

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

**International Data Supplement
2017 MLE-M3**



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Table of Contents

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

Table of Contents (cont'd)

Immunology

Antinuclear Antibody	47
Qualitative.....	47
Quantitative.....	47
Anti-dsDNA	49
Anti-RNP	49
Anti-RNP/Sm	50
Anti-SSA	50
Anti-SSB	51
Anti-SSA/SSB	51
Anti-Sm	52
Rubella	53
Qualitative.....	53
Quantitative.....	54
Syphilis Serology	55
VDRL Slide	55
VDRL Slide (Titer).....	56
MHA-TP	58
TPA.....	59
RPR	60
RPR (Titer).....	61
Viral Markers	64
Anti-HBc (IgM)	64
Anti-HBc (Total/IgG)	65
Anti-HIV	66
Anti-HAV (IgM).....	68
Anti-HAV (Total/IgG).....	69
HBeAg	70
Anti-HBs	71
HBsAg	72
Anti-HCV.....	73
Toxoplasma gondii	74
Qualitative (IgG).....	74
Quantitative (IgG)	74
Qualitative (IgM)	75
Quantitative (IgM)	75
Cytomegalovirus (CMV)	76
Qualitative (IgG).....	76
Quantitative (IgG)	76
Qualitative (IgM)	77
Quantitative (IgM)	77

Chemistry

CK-MB	78
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EVALUATION CRITERIA

The evaluation criteria used in the MLE Program is in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) federal requirements for proficiency testing. The criteria are included below.

Qualitative

For qualitative procedures, evaluation is based on participant or referee consensus. A minimum percentage of participants must receive a passing score or the challenge is not evaluated due to lack of consensus. These percentages are listed below.

Antimicrobial Susceptibility Testing	80% Consensus
Antinuclear Antibody	80% Consensus
Blood Bank	95% Consensus
Cytomegalovirus	80% Consensus
Microalbumin (Semi-Quantitative)	80% Consensus
Parasite Identification	80% Consensus
Rubella	80% Consensus
Syphilis Serology	80% Consensus
Toxoplasma	80% Consensus
Urine Dipstick	80% Consensus
Urine hCG	80% Consensus
Viral Markers	80% Consensus

Quantitative

For quantitative procedures, a mean and standard deviation (SD) are calculated for each peer group consisting of 10 or more laboratories. Acceptable performance is established based on a target value $\pm$ the intervals below. An explanation on how to calculate the range of acceptability based upon these limits is also provided in your MLE Program Guide on page 37 under the heading "Acceptable Ranges for Quantitative Results."

Activated Partial Thromboplastin Time	$\pm 15\%$
Automated Differential	± 3 SD
CK-MB (U/L)	± 3 SD
Cytomegalovirus	± 2 SD
Fibrinogen	$\pm 20\%$
Hematocrit	$\pm 6\%$
Hemoglobin	$\pm 7\%$
International Normalized Ratio (INR)	$\pm 20\%$
Platelet Count	$\pm 25\%$
Prothrombin Time	$\pm 15\%$
Red Blood Cell Count	$\pm 6\%$
Rubella	± 3 SD
Specific Gravity	± 0.010
Toxoplasma	± 2 SD
White Blood Cell Count	$\pm 15\%$

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

Specimen CL-11							Specimen CL-12					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	67	19.42	2.06	10.6	20.1	16.5 - 22.4	67	2.79	0.57	20.5	3.0	2.3 - 3.3
All Abbott Cell-Dyn Instruments	38	20.91	0.90	4.3	20.8	17.7 - 24.1	38	3.25	0.22	6.6	3.2	2.7 - 3.8
Abbott Cell-Dyn Ruby	32	20.94	0.79	3.8	20.8	17.7 - 24.1	32	3.28	0.22	6.7	3.2	2.7 - 3.8
Orphee Mythic 22	28	17.30	1.06	6.1	17.0	14.7 - 19.9	28	2.16	0.16	7.4	2.1	1.8 - 2.5
Specimen CL-13							Specimen CL-14					
All Method	67	7.19	0.81	11.2	7.5	6.1 - 8.3	67	19.49	2.05	10.5	20.4	16.5 - 22.5
All Abbott Cell-Dyn Instruments	38	7.79	0.25	3.3	7.8	6.6 - 9.0	37	20.84	0.67	3.2	20.7	17.7 - 24.0
Abbott Cell-Dyn Ruby	32	7.81	0.25	3.2	7.8	6.6 - 9.0	31	20.93	0.64	3.1	20.9	17.7 - 24.1
Orphee Mythic 22	27	6.29	0.38	6.1	6.3	5.3 - 7.3	27	17.29	1.11	6.4	17.1	14.6 - 19.9
Specimen CL-15												
All Method	67	2.79	0.56	19.9	3.1	2.3 - 3.3						
All Abbott Cell-Dyn Instruments	38	3.23	0.20	6.3	3.2	2.7 - 3.8						
Abbott Cell-Dyn Ruby	32	3.25	0.21	6.6	3.2	2.7 - 3.8						
Orphee Mythic 22	27	2.16	0.15	6.8	2.2	1.8 - 2.5						

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

Specimen CL-11							Specimen CL-12					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	68	5.151	0.142	2.8	5.11	4.84 - 5.46	68	2.110	0.071	3.4	2.11	1.98 - 2.24
All Abbott Cell-Dyn Instruments	38	5.187	0.133	2.6	5.17	4.87 - 5.50	38	2.128	0.052	2.5	2.13	2.00 - 2.26
Abbott Cell-Dyn Ruby	32	5.206	0.136	2.6	5.22	4.89 - 5.52	32	2.125	0.052	2.4	2.13	1.99 - 2.26
Orphee Mythic 22	29	5.101	0.142	2.8	5.07	4.79 - 5.41	29	2.086	0.086	4.1	2.08	1.96 - 2.22
Specimen CL-13							Specimen CL-14					
All Method	67	4.603	0.123	2.7	4.62	4.32 - 4.88	65	5.130	0.136	2.7	5.11	4.82 - 5.44
All Abbott Cell-Dyn Instruments	38	4.638	0.099	2.1	4.64	4.35 - 4.92	38	5.157	0.121	2.4	5.16	4.84 - 5.47
Abbott Cell-Dyn Ruby	32	4.649	0.098	2.1	4.65	4.36 - 4.93	32	5.173	0.113	2.2	5.17	4.86 - 5.49
Orphee Mythic 22	29	4.570	0.162	3.6	4.56	4.29 - 4.85	28	5.091	0.209	4.1	5.05	4.78 - 5.40
Specimen CL-15												
All Method	66	2.113	0.066	3.1	2.10	1.98 - 2.24						
All Abbott Cell-Dyn Instruments	38	2.128	0.055	2.6	2.12	1.99 - 2.26						
Abbott Cell-Dyn Ruby	32	2.121	0.051	2.4	2.12	1.99 - 2.25						
Orphee Mythic 22	29	2.092	0.101	4.8	2.08	1.96 - 2.22						

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

Specimen CL-11							Specimen CL-12					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	68	16.18	0.99	6.1	16.7	15.0 - 17.4	68	5.11	0.56	11.0	5.5	4.7 - 5.5
All Abbott Cell-Dyn Instruments	37	17.01	0.27	1.6	17.1	15.8 - 18.2	38	5.58	0.10	1.8	5.6	5.1 - 6.0
Abbott Cell-Dyn Ruby	32	17.08	0.20	1.2	17.1	15.8 - 18.3	32	5.58	0.10	1.7	5.6	5.1 - 6.0
Orphee Mythic 22	29	15.11	0.37	2.5	15.0	14.0 - 16.2	29	4.48	0.15	3.4	4.5	4.1 - 4.8
Specimen CL-13							Specimen CL-14					
All Method	68	12.76	1.16	9.1	13.4	11.8 - 13.7	68	16.10	0.94	5.8	16.4	14.9 - 17.3
All Abbott Cell-Dyn Instruments	38	13.73	0.27	1.9	13.8	12.7 - 14.7	37	16.88	0.30	1.8	16.9	15.6 - 18.1
Abbott Cell-Dyn Ruby	32	13.79	0.23	1.7	13.8	12.8 - 14.8	32	16.95	0.25	1.5	17.0	15.7 - 18.2
Orphee Mythic 22	28	11.50	0.23	2.0	11.5	10.6 - 12.4	29	15.10	0.38	2.5	15.1	14.0 - 16.2
Specimen CL-15												
All Method	67	5.10	0.57	11.2	5.5	4.7 - 5.5						
All Abbott Cell-Dyn Instruments	37	5.57	0.12	2.1	5.6	5.1 - 6.0						
Abbott Cell-Dyn Ruby	31	5.56	0.11	2.0	5.6	5.1 - 6.0						
Orphee Mythic 22	29	4.47	0.18	4.0	4.5	4.1 - 4.8						

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

Specimen CL-11							Specimen CL-12					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	67	45.93	2.07	4.5	45.8	43.1 - 48.7	66	15.47	0.69	4.4	15.3	14.5 - 16.4
All Abbott Cell-Dyn Instruments	36	44.70	1.50	3.4	44.8	42.0 - 47.4	36	15.11	0.44	2.9	15.1	14.2 - 16.1
Abbott Cell-Dyn Ruby	32	44.74	1.51	3.4	44.8	42.0 - 47.5	32	15.10	0.44	2.9	15.0	14.1 - 16.1
Orphee Mythic 22	28	46.91	1.05	2.2	46.9	44.0 - 49.8	29	15.85	0.63	4.0	15.9	14.9 - 16.9
Specimen CL-13							Specimen CL-14					
All Method	65	38.62	1.44	3.7	38.5	36.2 - 41.0	66	45.65	2.04	4.5	45.4	42.9 - 48.4
All Abbott Cell-Dyn Instruments	36	37.94	1.16	3.1	37.7	35.6 - 40.3	36	44.56	1.32	3.0	44.3	41.8 - 47.3
Abbott Cell-Dyn Ruby	32	37.98	1.12	3.0	37.8	35.7 - 40.3	32	44.58	1.16	2.6	44.5	41.9 - 47.3
Orphee Mythic 22	28	39.33	1.15	2.9	39.7	36.9 - 41.7	27	46.48	1.41	3.0	46.3	43.6 - 49.3
Specimen CL-15												
All Method	64	15.39	0.57	3.7	15.3	14.4 - 16.4						
All Abbott Cell-Dyn Instruments	36	15.09	0.37	2.4	15.0	14.1 - 16.0						
Abbott Cell-Dyn Ruby	32	15.07	0.37	2.4	15.0	14.1 - 16.0						
Orphee Mythic 22	28	15.78	0.56	3.6	15.7	14.8 - 16.8						

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

Specimen CL-11							Specimen CL-12					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	66	525.1	34.9	6.6	521	393 - 657	67	87.0	16.5	18.9	82	65 - 109
All Abbott Cell-Dyn Instruments	37	528.4	33.2	6.3	528	396 - 661	37	76.5	6.5	8.5	76	57 - 96
Abbott Cell-Dyn Ruby	31	532.9	28.5	5.3	531	399 - 667	31	76.2	5.7	7.5	76	57 - 96
Orphee Mythic 22	28	523.6	34.9	6.7	521	392 - 655	28	99.3	15.2	15.3	95	74 - 125
Specimen CL-13							Specimen CL-14					
All Method	66	281.1	21.3	7.6	280	210 - 352	67	523.7	33.2	6.3	526	392 - 655
All Abbott Cell-Dyn Instruments	36	280.3	19.2	6.9	280	210 - 351	37	528.0	31.0	5.9	531	395 - 660
Abbott Cell-Dyn Ruby	30	282.4	17.6	6.2	280	211 - 354	31	532.0	28.4	5.3	533	399 - 666
Orphee Mythic 22	29	283.3	23.1	8.2	283	212 - 355	29	520.8	33.9	6.5	524	390 - 651
Specimen CL-15												
All Method	66	86.1	15.9	18.5	83	64 - 108						
All Abbott Cell-Dyn Instruments	37	76.2	7.3	9.5	74	57 - 96						
Abbott Cell-Dyn Ruby	31	75.9	7.1	9.3	74	56 - 95						
Orphee Mythic 22	27	97.6	14.0	14.4	98	73 - 123						

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

Specimen CL-11							Specimen CL-12					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	67	76.25	2.02	2.7	76.4	70.1 - 82.4	65	50.09	2.50	5.0	50.0	42.5 - 57.7
All Abbott Cell-Dyn Instruments	36	77.49	1.01	1.3	77.6	74.4 - 80.6	36	51.64	2.04	4.0	51.4	45.5 - 57.8
Abbott Cell-Dyn Ruby	31	77.73	0.77	1.0	77.9	75.4 - 80.1	30	51.90	2.09	4.0	51.4	45.6 - 58.2
Orphee Mythic 22	28	74.49	1.25	1.7	74.6	70.7 - 78.3	28	48.05	1.38	2.9	47.9	43.9 - 52.2
Specimen CL-13							Specimen CL-14					
All Method	67	65.55	2.41	3.7	65.9	58.3 - 72.8	66	75.94	1.89	2.5	76.3	70.2 - 81.7
All Abbott Cell-Dyn Instruments	38	67.12	1.28	1.9	67.1	63.2 - 71.0	37	77.22	1.17	1.5	77.0	73.6 - 80.8
Abbott Cell-Dyn Ruby	32	67.26	1.10	1.6	67.2	63.9 - 70.6	31	77.34	0.83	1.1	77.0	74.8 - 79.9
Orphee Mythic 22	28	63.37	1.88	3.0	63.7	57.7 - 69.1	28	74.17	1.07	1.4	74.1	70.9 - 77.4
Specimen CL-15												
All Method	68	49.48	2.48	5.0	49.5	42.0 - 57.0						
All Abbott Cell-Dyn Instruments	38	50.91	1.95	3.8	50.7	45.0 - 56.8						
Abbott Cell-Dyn Ruby	32	51.00	1.82	3.6	50.9	45.5 - 56.5						
Orphee Mythic 22	29	47.56	1.74	3.7	47.7	42.3 - 52.8						

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

Specimen CL-11							Specimen CL-12					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	67	14.29	1.84	12.9	14.4	8.7 - 19.9	68	34.75	5.31	15.3	36.4	18.8 - 50.7
All Abbott Cell-Dyn Instruments	37	15.07	1.30	8.7	15.1	11.1 - 19.0	37	38.49	2.11	5.5	38.5	32.1 - 44.9
Abbott Cell-Dyn Ruby	32	14.94	1.17	7.8	15.1	11.4 - 18.5	31	38.01	1.76	4.6	38.1	32.7 - 43.3
Orphee Mythic 22	29	13.33	2.01	15.1	13.3	7.3 - 19.4	29	30.11	4.36	14.5	31.4	17.0 - 43.2
Specimen CL-13							Specimen CL-14					
All Method	68	20.12	4.11	20.4	22.0	7.7 - 32.5	67	14.46	1.95	13.5	14.7	8.6 - 20.4
All Abbott Cell-Dyn Instruments	37	22.79	1.11	4.9	23.0	19.4 - 26.2	36	14.89	1.20	8.1	15.3	11.2 - 18.6
Abbott Cell-Dyn Ruby	32	22.74	1.11	4.9	23.0	19.4 - 26.1	31	14.71	1.15	7.8	14.8	11.2 - 18.2
Orphee Mythic 22	29	16.40	3.64	22.2	15.8	5.4 - 27.4	29	13.78	2.36	17.1	13.7	6.7 - 20.9
Specimen CL-15												
All Method	66	34.92	5.24	15.0	36.6	19.1 - 50.7						
All Abbott Cell-Dyn Instruments	37	38.55	2.12	5.5	38.3	32.1 - 45.0						
Abbott Cell-Dyn Ruby	31	38.29	2.03	5.3	38.0	32.1 - 44.4						
Orphee Mythic 22	27	30.17	4.21	14.0	30.7	17.5 - 42.8						

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

Specimen CL-11							Specimen CL-12					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	68	5.02	3.24	64.5	2.9	0.0 - 14.8	68	10.73	6.55	61.0	6.8	0.0 - 30.4
All Abbott Cell-Dyn Instruments	38	2.41	0.65	27.1	2.4	0.4 - 4.4	38	5.61	0.96	17.2	5.6	2.7 - 8.5
Abbott Cell-Dyn Ruby	32	2.49	0.58	23.3	2.4	0.7 - 4.3	32	5.75	0.89	15.4	5.7	3.0 - 8.5
Orphee Mythic 22	29	8.52	1.52	17.9	8.6	3.9 - 13.1	29	17.58	4.07	23.1	16.9	5.3 - 29.8
Specimen CL-13							Specimen CL-14					
All Method	67	9.76	5.47	56.0	6.0	0.0 - 26.2	66	5.28	3.10	58.8	3.7	0.0 - 14.6
All Abbott Cell-Dyn Instruments	37	5.31	0.64	12.0	5.3	3.3 - 7.3	37	2.81	0.67	23.9	2.7	0.7 - 4.9
Abbott Cell-Dyn Ruby	31	5.35	0.59	11.1	5.3	3.5 - 7.2	32	2.87	0.70	24.3	2.8	0.7 - 5.0
Orphee Mythic 22	28	15.87	2.42	15.2	15.9	8.6 - 23.2	28	8.61	1.59	18.5	8.7	3.8 - 13.4
Specimen CL-15												
All Method	68	10.85	6.47	59.7	7.0	0.0 - 30.3						
All Abbott Cell-Dyn Instruments	38	5.88	1.26	21.3	6.2	2.1 - 9.7						
Abbott Cell-Dyn Ruby	31	6.12	0.85	13.8	6.5	3.5 - 8.7						
Orphee Mythic 22	29	17.49	4.30	24.6	17.8	4.5 - 30.4						

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

Specimen CL-11							Specimen CL-12					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	67	3.97	1.10	27.8	4.2	0.6 - 7.3	65	3.56	0.71	19.8	3.6	1.4 - 5.7
All Abbott Cell-Dyn Instruments	36	4.33	0.25	5.7	4.3	3.5 - 5.1	36	3.60	0.41	11.5	3.7	2.3 - 4.9
Abbott Cell-Dyn Ruby	31	4.33	0.24	5.7	4.3	3.5 - 5.1	30	3.67	0.34	9.3	3.7	2.6 - 4.8
Orphee Mythic 22	29	3.50	1.54	44.2	3.1	0.0 - 8.2	27	3.54	0.98	27.8	3.3	0.5 - 6.5
Specimen CL-13							Specimen CL-14					
All Method	64	4.02	0.70	17.5	4.1	1.9 - 6.2	67	3.79	1.01	26.7	4.2	0.7 - 6.9
All Abbott Cell-Dyn Instruments	37	4.23	0.24	5.8	4.2	3.4 - 5.0	37	4.28	0.21	4.9	4.3	3.6 - 5.0
Abbott Cell-Dyn Ruby	31	4.21	0.24	5.6	4.2	3.4 - 5.0	31	4.28	0.22	5.1	4.3	3.6 - 5.0
Orphee Mythic 22	26	3.81	1.14	29.8	3.6	0.4 - 7.3	28	3.11	1.27	40.8	2.8	0.0 - 7.0
Specimen CL-15												
All Method	63	3.62	0.49	13.5	3.6	2.1 - 5.1						
All Abbott Cell-Dyn Instruments	36	3.64	0.37	10.1	3.6	2.5 - 4.8						
Abbott Cell-Dyn Ruby	30	3.63	0.36	10.0	3.6	2.5 - 4.8						
Orphee Mythic 22	27	3.73	0.82	22.1	3.8	1.2 - 6.2						

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

Specimen CL-11							Specimen CL-12					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	65	0.42	0.20	48.0	0.4	0.0 - 1.1	68	0.58	0.43	74.3	0.5	0.0 - 1.9
All Abbott Cell-Dyn Instruments	37	0.43	0.26	60.7	0.4	0.0 - 1.3	38	0.63	0.42	67.5	0.6	0.0 - 2.0
Abbott Cell-Dyn Ruby	31	0.44	0.26	58.4	0.5	0.0 - 1.3	32	0.64	0.39	61.2	0.7	0.0 - 1.9
Orphee Mythic 22	28	0.42	0.15	36.7	0.4	0.0 - 0.9	29	0.47	0.37	79.8	0.4	0.0 - 1.6
Specimen CL-13							Specimen CL-14					
All Method	63	0.36	0.24	65.2	0.3	0.0 - 1.1	66	0.52	0.29	55.2	0.5	0.0 - 1.4
All Abbott Cell-Dyn Instruments	36	0.27	0.18	66.7	0.3	0.0 - 0.9	38	0.60	0.37	61.4	0.6	0.0 - 1.8
Abbott Cell-Dyn Ruby	31	0.28	0.18	63.1	0.3	0.0 - 0.9	32	0.64	0.37	57.8	0.6	0.0 - 1.8
Orphee Mythic 22	29	0.59	0.42	72.3	0.5	0.0 - 1.9	27	0.41	0.15	35.8	0.4	0.0 - 0.9
Specimen CL-15												
All Method	67	0.61	0.43	71.7	0.5	0.0 - 2.0						
All Abbott Cell-Dyn Instruments	37	0.71	0.43	61.0	0.7	0.0 - 2.1						
Abbott Cell-Dyn Ruby	32	0.77	0.42	55.4	0.8	0.0 - 2.1						
Orphee Mythic 22	28	0.40	0.27	67.8	0.3	0.0 - 1.3						

BLOOD BANK

ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Group A	55	100%	Acceptable
BB-12	Group AB	55	100%	Acceptable
BB-13	Group B	54	98.18%	Acceptable
	Group A	1	1.82%	
BB-14	Group O	55	100%	Acceptable
BB-15	Group A	54	98.18%	Acceptable
	Group B	1	1.82%	

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Rh Negative	55	100%	Acceptable
BB-12	Rh Positive	55	100%	Acceptable
BB-13	Rh Negative	55	100%	Acceptable
BB-14	Rh Positive	55	100%	Acceptable
BB-15	Rh Negative	55	100%	Acceptable

BLOOD BANK

UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	No unexpected antibody detected	29	96.67%	Acceptable
	Unexpected antibody detected	1	3.33%	
AB-12	No unexpected antibody detected	29	96.67%	Acceptable
	Unexpected antibody detected	1	3.33%	
AB-13	Unexpected antibody detected	29	96.67%	Acceptable
	No unexpected antibody detected	1	3.33%	
AB-14	Unexpected antibody detected	29	96.67%	Acceptable
	No unexpected antibody detected	1	3.33%	
AB-15	Unexpected antibody detected	28	93.33%	Acceptable
	No unexpected antibody detect	2	6.67%	

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	No antibody detected	16	94.12%	Acceptable
	Unable to identify, referred	1	5.88%	
AB-12	No antibody detected	16	94.12%	Acceptable
	Unable to identify, referred	1	5.88%	
AB-13	Anti-D	17	100%	Acceptable
AB-14	Anti-jk ^a	17	100%	Acceptable
AB-15	Anti-s	16	94.12%	Acceptable
	Anti-S	1	5.88%	

BLOOD BANK

COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	Compatible	38	97.44%	Acceptable
	Not Compatible	1	2.56%	
AB-12	Compatible	38	97.44%	Acceptable
	Not Compatible	1	2.56%	
AB-13	Not Compatible	38	97.44%	Acceptable
	Compatible	1	2.56%	
AB-14	Not Compatible	39	100%	Acceptable
AB-15	Compatible	36	92.31%	Acceptable
	Not Compatible	3	7.69%	

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	104	12.56	1.41	11.2	12.9	10.6 - 14.5	105	22.66	3.26	14.4	23.2	19.2 - 26.1
Dade Innovin												
Dade Behring BFT II	5	10.03	0.21	2.1	10.1	8.5 - 11.6	5	20.03	1.03	5.1	20.5	17.0 - 23.1
Sysmex CA-500/600 series	20	11.18	0.50	4.5	11.1	9.5 - 12.9	21	19.87	0.97	4.9	19.7	16.8 - 22.9
All Coagulation Instruments	28	10.96	0.65	5.9	11.0	9.3 - 12.7	29	19.78	0.97	4.9	19.7	16.8 - 22.8
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STA Compact	8	12.95	0.35	2.7	13.0	11.0 - 14.9	8	23.63	1.23	5.2	23.8	20.0 - 27.2
Diagnostica Stago STart 4/8	7	13.26	0.54	4.1	13.0	11.2 - 15.3	7	25.39	2.37	9.3	25.7	21.5 - 29.2
RAL Clot-SP	18	14.01	0.58	4.1	13.8	11.9 - 16.2	18	26.26	0.85	3.2	26.3	22.3 - 30.3
All Coagulation Instruments	34	13.58	0.69	5.1	13.5	11.5 - 15.7	34	25.49	1.72	6.8	25.7	21.6 - 29.4
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	10.82	0.13	1.2	10.8	9.1 - 12.5	5	22.78	1.26	5.5	22.9	19.3 - 26.2
IL TEST PT Fibrinogen												
IL ACL, all models	5	12.20	0.60	4.9	12.0	10.3 - 14.1	5	17.40	0.61	3.5	17.6	14.7 - 20.1
IL TEST PT-FIB HS PLUS												
IL ACL, all models	17	13.42	0.32	2.4	13.4	11.4 - 15.5	18	25.13	1.55	6.2	25.2	21.3 - 29.0

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	110	22.07	3.12	14.1	22.4	18.7 - 25.4	105	29.60	4.86	16.4	30.2	25.1 - 34.1
Dade Innovin												
Dade Behring BFT II	5	20.30	0.87	4.3	20.3	17.2 - 23.4	5	28.58	2.32	8.1	29.5	24.2 - 32.9
Sysmex CA-500/600 series	20	19.90	0.69	3.5	19.9	16.9 - 22.9	21	26.10	1.25	4.8	26.1	22.1 - 30.1
All Coagulation Instruments	30	19.73	0.93	4.7	19.8	16.7 - 22.7	29	26.45	1.62	6.1	26.1	22.4 - 30.5
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STA Compact	6	23.20	1.79	7.7	23.9	19.7 - 26.7	8	31.38	2.87	9.1	31.8	26.6 - 36.1
Diagnostica Stago STart 4/8	6	26.33	3.22	12.2	25.6	22.3 - 30.3	7	32.91	4.25	12.9	33.8	27.9 - 37.9
RAL Clot-SP	18	24.92	0.93	3.7	25.0	21.1 - 28.7	18	34.76	1.50	4.3	34.7	29.5 - 40.0
All Coagulation Instruments	32	24.57	1.43	5.8	24.9	20.8 - 28.3	34	33.64	2.92	8.7	34.1	28.5 - 38.7
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	22.25	0.54	2.4	22.4	18.9 - 25.6	5	31.36	2.75	8.8	31.6	26.6 - 36.1
IL TEST PT Fibrinogen												
IL ACL, all models	5	21.04	2.24	10.7	21.2	17.8 - 24.2	5	20.72	0.96	4.6	20.8	17.6 - 23.9
IL TEST PT-FIB HS PLUS												
IL ACL, all models	6	16.98	0.87	5.1	16.7	14.4 - 19.6	18	32.83	1.97	6.0	33.2	27.9 - 37.8

PROTHROMBIN TIME (seconds)

Specimen CG-15						
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	87	28.52	5.49	19.3	27.9	24.2 - 32.8
Dade Innovin						
Dade Behring BFT II	5	24.68	2.37	9.6	24.5	20.9 - 28.4
Sysmex CA-500/600 series	9	21.30	1.71	8.0	20.7	18.1 - 24.5
All Coagulation Instruments	17	22.34	2.23	10.0	22.0	18.9 - 25.7
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STA Compact	7	31.13	2.91	9.4	32.3	26.4 - 35.8
Diagnostica Stago STart 4/8	5	31.56	4.35	13.8	33.1	26.8 - 36.3
RAL Clot-SP	18	32.03	3.27	10.2	32.5	27.2 - 36.9
All Coagulation Instruments	31	32.11	3.84	12.0	32.4	27.2 - 37.0
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	27.04	2.44	9.0	27.3	22.9 - 31.1
IL TEST PT Fibrinogen						
IL ACL, all models	5	24.43	2.17	8.9	24.7	20.7 - 28.1
IL TEST PT-FIB HS PLUS						
IL ACL, all models	18	32.53	3.66	11.3	34.3	27.6 - 37.5

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	100	1.03	0.09	8.2	1.0	0.8 - 1.3	103	2.05	0.28	13.7	2.0	1.6 - 2.5
Dade Innovin												
Dade Behring BFT II	5	1.13	0.05	4.4	1.1	0.9 - 1.4	5	2.08	0.17	8.2	2.1	1.6 - 2.5
Sysmex CA-500/600 series	20	1.08	0.08	7.1	1.1	0.8 - 1.3	21	1.93	0.12	6.0	1.9	1.5 - 2.4
All Coagulation Instruments	28	1.08	0.07	6.7	1.1	0.8 - 1.3	29	1.94	0.13	6.5	1.9	1.5 - 2.4
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STA Compact	5	0.92	0.13	14.2	1.0	0.7 - 1.2	5	2.00	0.39	19.7	2.2	1.6 - 2.4
Diagnostica Stago STart 4/8	6	1.08	0.17	15.9	1.1	0.8 - 1.3	6	2.58	0.45	17.4	2.5	2.0 - 3.1
RAL Clot-SP	16	1.05	0.06	6.0	1.0	0.8 - 1.3	16	2.35	0.13	5.4	2.3	1.8 - 2.9
All Coagulation Instruments	26	1.03	0.07	6.7	1.0	0.8 - 1.3	26	2.35	0.18	7.6	2.3	1.8 - 2.9
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	0.92	0.08	9.1	0.9	0.7 - 1.2	5	1.96	0.27	13.8	2.0	1.5 - 2.4
IL TEST PT Fibrinogen												
IL ACL, all models	5	1.06	0.05	5.2	1.1	0.8 - 1.3	5	1.98	0.13	6.6	2.0	1.5 - 2.4
IL TEST PT-FIB HS PLUS												
IL ACL, all models	18	1.00	0.07	6.9	1.0	0.8 - 1.2	18	2.03	0.21	10.1	2.1	1.6 - 2.5

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-13						Specimen CG-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	100	1.11	0.09	7.7	1.1	0.8 - 1.4	103	2.79	0.51	18.2	2.7	2.2 - 3.4
Dade Innovin												
Dade Behring BFT II	5	1.18	0.05	4.3	1.2	0.9 - 1.5	5	2.80	0.29	10.5	2.8	2.2 - 3.4
Sysmex CA-500/600 series	21	1.09	0.07	6.4	1.1	0.8 - 1.4	21	2.50	0.18	7.2	2.5	1.9 - 3.0
All Coagulation Instruments	29	1.11	0.07	6.4	1.1	0.8 - 1.4	28	2.52	0.18	7.2	2.5	2.0 - 3.1
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STA Compact	5	0.98	0.16	16.8	1.0	0.7 - 1.2	5	2.86	0.74	25.8	3.1	2.2 - 3.5
Diagnostica Stago STart 4/8	6	1.18	0.19	16.4	1.2	0.9 - 1.5	6	3.78	0.62	16.5	3.7	3.0 - 4.6
RAL Clot-SP	16	1.13	0.07	6.1	1.1	0.9 - 1.4	16	3.34	0.22	6.5	3.4	2.6 - 4.1
All Coagulation Instruments	26	1.11	0.08	7.3	1.1	0.8 - 1.4	26	3.39	0.30	8.8	3.4	2.7 - 4.1
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	1.06	0.11	10.8	1.1	0.8 - 1.3	5	2.76	0.46	16.7	2.8	2.2 - 3.4
IL TEST PT Fibrinogen												
IL ACL, all models	5	1.22	0.04	3.7	1.2	0.9 - 1.5	5	2.68	0.18	6.7	2.8	2.1 - 3.3
IL TEST PT-FIB HS PLUS												
IL ACL, all models	17	1.11	0.09	7.7	1.1	0.8 - 1.4	18	2.76	0.27	9.8	2.7	2.2 - 3.4

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	85	2.64	0.57	21.4	2.7	2.1 - 3.2
Dade Innovin						
Dade Behring BFT II	5	2.45	0.26	10.8	2.5	1.9 - 3.0
Sysmex CA-500/600 series	9	2.06	0.22	10.6	2.1	1.6 - 2.5
All Coagulation Instruments	17	2.15	0.26	12.3	2.1	1.7 - 2.6
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STA Compact	5	2.88	0.40	14.0	3.0	2.3 - 3.5
Diagnostica Stago STart 4/8	5	3.10	0.32	10.2	3.2	2.4 - 3.8
RAL Clot-SP	16	3.01	0.44	14.5	3.1	2.4 - 3.7
All Coagulation Instruments	25	3.01	0.40	13.3	3.1	2.4 - 3.7
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	2.28	0.43	19.0	2.3	1.8 - 2.8
IL TEST PT Fibrinogen						
IL ACL, all models	5	3.60	0.40	11.1	3.8	2.8 - 4.4
IL TEST PT-FIB HS PLUS						
IL ACL, all models	18	2.69	0.38	14.0	2.8	2.1 - 3.3

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	64	30.1	5.1	16.9	30	25 - 35	64	38.9	4.7	12.0	39	33 - 45
Dade Actin FSL												
Sysmex CA-500/600 series	11	24.0	1.4	5.9	24	20 - 28	11	33.5	3.0	9.0	34	28 - 39
All Coagulation Instruments	13	24.2	1.5	6.3	24	20 - 28	12	34.3	1.1	3.1	34	29 - 40
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	6	34.2	3.8	11.0	33	29 - 40	6	43.3	3.9	9.0	42	36 - 50
Diagnostica Stago STart 4/8	5	32.8	2.2	6.8	33	27 - 38	5	43.3	3.3	7.6	43	36 - 50
All Coagulation Instruments	11	33.7	3.0	9.0	33	28 - 39	11	43.5	3.4	7.8	42	37 - 51
Hemoliance SynthASil												
IL ACL, all models	5	40.8	2.4	5.8	40	34 - 47	5	38.0	0.8	2.1	38	32 - 44
IL TEST APTT-SP												
IL ACL, all models	21	29.7	1.3	4.5	29	25 - 35	22	39.0	2.6	6.6	39	33 - 45

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

Specimen CG-13							Specimen CG-14					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	65	29.9	4.1	13.6	30	25 - 35	63	44.8	4.7	10.6	45	38 - 52
Dade Actin FSL												
Sysmex CA-500/600 series	11	24.5	1.2	5.0	25	20 - 29	11	37.6	4.3	11.5	39	31 - 44
All Coagulation Instruments	13	24.7	1.3	5.3	25	20 - 29	12	38.9	1.0	2.6	39	33 - 45
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	6	34.3	3.0	8.8	33	29 - 40	6	48.3	3.3	6.8	48	41 - 56
Diagnostica Stago STart 4/8	5	32.5	2.1	6.4	33	27 - 38	5	47.3	2.4	5.0	48	40 - 55
All Coagulation Instruments	11	33.6	2.6	7.7	33	28 - 39	11	48.1	2.8	5.8	49	40 - 56
Hemoliance SynthASil												
IL ACL, all models	5	29.5	0.6	2.0	30	25 - 34	5	43.3	1.9	4.4	43	36 - 50
IL TEST APTT-SP												
IL ACL, all models	22	30.7	1.4	4.4	31	26 - 36	22	45.2	2.5	5.5	45	38 - 53
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	57	62.0	10.0	16.2	61	52 - 72						
Dade Actin FSL												
Sysmex CA-500/600 series	10	54.3	3.8	7.1	55	46 - 63						
All Coagulation Instruments	12	54.2	3.5	6.4	54	46 - 63						
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	6	71.8	8.4	11.6	73	61 - 83						
Diagnostica Stago STart 4/8	5	62.3	6.7	10.7	59	52 - 72						
All Coagulation Instruments	9	68.7	8.8	12.8	70	58 - 79						
Hemoliance SynthASil												
IL ACL, all models	5	67.3	8.0	11.9	68	57 - 78						
IL TEST APTT-SP												
IL ACL, all models	22	63.0	5.9	9.4	64	53 - 73						

FIBRINOGEN (mg/dL)

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	37	430.5	67.2	15.6	441	344 - 517	36	296.0	37.3	12.6	303	236 - 356
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	7	407.3	60.0	14.7	411	325 - 489	7	261.7	33.0	12.6	276	209 - 315
All Coagulation Instruments	10	416.2	51.9	12.5	428	332 - 500	10	262.4	27.0	10.3	271	209 - 315
IL Fibrinogen-C												
IL ACL, all models	8	476.9	39.8	8.3	477	381 - 573	8	297.8	19.4	6.5	306	238 - 358
IL TEST PT-FIB HS PLUS												
IL ACL, all models	13	446.2	48.9	11.0	435	356 - 536	13	330.8	15.7	4.8	328	264 - 397
Specimen CG-13							Specimen CG-14					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	37	296.1	39.4	13.3	292	236 - 356	36	304.3	38.7	12.7	310	243 - 366
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	7	272.0	38.9	14.3	287	217 - 327	7	263.6	34.6	13.1	274	210 - 317
All Coagulation Instruments	10	274.0	32.1	11.7	282	219 - 329	10	268.6	29.7	11.1	275	214 - 323
IL Fibrinogen-C												
IL ACL, all models	8	311.3	24.7	7.9	325	249 - 374	8	302.9	16.1	5.3	310	242 - 364
IL TEST PT-FIB HS PLUS												
IL ACL, all models	13	313.9	37.6	12.0	303	251 - 377	13	339.3	27.9	8.2	337	271 - 408
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	33	104.2	11.8	11.3	106	83 - 125						
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	7	102.7	14.1	13.7	110	82 - 124						
IL Fibrinogen-C												
IL ACL, all models	7	100.9	13.6	13.5	101	80 - 122						
IL TEST PT-FIB HS PLUS												
IL ACL, all models	13	108.1	11.0	10.1	107	86 - 130						

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	394	1.0218	0.0053	0.5	1.020	1.011 - 1.032
All Arkray Methods	13	1.0265	0.0035	0.3	1.027	1.016 - 1.037
All DIRUI Methods	21	1.0223	0.0036	0.4	1.020	1.012 - 1.033
All Iris Diagnostics Methods	15	1.0255	0.0009	0.1	1.025	1.015 - 1.036
All Refractive Index Methods	36	1.0270	0.0025	0.2	1.027	1.017 - 1.038
All Roche Methods	136	1.0184	0.0050	0.5	1.015	1.008 - 1.029
All Siemens Methods	46	1.0209	0.0039	0.4	1.020	1.010 - 1.031
77 Elektronika LabUMat/2	15	1.0289	0.0021	0.2	1.029	1.018 - 1.039
Combi-Screen Test Strips	11	1.0232	0.0033	0.3	1.025	1.013 - 1.034
DIRUI H-100 / H-500 Urine Analyzer	16	1.0219	0.0032	0.3	1.020	1.011 - 1.032
Iris Diagnostics iChem Velocity Strips	12	1.0256	0.0011	0.1	1.026	1.015 - 1.036
Other Analyzer Method	13	1.0246	0.0063	0.6	1.025	1.014 - 1.035
Roche Chemstrips / Combur	16	1.0178	0.0041	0.4	1.015	1.007 - 1.028
Roche cobas u 411	86	1.0167	0.0024	0.2	1.015	1.006 - 1.027
Roche Urisys	48	1.0213	0.0065	0.6	1.020	1.011 - 1.032
SD UroColor Reagent Strips	24	1.0258	0.0046	0.4	1.025	1.015 - 1.036
Siemens Clinitek Advantus	32	1.0195	0.0019	0.2	1.020	1.009 - 1.030
UriScan Pro/II	19	1.0238	0.0023	0.2	1.025	1.013 - 1.034
UriScan Reagent Strips	22	1.0245	0.0021	0.2	1.025	1.014 - 1.035

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	414	-	-	-	292	65	54	1	-	1	1	-	-
77 Elektronika LabUMat/2	16	-	-	-	16	-	-	-	-	-	-	-	-
Acon Laboratories	9	-	-	-	2	2	5	-	-	-	-	-	-
Analyticon CombiScan 500	3	-	-	-	3	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	2	-	-	-	-	-	-	-
Arkray Aution Sticks	9	-	-	-	4	5	-	-	-	-	-	-	-
Arkray PocketChem UA	3	-	-	-	-	3	-	-	-	-	-	-	-
Combi-Screen Test Strips	11	-	-	-	10	1	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	16	-	-	-	8	6	2	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	5	-	-	-	1	3	1	-	-	-	-	-	-
HUMAN Combilyzer	1	-	-	-	1	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	1	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	11	-	-	-	11	-	-	-	-	-	-	-	-
Iris iChem VELOCITY Urine Chemistry System	3	-	-	-	3	-	-	-	-	-	-	-	-
Other Analyzer Method	12	-	-	-	6	4	1	-	-	-	1	-	-
Other Dipstick Method	10	-	-	-	6	-	4	-	-	-	-	-	-
Plasmatec URIPATH	3	-	-	-	1	-	2	-	-	-	-	-	-
Roche Chemstrips / Combur	20	-	-	-	20	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	9	-	-	-	9	-	-	-	-	-	-	-	-
Roche cobas u 411	85	-	-	-	82	-	3	-	-	-	-	-	-
Roche Miditron Junior/II	1	-	-	-	1	-	-	-	-	-	-	-	-
Roche Urilux S	1	-	-	-	1	-	-	-	-	-	-	-	-
Roche Urisys	48	-	-	-	47	-	-	1	-	-	-	-	-
SD UroColor Reagent Strips	22	-	-	-	10	4	8	-	-	-	-	-	-
Siemens Clinitek 500	2	-	-	-	-	-	2	-	-	-	-	-	-
Siemens Clinitek Advantus	35	-	-	-	2	20	12	-	-	1	-	-	-
Siemens Clinitek Atlas	4	-	-	-	1	3	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	6	-	-	-	3	3	-	-	-	-	-	-	-
Siemens Reagent Strips	13	-	-	-	1	1	11	-	-	-	-	-	-
Siemens Uristix	1	-	-	-	1	-	-	-	-	-	-	-	-
Urinometer	1	-	-	-	-	1	-	-	-	-	-	-	-
UriScan Pro/II	17	-	-	-	12	4	1	-	-	-	-	-	-
UriScan Reagent Strips	27	-	-	-	25	1	1	-	-	-	-	-	-
URIT Medical Uritest Analyzers	1	-	-	-	-	1	-	-	-	-	-	-	-
URIT Medical Uritest 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	417	410	1	2	1	1	-	-	1	-	1	-	-
77 Elektronika LabUMat/2	16	16	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	9	9	-	-	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	3	3	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	9	9	-	-	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	3	3	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	12	12	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	17	17	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	4	4	-	-	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	11	11	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	3	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	14	14	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	10	9	-	1	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	2	2	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	21	21	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	9	9	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	85	85	-	-	-	-	-	-	-	-	-	-	-
Roche Miditron Junior/II	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche Urilux S	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	47	47	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	23	20	1	-	-	1	-	-	1	-	-	-	-
Siemens Clinitek 500	2	2	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	36	35	-	-	-	-	-	-	-	-	1	-	-
Siemens Clinitek Atlas	4	4	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	7	7	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	12	12	-	-	-	-	-	-	-	-	-	-	-
Siemens Uristix	1	1	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	17	16	-	1	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	28	27	-	-	1	-	-	-	-	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest 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	416	7	18	51	29	17	78	4	45	31	136	
77 Elektronika LabUMat/2	16	-	-	-	-	-	12	-	-	-	4	
Acon Laboratories	9	-	-	4	1	1	3	-	-	-	-	
Analyticon CombiScan 500	3	-	-	-	-	1	-	-	-	-	2	
Arkray Aution Jet	2	-	-	-	-	-	2	-	-	-	-	
Arkray Aution Sticks	9	-	-	-	-	-	7	1	-	1	-	
Arkray PocketChem UA	3	-	-	-	-	-	1	-	-	1	1	
Combi-Screen Test Strips	12	-	-	-	-	-	2	-	1	3	6	
DIRUI H-100 / H-500 Urine Analyzer	17	1	-	7	4	-	-	1	3	-	1	
DIRUI H-800 Urine Analyzer	4	-	-	-	-	3	-	-	-	1	-	
HUMAN Combilyzer	1	-	-	-	-	-	1	-	-	-	-	
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	1	-	-	-	-	
Iris Diagnostics iChem Velocity Strips	11	-	-	-	1	1	-	-	5	4	-	
Iris Ichem VELOCITY Urine Chemistry System	3	-	-	-	1	-	-	-	1	1	-	
Other Analyzer Method	14	1	-	-	1	2	5	-	-	1	4	
Other Dipstick Method	10	1	-	4	1	-	2	-	-	1	1	
Plasmatec URIPATH	3	-	3	-	-	-	-	-	-	-	-	
Roche Chemstrips / Combur	20	1	-	-	-	1	13	-	-	1	4	
Roche cobas 6500 / u 601	9	-	-	-	-	-	-	-	-	-	9	
Roche cobas u 411	83	1	-	-	1	1	12	-	5	-	63	
Roche Mditron Junior/II	1	-	-	-	-	-	1	-	-	-	-	
Roche Urilux S	1	-	-	-	-	-	1	-	-	-	-	
Roche Urisys	48	-	-	-	-	1	12	-	2	-	33	
SD UroColor Reagent Strips	23	-	1	4	8	2	1	-	3	2	2	
Siemens Clinitek 500	2	-	-	-	-	-	-	-	2	-	-	
Siemens Clinitek Advantus	36	1	8	14	-	-	-	1	11	1	-	
Siemens Clinitek Atlas	4	-	-	-	-	2	-	-	-	-	2	
Siemens Clinitek Status / Status+	7	-	-	6	1	-	-	-	-	-	-	
Siemens Reagent Strips	12	-	5	6	-	-	-	-	1	-	-	
Siemens Uristix	1	-	-	-	-	-	-	-	-	-	1	
Urinometer	1	-	-	-	1	-	-	-	-	-	-	
UriScan Pro/II	18	-	-	2	-	-	-	-	7	8	1	
UriScan Reagent Strips	28	1	1	3	8	2	-	1	4	6	2	
URIT Medical Uritest Analyzers	1	-	-	-	-	-	1	-	-	-	-	
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	1	-	-	-	-	

URINALYSIS DIPSTICK–KETONES

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>Participant Results</u>								
							(1+)	(2+)	(3+)	(4+)	<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	416	13	1	1	1	-	54	110	26	1	13	30	147	13	6
77 Elektronika LabUMat/2	16	-	-	-	-	-	8	4	-	-	-	4	-	-	-
Acon Laboratories	9	4	-	-	-	-	1	4	-	-	-	-	-	-	-
Analyticon CombiScan 500	3	-	-	-	-	-	1	-	-	-	-	-	-	2	-
Arkray Aution Jet	2	-	-	-	-	-	-	2	-	-	-	-	-	-	-
Arkray Aution Sticks	9	-	-	-	-	-	-	6	-	-	-	-	3	-	-
Arkray PocketChem UA	3	-	-	-	-	-	1	1	-	-	-	-	1	-	-
Combi-Screen Test Strips	12	-	1	-	-	-	1	2	-	-	-	1	-	7	-
DIRUI H-100 / H-500 Urine Analyzer	17	-	-	-	-	-	9	2	1	-	-	1	3	-	1
DIRUI H-800 Urine Analyzer	4	-	-	-	-	-	3	-	-	-	-	1	-	-	-
HUMAN Combilyzer	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	11	-	-	-	-	-	-	1	1	-	-	3	6	-	-
Iris iChem VELOCITY Urine Chemistry System	3	-	-	-	-	-	-	-	-	-	-	2	1	-	-
Other Analyzer Method	14	1	-	-	-	-	3	4	-	-	-	2	4	-	-
Other Dipstick Method	10	2	-	-	-	-	1	7	-	-	-	-	-	-	-
Plasmatec URIPATH	3	-	-	-	-	-	1	2	-	-	-	-	-	-	-
Roche Chemstrips / Combur	19	5	-	-	-	-	1	7	3	-	1	-	1	-	1
Roche cobas 6500 / u 601	9	-	-	-	-	-	-	-	-	-	-	-	9	-	-
Roche cobas u 411	86	1	-	1	1	-	-	1	13	1	-	1	65	-	2
Roche Mditron Junior/II	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Roche Urisys	49	-	-	-	-	-	1	7	5	-	-	2	30	2	2
SD UroColor Reagent Strips	23	-	-	-	-	-	4	10	2	-	4	-	1	2	-
Siemens Clinitek 500	2	-	-	-	-	-	-	-	-	-	-	2	-	-	-
Siemens Clinitek Advantus	36	-	-	-	-	-	13	9	-	-	-	10	4	-	-
Siemens Clinitek Atlas	4	-	-	-	-	-	-	2	-	-	-	1	1	-	-
Siemens Clinitek Status / Status+	6	-	-	-	-	-	-	5	1	-	-	-	-	-	-
Siemens Reagent Strips	13	-	-	-	-	-	-	12	-	-	-	-	1	-	-
Urinometer	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
UriScan Pro/II	17	-	-	-	-	-	2	1	-	-	6	-	8	-	-
UriScan Reagent Strips	28	-	-	-	-	-	1	16	-	-	2	-	9	-	-
URIT Medical Uritest Analyzers	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Participant Results</u>					<u>0.5 - 1.0 mg/dL</u>	<u>2.0 - 4.0 mg/dL</u>	<u>6.0 - 10.0 mg/dL</u>	<u>>10.0 mg/dL</u>
						<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>				
ALL METHODS	401	399	-	-	1	-	-	-	-	-	1	-	-	-
77 Elektronika LabUMat/2	16	16	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	9	9	-	-	-	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	4	4	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	9	9	-	-	-	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	11	11	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	16	16	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	4	4	-	-	-	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	12	12	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	14	14	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	10	10	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	19	19	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	9	9	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	85	85	-	-	-	-	-	-	-	-	-	-	-	-
Roche Mditron Junior/II	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	48	48	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	22	22	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	36	35	-	-	1	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	4	4	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	6	6	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Uristix	1	1	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	17	16	-	-	-	-	-	-	-	-	1	-	-	-
UriScan Reagent Strips	27	27	-	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Normal or 0.0 - 0.2 mg/dL</u>	<u>1.0 or <2.0 mg/dL</u>	<u>2.0/3.0 mg/dL</u>	<u>4.0 or 4.0/6.0 mg/dL</u>	<u>≥8.0 or ≥12.0 mg/dL</u>
ALL METHODS	402	400	1	1	-	-
77 Elektronika LabUMat/2	15	15	-	-	-	-
Acon Laboratories	9	9	-	-	-	-
Analyticon CombiScan 500	3	3	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-
Arkray Aution Sticks	8	8	-	-	-	-
Arkray PocketChem UA	3	3	-	-	-	-
Combi-Screen Test Strips	12	12	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	16	16	-	-	-	-
DIRUI H-800 Urine Analyzer	4	4	-	-	-	-
HUMAN Combilyzer	1	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	12	12	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	3	-	-	-	-
Other Analyzer Method	14	14	-	-	-	-
Other Dipstick Method	10	10	-	-	-	-
Plasmatec URIPATH	2	2	-	-	-	-
Roche Chemstrips / Combur	19	19	-	-	-	-
Roche cobas 6500 / u 601	9	9	-	-	-	-
Roche cobas u 411	86	86	-	-	-	-
Roche Miditron Junior/II	1	1	-	-	-	-
Roche Urisys	48	48	-	-	-	-
SD UroColor Reagent Strips	23	22	1	-	-	-
Siemens Clinitek 500	2	2	-	-	-	-
Siemens Clinitek Advantus	36	35	-	1	-	-
Siemens Clinitek Atlas	4	4	-	-	-	-
Siemens Clinitek Status / Status+	6	6	-	-	-	-
Siemens Reagent Strips	2	2	-	-	-	-
Siemens Uristix	1	1	-	-	-	-
Urinometer	1	1	-	-	-	-
UriScan Pro/II	16	16	-	-	-	-
UriScan Reagent Strips	27	27	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN
Specimen UA-3

<u>Method</u>	<i>Participant Results</i>																	
	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>(5+)</u>	<u>5 - 25</u> <u>Ery/μL</u>	<u>50 -</u> <u>100</u> <u>Ery/μL</u>	<u>250</u> <u>Ery/μL</u>	<u>$\pm$0.03</u> <u>mg/dL</u>	<u>0.06</u> <u>-</u> <u>0.10</u> <u>mg/</u> <u>dL</u>	<u>0.2 -</u> <u>0.5</u> <u>mg/</u> <u>dL</u>	<u>$\geq$ 1.0</u> <u>mg/</u> <u>dL</u>
ALL METHODS	412	407	2	-	-	-	2	-	1	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	15	14	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	11	11	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	12	12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	14	14	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	10	10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	18	17	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	86	86	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Mditron Junior/II	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	48	48	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	23	22	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	36	35	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	5	5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	13	13	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Uristix	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	27	26	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-3

<u>Method</u>	<i>Participant Results</i>												
	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>25 µL</u>	<u>75 or 100 µL</u>	<u>250 or 500 µL</u>
ALL METHODS	400	11	1	3	1	-	34	38	95	3	8	32	174
77 Elektronika LabUMat/2	16	-	-	-	-	-	-	-	13	-	-	-	3
Acon Laboratories	8	-	-	-	-	-	3	3	2	-	-	-	-
Analyticon CombiScan 500	3	-	-	-	-	-	-	-	-	-	1	-	2
Arkray Aution Jet	2	1	-	-	-	-	-	-	-	-	-	-	1
Arkray Aution Sticks	8	-	-	-	-	-	-	-	1	-	1	-	6
Arkray PocketChem UA	3	-	-	-	-	-	-	-	-	-	-	-	3
Combi-Screen Test Strips	13	-	-	-	-	-	-	-	1	1	1	1	9
DIRUI H-100 / H-500 Urine Analyzer	16	-	1	-	-	-	7	2	1	-	-	3	2
DIRUI H-800 Urine Analyzer	4	-	-	-	-	-	-	-	3	-	-	-	1
HUMAN Combilyzer	1	-	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	-	-	-	-	1
Iris Diagnostics iChem Velocity Strips	12	-	-	-	-	-	-	-	6	-	-	-	6
Iris iChem VELOCITY Urine Chemistry System	3	-	-	-	-	-	-	-	1	-	-	-	2
Other Analyzer Method	14	1	-	-	-	-	-	1	4	-	-	2	6
Other Dipstick Method	10	-	-	-	-	-	2	2	3	-	2	-	1
Plasmatec URIPATH	3	-	-	-	-	-	-	-	3	-	-	-	-
Roche Chemstrips / Combur	18	-	-	-	-	-	1	-	13	-	-	-	4
Roche cobas 6500 / u 601	9	-	-	-	-	-	-	-	-	-	-	-	9
Roche cobas u 411	87	2	-	-	-	-	1	-	12	1	-	-	71
Roche Miditron Junior/II	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche Urisys	48	-	-	-	-	-	-	1	11	1	-	-	35
SD UroColor Reagent Strips	23	3	-	-	-	-	1	9	4	-	-	2	4
Siemens Clinitek 500	2	-	-	-	-	-	-	-	-	-	-	2	-
Siemens Clinitek Advantus	36	1	-	1	-	-	15	10	-	-	-	9	-
Siemens Clinitek Atlas	4	-	-	-	-	-	-	-	2	-	-	2	-
Siemens Clinitek Status / Status+	6	-	-	2	1	-	1	2	-	-	-	-	-
Siemens Reagent Strips	2	-	-	-	-	-	-	1	-	-	-	1	-
Siemens Uristix	1	-	-	-	-	-	-	-	-	-	-	1	-
Urinometer	1	-	-	-	-	-	-	-	1	-	-	-	-
UriScan Pro/II	15	-	-	-	-	-	-	3	-	-	2	5	5
UriScan Reagent Strips	26	3	-	-	-	-	3	3	9	-	1	4	3
URIT Medical Uritest Analyzers	1	-	-	-	-	-	-	-	1	-	-	-	-
URIT Medical Uritest 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	403	4	399
77 Elektronika LabUMat/2	16	-	16
Acon Laboratories	9	-	9
Analyticon CombiScan 500	3	-	3
Arkray Aution Jet	2	-	2
Arkray Aution Sticks	9	-	9
Arkray PocketChem UA	3	-	3
Combi-Screen Test Strips	12	-	12
DIRUI H-100 / H-500 Urine Analyzer	16	-	16
DIRUI H-800 Urine Analyzer	4	-	4
HUMAN Combilyzer	1	-	1
Iris Diagnostics Aution Max AX-4280	1	-	1
Iris Diagnostics iChem Velocity Strips	12	-	12
Iris Ichem VELOCITY Urine Chemistry System	3	-	3
Other Analyzer Method	14	1	13
Other Dipstick Method	10	-	10
Plasmatec URIPATH	3	-	3
Roche Chemstrips / Combur	19	-	19
Roche cobas 6500 / u 601	9	-	9
Roche cobas u 411	85	1	84
Roche Mditron Junior/II	1	-	1
Roche Urisys	48	-	48
SD UroColor Reagent Strips	24	-	24
Siemens Clinitek 500	2	-	2
Siemens Clinitek Advantus	36	1	35
Siemens Clinitek Atlas	4	-	4
Siemens Clinitek Status / Status+	5	-	5
Siemens Reagent Strips	2	-	2
Siemens Uristix	1	-	1
Urinometer	1	-	1
UriScan Pro/II	17	1	16
UriScan Reagent Strips	27	-	27
URIT Medical Uritest Analyzers	1	-	1
URIT Medical Uritest Reagent Strips	1	-	1

URINALYSIS –MICROALBUMIN (dipstick only)

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>10 mg/L</u>	<u>20 mg/L</u>	<u>30 mg/L</u>	<u>50 mg/L</u>	<u>80 mg/L</u>	<u>100 mg/L</u>	<u>150 mg/L</u>	<u>+ (4 - 8 mg/dL)</u>	<u>++ (>8 mg/dL)</u>
ALL METHODS	15	13	1	1	-	-	-	-	-	-	-
Beckman Coulter ICON microALB	1	1	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-
Other Analyzer Method	3	3	-	-	-	-	-	-	-	-	-
Roche cobas u 411	1	1	-	-	-	-	-	-	-	-	-
Roche Micral - 1 minute	3	2	-	1	-	-	-	-	-	-	-

URINALYSIS –URINE hCG

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	117	-	117
Acon Laboratories	8	-	8
Alere Acceava hCG-Urine	3	-	3
Alere Clearview hCG Cassette	15	-	15
Biotron 1-Step	5	-	5
Medline hCG Test Strip	1	-	1
Other Analyzer Method	1	-	1
Other Dipstick Method	3	-	3
Quidel QuickVue One-Step Combo	19	-	19
Roche Chemstrips / Combur	1	-	1
SD Bioline hCG	8	-	8
Stanbio QuStick	1	-	1

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Specimen UC-11, CC-11 (SUS-11)

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Amikacin	40	40	-	-	115	115	-	-	100.00%
Amoxicillin/Clavulanate	35	3	-	32	28	1	-	27	93.75%
Ampicillin	28	6	1	21	47	1	3	43	85.90%
Ampicillin/Sulbactam	18	12	-	6	32	8	2	22	See footnote ¹
Aztreonam	18	18	-	-	30	28	-	2	95.92%
Cefaclor	3	3	-	-	-	-	-	-	100.00%
Cefazolin	17	6	1	10	22	1	-	21	81.82%
Cefepime	32	32	-	-	119	117	-	2	98.75%
Cefixime	22	22	-	-	-	-	-	-	100.00%
Cefoperazone	7	7	-	-	-	-	-	-	100.00%
Cefotaxime	34	32	2	-	50	47	-	3	93.02%
Cefotetan	-	-	-	-	2	1	-	1	See footnote ¹
Cefoxitin	13	2	-	11	44	1	-	43	94.92%
Cefpodoxime	3	2	1	-	1	1	-	-	100.00%
Ceftazidime	34	33	-	1	84	82	-	2	96.77%
Ceftizoxime	-	-	-	-	1	1	-	-	Ungraded ²
Ceftriaxone	37	37	-	-	80	77	-	3	96.80%
Cefuroxime	32	25	1	6	46	14	1	31	See footnote ¹
Cephalexin	3	2	-	1	2	1	-	1	Inappropriate drug ³
Cephalothin	4	-	-	4	23	-	-	23	100.00%
Ciprofloxacin	49	49	-	-	143	142	1	-	99.50%
Colistin	2	2	-	-	13	13	-	-	Inappropriate drug ³
Doripenem	-	-	-	-	7	6	-	1	85.71%
Doxycycline	1	-	1	-	2	2	-	-	100.00%
Ertapenem	20	20	-	-	110	110	-	-	100.00%
Fosfomycin	4	1	1	2	18	4	1	13	Inappropriate drug ³
Gatifloxacin	1	1	-	-	1	1	-	-	Ungraded ²
Gentamicin	40	40	-	-	114	113	-	1	99.38%
Imipenem	33	32	1	-	82	74	7	1	92.50%
Kanamycin	-	-	-	-	1	1	-	-	Ungraded ²

¹ This drug is intrinsically resistant.

² This is an ungraded challenge due to lack of comparison group.

³ This is an inappropriate drug due to discontinued marketing status.

ANTIMICROBIAL SUSCEPTIBILITY TESTING (cont'd)
Specimen UC-11, CC-11 (SUS-11)

Specimen UC-11, CC-11 (SUS-11)	-----Disk Diffusion-----				-----MIC-----				
	Interpretative category data				Interpretative category data				
<u>Antimicrobial</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Acceptable (%)</u>
Levofloxacin	24	24	-	-	66	66	-	-	100.00%
Linezolid	1	1	-	-	1	1	-	-	See footnote ¹
Meropenem	27	27	-	-	104	104	-	-	100.00%
Minocycline	-	-	-	-	1	1	-	-	Ungraded ²
Moxifloxacin	5	5	-	-	-	-	-	-	Inappropriate drug ³
Nalidixic Acid	5	5	-	-	17	17	-	-	100.00%
Netilmicin	8	8	-	-	2	2	-	-	100.00%
Nitrofurantoin	35	20	4	11	72	14	49	9	82.45%
Norfloxacin	17	17	-	-	48	48	-	-	100.00%
Ofloxacin	13	13	-	-	1	1	-	-	100.00%
Oxacillin	-	-	-	-	1	-	-	1	Inappropriate drug ³
Penicillin	1	-	-	1	2	-	1	1	Inappropriate drug ³
Piperacillin	1	1	-	-	6	6	-	-	100.00%
Piperacillin/Tazobactam	25	25	-	-	78	77	-	1	99.07%
Rifampin	1	1	-	-	-	-	-	-	Inappropriate drug ³
Sulfisoxazole	1	1	-	-	1	1	-	-	Ungraded ²
Tetracycline	2	2	-	-	13	13	-	-	100.00%
Ticarcillin	-	-	-	-	2	1	-	1	Ungraded ²
Ticarcillin/Clavulanate	1	-	-	1	5	4	1	-	83.34%
Tigecycline	-	-	-	-	2	2	-	-	Inappropriate drug ³
Tobramycin	5	4	1	-	33	32	1	-	94.87%
Trimethoprim	1	1	-	-	3	2	1	-	100.00%
Trimethoprim/Sulfamethoxazole	41	40	-	1	134	133	1	-	98.91%
Vancomycin	1	-	-	1	1	1	-	-	Inappropriate drug ³

Organism(s) present: *Enterobacter aerogenes*.

PARASITOLOGY (PA Specimens)

Specimen PA-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	3	42.86%	Unacceptable
Enterobius vermicularis eggs	2	28.57%	Unacceptable
Schistosoma sp. eggs, NOS	1	14.29%	Unacceptable
Entamoeba histolytica	1	14.29%	Unacceptable

Parasite(s) present: *Iodamoeba buetschlii*. This specimen is graded to US statistics.

Specimen PA-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	4	50.00%	Acceptable
Entamoeba histolytica	2	25.00%	
Balantidium coli	1	12.50%	
Cryptosporidium sp., oocysts	1	12.50%	

Parasite(s) present: No parasite present. This specimen is graded to US statistics.

Specimen PA-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis larvae	11	84.62%	Acceptable
Ascaris lumbricoides eggs	1	7.69%	
Endolimax nana	1	7.69%	

Parasite(s) present: *Strongyloides stercoralis* larvae.

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Trichuris trichiura eggs	12	70.59%	Acceptable
Endolimax nana	2	11.76%	Acceptable
Parasite egg seen but no ID	1	5.88%	Acceptable
Entamoeba histolytica	1	5.88%	
Ascaris lumbricoides eggs	1	5.88%	

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

Specimen PA-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Trypanosoma sp., NOS	6	60.00%	Acceptable
Trypanosoma brucei sp.	2	20.00%	Acceptable
Trypanosoma cruzi	1	10.00%	
Leishmania sp.	1	10.00%	

Parasite(s) present: *Trypanosoma brucei rhodesiense*.

PARASITOLOGY (FP Specimens)

Specimen FP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hymenolepis nana eggs	195	73.58%	Acceptable
Parasite egg seen but no ID	2	0.75%	
Hymenolepis diminuta eggs	30	11.32%	
Taenia sp. eggs	11	4.15%	
Ascaris lumbricoides eggs	8	3.02%	
No parasite seen	6	2.26%	
Endolimax nana	4	1.51%	
Blastocystis hominis	3	1.13%	
Other parasite seen but no ID	1	0.38%	
Protozoan seen but no ID	1	0.38%	
Entamoeba coli	1	0.38%	
Entamoeba histolytica	1	0.38%	
Entamoeba hartmanni	1	0.38%	
Hookworm	1	0.38%	

Parasite(s) present: *Hymenolepis nana* eggs.

Specimen FP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	248	97.64%	Acceptable
Strongyloides stercoralis larvae	2	0.79%	
Parasite egg seen but no ID	1	0.39%	
Parasite larvae seen but no ID	1	0.39%	
Nonpath, protozoan present	1	0.39%	
Blastocystis hominis	1	0.39%	

Parasite(s) present: No parasite present.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Diphyllobothrium latum	188	67.38%	Acceptable
Fasciola hepatica eggs	30	10.75%	
Paragonimus westermani eggs	17	6.09%	
Endolimax nana	10	3.58%	
Hookworm	8	2.87%	
Entamoeba histolytica	5	1.79%	
Ascaris lumbricoides eggs	3	1.08%	
Blastocystis hominis	3	1.08%	
Parasite eggs seen but no ID	3	1.08%	
No parasite seen	2	0.72%	
Enterobius vermicularis eggs	2	0.72%	
Giardia lamblia	1	0.36%	
Clonorchis sinensis	1	0.36%	
Entamoeba hartmanni	1	0.36%	
Entamoeba coli	1	0.36%	
Microfilaria, NOS	1	0.36%	
Pollen artifact	1	0.36%	
Schistosoma sp. eggs, NOS	1	0.36%	
Other parasite seen but no ID	1	0.36%	

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

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	249	82.45%	Acceptable
Entamoeba histolytica	16	5.30%	
Blastocystis hominis	13	4.30%	
Entamoeba coli	11	3.64%	
Endolimax nana	3	0.99%	
Entamoeba hartmanni	1	0.33%	
Enterobius vermicularis eggs	1	0.33%	
Chilomastix mesnili	1	0.33%	
Ascaris lumbricoides eggs	1	0.33%	
Hookworm	1	0.33%	
Hymenolepis nana eggs	1	0.33%	
Isospora belli oocysts	1	0.33%	
Strongyloides stercoralis larvae	1	0.33%	
Trichostrongylus sp. eggs	1	0.33%	
Parasite egg seen but no ID	1	0.33%	

Parasite(s) present: *Giardia lamblia*.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium vivax	171	67.59%	Acceptable
Plasmodium sp., NOS	38	15.02%	Acceptable
Plasmodium sp., not falciparum	8	3.16%	Acceptable
Plasmodium malariae	12	4.74%	
No parasite seen	8	3.16%	
Plasmodium ovale	7	2.77%	
Plasmodium falciparum	6	2.37%	
Toxoplasma gondii	1	0.40%	
Leishmania sp.	1	0.40%	
Microfilaria-Loa loa	1	0.40%	

Parasite(s) present: *Plasmodium vivax*.

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	1	17	18	-	15	3
Bio-Rad	-	2	2	-	2	-
BioSystems	-	2	2	-	2	-
Immuno Concepts	-	1	1	-	1	-
INOVA Diagnostics	1	5	6	-	5	1
Kallestad	-	1	1	-	1	-
Zeus	-	1	1	-	1	-

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	16	16	2
Bio-Rad	-	2	2	-
BioSystems	-	2	2	-
Immuno Concepts	-	1	1	-
INOVA Diagnostics	1	5	4	2
Kallestad	-	1	1	-
Zeus	-	1	1	-

Antinuclear Antibody (ANA)—Quantitative (Titer)

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

ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	9
Bio-Rad	-	-	-	-	-	-	-	-	-	-	-	1
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	-	-	4
Kallestad	-	-	-	-	-	-	-	-	-	-	-	1
Zeus	-	-	-	-	-	-	-	-	-	-	-	1

Antinuclear Antibody (ANA)—Quantitative (Titer)

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

ALL METHODS	-	-	-	-	-	1	1	1	5	1	-	-
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	1	-	1	1	-	-
Kallestad	-	-	-	-	-	-	-	-	1	-	-	-
Zeus	-	-	-	-	-	-	-	-	1	-	-	-

Specimen AE-13

ALL METHODS	-	-	-	1	1	6	-	-	1	-	-	-
Bio-Rad	-	-	-	-	-	1	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	1	-	3	-	-	-	-	-	-
Kallestad	-	-	-	-	-	1	-	-	-	-	-	-
Zeus	-	-	-	-	-	1	-	-	-	-	-	-

Specimen AE-14

ALL METHODS	-	-	-	-	-	-	-	-	-	-	-	9
Bio-Rad	-	-	-	-	-	-	-	-	-	-	-	1
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	-	-	4
Kallestad	-	-	-	-	-	-	-	-	-	-	-	1
Zeus	-	-	-	-	-	-	-	-	-	-	-	1

Specimen AE-15

ALL METHODS	-	-	-	1	3	3	-	-	1	-	-	1
Bio-Rad	-	-	-	-	-	1	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	1	2	-	-	-	-	-	-	1
Kallestad	-	-	-	-	-	1	-	-	-	-	-	-
Zeus												

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	-	16	-	16	2	14
BioSystems	-	1	-	1	-	1
INOVA Diagnostics	-	9	-	9	2	7
Zeus	-	1	-	1	-	1

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	16	-	16
BioSystems	-	1	-	1
INOVA Diagnostics	-	9	-	9
Zeus	-	1	-	1

Anti-RNP

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	12	12	-	1	11
INOVA Diagnostics	-	9	9	-	-	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	12	-
INOVA Diagnostics	-	9	9	-

Anti-RNP/Sm

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	4	3	1	1	3

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

Anti-SSA

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	14	-	15	-	15
INOVA Diagnostics	-	10	-	10	-	10

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	14	5	10
INOVA Diagnostics	-	10	2	8

Specimen AE-15 is an ungraded challenge due to less than 80% participant consensus.

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	-	15	-	15	-	15
INOVA Diagnostics	-	10	-	10	-	10

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	14	-	15
INOVA Diagnostics	-	10	-	10

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	-	14	9	5	-	14
INOVA Diagnostics	-	10	9	1	-	10

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

Specimen AE-12 is an ungraded challenge due to less than 80% participant consensus.

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	19	1	-	20	-	20
Abbott Architect	12	1	-	13	-	13
bioMerieux Vidas, Mini Vidas	1	-	-	1	-	1
Roche cobas 6000 / e 601	3	-	-	3	-	3
Roche cobas e 411	1	-	-	1	-	1
Siemens ADVIA Centaur	1	-	-	1	-	1
VITROS ECI	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	-	20	19	1
Abbott Architect	-	13	12	1
bioMerieux Vidas, Mini Vidas	-	1	1	-
Roche cobas 6000 / e 601	-	3	3	-
Roche cobas e 411	-	1	1	-
Siemens ADVIA Centaur	-	1	1	-
VITROS ECI	-	1	1	-

Rubella—Quantitative (IU/mL)

<u><i>Specimen/Method</i></u>	<u><i>Labs</i></u>	<u><i>Mean</i></u>	<u><i>SD</i></u>	<u><i>CV</i></u>	<u><i>Median</i></u>	<u><i>Range</i></u>
Specimen RU-11						
All Method	24	26.66	17.13	64.2	16.6	0.0 - 78.1
Abbott Architect	13	14.00	1.67	11.9	13.9	8.9 - 19.1
Specimen RU-12						
All Method	24	0.12	0.19	163.2	0.0	0.0 - 0.7
Abbott Architect	13	0.00	0.01	0.0	0.0	0.0 - 0.1
Specimen RU-13						
All Method	24	0.12	0.19	163.2	0.0	0.0 - 0.7
Abbott Architect	13	0.00	0.01	0.0	0.0	0.0 - 0.1
Specimen RU-14						
All Method	24	0.11	0.19	172.0	0.0	0.0 - 0.7
Abbott Architect	13	0.00	0.01	0.0	0.0	0.0 - 0.1
Specimen RU-15						
All Method	24	41.87	24.62	58.8	27.4	0.0 - 115.8
Abbott Architect	13	23.44	2.55	10.9	23.3	15.7 - 31.1

Syphilis Serology—Qualitative: VDRL Slide

<u>Method</u>	Specimen SY-11			Specimen SY-12			Specimen SY-13		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>
ALL METHODS	41	-	2	-	-	43	41	-	2
Abbott Architect	2	-	-	-	-	2	2	-	-
BioSystems	1	-	-	-	-	1	1	-	-
Human	1	-	-	-	-	1	1	-	-
Omega Diagnostics	1	-	-	-	-	1	1	-	-
Plasmatec	3	-	-	-	-	3	3	-	-
SPINREACT	1	-	1	-	-	2	1	-	1
Standard Diagnostics	1	-	-	-	-	1	1	-	-
Wiener Lab	27	-	1	-	-	28	27	-	1

<u>Method</u>	Specimen SY-14			Specimen SY-15		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>
ALL METHODS	-	-	43	42	-	1
Abbott Architect	-	-	2	2	-	-
BioSystems	-	-	1	1	-	-
Human	-	-	1	1	-	-
Omega Diagnostics	-	-	1	1	-	-
Plasmatec	-	-	3	3	-	-
SPINREACT	-	-	2	1	-	1
Standard Diagnostics	-	-	1	1	-	-
Wiener Lab	-	-	28	28	-	-

Syphilis Serology—Quantitative: VDRL Slide Titer

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

ALL METHODS	-	-	2	10	17	5	1	-	2
Omega Diagnostics	-	-	-	1	-	-	-	-	-
Plasmatec	-	-	-	1	1	1	-	-	-
SPINREACT	-	-	-	-	-	-	1	-	-
Wiener Lab	-	-	2	6	15	4	-	-	1

Specimen SY-12

ALL METHODS	-	-	-	-	-	-	-	-	37
Omega Diagnostics	-	-	-	-	-	-	-	-	1
Plasmatec	-	-	-	-	-	-	-	-	3
SPINREACT	-	-	-	-	-	-	-	-	1
Wiener Lab	-	-	-	-	-	-	-	-	28

Specimen SY-13

ALL METHODS	-	3	21	8	2	1	-	-	2
Omega Diagnostics	-	-	1	-	-	-	-	-	-
Plasmatec	-	-	2	-	1	-	-	-	-
SPINREACT	-	-	-	-	-	1	-	-	-
Wiener Lab	-	3	16	8	-	-	-	-	1

Syphilis Serology—Quantitative: VDRL Slide Titer

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

ALL METHODS	-	-	-	-	-	-	-	-	37
Omega Diagnostics	-	-	-	-	-	-	-	-	1
Plasmatec	-	-	-	-	-	-	-	-	3
SPINREACT	-	-	-	-	-	-	-	-	1
Wiener Lab	-	-	-	-	-	-	-	-	28

Specimen SY-15

ALL METHODS	-	6	19	10	-	1	-	-	1
Omega Diagnostics	-	-	-	1	-	-	-	-	-
Plasmatec	-	-	2	1	-	-	-	-	-
SPINREACT	-	-	-	-	-	1	-	-	-
Wiener Lab	-	6	15	7	-	-	-	-	-

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	18	-	-	18	17	1
Abbott Architect	2	-	-	2	2	-
Biokit	1	-	-	1	1	-
Human	1	-	-	1	-	1
Omega Diagnostics	1	-	-	1	1	-
Plasmatec	4	-	-	4	4	-
Serodia	2	-	-	2	2	-
SPINREACT	1	-	-	1	1	-
Wiener Lab	1	-	-	1	1	-

	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	18	16	2
Abbott Architect	-	2	2	-
Biokit	-	1	1	-
Human	-	1	-	1
Omega Diagnostics	-	1	1	-
Plasmatec	-	4	4	-
Serodia	-	2	2	-
SPINREACT	-	1	1	-
Wiener Lab	-	1	1	-

Syphilis Serology—Qualitative: *Treponema pallidum* Antibodies

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	47	-	-	47	47	-
Abbott Architect	10	-	-	10	10	-
bioMerieux	1	-	-	1	1	-
Human	1	-	-	1	1	-
Plasmatec	2	-	-	2	2	-
Roche cobas 6000 / c 501	1	-	-	1	1	-
Roche cobas e 411	2	-	-	2	2	-
Serodia	13	-	-	13	13	-
Siemens ADVIA Centaur	1	-	-	1	1	-
SPINREACT	2	-	-	2	2	-
Standard Diagnostics	2	-	-	2	2	-
Wiener Lab	1	-	-	1	1	-

	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	47	47	-
Abbott Architect	-	10	10	-
bioMerieux	-	1	1	-
Human	-	1	1	-
Plasmatec	-	2	2	-
Roche cobas 6000 / c 501	-	1	1	-
Roche cobas e 411	-	2	2	-
Serodia	-	13	13	-
Siemens ADVIA Centaur	-	1	1	-
SPINREACT	-	2	2	-
Standard Diagnostics	-	2	2	-
Wiener Lab	-	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	87	1	-	88	86	2
Abbott Architect - Total	1	-	-	1	1	-
Becton Dickinson	1	-	-	1	1	-
bioMerieux	5	-	-	5	5	-
BioSystems	14	-	-	14	13	1
Human	8	-	-	8	8	-
Omega Diagnostics	14	-	-	14	14	-
Plasmatec	17	-	-	17	17	-
Pulse Scientific	1	-	-	1	1	-
SPINREACT	20	1	-	21	20	1
Standard Diagnostics	2	-	-	2	2	-
Wiener Lab	1	-	-	1	1	-

	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	88	85	3
Abbott Architect - Total	-	1	1	-
Becton Dickinson	-	1	1	-
bioMerieux	-	5	5	-
BioSystems	-	14	13	1
Human	-	8	7	1
Omega Diagnostics	-	14	14	-
Plasmatec	-	17	17	-
Pulse Scientific	-	1	1	-
SPINREACT	-	21	20	1
Standard Diagnostics	-	2	2	-
Wiener Lab	-	1	1	-

Syphilis Serology—Quantitative: RPR (Titer)

<u>Specimen/Method</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>	<u>N/A</u> <u>(Neg)</u>
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Specimen SY-11

ALL METHODS	-	4	25	34	6	2	-	1	2
Becton Dickinson	-	-	-	1	-	-	-	-	-
bioMerieux	-	-	3	-	-	-	-	-	1
BioSystems	-	1	5	5	1	-	-	-	-
Human	-	2	3	3	-	-	-	-	-
Omega Diagnostics	-	-	3	5	2	-	-	1	1
Plasmatec	-	-	4	7	1	-	-	-	-
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	1	6	10	-	2	-	-	-
Wiener Lab	-	-	-	-	1	-	-	-	-

Specimen SY-12

ALL METHODS	-	-	-	-	-	-	-	-	74
Becton Dickinson	-	-	-	-	-	-	-	-	1
bioMerieux	-	-	-	-	-	-	-	-	4
BioSystems	-	-	-	-	-	-	-	-	12
Human	-	-	-	-	-	-	-	-	8
Omega Diagnostics	-	-	-	-	-	-	-	-	12
Plasmatec	-	-	-	-	-	-	-	-	12
Pulse Scientific	-	-	-	-	-	-	-	-	1
SPINREACT	-	-	-	-	-	-	-	-	19
Wiener Lab	-	-	-	-	-	-	-	-	1

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

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

ALL METHODS	10	40	13	4	2	2	-	-	3
Becton Dickinson	-	1	-	-	-	-	-	-	-
bioMerieux	1	2	-	-	-	-	-	-	1
BioSystems	1	7	3	-	-	-	-	-	1
Human	2	6	-	-	-	-	-	-	-
Omega Diagnostics	1	6	1	1	1	1	-	-	1
Plasmatec	2	6	3	1	-	-	-	-	-
Pulse Scientific	-	-	-	-	-	1	-	-	-
SPINREACT	3	9	5	1	1	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-	-

Specimen SY-14

ALL METHODS	-	-	-	-	-	-	-	-	74
Becton Dickinson	-	-	-	-	-	-	-	-	1
bioMerieux	-	-	-	-	-	-	-	-	4
BioSystems	-	-	-	-	-	-	-	-	12
Human	-	-	-	-	-	-	-	-	8
Omega Diagnostics	-	-	-	-	-	-	-	-	12
Plasmatec	-	-	-	-	-	-	-	-	12
Pulse Scientific	-	-	-	-	-	-	-	-	1
SPINREACT	-	-	-	-	-	-	-	-	19
Wiener Lab	-	-	-	-	-	-	-	-	1

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

<u>Specimen/Method</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>	<u>N/A</u> <u>(Neg)</u>
Specimen SY-15									
ALL METHODS	12	42	10	1	4	1	-	-	4
Becton Dickinson	-	1	-	-	-	-	-	-	-
bioMerieux	1	2	-	-	-	-	-	-	1
BioSystems	2	6	2	-	1	-	-	-	1
Human	3	3	1	-	-	-	-	-	1
Omega Diagnostics	2	6	1	-	1	1	-	-	1
Plasmatec	-	9	3	-	-	-	-	-	-
Pulse Scientific	-	-	-	-	1	-	-	-	-
SPINREACT	3	12	2	1	1	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-	-

Viral Markers – Anti-HBc (IgM)

Specimen VM-11				Specimen VM-12			Specimen VM-13		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	28	27	1	-	56	-	-	56	-
Abbott Architect	21	2	-	-	23	-	-	23	-
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-	-	2	-
bioMerieux Vidas, Mini Vidas	2	-	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	15	-	-	15	-	-	15	-
Roche cobas e 411	-	6	-	-	6	-	-	6	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	-	1	-
Roche Modular Analytics	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	2	-	-	-	2	-	-	2	-
VITROS 3600/4600/5600	-	1	1	-	2	-	-	2	-
VITROS Eci	-	1	-	-	1	-	-	1	-

Specimen VM-14				Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	55	-	1	55	-
Abbott Architect	1	22	-	1	22	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-
bioMerieux Vidas, Mini Vidas	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	15	-	-	15	-
Roche cobas e 411	-	6	-	-	6	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-
Roche Modular Analytics	-	1	-	-	1	-
Siemens ADVIA Centaur	-	2	-	-	2	-
VITROS 3600/4600/5600	-	2	-	-	2	-
VITROS Eci	-	1	-	-	1	-

Viral Markers – Anti-HBc (Total / IgG)

Specimen VM-11				Specimen VM-12			Specimen VM-13		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	77	-	-	1	76	-	-	77	-
Abbott Architect	37	-	-	-	37	-	-	37	-
Abbott Architect - Total	1	-	-	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-	-	2	-
bioMerieux Vidas, Mini Vidas	2	-	-	1	1	-	-	2	-
DiaSorin	2	-	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	15	-	-	-	15	-	-	15	-
Roche cobas e 411	5	-	-	-	5	-	-	5	-
Roche Modular Analytics	3	-	-	-	3	-	-	3	-
Siemens ADVIA Centaur	4	-	-	-	4	-	-	4	-
VITROS 3600/4600/5600	3	-	-	-	3	-	-	3	-
VITROS ECI	1	-	-	-	1	-	-	1	-

Specimen VM-14				Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	74	3	-	77	-	-
Abbott Architect	35	2	-	37	-	-
Abbott Architect - Total	1	-	-	1	-	-
Beckman ACCESS / 2 / Dxl	2	-	-	2	-	-
bioMerieux Vidas, Mini Vidas	1	1	-	2	-	-
DiaSorin	2	-	-	2	-	-
Roche cobas 6000 / e 601	15	-	-	15	-	-
Roche cobas e 411	5	-	-	5	-	-
Roche Modular Analytics	3	-	-	3	-	-
Siemens ADVIA Centaur	4	-	-	4	-	-
VITROS 3600/4600/5600	3	-	-	3	-	-
VITROS ECI	1	-	-	1	-	-

Viral Markers – Anti-HIV

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	185	2	1	186	-	184	3	-
Abbott Architect	-	65	-	-	65	-	65	-	-
Abbott Architect - Total	-	1	-	-	1	-	1	-	-
Alere Determine HIV 1/2									
Ag/Ab Combo	-	3	-	-	3	-	3	-	-
Beckman ACCESS / 2 / Dxl	-	4	-	-	4	-	4	-	-
bioMerieux Vidas, Mini									
Vidas	-	11	-	-	11	-	11	-	-
DiaSorin	-	3	-	-	3	-	3	-	-
Human	-	1	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	38	1	-	39	-	39	-	-
Roche cobas e 411	-	17	1	-	18	-	18	-	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	1	-	-
Roche Modular Analytics	-	5	-	-	5	-	5	-	-
Siemens ADVIA Centaur	-	10	-	-	10	-	9	1	-
Standard Diagnostics	-	5	-	1	4	-	3	2	-
VITROS 3600/4600/5600	-	5	-	-	5	-	5	-	-
VITROS ECI	-	5	-	-	5	-	5	-	-

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	-	187	-	-	187	-
Abbott Architect	-	65	-	-	65	-
Abbott Architect - Total	-	1	-	-	1	-
Alere Determine HIV 1/2						
Ag/Ab Combo	-	3	-	-	3	-
Beckman ACCESS / 2 / Dxl	-	4	-	-	4	-
bioMerieux Vidas, Mini						
Vidas	-	11	-	-	11	-
DiaSorin	-	3	-	-	3	-
Human	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	39	-	-	39	-
Roche cobas e 411	-	18	-	-	18	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-
Roche Modular Analytics	-	5	-	-	5	-
Siemens ADVIA Centaur	-	10	-	-	10	-
Standard Diagnostics	-	5	-	-	5	-
VITROS 3600/4600/5600	-	5	-	-	5	-
VITROS ECI	-	5	-	-	5	-

Viral Markers – Anti-HAV (IgM)

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	71	-	1	70	-	2	69	-
Abbott Architect	-	28	-	-	28	-	-	28	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-	-	1	-
bioMerieux Vidas, Mini	-	4	-	-	4	-	-	4	-
Roche cobas 6000 / e 601	-	20	-	-	20	-	1	19	-
Roche cobas e 411	-	8	-	1	7	-	1	7	-
Roche Modular Analytics	-	3	-	-	3	-	-	3	-
Siemens ADVIA Centaur	-	5	-	-	5	-	-	5	-
Standard Diagnostics	-	1	-	-	1	-	-	1	-
VITROS ECI	-	1	-	-	1	-	-	1	-

	Specimen VM-14			Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	71	-	1	70	-
Abbott Architect	-	28	-	-	28	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-
bioMerieux Vidas, Mini	-	4	-	-	4	-
Roche cobas 6000 / e 601	-	20	-	-	20	-
Roche cobas e 411	-	8	-	1	7	-
Roche Modular Analytics	-	3	-	-	3	-
Siemens ADVIA Centaur	-	5	-	-	5	-
Standard Diagnostics	-	1	-	-	1	-
VITROS ECI	-	1	-	-	1	-

Viral Markers – Anti-HAV (Total/IgG)

Specimen VM-11				Specimen VM-12			Specimen VM-13		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	65	-	64	2	-	64	2	-
Abbott Architect	-	28	-	27	1	-	28	-	-
Beckman ACCESS / 2 / Dxl	-	1	-	1	-	-	1	-	-
bioMerieux Vidas, Mini									
Vidas	-	4	-	4	-	-	4	-	-
Roche cobas 6000 / e 601	1	15	-	16	-	-	15	1	-
Roche cobas e 411	-	4	-	4	-	-	4	-	-
Roche Elecsys 1010 / 2010	-	2	-	2	-	-	2	-	-
Roche Modular Analytics	-	2	-	2	-	-	2	-	-
Siemens ADVIA Centaur	-	5	-	5	-	-	5	-	-
Standard Diagnostics	-	1	-	-	1	-	-	1	-
VITROS 3600/4600/5600	-	1	-	1	-	-	1	-	-
VITROS ECI	-	1	-	1	-	-	1	-	-

Specimen VM-14				Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	65	-	64	1	1
Abbott Architect	-	28	-	27	-	1
Beckman ACCESS / 2 / Dxl	-	1	-	1	-	-
bioMerieux Vidas, Mini						
Vidas	-	4	-	4	-	-
Roche cobas 6000 / e 601	1	15	-	16	-	-
Roche cobas e 411	-	4	-	4	-	-
Roche Elecsys 1010 / 2010	-	2	-	2	-	-
Roche Modular Analytics	-	2	-	2	-	-
Siemens ADVIA Centaur	-	5	-	5	-	-
Standard Diagnostics	-	1	-	-	1	-
VITROS 3600/4600/5600	-	1	-	1	-	-
VITROS ECI	-	1	-	1	-	-

Viral Markers – HBeAg

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	45	-	-	45	-	-	45	-
Abbott Architect	-	17	-	-	17	-	-	17	-
bioMerieux Vidas, Mini									
Vidas	-	2	-	-	2	-	-	2	-
DiaSorin	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	14	-	-	14	-	-	14	-
Roche cobas e 411	-	4	-	-	4	-	-	4	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	-	1	-
Roche Modular Analytics	-	2	-	-	2	-	-	2	-
Siemens ADVIA Centaur	-	3	-	-	3	-	-	3	-

	Specimen VM-14			Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	45	-	8	37	-
Abbott Architect	-	17	-	3	14	-
bioMerieux Vidas, Mini						
Vidas	-	2	-	-	2	-
DiaSorin	-	2	-	2	-	-
Roche cobas 6000 / e 601	-	14	-	-	14	-
Roche cobas e 411	-	4	-	-	4	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-
Roche Modular Analytics	-	2	-	-	2	-
Siemens ADVIA Centaur	-	3	-	3	-	-

Viral Markers – Anti-HBs

Specimen VM-11				Specimen VM-12			Specimen VM-13		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	4	124	-	126	2	-	127	1	-
Abbott Architect	-	48	-	47	1	-	48	-	-
Beckman ACCESS / 2 / Dxl	3	-	-	3	-	-	3	-	-
bioMerieux Vidas, Mini									
Vidas	-	4	-	4	-	-	4	-	-
DiaSorin	1	-	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	33	-	33	-	-	33	-	-
Roche cobas e 411	-	12	-	12	-	-	12	-	-
Roche Elecsys 1010 / 2010	-	2	-	2	-	-	2	-	-
Roche Modular Analytics	-	3	-	3	-	-	3	-	-
Siemens ADVIA Centaur	-	8	-	8	-	-	8	-	-
VITROS 3600/4600/5600	-	6	-	6	-	-	6	-	-
VITROS Eci	-	3	-	3	-	-	3	-	-

Specimen VM-14				Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	127	-	1	2	126	-
Abbott Architect	48	-	-	-	48	-
Beckman ACCESS / 2 / Dxl	3	-	-	-	3	-
bioMerieux Vidas, Mini						
Vidas	4	-	-	-	4	-
DiaSorin	1	-	-	1	-	-
Roche cobas 6000 / e 601	32	-	1	-	33	-
Roche cobas e 411	12	-	-	-	12	-
Roche Elecsys 1010 / 2010	2	-	-	-	2	-
Roche Modular Analytics	3	-	-	-	3	-
Siemens ADVIA Centaur	8	-	-	-	8	-
VITROS 3600/4600/5600	6	-	-	-	6	-
VITROS Eci	3	-	-	-	3	-

Viral Markers – HBsAg

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	158	21	3	7	175	-	2	179	-
Abbott Architect	60	1	1	1	61	-	1	61	-
Abbott Architect - Total	1	-	-	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	4	-	-	4	-	-	-	4	-
bioMerieux Vidas, Mini Vidas	6	-	-	-	6	-	-	6	-
DiaSorin	2	-	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	35	-	2	-	37	-	-	37	-
Roche cobas e 411	20	1	-	2	19	-	1	20	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-	-	1	-
Roche Modular Analytics	4	-	-	-	4	-	-	4	-
Siemens ADVIA Centaur	10	-	-	-	10	-	-	10	-
Standard Diagnostics	-	8	-	-	8	-	-	8	-
VITROS 3600/4600/5600	6	-	-	-	6	-	-	6	-
VITROS ECI	5	1	-	-	6	-	-	5	-

	Specimen VM-14			Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	138	39	4	181	1	-
Abbott Architect	59	1	2	62	-	-
Beckman ACCESS / 2 / Dxl	1	-	-	1	-	-
Bio-Rad Evolis	-	4	-	4	-	-
bioMerieux Vidas, Mini Vidas	5	1	-	6	-	-
DiaSorin	2	-	-	2	-	-
Roche cobas 6000 / e 601	33	2	2	37	-	-
Roche cobas e 411	20	1	-	21	-	-
Roche Elecsys 1010 / 2010	1	-	-	1	-	-
Roche Modular Analytics	4	-	-	4	-	-
Siemens ADVIA Centaur	10	-	-	10	-	-
Standard Diagnostics	-	8	-	7	1	-
VITROS 3600/4600/5600	-	6	-	6	-	-
VITROS ECI	-	5	-	6	-	-

Viral Markers – Anti-HCV

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	164	-	1	164	-	45	117	3
Abbott Architect	-	64	-	-	64	-	-	64	-
Abbott Architect - Total	-	1	-	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	3	-	-	3	-	-	3	-
bioMerieux Vidas, Mini Vidas	-	4	-	-	4	-	-	4	-
DiaSorin	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	33	-	-	33	-	29	2	2
Roche cobas e 411	1	16	-	1	16	-	13	3	1
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	1	-	-
Roche Modular Analytics	-	3	-	-	3	-	1	2	-
Siemens ADVIA Centaur	-	9	-	-	9	-	-	9	-
Standard Diagnostics	-	5	-	-	5	-	-	5	-
VITROS 3600/4600/5600	-	6	-	-	6	-	-	6	-
VITROS ECI	-	5	-	-	5	-	-	5	-

	Specimen VM-14			Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	163	2	-	1	164	-
Abbott Architect	64	-	-	-	64	-
Abbott Architect - Total	1	-	-	-	1	-
Beckman ACCESS / 2 / Dxl	3	-	-	-	3	-
bioMerieux Vidas, Mini Vidas	4	-	-	-	4	-
DiaSorin	2	-	-	-	2	-
Roche cobas 6000 / e 601	32	1	-	1	32	-
Roche cobas e 411	17	-	-	-	17	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-
Roche Modular Analytics	2	1	-	-	3	-
Siemens ADVIA Centaur	9	-	-	-	9	-
Standard Diagnostics	5	-	-	-	5	-
VITROS 3600/4600/5600	6	-	-	-	6	-
VITROS ECI	5	-	-	-	5	-

Toxoplasma gondii Antibody (IgG) - Qualitative

<u>Method</u>	Specimen TOX-5		Specimen TOX-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	22	22	-
Abbott Architect	-	11	11	-
Beckman ACCESS / 2 / Dxl	-	1	1	-
bioMerieux Vidas, Mini Vidas	-	2	2	-
Roche cobas 6000 / e 601	-	3	3	-
Roche cobas e 411	-	2	2	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen TOX-5						
All Method	23	0.489	1.001	204.7	0.30	0.00 - 2.49
Abbott Architect	12	0.383	0.111	29.1	0.40	0.16 - 0.61
Roche cobas 6000 / e 601	4	0.130	0.001	0.0	0.13	0.12 - 0.14
Roche cobas e 411	3	0.140	0.017	12.4	0.13	0.10 - 0.18
Specimen TOX-6						
All Method	21	569.681	318.511	55.9	650.00	0.00 - 1206.71
Abbott Architect	12	510.208	335.845	65.8	477.60	0.00 - 1181.90
Roche cobas 6000 / e 601	3	695.933	117.160	16.8	650.00	461.61 - 930.26
Roche cobas e 411	2	-	-	-	878.50	0.00 - 1206.71

Toxoplasma gondii Antibody (IgM) - Qualitative

<u>Method</u>	Specimen TOX-5		Specimen TOX-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	24	24	1
Abbott Architect	1	11	11	1
Beckman ACCESS / 2 / Dxl	-	1	1	-
bioMerieux Vidas, Mini Vidas	-	2	2	-
Roche cobas 6000 / e 601	-	4	4	-
Roche cobas e 411	-	3	3	-

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	19	0.137	0.093	67.8	0.10	0.00 - 0.33
Abbott Architect	9	0.098	0.058	59.8	0.09	0.00 - 0.22
Roche cobas 6000 / e 601	3	0.250	0.062	25.0	0.23	0.12 - 0.38
Specimen TOX-6						
All Method	19	9.822	4.931	50.2	6.64	0.00 - 19.69
Abbott Architect	9	6.322	0.668	10.6	6.41	4.98 - 7.66
Roche cobas 6000 / e 601	3	15.140	0.772	5.1	15.54	13.59 - 16.69

Cytomegalovirus (CMV) Antibodies (IgG) - Qualitative

<u>Method</u>	<u>Specimen CMV-5</u>		<u>Specimen CMV-6</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	1	15	-
Abbott Architect	11	-	11	-
bioMerieux Vidas, Mini Vidas	1	-	1	-
Roche cobas 6000 / e 601	2	-	2	-
Roche cobas e 411	-	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	18.801	14.607	77.7	24.40	0.00 - 48.02
Abbott Architect	10	30.190	4.875	16.1	30.25	20.43 - 39.95
Specimen CMV-6						
All Method	17	38.109	16.060	42.1	42.55	5.98 - 70.23
Abbott Architect	10	46.700	8.618	18.5	49.50	29.46 - 63.94

Cytomegalovirus (CMV) Antibodies (IgM) - Qualitative

<u>Method</u>	<u>Specimen CMV-5</u>		<u>Specimen CMV-6</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	-	18
Abbott Architect	-	11	-	11
bioMerieux Vidas, Mini Vidas	-	1	-	1
Roche cobas 6000 / e 601	-	3	-	3
Roche cobas e 411	-	2	-	2
Siemens Immulite 2000	-	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	12	0.197	0.066	33.3	0.21	0.06 - 0.33
Abbott Architect	8	0.215	0.035	16.3	0.22	0.14 - 0.29
Specimen CMV-6						
All Method	12	0.158	0.054	34.3	0.16	0.04 - 0.27
Abbott Architect	8	0.160	0.043	26.7	0.16	0.07 - 0.25

CK-MB - Quantitative (U/L)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen CK-11						
All Method	11	52.98	11.06	20.9	48.8	19.8 - 86.2
Roche cobas 6000 / c 501	8	52.76	11.74	22.2	49.1	17.5 - 88.0
Specimen CK-12						
All Method	11	18.56	2.89	15.6	17.9	9.8 - 27.3
Roche cobas 6000 / c 501	8	18.75	3.23	17.2	18.0	9.0 - 28.5
Specimen CK-13						
All Method	11	7.83	0.57	7.3	7.9	6.1 - 9.6
Roche cobas 6000 / c 501	8	7.78	0.32	4.1	7.9	6.8 - 8.8
Specimen CK-14						
All Method	11	27.58	5.20	18.9	28.6	11.9 - 43.2
Roche cobas 6000 / c 501	8	26.78	4.58	17.1	27.8	13.0 - 40.6
Specimen CK-15						
All Method	11	85.79	19.19	22.4	85.7	28.2 - 143.4
Roche cobas 6000 / c 501	8	82.46	16.95	20.6	88.0	31.6 - 133.4

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