL-15											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	22	13.17	6.06	46.1	13.6	0.0 - 31.4						
All Abbott Cell-Dyn Instruments	12	5.82	0.70	12.0	6.1	3.7 - 8.0						
Abbott Cell-Dyn Ruby	11	5.82	0.70	12.0	6.1	3.7 - 8.0						
Orphee Mythic 22	10	17.78	3.22	18.1	17.0	8.1 - 27.5						

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

<u>Instrument</u>	Specimen CL-11						Specimen CL-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	3.56	1.18	33.0	3.6	0.0 - 7.1	22	3.34	0.96	28.8	3.0	0.4 - 6.3
All Abbott Cell-Dyn Instruments	12	4.84	0.51	10.6	4.8	3.3 - 6.4	12	4.14	0.75	18.1	4.3	1.8 - 6.4
Abbott Cell-Dyn Ruby	11	4.84	0.51	10.6	4.8	3.3 - 6.4	11	4.14	0.75	18.1	4.3	1.8 - 6.4
Orphee Mythic 22	10	2.86	0.89	31.0	3.2	0.2 - 5.6	10	2.78	0.76	27.5	2.9	0.4 - 5.1
<u>Instrument</u>	Specimen CL-13						Specimen CL-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	3.29	0.97	29.6	3.2	0.3 - 6.3	22	2.04	1.11	54.2	1.8	0.0 - 5.4
All Abbott Cell-Dyn Instruments	12	4.36	0.24	5.5	4.3	3.6 - 5.1	12	3.44	0.19	5.7	3.5	2.8 - 4.1
Abbott Cell-Dyn Ruby	11	4.36	0.24	5.5	4.3	3.6 - 5.1	11	3.44	0.19	5.7	3.5	2.8 - 4.1
Orphee Mythic 22	10	2.71	0.78	28.9	3.1	0.3 - 5.1	10	1.38	0.56	40.9	1.5	0.0 - 3.1
<u>Instrument</u>	Specimen CL-15											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	22	3.55	0.75	21.0	3.6	1.3 - 5.8						
All Abbott Cell-Dyn Instruments	12	4.12	0.36	8.6	4.1	3.0 - 5.2						
Abbott Cell-Dyn Ruby	11	4.12	0.36	8.6	4.1	3.0 - 5.2						
Orphee Mythic 22	10	3.11	0.69	22.2	3.1	1.0 - 5.2						

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

<u>Instrument</u>	Specimen CL-11						Specimen CL-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	0.49	0.39	80.3	0.5	0.0 - 1.7	22	0.53	0.41	76.2	0.5	0.0 - 1.8
All Abbott Cell-Dyn Instruments	12	0.16	0.13	83.9	0.1	0.0 - 0.6	12	0.26	0.29	110.8	0.1	0.0 - 1.2
Abbott Cell-Dyn Ruby	11	0.16	0.13	83.9	0.1	0.0 - 0.6	11	0.26	0.29	110.8	0.1	0.0 - 1.2
Orphee Mythic 22	10	0.66	0.42	63.5	0.6	0.0 - 2.0	10	0.71	0.44	61.6	0.6	0.0 - 2.1
	Specimen CL-13						Specimen CL-14					
All Method	22	0.38	0.25	64.9	0.4	0.0 - 1.2	22	0.49	0.35	72.8	0.4	0.0 - 1.6
All Abbott Cell-Dyn Instruments	12	0.14	0.05	39.1	0.1	0.0 - 0.4	12	0.26	0.11	43.9	0.3	0.0 - 0.7
Abbott Cell-Dyn Ruby	11	0.14	0.05	39.1	0.1	0.0 - 0.4	11	0.26	0.11	43.9	0.3	0.0 - 0.7
Orphee Mythic 22	10	0.71	0.60	84.0	0.5	0.0 - 2.6	10	0.56	0.40	71.7	0.5	0.0 - 1.8
	Specimen CL-15											
All Method	22	0.36	0.30	82.5	0.3	0.0 - 1.3						
All Abbott Cell-Dyn Instruments	12	0.10	0.01	0.0	0.1	0.0 - 0.2						
Abbott Cell-Dyn Ruby	11	0.10	0.01	0.0	0.1	0.0 - 0.2						
Orphee Mythic 22	10	0.49	0.32	66.2	0.4	0.0 - 1.5						

BLOOD BANK

ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Group B	22	100.00%	Acceptable
BB-12	Group O	22	100.00%	Acceptable
BB-13	Group A	22	100.00%	Acceptable
BB-14	Group O	22	100.00%	Acceptable
BB-15	Group A	22	100.00%	Acceptable

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Rh Positive	22	100.00%	Acceptable
BB-12	Rh Negative	22	100.00%	Acceptable
BB-13	Rh Negative	22	100.00%	Acceptable
BB-14	Rh Positive	22	100.00%	Acceptable
BB-15	Rh Positive	22	100.00%	Acceptable

BLOOD BANK

UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	No unexpected antibody detected	18	100.00%	Acceptable
AB-12	Unexpected antibody detected	18	100.00%	Acceptable
AB-13	No unexpected antibody detected	18	100.00%	Acceptable
AB-14	No unexpected antibody detected	18	100.00%	Acceptable
AB-15	Unexpected antibody detected	18	100.00%	Acceptable

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	No antibody detected	10	100.00%	Acceptable
AB-12	Anti-E	10	100.00%	Acceptable
AB-13	No antibody detected	10	100.00%	Acceptable
AB-14	No antibody detected	10	100.00%	Acceptable
AB-15	Anti-M	10	100.00%	Acceptable

BLOOD BANK

COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	Compatible	15	100.00%	Acceptable
AB-12	Not Compatible	15	100.00%	Acceptable
AB-13	Compatible	15	100.00%	Acceptable
AB-14	Compatible	15	100.00%	Acceptable
AB-15	Compatible	15	100.00%	Acceptable

Coagulation

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	48	14.97	1.90	12.7	15.2	12.7 - 17.3	48	33.65	5.60	16.7	33.7	28.5 - 38.7
All IL ACL models	5	15.10	0.14	0.9	15.1	12.8 - 17.4	5	21.70	0.28	1.3	21.7	18.4 - 25.0
Dade Innovin												
Dade Behring BFT II	5	12.73	0.25	2.0	12.8	10.8 - 14.7	5	31.80	2.00	6.3	32.0	27.0 - 36.6
Sysmex CA-500/600 series	12	12.94	0.28	2.2	13.0	11.0 - 14.9	12	29.00	0.68	2.3	29.0	24.6 - 33.4
All Coagulation Instruments	18	12.87	0.29	2.3	12.9	10.9 - 14.8	18	29.60	1.58	5.3	29.3	25.1 - 34.1
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	8	16.94	0.31	1.8	16.9	14.3 - 19.5	8	38.95	0.59	1.5	39.2	33.1 - 44.8
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	6	17.10	0.45	2.6	17.1	14.5 - 19.7	6	39.37	1.57	4.0	39.4	33.4 - 45.3
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	14.90	0.75	5.1	15.2	12.6 - 17.2	5	35.88	0.78	2.2	35.5	30.4 - 41.3

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-13						Specimen CG-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	48	11.51	1.39	12.1	11.5	9.7 - 13.3	48	20.67	2.63	12.7	20.2	17.5 - 23.8
All IL ACL models	5	12.05	0.07	0.6	12.1	10.2 - 13.9	5	16.65	0.21	1.3	16.7	14.1 - 19.2
Dade Innovin												
Dade Behring BFT II	5	9.40	0.29	3.1	9.5	7.9 - 10.9	5	18.60	0.80	4.3	18.8	15.8 - 21.4
Sysmex CA-500/600 series	12	10.22	0.25	2.4	10.3	8.6 - 11.8	12	18.17	0.33	1.8	18.3	15.4 - 20.9
All Coagulation Instruments	18	10.03	0.44	4.4	10.1	8.5 - 11.6	18	18.22	0.53	2.9	18.3	15.4 - 21.0
Diag Stago STA Neoplastine Cl+												
Diagnostica Stago STart Max	8	12.95	0.20	1.5	12.9	11.0 - 14.9	8	23.35	0.60	2.5	23.4	19.8 - 26.9
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	6	13.22	0.55	4.2	13.0	11.2 - 15.2	6	23.43	0.23	1.0	23.5	19.9 - 27.0
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	11.20	0.58	5.2	11.4	9.5 - 12.9	5	20.70	0.81	3.9	20.4	17.5 - 23.9

<u>Reagent/Instrument</u>	Specimen CG-15					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	48	11.91	1.52	12.7	11.8	10.1 - 13.7
All IL ACL models	5	12.25	0.07	0.6	12.3	10.4 - 14.1
Dade Innovin						
Dade Behring BFT II	5	9.60	0.22	2.3	9.7	8.1 - 11.1
Sysmex CA-500/600 series	12	10.57	0.28	2.6	10.6	8.9 - 12.2
All Coagulation Instruments	18	10.32	0.51	4.9	10.4	8.7 - 11.9
Diag Stago STA Neoplastine Cl+						
Diagnostica Stago STart Max	8	13.34	0.27	2.0	13.3	11.3 - 15.4
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STart Max	6	13.85	0.52	3.7	13.6	11.7 - 16.0
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	11.46	0.47	4.1	11.5	9.7 - 13.2

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	47	1.29	0.08	5.9	1.3	1.0 - 1.6	47	3.21	0.46	14.5	3.2	2.5 - 3.9
Dade Innovin												
Dade Behring BFT II	5	1.35	0.06	4.3	1.4	1.0 - 1.7	5	3.05	0.24	7.8	3.2	2.4 - 3.7
Sysmex CA-500/600 series	12	1.28	0.06	4.9	1.3	1.0 - 1.6	12	2.93	0.14	4.9	3.0	2.3 - 3.6
All Coagulation Instruments	18	1.28	0.07	5.5	1.3	1.0 - 1.6	18	2.96	0.17	5.7	3.0	2.3 - 3.6
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	8	1.31	0.04	2.7	1.3	1.0 - 1.6	8	3.74	0.07	2.0	3.8	2.9 - 4.5
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	6	1.35	0.05	4.1	1.4	1.0 - 1.7	6	3.78	0.17	4.6	3.8	3.0 - 4.6
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	1.30	0.14	10.9	1.3	1.0 - 1.6	5	3.26	0.30	9.1	3.3	2.6 - 4.0

<u>Reagent/Instrument</u>	Specimen CG-13						Specimen CG-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	47	0.97	0.06	6.6	1.0	0.7 - 1.2	47	1.85	0.16	8.9	1.9	1.4 - 2.3
Dade Innovin												
Dade Behring BFT II	5	1.03	0.05	4.9	1.0	0.8 - 1.3	5	1.90	0.14	7.4	2.0	1.5 - 2.3
Sysmex CA-500/600 series	12	1.00	0.04	4.3	1.0	0.8 - 1.2	12	1.75	0.19	11.0	1.8	1.4 - 2.1
All Coagulation Instruments	18	1.00	0.05	4.9	1.0	0.8 - 1.2	18	1.82	0.11	5.9	1.8	1.4 - 2.2
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	8	0.96	0.05	5.4	1.0	0.7 - 1.2	8	2.00	0.05	2.7	2.0	1.6 - 2.4
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	6	1.02	0.04	4.0	1.0	0.8 - 1.3	6	1.98	0.04	2.1	2.0	1.5 - 2.4
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	0.96	0.05	5.7	1.0	0.7 - 1.2	5	1.82	0.19	10.6	1.8	1.4 - 2.2

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

Specimen CG-15

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	47	1.00	0.06	6.0	1.0	0.8 - 1.2
Dade Innovin						
Dade Behring BFT II	5	1.05	0.06	5.5	1.1	0.8 - 1.3
Sysmex CA-500/600 series	12	1.02	0.04	4.0	1.0	0.8 - 1.3
All Coagulation Instruments	18	1.02	0.04	4.3	1.0	0.8 - 1.3
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	8	1.00	0.01	0.0	1.0	0.8 - 1.2
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STart Max	6	1.03	0.05	5.0	1.0	0.8 - 1.3
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	0.98	0.08	8.5	1.0	0.7 - 1.2

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

Specimen CG-11

Specimen CG-12

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	24	31.9	4.2	13.3	32	27 - 37	24	59.6	13.5	22.7	57	50 - 69
Dade Actin FSL												
Sysmex CA-500/600 series	7	28.6	4.3	15.0	27	24 - 33	7	48.9	4.4	9.0	49	41 - 57
All Coagulation Instruments	8	28.8	4.0	13.9	28	24 - 34	8	49.6	4.6	9.3	50	42 - 58
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	5	37.3	0.6	1.5	37	31 - 43	5	68.3	3.2	4.7	67	58 - 79
HemosIL APTT-SP												
IL ACL, all models	5	32.0	2.7	8.5	33	27 - 37	5	63.5	6.6	10.4	63	53 - 74

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

<u>Reagent/Instrument</u>	Specimen CG-13						Specimen CG-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	24	27.0	2.5	9.3	28	22 - 32	24	38.9	8.3	21.2	40	33 - 45
Dade Actin FSL												
Sysmex CA-500/600 series	7	24.4	1.0	4.0	24	20 - 29	7	29.8	3.1	10.3	31	25 - 35
All Coagulation Instruments	8	24.6	1.1	4.3	25	20 - 29	8	30.6	3.4	11.1	31	25 - 36
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	5	29.7	0.6	1.9	30	25 - 35	5	43.3	1.5	3.5	43	36 - 50
HemosIL APTT-SP												
IL ACL, all models	5	27.5	1.0	3.6	28	23 - 32	5	40.5	1.9	4.7	40	34 - 47

<u>Reagent/Instrument</u>	Specimen CG-15					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	24	29.5	4.7	15.8	29	25 - 34
Dade Actin FSL						
Sysmex CA-500/600 series	7	25.3	1.8	7.1	26	21 - 30
All Coagulation Instruments	8	25.4	1.7	6.6	26	21 - 30
Diagnostica Stago STA C.K. Prest						
Diagnostica Stago STA Compact / Max	5	31.0	1.0	3.2	31	26 - 36
HemosIL APTT-SP						
IL ACL, all models	5	33.0	5.6	17.0	32	28 - 38

FIBRINOGEN (mg/dL)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	12	156.9	29.0	18.5	163	125 - 189	12	254.9	26.2	10.3	257	203 - 306

<u>Reagent/Instrument</u>	Specimen CG-13						Specimen CG-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	12	269.0	29.8	11.1	276	215 - 323	12	247.1	21.8	8.8	245	197 - 297

<u>Reagent/Instrument</u>	Specimen CG-15					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	12	436.1	66.1	15.1	438	348 - 524

PROTHROMBIN TIME (seconds) – XS Samples

<u>Reagent/Instrument</u>	Specimen XS-11						Specimen XS-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	25	33.72	0.99	2.9	33.6	28.6 - 38.8	25	23.60	0.39	1.7	23.6	20.0 - 27.2
All Roche CoaguChek XS Plus Instruments	14	33.61	1.16	3.5	33.6	28.5 - 38.7	14	23.62	0.50	2.1	23.8	20.0 - 27.2
Roche CoaguChek Pro II	11	33.85	0.74	2.2	33.6	28.7 - 39.0	11	23.56	0.20	0.9	23.6	20.0 - 27.1
Roche CoaguChek XS Plus - Waived	9	33.23	1.27	3.8	33.0	28.2 - 38.3	9	23.47	0.54	2.3	23.6	19.9 - 27.0
Roche CoaguChek XS Plus	5	34.30	0.51	1.5	34.4	29.1 - 39.5	5	23.90	0.25	1.1	23.9	20.3 - 27.5

<u>Reagent/Instrument</u>	Specimen XS-13						Specimen XS-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	5	33.38	1.02	3.1	33.4	28.3 - 38.4	5	13.88	0.39	2.8	13.9	11.7 - 16.0
All Roche CoaguChek XS Plus Instruments	5	33.38	1.02	3.1	33.4	28.3 - 38.4	5	13.88	0.39	2.8	13.9	11.7 - 16.0
Roche CoaguChek XS Plus - Waived	3	-	-	-	32.5	27.6 - 37.4	3	-	-	-	13.9	11.8 - 16.0
Roche CoaguChek XS Plus	2	-	-	-	34.3	29.1 - 39.4	2	-	-	-	13.9	11.7 - 16.0

<u>Reagent/Instrument</u>	Specimen XS-15					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	5	24.88	1.60	6.4	25.5	21.1 - 28.7
All Roche CoaguChek XS Plus Instruments	5	24.88	1.60	6.4	25.5	21.1 - 28.7
Roche CoaguChek XS Plus - Waived	3	-	-	-	24.1	20.4 - 27.7
Roche CoaguChek XS Plus	2	-	-	-	25.7	21.8 - 29.6

INTERNATIONAL NORMALIZED RATIO (INR)– XS Samples

<u>Reagent/Instrument</u>	Specimen XS-11						Specimen XS-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	52	2.82	0.09	3.2	2.8	2.2 - 3.4	53	1.97	0.06	3.0	2.0	1.5 - 2.4
All Roche CoaguChek XS Plus Instruments	29	2.78	0.11	3.8	2.8	2.2 - 3.4	29	1.96	0.07	3.4	2.0	1.5 - 2.4
Roche CoaguChek Pro II	24	2.84	0.08	2.7	2.9	2.2 - 3.5	24	1.97	0.05	2.4	2.0	1.5 - 2.4
Roche CoaguChek XS Plus - Waived	23	2.77	0.11	4.0	2.8	2.2 - 3.4	23	1.96	0.07	3.7	2.0	1.5 - 2.4
Roche CoaguChek XS Plus	6	2.83	0.08	2.9	2.9	2.2 - 3.4	6	1.98	0.04	2.1	2.0	1.5 - 2.4

<u>Reagent/Instrument</u>	Specimen XS-13						Specimen XS-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	2.79	0.07	2.7	2.8	2.2 - 3.4	17	1.15	0.05	4.5	1.1	0.9 - 1.4
All Roche CoaguChek XS Plus Instruments	7	2.79	0.09	3.2	2.8	2.2 - 3.4	7	1.14	0.05	4.7	1.1	0.9 - 1.4
Roche CoaguChek Pro II	10	2.80	0.07	2.4	2.8	2.2 - 3.4	10	1.15	0.05	4.6	1.2	0.9 - 1.4
Roche CoaguChek XS Plus - Waived	5	2.76	0.09	3.2	2.7	2.2 - 3.4	5	1.14	0.05	4.8	1.1	0.9 - 1.4
Roche CoaguChek XS Plus	2	-	-	-	2.9	2.2 - 3.5	2	-	-	-	1.2	0.9 - 1.4

<u>Reagent/Instrument</u>	Specimen XS-15					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	2.12	0.08	3.5	2.1	1.6 - 2.6
All Roche CoaguChek XS Plus Instruments	7	2.10	0.10	4.8	2.1	1.6 - 2.6
Roche CoaguChek Pro II	10	2.14	0.05	2.4	2.1	1.7 - 2.6
Roche CoaguChek XS Plus - Waived	5	2.08	0.11	5.3	2.1	1.6 - 2.5
Roche CoaguChek XS Plus	2	-	-	-	2.2	1.7 - 2.6

URINALYSIS DIPSTICK–SPECIFIC GRAVITY**Specimen UA-3**

<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	118	1.0229	0.0052	0.5	1.022	1.012 - 1.033
All Arkray Methods	5	1.0264	0.0042	0.4	1.027	1.016 - 1.037
All Refractive Index Methods	11	1.0265	0.0035	0.3	1.026	1.016 - 1.037
All Roche Methods	35	1.0199	0.0057	0.6	1.020	1.009 - 1.030
All Siemens Methods	35	1.0229	0.0028	0.3	1.025	1.012 - 1.033
77 Elektronika LabUMat/2	9	1.0313	0.0018	0.2	1.030	1.021 - 1.042
Acon Laboratories	5	1.0240	0.0042	0.4	1.025	1.014 - 1.034
Roche Chemstrips / Combur	10	1.0180	0.0026	0.3	1.020	1.008 - 1.028
Roche cobas u 411	15	1.0183	0.0025	0.2	1.020	1.008 - 1.029
Roche Urisys	17	1.0202	0.0066	0.6	1.015	1.010 - 1.031
Siemens Clinitek Advantus	15	1.0233	0.0025	0.2	1.025	1.013 - 1.034
Siemens Clinitek Status / Status+	17	1.0218	0.0024	0.2	1.020	1.011 - 1.032

URINALYSIS DIPSTICK-pH

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>≤3.5</u>	<u>4.0</u>	<u>4.5</u>	<u>5.0</u>	<u>5.5</u>	<u>6.0</u>	<u>6.5</u>	<u>7.0</u>	<u>7.5</u>	<u>8.0</u>	<u>8.5</u>	<u>≥9.0</u>
ALL METHODS	147	-	-	-	105	21	21	-	-	-	-	-	-
77 Elektronika LabUMat/2	9	-	-	-	9	-	-	-	-	-	-	-	-
Acon Laboratories	5	-	-	-	1	1	3	-	-	-	-	-	-
Arkray Aution Jet	1	-	-	-	1	-	-	-	-	-	-	-	-
Arkray Aution Sticks	4	-	-	-	3	1	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	1	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	1	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	2	-	-	-	2	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	1	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	2	-	-	-	-	-	-	-	-
Other Analyzer Method	2	-	-	-	2	-	-	-	-	-	-	-	-
Other Dipstick Method	4	-	-	-	1	-	3	-	-	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	1	-	-	-	-	-	-
Roche Chemstrips / Combur	23	-	-	-	23	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	1	-	-	-	-	-	-	-	-
Roche cobas u 411	15	-	-	-	15	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	4	-	-	-	4	-	-	-	-	-	-	-	-
Roche Urisys	19	-	-	-	19	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	3	-	-	-	2	-	1	-	-	-	-	-	-
Siemens Clinitek Advantus	16	-	-	-	2	11	3	-	-	-	-	-	-
Siemens Clinitek Atlas	1	-	-	-	1	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	-	-	-	11	7	-	-	-	-	-	-	-
Siemens Reagent Strips	12	-	-	-	2	-	10	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	1	-	-	-	-	-	-	-	-
UriScan Reagent Strips	1	-	-	-	1	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–PROTEIN QUALITATIVE
Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>10 - 20</u> <u>mg/dL</u>	<u>30 - 70</u> <u>mg/dL</u>	<u>75</u> <u>mg/dL</u>	<u>100 - 200</u> <u>mg/dL</u>	<u>≥300 - 600</u> <u>mg/dL</u>	<u>>600 or ≥1000</u> <u>mg/dL</u>
ALL METHODS	148	144	2	-	-	1	1	-	-	-	-	-	-
77 Elektronika LabUMat/2	9	9	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	5	3	2	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	4	4	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	2	2	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	2	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	2	2	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	4	4	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	24	23	-	-	-	1	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	15	15	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	4	3	-	-	-	-	1	-	-	-	-	-	-
Roche Urisys	19	19	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	3	3	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	16	16	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	18	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	12	12	-	-	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Negative or Normal</u>	<u>Trace</u>	<u>(1+)</u>	<u>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	147	3	29	15	1	11	59	1	2	2	24
77 Elektronika LabUMat/2	9	-	-	-	-	-	4	-	-	-	5
Acon Laboratories	5	-	-	-	-	-	5	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	1	-	-	-	-
Arkray Aution Sticks	4	-	-	-	-	2	2	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	1	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	2	-	-	-	-	-	1	-	1	-	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	-	1	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	-	1	1	-	-	-	-
Other Analyzer Method	2	-	-	-	-	-	-	-	-	1	1
Other Dipstick Method	4	-	-	-	-	1	3	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	23	-	-	-	-	2	20	1	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	1	-	-	-	-
Roche cobas u 411	15	-	-	-	-	1	7	-	-	-	7
Roche cobas u 601 / 701	4	-	-	-	-	-	-	-	-	-	4
Roche Urisys	19	-	-	-	-	2	10	-	-	-	7
SD UroColor Reagent Strips	3	-	-	-	1	1	1	-	-	-	-
Siemens Clinitek Advantus	16	-	13	3	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	-	-	-	-	1	-	-	-	-	-
Siemens Clinitek Status / Status+	18	-	7	10	-	-	-	-	1	-	-
Siemens Reagent Strips	12	2	9	1	-	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	1	-	-	-	-
UriScan Reagent Strips	1	-	-	1	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–KETONES

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Participant Results</u>													
		<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>5 - 10</u> <u>mg/dL</u>	<u>15 - 25</u> <u>mg/dL</u>	<u>40 - 60</u> <u>mg/dL</u>	<u>≥80 - 100</u> <u>mg/dL</u>	<u>≥150</u> <u>mg/dL</u>
ALL METHODS	147	7	1	-	1	-	16	51	37	6	-	4	16	-	8
77 Elektronika LabUMat/2	9	-	-	-	-	-	1	3	-	-	-	1	4	-	-
Acon Laboratories	5	3	-	-	-	-	-	1	-	1	-	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Arkray Aution Sticks	4	-	-	-	-	-	-	4	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	2	-	-	-	-	-	-	-	1	-	-	-	1	-	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	-	-	1	1	-	-	-	-	-	-	-
Other Analyzer Method	2	-	-	-	-	-	-	1	-	-	-	1	-	-	-
Other Dipstick Method	4	3	-	-	-	-	-	-	1	-	-	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Roche Chemstrips / Combur	23	1	-	-	-	-	1	7	13	-	-	1	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Roche cobas u 411	16	-	-	-	-	-	-	-	5	3	-	-	1	-	7
Roche cobas u 601 / 701	3	-	-	-	-	-	-	-	-	-	-	-	2	-	1
Roche Urisys	19	-	-	-	1	-	1	2	6	2	-	-	7	-	-
SD UroColor Reagent Strips	3	-	1	-	-	-	-	2	-	-	-	-	-	-	-
Siemens Clinitek Advantus	16	-	-	-	-	-	11	5	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	-	-	-	-	-	-	16	1	-	-	-	1	-	-
Siemens Reagent Strips	12	-	-	-	-	-	-	3	9	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
UriScan Reagent Strips	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-3

<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	122	122	-	-	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	5	5	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	10	10	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	15	15	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	19	19	-	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>				
		<u>Normal or 0.0 - 0.2 mg/dL or <3.2 μmol/L</u>	<u>1.0 or <2.0 mg/dL or 16 or 17 μmol/L</u>	<u>2.0/3.0 mg/dL or 34 or 35 μmol/L</u>	<u>4.0 or 4.0/6.0 mg/dL or 70 μmol/L</u>	<u>≥8.0 or ≥12.0 mg/dL or ≥140 or 200 μmol/L</u>
ALL METHODS	122	121	1	-	-	-
77 Elektronika LabUMat/2	9	9	-	-	-	-
Acon Laboratories	5	4	1	-	-	-
Arkray Aution Jet	1	1	-	-	-	-
Arkray Aution Sticks	4	4	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	2	2	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	1	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	2	-	-	-	-
Other Analyzer Method	2	2	-	-	-	-
Other Dipstick Method	4	4	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-
Roche Chemstrips / Combur	10	10	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-
Roche cobas u 411	15	15	-	-	-	-
Roche cobas u 601 / 701	4	4	-	-	-	-
Roche Urisys	19	19	-	-	-	-
SD UroColor Reagent Strips	3	3	-	-	-	-
Siemens Clinitek Advantus	16	16	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-
Siemens Clinitek Status / Status+	16	16	-	-	-	-
Siemens Reagent Strips	2	2	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>(5+)</u>	<u>5 - 25</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>\geq1.0</u> <u>mg/</u> <u>dL</u>
ALL METHODS	147	145	-	-	-	-	-	-	-	-	-	2	-	-	-	-	-	-
77 Elektronika LabUMat/2	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	5	5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	21	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	16	15	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Roche cobas u 601 / 701	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Mditron Junior/II	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	19	19	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	18	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	12	12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>15 or 25 µL</u>	<u>75 or 100 µL</u>	<u>250 or 500 µL</u>
ALL METHODS	134	-	1	4	-	-	27	17	53	-	-	-	32
77 Elektronika LabUMat/2	9	-	-	-	-	-	-	-	3	-	-	-	6
Acon Laboratories	5	-	-	-	-	-	2	3	-	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	-	-	-	-	-	-	1
Arkray Aution Sticks	3	-	-	-	-	-	-	-	-	-	-	-	3
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	2	-	-	-	-	-	-	-	2	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	-	-	-	1	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	-	-	-	-	2	-	-	-	-
Other Analyzer Method	2	-	-	-	-	-	-	-	-	-	-	-	2
Other Dipstick Method	4	-	-	-	-	-	-	3	1	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche Chemstrips / Combur	23	-	-	-	-	-	-	1	21	-	-	-	1
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche cobas u 411	16	-	-	-	-	-	-	-	8	-	-	-	8
Roche cobas u 601 / 701	3	-	-	-	-	-	-	-	-	-	-	-	3
Roche Urisys	19	-	-	1	-	-	-	1	9	-	-	-	8
SD UroColor Reagent Strips	3	-	-	-	-	-	-	2	1	-	-	-	-
Siemens Clinitek Advantus	16	-	-	-	-	-	15	1	-	-	-	-	-
Siemens Clinitek Atlas	1	-	-	-	-	-	-	1	-	-	-	-	-
Siemens Clinitek Status / Status+	16	-	-	3	-	-	9	4	-	-	-	-	-
Siemens Reagent Strips	2	-	1	-	-	-	1	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	1	-	-	-	-
UriScan Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-

URINALYSIS DIPSTICK–NITRITE**Specimen UA-3*****Participant Results***

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	135	8	127
77 Elektronika LabUMat/2	9	-	9
Acon Laboratories	5	-	5
Arkray Aution Jet	1	-	1
Arkray Aution Sticks	4	-	4
DIRUI H-800 Urine Analyzer	1	-	1
Iris Diagnostics Aution Max AX-4280	1	-	1
Iris Diagnostics iChem Velocity Strips	2	-	2
Iris Diagnostics vChem Urine Strips	1	-	1
Iris Ichem VELOCITY Urine Chemistry System	2	-	2
Other Analyzer Method	2	-	2
Other Dipstick Method	4	2	2
Plasmatec URIPATH	1	-	1
Roche Chemstrips / Combur	22	1	21
Roche cobas 6500 / u 601	1	-	1
Roche cobas u 411	16	2	14
Roche cobas u 601 / 701	3	-	3
Roche SuperUA/ChemstripUA	1	-	1
Roche Urisys	19	1	18
SD UroColor Reagent Strips	3	1	2
Siemens Clinitek Advantus	16	-	16
Siemens Clinitek Atlas	1	-	1
Siemens Clinitek Status / Status+	16	-	16
Siemens Reagent Strips	2	1	1
Sysmex UN Series	1	-	1
UriScan Reagent Strips	1	-	1

URINALYSIS –MICROALBUMIN (dipstick only)

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>									
		<u>Negative</u>	<u>10 mg/L</u>	<u>20 mg/L</u>	<u>30 mg/L</u>	<u>50 mg/L</u>	<u>80 mg/L</u>	<u>100 mg/L</u>	<u>150 mg/L</u>	<u>+(4 - 8 mg/dL)</u>	<u>++ (>8 mg/dL)</u>
ALL METHODS	8	6	1	1	-	-	-	-	-	-	-
Other Analyzer Method	2	2	-	-	-	-	-	-	-	-	-
Other Dipstick Method	1	1	-	-	-	-	-	-	-	-	-
Roche Micral - 1 minute	2	1	-	1	-	-	-	-	-	-	-

URINALYSIS –URINE hCG

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>	
		<u>Positive</u>	<u>Negative</u>
ALL METHODS	78	-	78
Abon (Alere) Biopharm	5	-	5
Acon Laboratories	3	-	3
Alere Clearview hCG Cassette	4	-	4
Alere hCG Combo Cassette	20	-	20
bioMerieux VIKIA hCG-D	1	-	1
Biosynex	1	-	1
Other Dipstick Method	1	-	1
SD Bioline hCG	7	-	7
Siemens Clinitek Status / Status+	10	-	10

MISCELLANEOUS CULTURES

Specimen BA-7 – CSF Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Acinetobacter lwoffii	42	41.18%	Acceptable
Acinetobacter sp.	20	9.80%	Acceptable
Gram negative coccobacilli	4	3.92%	Acceptable
Gram negative bacilli	1	0.98%	Acceptable
Moraxella sp.	20	19.61%	
Gram negative diplococci	7	6.86%	

Organism(s) present: *Acinetobacter lwoffii*. This challenge was graded by referee group.

Specimen BA-8 – Sputum Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus aureus	85	57.05%	Acceptable
Gram positive cocci	3	2.01%	Acceptable
Moraxella catarrhalis	35	23.49%	Acceptable
Moraxella sp.	16	10.74%	Acceptable
Gram negative diplococci	4	2.68%	Acceptable
Normal flora	2	1.34%	Acceptable

Organism(s) present: *Staphylococcus aureus* and *Moraxella catarrhalis*

MISCELLANEOUS CULTURES

Specimen BA-9 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pasteurella multocida	52	34.44%	Acceptable
Pasteurella sp.	15	9.93%	Acceptable
Gram negative coccobacilli	1	0.66%	Acceptable
Staphylococcus epidermidis	59	39.07%	Acceptable
Staph – coagulase negative	6	3.97%	Acceptable
Staphylococcus sp.	4	2.65%	Acceptable
Gram positive cocci	1	0.66%	Acceptable
Haemophilus parainfluenzae	7	4.64%	

Organism(s) present: *Pasteurella multocida* and *Staphylococcus epidermidis*

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen UC-11, CC-11 (SUS-11) Organism(s) present: *Pseudomonas aeruginosa*

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>
	<i>Interpretative category data</i>				<i>Interpretative category data</i>				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Amikacin	25	25	-	-	117	117	-	-	100.00%
Amoxicillin/Clavulanate	4	1	-	3	1	-	-	1	80.00%
Ampicillin	2	1	-	1	8	1	-	7	80.00%
Ampicillin/Sulbactam	2	1	-	1	8	1	-	7	80.00%
Aztreonam	10	10	-	-	31	27	2	2	90.24%
Cefazolin	2	-	-	2	14	2	-	12	Inappropriate drug ¹
Cefdinir	1	1	-	-	1	1	-	-	Inappropriate drug ¹
Cefepime	23	22	-	1	135	134	-	1	98.73%
Cefixime	2	-	-	2	-	-	-	-	Inappropriate drug ¹
Cefoperazone	1	1	-	-	1	-	-	1	Inappropriate drug ¹
Cefotaxime	2	1	-	1	16	1	1	14	83.33%
Cefoxitin	-	-	-	-	4	1	-	3	Inappropriate drug ¹
Ceftazidime	24	24	-	-	132	127	1	4	96.79%
Ceftizoxime	1	-	-	1	1	1	-	-	Inappropriate drug ¹
Ceftolozane/Tazobactam	3	3	-	-	7	7	-	-	100.00%
Ceftriaxone	2	1	-	1	16	2	-	14	83.33%
Cefuroxime	4	-	-	4	4	2	-	2	Inappropriate drug ¹
Ciprofloxacin	29	29	-	-	143	141	1	1	98.84%
Colistin	1	1	-	-	11	10	1	-	91.67%
Daptomycin	-	-	-	-	1	1	-	-	Inappropriate drug ¹
Doripenem	2	2	-	-	17	17	-	-	100.00%
Ertapenem	2	1	-	1	8	1	-	7	80.00%
Fosfomycin	-	-	-	-	5	1	-	4	80.00%
Gentamicin	27	26	1	-	132	131	-	1	98.74%
Imipenem	20	20	-	-	98	92	5	1	94.92%
Levofloxacin	17	17	-	-	63	61	1	1	97.50%
Linezolid	-	-	-	-	1	1	-	-	Inappropriate drug ¹
Meropenem	20	20	-	-	120	118	1	1	98.57%
Nalidixic Acid	2	-	-	2	1	1	-	-	Inappropriate drug ¹
Netilmicin	3	3	-	-	-	-	-	-	100.00%

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

ANTIMICROBIAL SUSCEPTIBILITY TESTING (cont'd)

Specimen UC-11, CC-11 (SUS-11) Organism(s) present: *Pseudomonas aeruginosa*

<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>	
Nitrofurantoin	4	-	-	4	7	4	-	3	Inappropriate drug ¹
Norfloxacin	9	9	-	-	23	23	-	-	100.00%
Ofloxacin	8	8	-	-	1	1	-	-	100.00%
Oxacillin	-	-	-	-	1	1	-	-	Inappropriate drug ¹
Penicillin	1	-	-	1	2	1	-	1	Inappropriate drug ¹
Piperacillin	1	1	-	-	7	6	1	-	100.00%
Piperacillin/Tazobactam	21	20	-	1	112	106	3	3	94.74%
Polymyxin B	1	1	-	-	2	1	1	-	100.00%
Rifampin	-	-	-	-	1	1	-	-	Inappropriate drug ¹
Tetracycline	-	-	-	-	5	2	-	3	80.00%
Ticarcillin/Clavulanate	1	1	-	-	3	3	-	-	100.00%
Tigecycline	-	-	-	-	2	-	-	2	100.00%
Tobramycin	9	9	-	-	26	26	-	-	100.00%
Trimethoprim	-	-	-	-	1	-	-	1	100.00%
Trimethoprim/Sulfamethoxazole	3	-	-	3	11	1	1	9	85.71%
Vancomycin	-	-	-	-	1	1	-	-	Inappropriate drug ¹

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

PARASITOLOGY (PA Specimens)

Specimen PA-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	2	100.00%	Acceptable
Parasite(s) present: Negative (sterile)			

Specimen PA-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	2	100.00%	Acceptable
Parasite(s) present: <i>Giardia lamblia</i>			

Specimen PA-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis larvae	10	90.91%	Acceptable
Taenia sp. eggs	1	9.09%	
Parasite(s) present: <i>Strongyloides stercoralis</i>			

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Trichuris trichiura eggs	11	84.62%	Acceptable
Ascaris lumbricoides eggs	2	15.38%	

Parasite(s) present: *Trichuris trichiura*, *Entamoeba hartmanni*, and *Endolimax nana*

Specimen PA-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Trypanosoma sp.	8	72.73%	Acceptable
Trypanosoma brucei sp.	1	9.09%	Acceptable

Parasite(s) present: *Trypanosoma brucei rhodesiense*

PARASITOLOGY (FP Specimens)

Specimen FP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis larvae	193	45.95%	Acceptable
Endolimax nana	68	16.19%	Acceptable
Blastocystis hominis	115	27.38%	Acceptable
Parasite egg or larva seen – no ID	2	0.48%	Acceptable
Entamoeba histolytica	8	1.90%	
Iodamoeba buetschlii	6	1.43%	

Parasite(s) present: *Strongyloides stercoralis*, *Endolimax nana*, and *Blastocystis hominis*. This challenge was graded by referee group.

PARASITOLOGY (FP Specimens)

Specimen FP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	227	83.46%	Acceptable
Giardia lamblia	13	4.78%	
Endolimax nana	8	2.94%	
Entamoeba coli	5	1.84%	

Parasite(s) present: Negative (sterile)

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	260	67.18%	Acceptable
Trichuris trichiura eggs	112	28.94%	Acceptable
Parasite egg or larva seen – no ID	1	0.26%	Acceptable
Endolimax nana	3	0.78%	

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

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Clonorchis sinensis	126	44.68%	Acceptable
Parasite egg or larva seen – no ID	2	0.71%	Acceptable
No parasite seen	87	30.85%	
Diphyllobothrium latum	14	4.96%	
Taenia sp. eggs	8	2.84%	
Trichuris trichiura eggs	6	2.13%	
Enterobius vermicularis eggs	5	1.77%	
Giardia lamblia	5	1.77%	

Parasite(s) present: *Clonorchis sinensis*. This challenge was graded by referee group.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Trypanosoma cruzi	145	54.51%	Acceptable
Trypanosoma sp.	104	39.10%	Acceptable
Leishmania sp.	4	1.50%	
Plasmodium vivax	4	1.50%	
Plasmodium falciparum	4	1.50%	

Parasite(s) present: *Trypanosoma cruzi*

Antinuclear Antibody (ANA) - Qualitative

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	22	-	22	-	22
Bio-Rad	-	2	-	2	-	2
BioSystems	-	2	-	2	-	2
Human	-	1	-	1	-	1
Immuno Concepts	-	2	-	2	-	2
INOVA Diagnostics	-	9	-	9	-	9
Kallestad	-	1	-	1	-	1

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	22	-	21	1
Bio-Rad	2	-	2	-
BioSystems	2	-	2	-
Human	1	-	1	-
Immuno Concepts	2	-	2	-
INOVA Diagnostics	9	-	8	1
Kallestad	1	-	1	-

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

<u>Specimen/Method</u>	<u>N/A</u> <u>(Neg)</u>	<u>8/</u> <u>10</u>	<u>16/</u> <u>20</u>	<u>32/</u> <u>40</u>	<u>64/</u> <u>80</u>	<u>128/</u> <u>160</u>	<u>256/</u> <u>320</u>	<u>512/</u> <u>640</u>	<u>>640</u>	<u>1024/</u> <u>1280</u>	<u>2048/</u> <u>2560</u>	<u>≥2560</u>
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Specimen AE-11

ALL METHODS	17	-	-	1	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	8	-	-	-	-	-	-	-	-	-	-	-
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>
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Specimen AE-12

ALL METHODS	17	-	-	1	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	8	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

Specimen AE-13

ALL METHODS	17	-	-	1	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	8	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

Specimen AE-14

ALL METHODS	-	-	-	1	-	1	3	8	-	4	1	-
Bio-Rad	-	-	-	-	-	-	-	-	-	2	-	-
Immuno Concepts	-	-	-	1	-	-	-	2	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	1	3	-	2	1	-
Kallestad	-	-	-	-	-	-	-	1	-	-	-	-

Specimen AE-15

ALL METHODS	1	-	-	1	-	-	1	3	-	6	4	2
Bio-Rad	-	-	-	-	-	-	-	-	-	1	1	-
Immuno Concepts	-	-	-	1	-	-	-	-	-	2	-	-
INOVA Diagnostics	1	-	-	-	-	-	1	-	-	3	2	1
Kallestad	-	-	-	-	-	-	-	-	-	-	-	1

Anti-dsDNA

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	-	21	-	21
BioSystems	-	2	-	2	-	2
Human	-	1	-	1	-	1
Immuno Concepts	-	2	-	2	-	2
INOVA Diagnostics	-	9	-	9	-	9
Kallestad	-	1	-	1	-	1

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	7	-	21
BioSystems	2	-	-	2
Human	-	1	-	1
Immuno Concepts	1	1	-	2
INOVA Diagnostics	7	2	-	9
Kallestad	-	1	-	1

Anti-RNP

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	13	1	14	-	15
INOVA Diagnostics	2	7	1	8	-	9

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	3	13	2
INOVA Diagnostics	7	2	8	1

Anti-RNP/Sm

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

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

Anti-SSA

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	-	21	-	20
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	11	-	11	-	11

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	19	-	21
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	11	-	11

Anti-SSB

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	-	21	-	21
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	11	-	11	-	11

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	-	21
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	11	-	11

Anti-SSA/SSB

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

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

Anti-Sm

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	19	-	20	-	20
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	1	10	-	11	-	11

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	17	6	14
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	11	5	6

Rubella—Qualitative

<u>Method</u>	Specimen RU-11		Specimen RU-12		Specimen RU-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	1	-	18	-	18
Abbott Architect	11	1	-	12	-	12
Roche cobas 6000 / e 601	3	-	-	3	-	3
Roche cobas e 411	1	-	-	1	-	1
Siemens Atellica	1	-	-	1	-	1

<u>Method</u>	Specimen RU-14		Specimen RU-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	17	1
Abbott Architect	-	12	11	1
Roche cobas 6000 / e 601	-	3	3	-
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-11						
All Method	22	28.83	17.70	61.4	18.0	0.0 - 82.0
Abbott Architect	13	17.01	1.42	8.3	16.9	12.7 - 21.3
Roche cobas 6000 / e 601	5	53.10	2.19	4.1	52.6	46.5 - 59.7
Specimen RU-12						
All Method	21	0.07	0.10	141.0	0.0	0.0 - 0.4
Abbott Architect	12	0.00	0.01	0.0	0.0	0.0 - 0.1
Roche cobas 6000 / e 601	5	0.22	0.16	74.7	0.2	0.0 - 0.8
Specimen RU-13						
All Method	22	0.09	0.14	164.9	0.0	0.0 - 0.6
Abbott Architect	13	0.00	0.01	0.0	0.0	0.0 - 0.1
Roche cobas 6000 / e 601	5	0.22	0.16	74.7	0.2	0.0 - 0.8
Specimen RU-14						
All Method	21	0.05	0.07	157.4	0.0	0.0 - 0.3
Abbott Architect	13	0.00	0.01	0.0	0.0	0.0 - 0.1
Roche cobas 6000 / e 601	5	0.22	0.16	74.7	0.2	0.0 - 0.8
Specimen RU-15						
All Method	22	48.39	27.24	56.3	31.3	0.0 - 130.1
Abbott Architect	13	29.55	1.97	6.7	30.7	23.6 - 35.5
Roche cobas 6000 / e 601	5	85.68	3.92	4.6	85.5	73.9 - 97.5

Syphilis Serology—Qualitative: VDRL Slide

<u>Method</u>	Specimen SY-11			Specimen SY-12			Specimen SY-13		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	-	53	53	-	-	53	-	-
Abbott Architect	-	-	2	2	-	-	2	-	-
Acon Laboratories	-	-	2	2	-	-	2	-	-
Omega Diagnostics	-	-	1	1	-	-	1	-	-
Plasmatec	-	-	1	1	-	-	1	-	-
Roche cobas 6000 / e 601	-	-	1	1	-	-	1	-	-
SPINREACT	-	-	2	2	-	-	2	-	-
Wiener Lab	-	-	41	41	-	-	41	-	-

<u>Method</u>	Specimen SY-14			Specimen SY-15		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	52	-	-	1	-	51
Abbott Architect	2	-	-	-	-	2
Acon Laboratories	2	-	-	-	-	2
Omega Diagnostics	1	-	-	-	-	1
Plasmatec	1	-	-	-	-	1
Roche cobas 6000 / e 601	1	-	-	-	-	1
SPINREACT	2	-	-	-	-	2
Wiener Lab	40	-	-	1	-	39

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-11									
ALL METHODS	49	-	-	-	-	-	-	-	-
Omega Diagnostics	1	-	-	-	-	-	-	-	-
Plasmatec	1	-	-	-	-	-	-	-	-
Wiener Lab	43	-	-	-	-	-	-	-	-
Specimen SY-12									
ALL METHODS	-	-	2	9	10	23	3	1	1
Omega Diagnostics	-	-	-	-	-	1	-	-	-
Plasmatec	-	-	-	-	-	1	-	-	-
Wiener Lab	-	-	2	7	10	20	2	1	1
Specimen SY-13									
ALL METHODS	-	-	3	21	15	6	3	-	1
Omega Diagnostics	-	-	-	-	-	-	1	-	-
Plasmatec	-	-	-	-	1	-	-	-	-
Wiener Lab	-	-	2	19	14	5	2	-	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-14									
ALL METHODS	-	-	10	14	18	5	-	-	1
Omega Diagnostics	-	-	-	-	-	1	-	-	-
Plasmatec	-	-	-	-	1	-	-	-	-
Wiener Lab	-	-	8	13	16	4	-	-	1
Specimen SY-15									
ALL METHODS	46	-	1	1	-	-	-	-	-
Omega Diagnostics	1	-	-	-	-	-	-	-	-
Plasmatec	1	-	-	-	-	-	-	-	-
Wiener Lab	40	-	1	1	-	-	-	-	-

Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	13	13	-	13	-
Abbott Architect	-	1	1	-	1	-
Biokit	-	1	1	-	1	-
Human	-	1	1	-	1	-
Plasmatec	-	1	1	-	1	-
Roche cobas e 411	-	1	1	-	1	-
Serodia	-	4	4	-	4	-
Standard Diagnostics	-	2	2	-	2	-

	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	13	-	1	12
Abbott Architect	1	-	-	1
Biokit	1	-	-	1
Human	1	-	-	1
Plasmatec	1	-	-	1
Roche cobas e 411	1	-	-	1
Serodia	4	-	-	4
Standard Diagnostics	2	-	-	2

Syphilis Serology—Qualitative: *Treponema pallidum* Antibodies

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	53	52	2	52	2
Abbott Architect	-	11	10	1	10	1
Abon (Alere) Biopharm	-	2	2	-	2	-
Bio-Rad Evolis	-	1	1	-	1	-
bioMerieux	-	1	1	-	1	-
DiaSorin	-	2	2	-	2	-
Human	-	2	2	-	2	-
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	-	1	1	-	1	-
Serodia	-	9	9	-	9	-
Siemens Immulite 2000	-	1	1	-	1	-
SPINREACT	-	1	1	-	1	-
Standard Diagnostics	-	6	5	1	5	1
Wiener Lab	1	1	2	-	2	-
Zeus	-	1	1	-	1	-

Syphilis Serology—Qualitative: *Treponema pallidum* Antibodies

	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	51	3	-	54
Abbott Architect	9	2	-	11
Abon (Alere) Biopharm	2	-	-	2
Bio-Rad Evolis	1	-	-	1
bioMerieux	1	-	-	1
DiaSorin	2	-	-	2
Human	2	-	-	2
Plasmatec	1	-	-	1
Roche cobas 6000 / c 501	1	-	-	1
Roche cobas 8000/e801	1	-	-	1
Roche cobas e 411	1	-	-	1
SD Bioline	1	-	-	1
Serodia	9	-	-	9
Siemens Immulite 2000	1	-	-	1
SPINREACT	1	-	-	1
Standard Diagnostics	5	1	-	6
Wiener Lab	2	-	-	2
Zeus	1	-	-	1

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	2	62	64	-	64	-
Atlas Medical	-	3	3	-	3	-
Becton Dickinson	-	4	4	-	4	-
bioMerieux	-	5	5	-	5	-
BioSystems	2	10	12	-	12	-
Human	-	5	5	-	5	-
Lorne Laboratories	-	2	2	-	2	-
Omega Diagnostics	-	4	4	-	4	-
Plasmatec	-	5	5	-	5	-
Pulse Scientific	-	1	1	-	1	-
SPINREACT	-	17	17	-	17	-

Syphilis Serology—Qualitative: RPR

	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	64	-	3	61
Atlas Medical	3	-	-	3
Becton Dickinson	4	-	-	4
bioMerieux	5	-	1	4
BioSystems	12	-	1	11
Human	5	-	1	4
Lorne Laboratories	2	-	-	2
Omega Diagnostics	4	-	-	4
Plasmatec	5	-	-	5
Pulse Scientific	1	-	-	1
SPINREACT	17	-	-	17

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-11									
ALL METHODS	58	1	-	-	-	-	-	-	-
Atlas Medical	2	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-
bioMerieux	3	-	-	-	-	-	-	-	-
BioSystems	12	1	-	-	-	-	-	-	-
Human	5	-	-	-	-	-	-	-	-
Lorne Laboratories	2	-	-	-	-	-	-	-	-
Omega Diagnostics	3	-	-	-	-	-	-	-	-
Plasmatec	2	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	21	-	-	-	-	-	-	-	-
Specimen SY-12									
ALL METHODS	1	-	7	23	22	3	1	2	-
Atlas Medical	-	-	1	1	-	-	-	-	-
Becton Dickinson	-	-	-	4	-	-	-	-	-
bioMerieux	-	-	1	2	-	-	-	-	-
BioSystems	1	-	1	4	6	-	-	1	-
Human	-	-	1	2	1	-	-	1	-
Lorne Laboratories	-	-	-	1	1	-	-	-	-
Omega Diagnostics	-	-	-	2	1	-	-	-	-
Plasmatec	-	-	-	-	1	1	-	-	-
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	-	2	5	11	2	1	-	-

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

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>
Specimen SY-13									
ALL METHODS	1	1	19	23	10	1	2	1	1
Atlas Medical	-	-	1	1	-	-	-	-	-
Becton Dickinson	-	-	2	2	-	-	-	-	-
bioMerieux	-	-	3	-	-	-	-	-	-
BioSystems	1	1	2	4	3	-	2	-	-
Human	-	-	2	1	1	-	-	-	1
Lorne Laboratories	-	-	1	1	-	-	-	-	-
Omega Diagnostics	-	-	2	-	-	1	-	-	-
Plasmatec	-	-	-	1	1	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	-	4	12	4	-	-	1	-
Specimen SY-14									
ALL METHODS	-	6	18	26	4	4	-	-	1
Atlas Medical	-	1	-	1	-	-	-	-	-
Becton Dickinson	-	1	2	1	-	-	-	-	-
bioMerieux	-	1	2	-	-	-	-	-	-
BioSystems	-	1	3	6	1	2	-	-	-
Human	-	1	1	2	-	1	-	-	-
Lorne Laboratories	-	-	1	1	-	-	-	-	-
Omega Diagnostics	-	-	2	-	1	-	-	-	-
Plasmatec	-	-	-	2	-	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	-	6	11	2	1	-	-	1

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

<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-15									
ALL METHODS	58	1	-	-	-	-	-	-	-
Atlas Medical	2	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-
bioMerieux	3	-	-	-	-	-	-	-	-
BioSystems	13	-	-	-	-	-	-	-	-
Human	5	-	-	-	-	-	-	-	-
Lorne Laboratories	2	-	-	-	-	-	-	-	-
Omega Diagnostics	3	-	-	-	-	-	-	-	-
Plasmatec	2	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	21	-	-	-	-	-	-	-	-

Viral Markers – Anti-HBc (IgM)

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	41	-	2	39	-	-	41	-
Abbott Alinity	-	2	-	-	2	-	-	2	-
Abbott Architect	-	21	-	-	21	-	-	21	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	6	-	-	6	-	-	6	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
Roche cobas e 411	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	2	-	2	-	-	-	2	-
VITROS									
3600/4600/5600/7600	-	4	-	-	4	-	-	4	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	13	28	-	-	41	-
Abbott Alinity	1	1	-	-	2	-
Abbott Architect	9	12	-	-	21	-
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	6	-	-	6	-
Roche cobas 8000/e801	-	4	-	-	4	-
Roche cobas e 411	-	1	-	-	1	-
Siemens ADVIA Centaur	2	-	-	-	2	-
VITROS						
3600/4600/5600/7600	-	4	-	-	4	-

Viral Markers – Anti-HBc (Total / IgG)

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	5	62	-	66	1	-	-	67	-
Abbott Alinity	-	6	-	6	-	-	-	6	-
Abbott Architect	-	35	-	34	1	-	-	35	-
Beckman ACCESS / 2 / Dxl	1	1	-	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	2	2	-	4	-	-	-	4	-
Siemens ADVIA Centaur	2	-	-	2	-	-	-	2	-
Siemens Atellica	-	1	-	1	-	-	-	1	-
Siemens Immulite 2000	-	1	-	1	-	-	-	1	-
VITROS									
3600/4600/5600/7600	-	3	-	3	-	-	-	3	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	66	1	-	63	4	-
Abbott Alinity	6	-	-	6	-	-
Abbott Architect	34	1	-	33	2	-
Beckman ACCESS / 2 / Dxl	2	-	-	2	-	-
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	8	-	-	8	-	-
Roche cobas 8000/e801	4	-	-	4	-	-
Roche cobas e 411	4	-	-	3	1	-
Siemens ADVIA Centaur	2	-	-	2	-	-
Siemens Atellica	1	-	-	1	-	-
Siemens Immulite 2000	1	-	-	1	-	-
VITROS						
3600/4600/5600/7600	3	-	-	3	-	-

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	141	-	2	141	-	140	3	-
Abbott Alinity	-	8	-	-	8	-	8	-	-
Abbott Architect	1	60	-	1	60	-	60	1	-
Acon Laboratories	-	1	-	-	1	-	1	-	-
Alere Clearview HIV1/2 STAT-PAK	-	3	-	-	3	-	2	1	-
Alere Determine HIV - moderate	-	3	-	-	3	-	3	-	-
Alere Determine HIV - waived	-	1	-	-	1	-	1	-	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	-	4	-	-	4	-	4	-	-
DiaSorin	-	3	-	-	3	-	3	-	-
Human	-	1	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	3	-	-	3	-	3	-	-
Roche cobas 8000/e801	1	16	-	1	16	-	16	1	-
Roche cobas e 411	-	3	-	-	3	-	3	-	-
Roche Elecsys 1010 / 2010	-	9	-	-	9	-	9	-	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	1	-	-
Roche Modular Analytics	-	2	-	-	2	-	2	-	-
Siemens ADVIA Centaur	-	4	-	-	4	-	4	-	-
Siemens Atellica	-	1	-	-	1	-	1	-	-
Standard Diagnostics	-	1	-	-	1	-	1	-	-
VITROS	-	5	-	-	5	-	5	-	-
3600/4600/5600/7600	-	5	-	-	5	-	5	-	-
VITROS ECI	-	1	-	-	1	-	1	-	-

Viral Markers – Anti-HIV- cont'd

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	3	139	1	4	138	-
Abbott Alinity	-	8	-	-	8	-
Abbott Architect	-	61	-	1	59	-
Acon Laboratories	-	1	-	1	-	-
Alere Clearview HIV1/2 STAT-PAK	-	3	-	-	3	-
Alere Determine HIV - moderate	-	3	-	-	3	-
Alere Determine HIV - waived	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	-	4	-	-	4	-
DiaSorin	-	3	-	-	3	-
Human	-	1	-	-	1	-
Roche cobas 6000 / e 601	1	15	1	2	15	-
Roche cobas 8000/e801	-	3	-	-	3	-
Roche cobas e 411	1	8	-	-	9	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-
Roche Modular Analytics	-	2	-	-	2	-
Siemens ADVIA Centaur	1	3	-	-	4	-
Siemens Atellica	-	1	-	-	1	-
Standard Diagnostics VITROS	-	5	-	-	5	-
3600/4600/5600/7600	-	5	-	-	5	-
VITROS Eci	-	1	-	-	1	-

Viral Markers – Anti-HAV (IgM)

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	55	-	-	55	-	-	55	-
Abbott Architect	-	30	-	-	30	-	-	30	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	10	-	-	10	-	-	10	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
Siemens ADVIA Centaur	-	2	-	-	2	-	-	2	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
Standard Diagnostics	-	3	-	-	3	-	-	3	-
VITROS 3600/4600/5600/7600	-	1	-	-	1	-	-	1	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	55	-	53	2	-
Abbott Architect	-	30	-	30	-	-
bioMerieux Vidas, Mini Vidas	-	3	-	3	-	-
Roche cobas 6000 / e 601	-	10	-	10	-	-
Roche cobas 8000/e801	-	4	-	4	-	-
Siemens ADVIA Centaur	-	2	-	2	-	-
Siemens Atellica	-	1	-	1	-	-
Standard Diagnostics	-	3	-	1	2	-
VITROS 3600/4600/5600/7600	-	1	-	1	-	-

Viral Markers – Anti-HAV (Total/IgG)

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	39	-	-	-	39	-	39	-	-
Abbott Architect	24	-	-	-	24	-	24	-	-
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-	1	-	-
bioMerieux Vidas, Mini Vidas	1	-	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	3	-	-	-	3	-	3	-	-
Roche cobas 8000/e801	3	-	-	-	3	-	3	-	-
Roche cobas e 411	3	-	-	-	3	-	3	-	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-	1	-	-
Siemens ADVIA Centaur	2	-	-	-	2	-	2	-	-
Siemens Atellica	1	-	-	-	1	-	1	-	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	39	-	-	39	-	-
Abbott Architect	24	-	-	24	-	-
Beckman ACCESS / 2 / Dxl	1	-	-	1	-	-
bioMerieux Vidas, Mini Vidas	1	-	-	1	-	-
Roche cobas 6000 / e 601	3	-	-	3	-	-
Roche cobas 8000/e801	3	-	-	3	-	-
Roche cobas e 411	3	-	-	3	-	-
Roche Elecsys 1010 / 2010	1	-	-	1	-	-
Siemens ADVIA Centaur	2	-	-	2	-	-
Siemens Atellica	1	-	-	1	-	-

Viral Markers – HBeAg

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	30	-	30	-	-	-	30	-
Abbott Architect	-	14	-	14	-	-	-	14	-
bioMerieux Vidas, Mini									
Vidas	-	1	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	8	-	8	-	-	-	8	-
Roche cobas 8000/e801	-	5	-	5	-	-	-	5	-
Siemens Atellica	-	1	-	1	-	-	-	1	-
VITROS									
3600/4600/5600/7600	-	1	-	1	-	-	-	1	-

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	30	-	-	-	30	-
Abbott Architect	14	-	-	-	14	-
bioMerieux Vidas, Mini						
Vidas	1	-	-	-	1	-
Roche cobas 6000 / e 601	8	-	-	-	8	-
Roche cobas 8000/e801	5	-	-	-	5	-
Siemens Atellica	1	-	-	-	1	-
VITROS						
3600/4600/5600/7600	1	-	-	-	1	-

Viral Markers – Anti-HBs

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	88	2	-	4	86	-	88	2	-
Abbott Alinity	5	-	-	-	5	-	5	-	-
Abbott Architect	41	-	-	-	41	-	41	-	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	3	-	-	-	3	-	3	-	-
Roche cobas 6000 / e 601	11	-	-	1	10	-	11	-	-
Roche cobas 8000/e801	4	-	-	-	4	-	4	-	-
Roche cobas e 411	7	-	-	1	6	-	7	-	-
Roche Elecsys 1010 / 2010	2	-	-	-	2	-	2	-	-
Roche Modular Analytics	1	-	-	-	1	-	1	-	-
SD Bioline	-	1	-	1	-	-	-	1	-
Siemens ADVIA Centaur	3	-	-	-	3	-	3	-	-
Siemens Atellica	1	-	-	-	1	-	1	-	-
Siemens Immulite 2000	1	-	-	-	1	-	1	-	-
Standard Diagnostics	1	-	-	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	5	-	-	-	5	-	5	-	-
VITROS Eci	2	-	-	-	2	-	2	-	-

Viral Markers – Anti-HBs

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	4	86	-	-	89	1
Abbott Alinity	-	5	-	-	5	-
Abbott Architect	-	41	-	-	41	-
Beckman ACCESS / 2 / Dxl	-	3	-	-	3	-
bioMerieux Vidas, Mini						
Vidas	-	1	-	-	1	-
Roche cobas 6000 / e 601	1	10	-	-	11	-
Roche cobas 8000/e801	-	4	-	-	4	-
Roche cobas e 411	1	6	-	-	7	-
Roche Elecsys 1010 / 2010	-	2	-	-	1	1
Roche Modular Analytics	-	1	-	-	1	-
SD Bioline	1	-	-	-	1	-
Siemens ADVIA Centaur	-	3	-	-	3	-
Siemens Atellica	-	1	-	-	1	-
Siemens Immulite 2000	-	1	-	-	1	-
Standard Diagnostics	-	1	-	-	1	-
VITROS						
3600/4600/5600/7600	-	5	-	-	5	-
VITROS Eci	-	2	-	-	2	-

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	142	-	141	1	-	-	142	-
Abbott Alinity	-	8	-	8	-	-	-	8	-
Abbott Architect	-	59	-	59	-	-	-	59	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	-	4	-	4	-	-	-	4	-
DiaSorin	-	2	-	2	-	-	-	2	-
DiaSorin	-	1	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	15	-	15	-	-	-	15	-
Roche cobas 8000/e801	-	4	-	4	-	-	-	4	-
Roche cobas e 411	-	10	-	10	-	-	-	10	-
Roche Elecsys 1010 / 2010	-	1	-	1	-	-	-	1	-
Roche Modular Analytics	-	2	-	2	-	-	-	2	-
SD Biline	-	2	-	2	-	-	-	2	-
Siemens ADVIA Centaur	-	6	-	6	-	-	-	6	-
Siemens Atellica	-	1	-	1	-	-	-	1	-
Standard Diagnostics	-	13	-	12	1	-	-	13	-
VITROS 3600/4600/5600/7600	-	5	-	5	-	-	-	5	-
VITROS Eci	-	1	-	1	-	-	-	1	-

Viral Markers – HBsAg-cont'd

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	140	2	-	73	60	9
Abbott Alinity	8	-	-	7	1	-
Abbott Architect	58	1	-	41	13	5
Beckman ACCESS / 2 / Dxl	4	-	-	2	2	-
bioMerieux Vidas, Mini						
Vidas	2	-	-	-	2	-
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	15	-	-	7	7	1
Roche cobas 8000/e801	4	-	-	2	-	2
Roche cobas e 411	10	-	-	3	7	-
Roche Elecsys 1010 / 2010	1	-	-	-	-	1
Roche Modular Analytics	2	-	-	-	2	-
SD Bioline	2	-	-	-	2	-
Siemens ADVIA Centaur	6	-	-	4	2	-
Siemens Atellica	1	-	-	-	1	-
Standard Diagnostics	12	1	-	-	13	-
VITROS						
3600/4600/5600/7600	5	-	-	5	-	-
VITROS Eci	1	-	-	1	-	-

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-11			Specimen VM-12			Specimen VM-13		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	122	-	25	96	2	1	122	-
Abbott Alinity	-	8	-	-	8	-	-	8	-
Abbott Architect	1	58	-	1	58	-	1	58	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-	-	2	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	-	1	-
DiaSorin	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	11	-	11	-	-	-	11	-
Roche cobas 8000/e801	-	3	-	2	-	1	-	3	-
Roche cobas e 411	-	11	-	8	2	1	-	11	-
Roche Modular Analytics	-	1	-	1	-	-	-	1	-
Siemens ADVIA Centaur	-	3	-	-	3	-	-	3	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
Standard Diagnostics	-	9	-	-	9	-	-	9	-
VITROS									
3600/4600/5600/7600	-	4	-	-	4	-	-	4	-
VITROS Eci	-	1	-	-	1	-	-	1	-
Wantai BioPharm	-	1	-	1	-	-	-	1	-

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-14			Specimen VM-15		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	30	93	-	31	92	-
Abbott Alinity	-	8	-	-	8	-
Abbott Architect	3	56	-	3	56	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-
DiaSorin	-	1	-	-	1	-
Roche cobas 6000 / e 601	11	-	-	11	-	-
Roche cobas 8000/e801	3	-	-	3	-	-
Roche cobas e 411	9	2	-	9	2	-
Roche Modular Analytics	1	-	-	1	-	-
Siemens ADVIA Centaur	-	3	-	-	3	-
Siemens Atellica	-	1	-	-	1	-
Standard Diagnostics	-	9	-	-	9	-
VITROS						
3600/4600/5600/7600	-	4	-	-	4	-
VITROS Eci	-	1	-	-	1	-
Wantai BioPharm	1	-	-	1	-	-

Toxoplasma gondii Antibody (IgG) - Qualitative

<u>Method</u>	Specimen TOX-5			Specimen TOX-6		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	20	-	20	-	-
Abbott Architect	-	13	-	13	-	-
bioMerieux Vidas, Mini Vidas	-	2	-	2	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas e 411	-	2	-	2	-	-
VITROS 3600/4600/5600/7600	-	1	-	1	-	-
VITROS Eci	-	1	-	1	-	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen TOX-5						
All Method	23	0.243	0.187	77.1	0.20	0.00 - 0.81
All Roche Instruments	5	0.130	0.001	0.0	0.13	0.12 - 0.14
Abbott Architect	16	0.325	0.161	49.6	0.30	0.00 - 0.81
Specimen TOX-6						
All Method	23	64.037	25.433	39.7	51.40	0.00 - 140.34
All Roche Instruments	5	115.367	16.988	14.7	110.70	64.40 - 166.33
Abbott Architect	16	49.884	2.568	5.1	50.55	42.18 - 57.59

Toxoplasma gondii Antibody (IgM) - Qualitative

<u>Method</u>	Specimen TOX-5			Specimen TOX-6		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	21	-	21	-	-
Abbott Architect	-	14	-	14	-	-
bioMerieux Vidas, Mini Vidas	-	2	-	2	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas e 411	-	2	-	2	-	-
VITROS 3600/4600/5600/7600	-	1	-	1	-	-
VITROS ECI	-	1	-	1	-	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen TOX-5						
All Method	20	0.145	0.050	34.5	0.15	0.00 - 0.30
All Roche Instruments	5	0.227	0.038	16.7	0.21	0.11 - 0.35
Abbott Architect	13	0.135	0.024	18.0	0.14	0.06 - 0.21
Specimen TOX-6						
All Method	20	14.727	7.501	50.9	13.02	0.00 - 37.23
All Roche Instruments	5	31.033	1.432	4.6	30.42	26.73 - 35.33
Abbott Architect	13	12.853	1.399	10.9	13.23	8.65 - 17.06

Cytomegalovirus (CMV) Antibodies (IgG) - Qualitative

<u>Method</u>	Specimen CMV-5			Specimen CMV-6		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	15	1	-	15	1	-
Abbott Architect	13	-	-	13	-	-
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	1	-	-	1	-	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen CMV-5						
All Method	17	20.535	9.586	46.7	22.20	0.00 - 49.30
Abbott Architect	14	23.993	6.319	26.3	24.40	5.03 - 42.95
Specimen CMV-6						
All Method	16	44.204	7.918	17.9	46.35	20.45 - 67.96
Abbott Architect	14	44.586	8.295	18.6	46.75	19.70 - 69.48

Cytomegalovirus (CMV) Antibodies (IgM) - Qualitative

<u>Method</u>	Specimen CMV-5			Specimen CMV-6		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	17	-	-	-	17	-
Abbott Architect	15	-	-	-	15	-
Roche cobas 6000 / e 601	1	-	-	-	1	-
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-5						
All Method	14	9.566	1.959	20.5	9.64	3.68 - 15.45
Abbott Architect	12	10.136	1.416	14.0	9.92	5.88 - 14.39
Specimen CMV-6						
All Method	14	0.261	0.126	48.5	0.24	0.00 - 0.65
Abbott Architect	12	0.292	0.107	36.5	0.27	0.00 - 0.62

Neonatal Bilirubin, Total (mg/dL)

<u>Method</u>	Specimen NB-11						Specimen NB-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	47	14.71	0.78	5.3	14.8	11.7 - 17.7	48	10.13	0.62	6.1	10.3	8.1 - 12.2
No Reagent Required												
Bilirubinometer / Unistat	35	15.00	0.44	2.9	15.1	12.0 - 18.0	36	10.36	0.34	3.3	10.4	8.2 - 12.5
All Chemistry Instruments	40	14.95	0.52	3.5	15.0	11.9 - 18.0	40	10.35	0.36	3.5	10.4	8.2 - 12.5
<u>Method</u>	Specimen NB-13						Specimen NB-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	48	5.71	0.38	6.7	5.7	4.5 - 6.9	45	0.02	0.05	252.3	0.0	0.0 - 0.5
No Reagent Required												
Bilirubinometer / Unistat	38	5.67	0.35	6.2	5.7	4.5 - 6.8	37	0.00	0.01	0.0	0.0	0.0 - 0.4
All Chemistry Instruments	42	5.72	0.39	6.8	5.7	4.5 - 6.9	39	0.01	0.04	460.5	0.0	0.0 - 0.5
<u>Method</u>	Specimen NB-15											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	48	5.71	0.39	6.8	5.7	4.5 - 6.9						
No Reagent Required												
Bilirubinometer / Unistat	38	5.68	0.39	6.8	5.7	4.5 - 6.9						
All Chemistry Instruments	42	5.71	0.40	7.1	5.7	4.5 - 6.9						

Bilirubin, Direct (mg/dL)

<u>Method</u>	Specimen NB-11						Specimen NB-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	11	5.39	0.57	10.6	5.2	4.2 - 6.6	11	4.78	0.49	10.2	4.7	3.8 - 5.8
<u>Method</u>	Specimen NB-13						Specimen NB-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	11	1.58	0.26	16.2	1.6	1.0 - 2.1	11	0.13	0.15	117.0	0.1	0.0 - 0.5
<u>Method</u>	Specimen NB-15											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	11	1.58	0.24	15.2	1.6	1.1 - 2.1						

Glycohemoglobin (percent)

<u>Method</u>	Specimen GH-5						Specimen GH-6					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	118	10.64	0.40	3.7	10.7	10.1 - 11.2	120	7.39	0.28	3.8	7.4	7.0 - 7.8
All Bio-Rad Methods	5	11.04	0.11	1.0	11.0	10.4 - 11.6	5	7.84	0.17	2.1	7.8	7.4 - 8.3
All Enzymatic A1c Methods	7	10.04	0.67	6.6	10.2	9.5 - 10.6	7	6.87	0.16	2.3	6.9	6.5 - 7.3
All Hemoglobin A1c Methods	113	10.67	0.41	3.8	10.7	10.1 - 11.3	113	7.42	0.25	3.4	7.4	7.0 - 7.8
All Roche Methods	9	10.74	0.27	2.5	10.7	10.2 - 11.3	8	7.16	0.12	1.7	7.2	6.8 - 7.6
All TOSOH Methods	15	10.11	0.29	2.8	10.1	9.6 - 10.7	15	7.22	0.22	3.1	7.2	6.8 - 7.6
Abbott Architect Hb A1C	5	10.18	0.05	0.5	10.2	9.6 - 10.7	5	6.85	0.06	0.8	6.9	6.5 - 7.2
Beckman AU A1c	9	10.66	0.27	2.5	10.6	10.1 - 11.2	9	7.28	0.22	3.1	7.2	6.9 - 7.7
Bio-Rad D-10 HbA1C	5	11.04	0.11	1.0	11.0	10.4 - 11.6	5	7.84	0.17	2.1	7.8	7.4 - 8.3
Roche cobas c 501 HbA1c	5	10.80	0.10	0.9	10.8	10.2 - 11.4	5	7.23	0.13	1.7	7.2	6.8 - 7.6
Roche Integra A1C	5	10.68	0.41	3.9	10.7	10.1 - 11.3	5	7.10	0.08	1.1	7.1	6.7 - 7.5
Siemens DCA Vantage	52	10.82	0.39	3.6	10.8	10.2 - 11.4	53	7.52	0.20	2.7	7.5	7.1 - 7.9
Siemens Dimension HA1C	5	10.44	0.31	3.0	10.5	9.9 - 11.0	5	7.26	0.15	2.1	7.2	6.8 - 7.7
Siemens Dimension HB1C	10	10.63	0.19	1.8	10.7	10.0 - 11.2	10	7.43	0.13	1.7	7.4	7.0 - 7.9
TOSOH G8	15	10.11	0.29	2.8	10.1	9.6 - 10.7	15	7.22	0.22	3.1	7.2	6.8 - 7.6

Whole Blood Glucose (mg/dL)

<u>Method</u>	Specimen WBG-11						Specimen WBG-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	849	209.4	17.1	8.2	214	167 - 252	858	114.6	12.2	10.6	117	91 - 138
All Abbott Methods	40	185.3	13.8	7.4	186	148 - 223	40	95.0	8.5	9.0	95	76 - 114
All Arkray Methods	8	237.5	39.3	16.5	219	190 - 285	8	132.6	8.1	6.1	130	106 - 160
All Bayer Methods	20	168.3	16.7	9.9	164	134 - 202	19	88.3	8.2	9.3	86	70 - 106
All Hemocue Methods	52	212.3	7.2	3.4	212	169 - 255	53	130.0	7.3	5.7	130	103 - 156
All Lifescan Methods	11	223.2	20.6	9.2	226	178 - 268	11	116.0	8.2	7.1	116	92 - 140
All Roche Methods	514	214.7	5.6	2.6	214	171 - 258	514	117.3	4.2	3.6	117	93 - 141
Abbott FreeStyle Lite/Freedom Lite	7	196.0	6.1	3.1	193	156 - 236	7	105.9	3.0	2.9	106	84 - 128
Abbott FreeStyle Precision Pro	20	184.5	15.5	8.4	184	147 - 222	20	92.9	7.9	8.5	93	74 - 112
Abbott Precis. Xtra/Optium	5	172.0	6.9	4.0	170	137 - 207	5	86.8	6.3	7.3	90	69 - 105
Abbott Precision XceedPro	8	186.0	10.2	5.5	187	148 - 224	8	96.0	4.9	5.1	98	76 - 116
Arkray Platinum	23	218.3	4.0	1.9	218	174 - 263	24	130.4	3.1	2.4	130	104 - 157
Bayer Contour	23	168.7	15.9	9.4	165	134 - 203	22	88.5	7.7	8.7	87	70 - 107
HemoCue Glucose 201	63	211.8	6.6	3.1	210	169 - 255	64	130.8	7.1	5.4	131	104 - 157
Home Diagnostics True Balance / TrueTrack	11	440.8	73.7	16.7	473	352 - 529	11	325.4	72.3	22.2	299	260 - 391
Lifescan One Touch Ultra	33	239.6	10.6	4.4	240	191 - 288	33	124.0	6.9	5.6	123	99 - 149
Medline EvenCare G2 / G3	16	208.0	22.2	10.7	211	166 - 250	16	118.4	8.7	7.4	119	94 - 143
NOVA Biomedical StatStrip	71	173.7	14.3	8.2	176	138 - 209	70	93.9	9.2	9.8	97	75 - 113
Other Waived Method	12	180.9	11.1	6.2	178	144 - 218	12	98.1	7.9	8.1	97	78 - 118
Quintet / AC	28	214.6	6.4	3.0	216	171 - 258	29	112.9	3.7	3.3	113	90 - 136
Roche Accu-Chek Aviva	5	211.6	4.5	2.1	209	169 - 254	5	114.2	2.2	1.9	113	91 - 138
Roche Accu-Chek Inform	10	213.0	3.3	1.5	213	170 - 256	10	111.5	1.4	1.2	112	89 - 134
Roche Accu-Chek Inform II	351	213.8	5.1	2.4	214	171 - 257	350	116.7	4.1	3.5	117	93 - 141
Roche Accu-Chek Performa	149	217.1	6.3	2.9	216	173 - 261	149	119.2	3.6	3.1	119	95 - 144
True Metrix Pro	18	188.1	29.4	15.6	190	150 - 226	16	98.8	3.0	3.0	99	79 - 119

Whole Blood Glucose (mg/dL) cont'd

<u>Method</u>	Specimen WBG-13						Specimen WBG-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	193	297.7	30.6	10.3	301	238 - 358	192	97.8	9.0	9.2	101	78 - 118
All Abbott Methods	7	262.0	9.0	3.4	266	209 - 315	7	80.9	7.3	9.0	80	64 - 98
All Bayer Methods	1	-	-	-	313	250 - 376	1	-	-	-	108	86 - 130
All Lifescan Methods	4	-	-	-	343	276 - 415	4	-	-	-	104	83 - 126
All Roche Methods	95	303.5	5.7	1.9	303	242 - 365	99	102.2	2.9	2.8	103	81 - 123
Abbott Precis. Xtra/Optium	5	259.4	9.5	3.7	261	207 - 312	5	77.8	6.2	8.0	79	62 - 94
Abbott Precision XceedPro	2	-	-	-	269	214 - 323	2	-	-	-	89	70 - 107
Bayer Contour	1	-	-	-	313	238 - 358	1	-	-	-	108	78 - 118
Lifescan One Touch Ultra	28	354.7	11.0	3.1	354	283 - 426	28	106.4	4.2	3.9	104	85 - 128
Medline EvenCare G2 / G3	1	-	-	-	274	219 - 329	1	-	-	-	91	72 - 110
NOVA Biomedical StatStrip	43	264.4	12.3	4.6	265	211 - 318	43	87.6	5.9	6.8	89	70 - 106
Other Waived Method	11	265.1	10.0	3.8	266	212 - 319	11	85.3	6.5	7.6	82	68 - 103
Roche Accu-Chek Inform	10	299.4	2.8	0.9	300	239 - 360	10	100.5	1.4	1.4	100	80 - 121
Roche Accu-Chek Inform II	83	304.1	5.8	1.9	305	243 - 365	83	102.4	2.9	2.9	103	81 - 123
Roche Accu-Chek Performa	6	285.7	9.8	3.4	283	228 - 343	6	101.8	2.8	2.7	103	81 - 123
True Metrix Pro	1	-	-	-	274	219 - 329	1	-	-	-	91	72 - 110

<u>Method</u>	Specimen WBG-15					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	192	407.5	33.6	8.3	416	326 - 489
All Abbott Methods	7	350.9	27.9	8.0	347	280 - 422
All Bayer Methods	1	-	-	-	431	344 - 518
All Lifescan Methods	4	-	-	-	443	354 - 532
All Roche Methods	96	418.8	6.9	1.6	420	335 - 503
Abbott Precis. Xtra/Optium	5	337.6	19.7	5.8	344	270 - 406
Abbott Precision XceedPro	2	-	-	-	384	307 - 461
Bayer Contour	1	-	-	-	431	326 - 489
Lifescan One Touch Ultra	26	459.4	4.5	1.0	459	367 - 552
Medline EvenCare G2 / G3	1	-	-	-	343	274 - 412
NOVA Biomedical StatStrip	43	368.1	16.1	4.4	371	294 - 442
Other Waived Method	11	369.5	42.3	11.5	369	295 - 444
Roche Accu-Chek Inform	10	414.3	6.2	1.5	414	331 - 498
Roche Accu-Chek Inform II	82	420.0	6.2	1.5	420	335 - 504
Roche Accu-Chek Performa	6	400.8	9.2	2.3	403	320 - 481
True Metrix Pro	1	-	-	-	393	314 - 472

Folate (ng/mL)

<u>Method</u>	Specimen SC-5						Specimen SC-6					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	26	5.80	1.69	29.2	6.9	4.0 - 7.6	26	2.18	0.60	27.6	2.6	1.1 - 3.2
All Roche Instruments	9	5.26	0.55	10.5	5.5	3.6 - 6.9	9	1.86	0.33	17.9	2.0	0.8 - 2.9
All Siemens Dimension Instruments	7	4.27	0.52	12.1	4.4	2.9 - 5.6	7	1.97	0.23	11.6	2.0	0.9 - 3.0
All TOSOH Instruments	6	4.63	0.38	8.2	4.6	3.2 - 6.1	6	2.07	0.29	14.2	2.0	1.0 - 3.1
Abbott Architect	6	9.00	2.10	23.4	8.7	6.3 - 11.7	6	3.40	1.38	40.5	3.1	2.3 - 4.5
Beckman ACCESS / 2 / Dxl	24	8.49	0.79	9.3	8.8	5.9 - 11.1	24	2.90	0.33	11.3	3.0	1.9 - 4.0
Roche cobas e 601/e 602	6	5.18	0.59	11.5	5.3	3.6 - 6.8	6	1.78	0.40	22.3	2.0	0.7 - 2.8
Siemens Dimension	5	4.34	0.58	13.3	4.5	3.0 - 5.7	5	1.98	0.26	13.1	2.0	0.9 - 3.0

CK-MB - Quantitative (U/L)

<u>Method</u>	Specimen CK-11						Specimen CK-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	6	5.45	0.64	11.7	5.5	3.5 - 7.4	6	25.40	4.81	18.9	25.4	10.9 - 39.9
<u>Method</u>	Specimen CK-13						Specimen CK-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	6	15.85	2.62	16.5	15.9	8.0 - 23.7	6	83.40	18.95	22.7	83.4	26.5 - 140.3
<u>Method</u>	Specimen CK-15											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	6	44.55	9.26	20.8	44.6	16.7 - 72.4						

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