

# **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-M1**



Total Commitment to Education and Service  
Provided by ACP, Inc.

# Table of Contents

<b>Evaluation Criteria</b> .....	<b>4</b>
<b>Hematology</b>	
<b>Sedimentation Rate</b> .....	<b>5</b>
<b>Hematology with 5-part Automated Differential (CL Samples – Module 223)</b> .....	<b>5</b>
White Blood Cell Count .....	5
Red Blood Cell Count .....	6
Hemoglobin.....	6
Hematocrit .....	7
Platelet Count .....	7
Automated Differential .....	8
<b>Blood Bank</b>	
<b>ABO Group</b> .....	11
<b>Rh Factor (D Type)</b> .....	11
<b>Unexpected Antibody Detection</b> .....	12
<b>Antibody Identification</b> .....	12
<b>Compatibility Testing</b> .....	13
<b>Coagulation</b>	
<b>Prothrombin Time</b> .....	14
International Normalized Ratio (INR) .....	16
<b>Activated Partial Thromboplastin Time</b> .....	17
<b>Fibrinogen</b> .....	19
<b>Prothrombin Time (XS Samples)</b> .....	20
International Normalized Ratio (INR) (XS Samples) .....	21
<b>Urinalysis</b>	
<b>Urinalysis Dipstick</b> .....	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
<b>Urine hCG</b> .....	32
<b>Microbiology</b>	
<b>Miscellaneous Cultures</b> .....	33
<b>Antimicrobial Susceptibility Testing</b> .....	35
<b>Parasitology (PA Specimens)</b> .....	37
<b>Parasitology (FP Specimens)</b> .....	39
<b>Immunology</b>	
<b>Antinuclear Antibody</b> .....	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
<b>Syphilis Serology</b> .....	52
VDRL Slide.....	52
VDRL Slide (Titer).....	53
MHA-TP.....	55
TPA.....	56
RPR.....	57
RPR (Titer).....	58
<b>Viral Markers</b> .....	61
Anti-HBc (IgM).....	61
Anti-HBc (Total/IgG).....	62
Anti-HIV.....	63
Anti-HAV (IgM).....	65
Anti-HAV (Total/IgG).....	66
HBeAg.....	67
Anti-HBs.....	68
HBsAg.....	69
Anti-HCV.....	70
<b>Toxoplasma gondii</b> .....	71
Qualitative (IgG).....	71
Quantitative (IgG).....	71
Qualitative (IgM).....	72
Quantitative (IgM).....	72
<b>Cytomegalovirus (CMV)</b> .....	73
Qualitative (IgG).....	73
Quantitative (IgG).....	73
Qualitative (IgM).....	74
Quantitative (IgM).....	74

## Chemistry

<b>Bilirubin, Neonatal (Total)</b> .....	75
<b>Bilirubin, Direct (NB Specimens)</b> .....	75
<b>Glycohemoglobin (GH Specimens)</b> .....	76
<b>Glucose, Whole Blood (WBG Specimens)</b> .....	76
<b>Folate</b> .....	78
<b>CK-MB</b> .....	78

## 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	$\pm 3$ SD	International Normalized Ratio (INR)	$\pm 20\%$
Bilirubin, Neonatal (Total)	$\pm 0.4$ mg/dL or $20\% *$	Platelet Count	$\pm 25\%$
Bilirubin, Direct	$\pm 2$ SD	Prothrombin Time	$\pm 15\%$
CK-MB (U/L)	$\pm 3$ SD	Red Blood Cell Count	$\pm 6\%$
Cytomegalovirus	$\pm 3$ SD	Rubella	$\pm 3$ SD
Fibrinogen	$\pm 20\%$	Sedimentation Rate	$\pm 3$ SD
Folate	$\pm 1$ ng/mL or $\pm 30\%*$	Specific Gravity	$\pm 0.010$
Glucose, Whole Blood	$\pm 12$ mg/dL or $\pm 20\%*$	Toxoplasma	$\pm 2$ 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-1						Specimen ES-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	148	41.3	9.2	22.2	39	22 - 60	146	8.2	2.6	32.0	8	2 - 14
All Automated Methods	33	52.1	9.2	17.7	53	33 - 71	33	9.5	3.1	32.9	9	3 - 16
All Dicese Methods	10	55.0	8.8	16.0	56	37 - 73	10	10.3	3.9	38.3	9	2 - 19
All Manual Methods	107	37.8	6.6	17.3	37	24 - 51	105	7.8	2.4	31.1	8	2 - 13
All Vital Diagnostics Methods	16	51.4	9.6	18.7	48	32 - 71	16	8.1	2.0	25.4	8	3 - 13
Vital Diagnostics Excyte M/10	11	47.8	6.0	12.5	46	35 - 60	11	7.6	1.9	25.0	7	3 - 12
Westergren - diluted	83	36.4	4.8	13.2	36	26 - 47	86	7.4	2.3	30.4	7	2 - 12
Westergren - undiluted	18	41.1	8.6	21.0	38	23 - 59	16	9.2	2.1	23.2	10	4 - 14

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

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	13	18.32	1.33	7.2	17.8	15.5 - 21.1	13	2.68	0.47	17.5	2.7	2.2 - 3.1
All Abbott Cell-Dyn Instruments	6	19.60	0.62	3.1	19.4	16.6 - 22.6	6	3.12	0.08	2.4	3.1	2.6 - 3.6
Abbott Cell-Dyn Ruby	6	19.60	0.62	3.1	19.4	16.6 - 22.6	6	3.12	0.08	2.4	3.1	2.6 - 3.6
Orphee Mythic 22	5	17.02	0.28	1.6	17.1	14.4 - 19.6	5	2.25	0.10	4.4	2.3	1.9 - 2.6

  

<u>Instrument</u>	Specimen CL-3						Specimen CL-4					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	13	2.68	0.44	16.6	2.6	2.2 - 3.1	13	7.09	0.63	8.9	7.1	6.0 - 8.2
All Abbott Cell-Dyn Instruments	6	3.10	0.13	4.1	3.2	2.6 - 3.6	6	7.67	0.21	2.7	7.7	6.5 - 8.9
Abbott Cell-Dyn Ruby	6	3.10	0.13	4.1	3.2	2.6 - 3.6	6	7.67	0.21	2.7	7.7	6.5 - 8.9
Orphee Mythic 22	5	2.30	0.01	0.0	2.3	1.9 - 2.7	5	6.53	0.22	3.4	6.6	5.5 - 7.6

  

<u>Instrument</u>	Specimen CL-5					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	13	18.18	1.37	7.6	17.8	15.4 - 21.0
All Abbott Cell-Dyn Instruments	6	19.33	0.81	4.2	19.3	16.4 - 22.3
Abbott Cell-Dyn Ruby	6	19.33	0.81	4.2	19.3	16.4 - 22.3
Orphee Mythic 22	5	16.83	0.61	3.6	16.8	14.3 - 19.4

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

<i><u>Instrument</u></i>	<b>Specimen CL-1</b>						<b>Specimen CL-2</b>					
	<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	13	5.029	0.149	3.0	4.98	4.72 - 5.34	13	2.155	0.052	2.4	2.15	2.02 - 2.29
All Abbott Cell-Dyn Instruments	6	5.133	0.154	3.0	5.10	4.82 - 5.45	6	2.195	0.035	1.6	2.21	2.06 - 2.33
Abbott Cell-Dyn Ruby	6	5.133	0.154	3.0	5.10	4.82 - 5.45	6	2.195	0.035	1.6	2.21	2.06 - 2.33
Orphee Mythic 22	5	4.938	0.079	1.6	4.95	4.64 - 5.24	5	2.124	0.047	2.2	2.14	1.99 - 2.26
<i><u>Instrument</u></i>	<b>Specimen CL-3</b>						<b>Specimen CL-4</b>					
	<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	13	2.158	0.061	2.8	2.16	2.02 - 2.29	13	4.668	0.104	2.2	4.63	4.38 - 4.95
All Abbott Cell-Dyn Instruments	6	2.203	0.049	2.2	2.21	2.07 - 2.34	6	4.735	0.094	2.0	4.74	4.45 - 5.02
Abbott Cell-Dyn Ruby	6	2.203	0.049	2.2	2.21	2.07 - 2.34	6	4.735	0.094	2.0	4.74	4.45 - 5.02
Orphee Mythic 22	5	2.122	0.049	2.3	2.12	1.99 - 2.25	5	4.614	0.095	2.1	4.59	4.33 - 4.90
<i><u>Instrument</u></i>	<b>Specimen CL-5</b>											
	<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	13	4.988	0.113	2.3	5.01	4.68 - 5.29						
All Abbott Cell-Dyn Instruments	6	5.087	0.044	0.9	5.10	4.78 - 5.40						
Abbott Cell-Dyn Ruby	6	5.087	0.044	0.9	5.10	4.78 - 5.40						
Orphee Mythic 22	5	4.878	0.079	1.6	4.85	4.58 - 5.18						

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

<i><u>Instrument</u></i>	<b>Specimen CL-1</b>						<b>Specimen CL-2</b>					
	<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	13	15.80	0.82	5.2	15.4	14.6 - 17.0	13	5.17	0.49	9.4	5.0	4.8 - 5.6
All Abbott Cell-Dyn Instruments	6	16.53	0.58	3.5	16.3	15.3 - 17.7	6	5.65	0.08	1.5	5.6	5.2 - 6.1
Abbott Cell-Dyn Ruby	6	16.53	0.58	3.5	16.3	15.3 - 17.7	6	5.65	0.08	1.5	5.6	5.2 - 6.1
Orphee Mythic 22	5	15.16	0.32	2.1	15.3	14.0 - 16.3	5	4.68	0.18	3.8	4.7	4.3 - 5.1
<i><u>Instrument</u></i>	<b>Specimen CL-3</b>						<b>Specimen CL-4</b>					
	<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	13	5.15	0.48	9.2	5.0	4.7 - 5.6	13	12.55	0.82	6.5	12.8	11.6 - 13.5
All Abbott Cell-Dyn Instruments	6	5.62	0.04	0.7	5.6	5.2 - 6.1	6	13.30	0.14	1.1	13.3	12.3 - 14.3
Abbott Cell-Dyn Ruby	6	5.62	0.04	0.7	5.6	5.2 - 6.1	6	13.30	0.14	1.1	13.3	12.3 - 14.3
Orphee Mythic 22	5	4.68	0.19	4.1	4.7	4.3 - 5.1	5	11.90	0.64	5.4	11.9	11.0 - 12.8
<i><u>Instrument</u></i>	<b>Specimen CL-5</b>											
	<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	13	15.61	0.61	3.9	15.5	14.5 - 16.8						
All Abbott Cell-Dyn Instruments	6	16.18	0.16	1.0	16.2	15.0 - 17.4						
Abbott Cell-Dyn Ruby	6	16.18	0.16	1.0	16.2	15.0 - 17.4						
Orphee Mythic 22	5	15.08	0.38	2.5	15.1	14.0 - 16.2						

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

<u>Instrument</u>	<b>Specimen CL-1</b>						<b>Specimen CL-2</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	13	46.31	2.27	4.9	47.9	43.5 - 49.1	13	16.35	0.96	5.9	16.4	15.3 - 17.4
All Abbott Cell-Dyn Instruments	6	44.48	1.98	4.5	43.7	41.8 - 47.2	6	15.57	0.51	3.3	15.6	14.6 - 16.6
Abbott Cell-Dyn Ruby	6	44.48	1.98	4.5	43.7	41.8 - 47.2	6	15.57	0.51	3.3	15.6	14.6 - 16.6
Orphee Mythic 22	5	47.62	0.98	2.1	47.9	44.7 - 50.5	5	17.26	0.68	3.9	17.1	16.2 - 18.3
<b>Specimen CL-3</b>												
All Method	13	16.43	0.91	5.6	16.5	15.4 - 17.5	13	39.49	1.51	3.8	39.4	37.1 - 41.9
All Abbott Cell-Dyn Instruments	6	15.60	0.57	3.6	15.3	14.6 - 16.6	6	38.20	0.93	2.4	37.9	35.9 - 40.5
Abbott Cell-Dyn Ruby	6	15.60	0.57	3.6	15.3	14.6 - 16.6	6	38.20	0.93	2.4	37.9	35.9 - 40.5
Orphee Mythic 22	5	17.24	0.54	3.1	17.0	16.2 - 18.3	5	40.66	1.06	2.6	40.9	38.2 - 43.1
<b>Specimen CL-5</b>												
All Method	13	45.85	1.83	4.0	46.3	43.0 - 48.6						
All Abbott Cell-Dyn Instruments	6	44.22	1.06	2.4	44.5	41.5 - 46.9						
Abbott Cell-Dyn Ruby	6	44.22	1.06	2.4	44.5	41.5 - 46.9						
Orphee Mythic 22	5	46.84	0.73	1.6	46.4	44.0 - 49.7						

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

<u>Instrument</u>	<b>Specimen CL-1</b>						<b>Specimen CL-2</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	13	500.3	20.1	4.0	504	375 - 626	13	97.3	14.0	14.4	96	72 - 122
All Abbott Cell-Dyn Instruments	6	512.2	18.2	3.6	512	384 - 641	6	84.5	3.4	4.0	84	63 - 106
Abbott Cell-Dyn Ruby	6	512.2	18.2	3.6	512	384 - 641	6	84.5	3.4	4.0	84	63 - 106
Orphee Mythic 22	5	492.0	14.9	3.0	488	369 - 615	5	109.6	10.6	9.7	108	82 - 137
<b>Specimen CL-3</b>												
All Method	13	93.8	14.5	15.5	95	70 - 118	13	273.5	11.9	4.4	271	205 - 342
All Abbott Cell-Dyn Instruments	6	81.0	1.8	2.2	82	60 - 102	6	267.3	8.5	3.2	266	200 - 335
Abbott Cell-Dyn Ruby	6	81.0	1.8	2.2	82	60 - 102	6	267.3	8.5	3.2	266	200 - 335
Orphee Mythic 22	5	106.4	12.6	11.9	103	79 - 133	5	280.8	14.6	5.2	279	210 - 351
<b>Specimen CL-5</b>												
All Method	13	493.5	16.2	3.3	497	370 - 617						
All Abbott Cell-Dyn Instruments	6	502.3	11.8	2.4	504	376 - 628						
Abbott Cell-Dyn Ruby	6	502.3	11.8	2.4	504	376 - 628						
Orphee Mythic 22	5	487.0	18.5	3.8	491	365 - 609						

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

<u>Instrument</u>	<b>Specimen CL-1</b>						<b>Specimen CL-2</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	13	74.10	1.06	1.4	74.3	70.9 - 77.3	13	44.47	2.49	5.6	44.0	36.9 - 52.0
All Abbott Cell-Dyn Instruments	6	74.78	0.56	0.7	75.0	73.1 - 76.5	6	46.65	1.12	2.4	46.7	43.2 - 50.1
Abbott Cell-Dyn Ruby	6	74.78	0.56	0.7	75.0	73.1 - 76.5	6	46.65	1.12	2.4	46.7	43.2 - 50.1
Orphee Mythic 22	5	73.60	1.27	1.7	73.7	69.7 - 77.5	5	42.08	1.63	3.9	42.3	37.1 - 47.0
<u>Instrument</u>	<b>Specimen CL-3</b>						<b>Specimen CL-4</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	13	43.45	2.64	6.1	43.9	35.5 - 51.4	13	60.52	1.15	1.9	60.7	57.0 - 64.0
All Abbott Cell-Dyn Instruments	6	45.32	1.21	2.7	45.5	41.6 - 49.0	6	61.37	0.85	1.4	61.6	58.8 - 64.0
Abbott Cell-Dyn Ruby	6	45.32	1.21	2.7	45.5	41.6 - 49.0	6	61.37	0.85	1.4	61.6	58.8 - 64.0
Orphee Mythic 22	5	41.50	2.98	7.2	42.1	32.5 - 50.5	5	59.60	0.90	1.5	59.7	56.9 - 62.3
<u>Instrument</u>	<b>Specimen CL-5</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	13	73.97	1.19	1.6	74.0	70.4 - 77.6						
All Abbott Cell-Dyn Instruments	6	75.00	0.61	0.8	74.8	73.1 - 76.9						
Abbott Cell-Dyn Ruby	6	75.00	0.61	0.8	74.8	73.1 - 76.9						
Orphee Mythic 22	5	73.04	0.88	1.2	73.4	70.4 - 75.7						

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

<u>Instrument</u>	<b>Specimen CL-1</b>						<b>Specimen CL-2</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	13	13.69	2.33	17.0	13.8	6.6 - 20.7	13	33.64	5.04	15.0	32.8	18.5 - 48.8
All Abbott Cell-Dyn Instruments	6	15.93	0.73	4.6	15.9	13.7 - 18.2	6	38.48	1.74	4.5	38.5	33.2 - 43.8
Abbott Cell-Dyn Ruby	6	15.93	0.73	4.6	15.9	13.7 - 18.2	6	38.48	1.74	4.5	38.5	33.2 - 43.8
Orphee Mythic 22	5	11.48	0.67	5.9	11.7	9.4 - 13.5	5	29.06	1.91	6.6	28.8	23.3 - 34.9
<u>Instrument</u>	<b>Specimen CL-3</b>						<b>Specimen CL-4</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	13	33.83	5.54	16.4	33.2	17.2 - 50.5	13	19.56	4.60	23.5	19.3	5.7 - 33.4
All Abbott Cell-Dyn Instruments	6	39.05	2.46	6.3	39.4	31.6 - 46.5	6	23.97	0.93	3.9	23.9	21.1 - 26.8
Abbott Cell-Dyn Ruby	6	39.05	2.46	6.3	39.4	31.6 - 46.5	6	23.97	0.93	3.9	23.9	21.1 - 26.8
Orphee Mythic 22	5	28.70	2.06	7.2	29.1	22.5 - 34.9	5	15.36	2.15	14.0	16.1	8.8 - 21.9
<u>Instrument</u>	<b>Specimen CL-5</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	13	13.69	2.17	15.8	14.1	7.1 - 20.3						
All Abbott Cell-Dyn Instruments	6	15.68	0.82	5.2	15.9	13.2 - 18.2						
Abbott Cell-Dyn Ruby	6	15.68	0.82	5.2	15.9	13.2 - 18.2						
Orphee Mythic 22	5	11.60	0.74	6.4	11.7	9.3 - 13.9						



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

<u>Instrument</u>	<b>Specimen CL-1</b>						<b>Specimen CL-2</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	13	7.95	3.57	44.9	9.6	0.0 - 18.7	13	16.05	6.89	42.9	17.7	0.0 - 36.8
All Abbott Cell-Dyn Instruments	6	4.30	0.44	10.2	4.2	2.9 - 5.7	6	9.13	1.60	17.5	8.5	4.3 - 14.0
Abbott Cell-Dyn Ruby	6	4.30	0.44	10.2	4.2	2.9 - 5.7	6	9.13	1.60	17.5	8.5	4.3 - 14.0
Orphee Mythic 22	5	11.32	0.48	4.2	11.4	9.8 - 12.8	5	22.70	0.92	4.1	22.4	19.9 - 25.5
<u>Instrument</u>	<b>Specimen CL-3</b>						<b>Specimen CL-4</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	13	16.74	7.15	42.7	19.0	0.0 - 38.2	13	10.59	5.19	49.0	12.7	0.0 - 26.2
All Abbott Cell-Dyn Instruments	6	9.67	2.33	24.1	8.9	2.6 - 16.7	6	5.35	0.54	10.0	5.5	3.7 - 7.0
Abbott Cell-Dyn Ruby	6	9.67	2.33	24.1	8.9	2.6 - 16.7	6	5.35	0.54	10.0	5.5	3.7 - 7.0
Orphee Mythic 22	5	23.60	1.67	7.1	22.8	18.5 - 28.7	5	15.60	1.45	9.3	16.3	11.2 - 20.0
<u>Instrument</u>	<b>Specimen CL-5</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	13	8.03	3.55	44.2	9.3	0.0 - 18.7						
All Abbott Cell-Dyn Instruments	6	4.43	0.40	9.0	4.6	3.2 - 5.7						
Abbott Cell-Dyn Ruby	6	4.43	0.40	9.0	4.6	3.2 - 5.7						
Orphee Mythic 22	5	11.56	0.62	5.4	11.3	9.7 - 13.5						

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

<u>Instrument</u>	<b>Specimen CL-1</b>						<b>Specimen CL-2</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	13	3.48	1.17	33.6	3.8	0.0 - 7.0	13	5.52	0.72	13.0	5.3	3.3 - 7.7
All Abbott Cell-Dyn Instruments	6	4.47	0.39	8.8	4.5	3.2 - 5.7	6	5.37	0.48	9.0	5.3	3.9 - 6.9
Abbott Cell-Dyn Ruby	6	4.47	0.39	8.8	4.5	3.2 - 5.7	6	5.37	0.48	9.0	5.3	3.9 - 6.9
Orphee Mythic 22	5	2.44	0.92	37.5	2.9	0.0 - 5.2	5	5.90	0.96	16.3	6.1	3.0 - 8.8
<u>Instrument</u>	<b>Specimen CL-3</b>						<b>Specimen CL-4</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	13	5.52	0.37	6.7	5.5	4.4 - 6.7	13	8.53	1.62	19.0	9.0	3.6 - 13.4
All Abbott Cell-Dyn Instruments	6	5.52	0.24	4.4	5.5	4.7 - 6.3	6	8.20	1.92	23.4	8.8	2.4 - 14.0
Abbott Cell-Dyn Ruby	6	5.52	0.24	4.4	5.5	4.7 - 6.3	6	8.20	1.92	23.4	8.8	2.4 - 14.0
Orphee Mythic 22	5	5.70	0.29	5.1	5.7	4.8 - 6.6	5	8.92	1.51	16.9	9.3	4.3 - 13.5
<u>Instrument</u>	<b>Specimen CL-5</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	13	3.68	0.80	21.9	4.1	1.2 - 6.1						
All Abbott Cell-Dyn Instruments	6	4.30	0.15	3.6	4.3	3.8 - 4.8						
Abbott Cell-Dyn Ruby	6	4.30	0.15	3.6	4.3	3.8 - 4.8						
Orphee Mythic 22	5	2.93	0.53	18.0	3.1	1.3 - 4.6						

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

<u><i>Instrument</i></u>	<b>Specimen CL-1</b>						<b>Specimen CL-2</b>					
	<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>	<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>
All Method	13	0.43	0.15	35.9	0.4	0.0 - 0.9	13	0.46	0.25	54.9	0.4	0.0 - 1.3
All Abbott Cell-Dyn Instruments	6	0.45	0.10	23.3	0.5	0.1 - 0.8	6	0.38	0.19	50.6	0.5	0.0 - 1.0
Abbott Cell-Dyn Ruby	6	0.45	0.10	23.3	0.5	0.1 - 0.8	6	0.38	0.19	50.6	0.5	0.0 - 1.0
Orphee Mythic 22	5	0.36	0.11	31.7	0.4	0.0 - 0.8	5	0.60	0.32	54.0	0.4	0.0 - 1.6
	<b>Specimen CL-3</b>						<b>Specimen CL-4</b>					
All Method	13	0.46	0.31	66.5	0.4	0.0 - 1.4	13	0.39	0.24	62.0	0.3	0.0 - 1.2
All Abbott Cell-Dyn Instruments	6	0.40	0.33	83.7	0.4	0.0 - 1.5	6	0.23	0.15	64.5	0.2	0.0 - 0.7
Abbott Cell-Dyn Ruby	6	0.40	0.33	83.7	0.4	0.0 - 1.5	6	0.23	0.15	64.5	0.2	0.0 - 0.7
Orphee Mythic 22	5	0.56	0.34	61.3	0.4	0.0 - 1.6	5	0.54	0.24	44.6	0.6	0.0 - 1.3
	<b>Specimen CL-5</b>											
All Method	13	0.50	0.22	44.0	0.5	0.0 - 1.2						
All Abbott Cell-Dyn Instruments	6	0.55	0.19	34.0	0.6	0.0 - 1.2						
Abbott Cell-Dyn Ruby	6	0.55	0.19	34.0	0.6	0.0 - 1.2						
Orphee Mythic 22	5	0.42	0.24	56.8	0.3	0.0 - 1.2						

## BLOOD BANK

### ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-1	Group A	23	100%	Acceptable
BB-2	Group B	23	100%	Acceptable
BB-3	Group O	23	100%	Acceptable
BB-4	Group O	23	100%	Acceptable
BB-5	Group A	23	100%	Acceptable

### RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-1	Rh Positive	23	100%	Acceptable
BB-2	Rh Positive	23	100%	Acceptable
BB-3	Rh Negative	23	100%	Acceptable
BB-4	Rh Positive	23	100%	Acceptable
BB-5	Rh Negative	23	100%	Acceptable

## BLOOD BANK

### UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	Unexpected antibody detected	18	100%	Acceptable
AB-2	No unexpected antibody detected	18	100%	Acceptable
AB-3	Unexpected antibody detected	18	100%	Acceptable
AB-4	No unexpected antibody detected	18	88.89%	Acceptable
	Unexpected antibody detected	2	11.11%	
AB-5	No unexpected antibody detected	17	94.44%	Acceptable
	Unexpected antibody detected	1	5.56%	

### ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	Anti-E	11	100%	Acceptable
AB-2	No antibody detected	11	100%	Acceptable
AB-3	Anti-D	11	100%	Acceptable
AB-4	No antibody detected	11	100%	Acceptable
AB-5	No antibody detected	11	100%	Acceptable

## BLOOD BANK

### COMPATIBILITY TESTING

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

Specimen AB-4 is graded by referee consensus.

## Coagulation

### PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	<u>Specimen CG-1</u>						<u>Specimen CG-2</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	52	36.20	6.15	17.0	35.9	30.7 - 41.7	52	12.06	1.65	13.7	11.6	10.2 - 13.9
Dade Innovin												
Dade Behring BFT II	5	34.78	2.53	7.3	35.8	29.5 - 40.0	5	10.00	0.42	4.2	9.9	8.5 - 11.5
Sysmex CA-500/600 series	14	31.94	1.23	3.8	32.1	27.1 - 36.8	14	10.57	0.29	2.8	10.5	8.9 - 12.2
All Coagulation Instruments	20	32.43	2.03	6.3	32.2	27.5 - 37.3	20	10.44	0.38	3.6	10.5	8.8 - 12.1
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	7	43.01	2.02	4.7	43.3	36.5 - 49.5	7	14.14	0.74	5.2	14.1	12.0 - 16.3
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	40.43	2.86	7.1	41.1	34.3 - 46.5	5	13.47	0.23	1.7	13.6	11.4 - 15.5
Diagnostica Stago STart Max	5	43.44	1.35	3.1	44.2	36.9 - 50.0	5	14.17	0.15	1.1	14.2	12.0 - 16.3
All Coagulation Instruments	10	42.54	2.27	5.3	42.8	36.1 - 49.0	10	13.96	0.38	2.7	14.1	11.8 - 16.1
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	39.94	2.82	7.1	40.0	33.9 - 46.0	5	11.58	0.37	3.2	11.7	9.8 - 13.4

**PROTHROMBIN TIME (seconds)**

<u>Reagent/Instrument</u>	<b>Specimen CG-3</b>						<b>Specimen CG-4</b>					
	<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	24.84	3.80	15.3	24.5	21.1 - 28.6	52	12.44	1.72	13.8	11.7	10.5 - 14.4
Dade Innovin												
Dade Behring BFT II	5	23.53	2.33	9.9	23.8	19.9 - 27.1	5	10.55	0.55	5.2	10.5	8.9 - 12.2
Sysmex CA-500/600 series	14	21.74	0.78	3.6	21.9	18.4 - 25.0	14	11.11	0.24	2.2	11.0	9.4 - 12.8
All Coagulation Instruments	20	22.05	1.41	6.4	21.9	18.7 - 25.4	20	10.96	0.39	3.5	11.0	9.3 - 12.6
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	7	28.90	1.57	5.4	28.8	24.5 - 33.3	7	14.80	0.52	3.5	15.0	12.5 - 17.1
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	27.20	1.32	4.9	27.7	23.1 - 31.3	5	13.80	0.10	0.7	13.8	11.7 - 15.9
Diagnostica Stago STart Max	5	30.31	0.94	3.1	30.2	25.7 - 34.9	5	14.81	0.28	1.9	14.9	12.5 - 17.1
All Coagulation Instruments	10	29.38	1.80	6.1	30.0	24.9 - 33.8	10	14.51	0.54	3.7	14.7	12.3 - 16.7
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	26.68	1.51	5.7	26.9	22.6 - 30.7	5	11.38	0.51	4.5	11.3	9.6 - 13.1

<u>Reagent/Instrument</u>	<b>Specimen CG-5</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	52	15.55	2.07	13.3	15.1	13.2 - 17.9
Dade Innovin						
Dade Behring BFT II	5	14.03	1.15	8.2	14.2	11.9 - 16.2
Sysmex CA-500/600 series	14	13.79	0.42	3.0	13.8	11.7 - 15.9
All Coagulation Instruments	20	13.82	0.61	4.4	13.8	11.7 - 15.9
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	7	18.20	1.40	7.7	18.6	15.4 - 21.0
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STA Compact	5	16.57	0.21	1.3	16.5	14.0 - 19.1
Diagnostica Stago STart Max	5	18.31	0.62	3.4	18.4	15.5 - 21.1
All Coagulation Instruments	10	17.79	0.99	5.6	17.9	15.1 - 20.5
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	15.08	1.14	7.6	14.7	12.8 - 17.4

**PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)**

<b><u>Reagent/Instrument</u></b>	<b>Specimen CG-1</b>						<b>Specimen CG-2</b>					
	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
All Method	52	3.61	0.59	16.2	3.5	2.8 - 4.4	52	1.03	0.08	7.9	1.0	0.8 - 1.3
Dade Innovin												
Dade Behring BFT II	5	3.35	0.17	5.2	3.4	2.6 - 4.1	5	1.10	0.01	0.0	1.1	0.8 - 1.4
Sysmex CA-500/600 series	14	3.22	0.20	6.1	3.2	2.5 - 3.9	14	1.04	0.06	6.1	1.0	0.8 - 1.3
All Coagulation Instruments	20	3.24	0.23	7.2	3.2	2.5 - 3.9	20	1.04	0.07	6.5	1.1	0.8 - 1.3
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	7	4.20	0.21	5.1	4.2	3.3 - 5.1	7	1.08	0.07	6.6	1.1	0.8 - 1.3
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	4.20	0.46	10.9	4.3	3.3 - 5.1	5	0.97	0.06	6.0	1.0	0.7 - 1.2
Diagnostica Stago STart Max	5	4.25	0.18	4.1	4.3	3.4 - 5.1	5	1.10	0.01	0.0	1.1	0.8 - 1.4
All Coagulation Instruments	10	4.23	0.27	6.4	4.3	3.3 - 5.1	10	1.06	0.07	6.9	1.1	0.8 - 1.3
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	3.50	0.45	12.8	3.4	2.8 - 4.2	5	0.98	0.08	8.5	1.0	0.7 - 1.2

  

<b><u>Reagent/Instrument</u></b>	<b>Specimen CG-3</b>						<b>Specimen CG-4</b>					
	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
All Method	52	2.33	0.32	13.9	2.3	1.8 - 2.8	52	1.08	0.09	8.7	1.1	0.8 - 1.3
Dade Innovin												
Dade Behring BFT II	5	2.35	0.21	8.9	2.4	1.8 - 2.9	5	1.15	0.06	5.0	1.2	0.9 - 1.4
Sysmex CA-500/600 series	14	2.17	0.13	5.8	2.2	1.7 - 2.7	14	1.09	0.06	5.6	1.1	0.8 - 1.4
All Coagulation Instruments	20	2.20	0.17	7.7	2.2	1.7 - 2.7	20	1.10	0.06	5.9	1.1	0.8 - 1.4
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	7	2.59	0.15	5.6	2.6	2.0 - 3.2	7	1.15	0.05	4.6	1.2	0.9 - 1.4
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	2.50	0.26	10.6	2.6	2.0 - 3.0	5	1.03	0.06	5.6	1.0	0.8 - 1.3
Diagnostica Stago STart Max	5	2.75	0.08	3.0	2.7	2.2 - 3.3	5	1.13	0.05	4.6	1.1	0.9 - 1.4
All Coagulation Instruments	10	2.67	0.19	7.3	2.7	2.1 - 3.3	10	1.10	0.07	6.4	1.1	0.8 - 1.4
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	2.28	0.28	12.2	2.3	1.8 - 2.8	5	0.94	0.11	12.1	0.9	0.7 - 1.2



**PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)**

**Specimen CG-5**

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	52	1.38	0.15	10.8	1.4	1.1 - 1.7
Dade Innovin						
Dade Behring BFT II	5	1.50	0.08	5.4	1.5	1.2 - 1.8
Sysmex CA-500/600 series	14	1.35	0.07	4.9	1.4	1.0 - 1.7
All Coagulation Instruments	20	1.38	0.09	6.7	1.4	1.1 - 1.7
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	7	1.48	0.13	8.7	1.5	1.1 - 1.8
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STA Compact	5	1.33	0.06	4.3	1.3	1.0 - 1.6
Diagnostica Stago STart Max	5	1.47	0.05	3.5	1.5	1.1 - 1.8
All Coagulation Instruments	10	1.42	0.08	5.9	1.4	1.1 - 1.8
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	1.28	0.16	12.8	1.2	1.0 - 1.6

**ACTIVATED PARTIAL THROMBOPLASTIN (seconds)**

**Specimen CG-1**

**Specimen CG-2**

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	37	47.0	3.5	7.4	46	39 - 55	37	26.8	2.6	9.5	27	22 - 31
Dade Actin FSL												
Sysmex CA-500/600 series	8	42.4	4.3	10.2	44	36 - 49	8	25.0	2.9	11.5	24	21 - 29
All Coagulation Instruments	9	43.0	4.4	10.3	44	36 - 50	9	24.9	2.7	10.9	24	21 - 29
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	5	52.5	0.7	1.3	53	44 - 61	5	27.0	4.4	16.1	29	22 - 32
Hemoliance SynthASil												
IL ACL, all models	5	50.0	0.1	0.0	50	42 - 58	5	27.5	0.7	2.6	28	23 - 32
HemosIL APTT-SP												
IL ACL, all models	5	45.5	3.5	7.7	46	38 - 53	5	27.0	1.2	4.3	27	22 - 32
IL TEST APTT-SP												
IL ACL, all models	5	46.3	1.5	3.3	46	39 - 54	5	29.3	0.6	2.0	29	24 - 34

**ACTIVATED PARTIAL THROMBOPLASTIN (seconds)**

<u>Reagent/Instrument</u>	<b>Specimen CG-3</b>						<b>Specimen CG-4</b>					
	<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	39.3	5.0	12.8	38	33 - 46	37	30.3	5.3	17.6	30	25 - 35
Dade Actin FSL												
Sysmex CA-500/600 series	8	36.5	0.8	2.1	37	31 - 42	8	25.0	0.5	2.1	25	21 - 29
All Coagulation Instruments	9	36.9	1.4	3.7	37	31 - 43	9	25.1	0.6	2.4	25	21 - 29
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	5	38.7	5.8	14.9	42	32 - 45	5	29.0	2.6	9.1	30	24 - 34
Hemoliance SynthASil												
IL ACL, all models	5	39.5	0.7	1.8	40	33 - 46	5	40.5	0.7	1.7	41	34 - 47
HemosIL APTT-SP												
IL ACL, all models	5	37.0	1.6	4.4	37	31 - 43	5	35.0	5.9	16.8	35	29 - 41
IL TEST APTT-SP												
IL ACL, all models	5	38.0	0.1	0.0	38	32 - 44	5	33.3	1.5	4.6	33	28 - 39

<u>Reagent/Instrument</u>	<b>Specimen CG-5</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	37	37.3	5.7	15.4	38	31 - 43
Dade Actin FSL						
Sysmex CA-500/600 series	8	31.7	6.1	19.1	29	26 - 37
All Coagulation Instruments	9	31.7	5.5	17.4	29	26 - 37
Diagnostica Stago STA C.K. Prest						
Diagnostica Stago STA Compact	5	41.5	0.7	1.7	42	35 - 48
Hemoliance SynthASil						
IL ACL, all models	5	37.5	0.7	1.9	38	31 - 44
HemosIL APTT-SP						
IL ACL, all models	5	36.0	4.1	11.3	36	30 - 42
IL TEST APTT-SP						
IL ACL, all models	5	44.3	0.6	1.3	44	37 - 51

**FIBRINOGEN (mg/dL)**

Specimen CG-1							Specimen CG-2					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	12	257.9	17.0	6.6	265	206 - 310	12	279.6	15.3	5.5	283	223 - 336
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	5	255.0	16.8	6.6	261	204 - 306	5	277.3	26.3	9.5	292	221 - 333
Specimen CG-3							Specimen CG-4					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	12	258.0	18.4	7.1	255	206 - 310	12	456.0	48.3	10.6	443	364 - 548
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	5	247.7	9.8	4.0	242	198 - 298	5	457.7	47.2	10.3	463	366 - 550
Specimen CG-5												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	12	137.3	11.5	8.4	136	109 - 165						
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	5	138.3	13.7	9.9	136	110 - 166						

**PROTHROMBIN TIME (seconds) – XS Samples**

<u>Reagent/Instrument</u>	<b>Specimen XS-1</b>						<b>Specimen XS-2</b>					
	<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	13.99	0.40	2.8	14.0	11.8 - 16.1	25	25.46	0.75	3.0	25.3	21.6 - 29.3
All Roche CoaguChek XS Plus Instruments	13	14.01	0.41	2.9	14.0	11.9 - 16.2	13	25.34	0.74	2.9	25.2	21.5 - 29.2
Roche CoaguChek Pro II	11	13.90	0.22	1.6	14.0	11.8 - 16.0	11	25.67	0.76	2.9	25.8	21.8 - 29.6
Roche CoaguChek XS Plus - Waived	8	13.99	0.45	3.2	14.0	11.8 - 16.1	8	25.13	0.73	2.9	25.2	21.3 - 28.9
Roche CoaguChek XS Plus	5	14.04	0.36	2.6	14.0	11.9 - 16.2	5	25.68	0.69	2.7	25.8	21.8 - 29.6

  

<u>Reagent/Instrument</u>	<b>Specimen XS-3</b>						<b>Specimen XS-4</b>					
	<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	4	13.90	0.41	2.9	13.9	11.8 - 16.0	4	36.20	1.59	4.4	35.9	30.7 - 41.7
All Roche CoaguChek XS Plus Instruments	3	-	-	-	14.2	11.9 - 16.2	3	-	-	-	36.5	31.0 - 42.0
Roche CoaguChek XS Plus - Waived	1	-	-	-	13.6	11.5 - 15.7	1	-	-	-	34.7	29.4 - 40.0
Roche CoaguChek XS Plus	2	-	-	-	14.3	12.1 - 16.4	2	-	-	-	37.4	31.7 - 43.1

  

<u>Reagent/Instrument</u>	<b>Specimen XS-5</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	4	25.35	1.04	4.1	25.5	21.5 - 29.2
All Roche CoaguChek XS Plus Instruments	3	-	-	-	26.1	21.6 - 29.4
Roche CoaguChek XS Plus - Waived	1	-	-	-	24.1	20.4 - 27.8
Roche CoaguChek XS Plus	2	-	-	-	26.2	22.2 - 30.2

**INTERNATIONAL NORMALIZED RATIO (INR)– XS Samples**

Specimen XS-1							Specimen XS-2					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	54	1.17	0.05	3.9	1.2	0.9 - 1.5	51	2.12	0.07	3.3	2.1	1.6 - 2.6
All Roche CoaguChek XS Plus Instruments	28	1.18	0.04	3.8	1.2	0.9 - 1.5	26	2.10	0.08	3.8	2.1	1.6 - 2.6
Roche CoaguChek Pro II	24	1.17	0.05	4.1	1.2	0.9 - 1.5	24	2.14	0.05	2.4	2.1	1.7 - 2.6
Roche CoaguChek XS Plus - Waived	23	1.17	0.04	3.8	1.2	0.9 - 1.5	21	2.09	0.07	3.5	2.1	1.6 - 2.6
Roche CoaguChek XS Plus	5	1.18	0.04	3.8	1.2	0.9 - 1.5	5	2.16	0.09	4.1	2.2	1.7 - 2.6
Specimen XS-3							Specimen XS-4					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	1.18	0.04	3.7	1.2	0.9 - 1.5	17	3.01	0.10	3.2	3.0	2.4 - 3.7
All Roche CoaguChek XS Plus Instruments	6	1.18	0.04	3.5	1.2	0.9 - 1.5	6	2.97	0.14	4.6	3.0	2.3 - 3.6
Roche CoaguChek Pro II	10	1.18	0.04	3.6	1.2	0.9 - 1.5	10	3.04	0.05	1.7	3.0	2.4 - 3.7
Roche CoaguChek XS Plus - Waived	4	1.18	0.05	4.3	1.2	0.9 - 1.5	4	2.90	0.08	2.8	2.9	2.3 - 3.5
Roche CoaguChek XS Plus	2	-	-	-	1.2	0.9 - 1.5	2	-	-	-	3.1	2.4 - 3.8
Specimen XS-5												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	17	2.12	0.07	3.1	2.1	1.6 - 2.6						
All Roche CoaguChek XS Plus Instruments	6	2.10	0.09	4.3	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	4	2.05	0.06	2.8	2.1	1.6 - 2.5						
Roche CoaguChek XS Plus	2	-	-	-	2.2	1.7 - 2.7						

**URINALYSIS DIPSTICK–SPECIFIC GRAVITY**

**Specimen UA-1**

<b><u>Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
All Method	110	1.0156	0.0081	0.8	1.015	1.005 - 1.026
All Arkray Methods	9	1.0302	0.0011	0.1	1.030	1.020 - 1.041
All Iris Diagnostics Methods	5	1.0238	0.0015	0.1	1.024	1.013 - 1.034
All Refractive Index Methods	15	1.0277	0.0039	0.4	1.030	1.017 - 1.038
All Roche Methods	31	1.0121	0.0038	0.4	1.010	1.002 - 1.023
All Siemens Methods	24	1.0133	0.0038	0.4	1.015	1.003 - 1.024
77 Elektronika LabUMat/2	9	1.0286	0.0049	0.5	1.030	1.018 - 1.039
Acon Laboratories	7	1.0100	0.0029	0.3	1.010	1.000 - 1.020
Arkray Aution Sticks	8	1.0304	0.0010	0.1	1.030	1.020 - 1.041
Roche Chemstrips / Combur	10	1.0095	0.0043	0.4	1.010	0.999 - 1.020
Roche cobas u 411	15	1.0137	0.0044	0.4	1.015	1.003 - 1.024
Roche Urisys	14	1.0104	0.0024	0.2	1.010	1.000 - 1.021
Siemens Clinitek Advantus	5	1.0100	0.0001	0.0	1.010	1.000 - 1.020
Siemens Clinitek Status / Status+	16	1.0156	0.0016	0.2	1.015	1.005 - 1.026

## URINALYSIS DIPSTICK-pH

Specimen UA-1

### Participant Results

<u>Method</u>	<u>Labs</u>	<u>≤3.5</u>	<u>4.0</u>	<u>4.5</u>	<u>5.0</u>	<u>5.5</u>	<u>6.0</u>	<u>6.5</u>	<u>7.0</u>	<u>7.5</u>	<u>8.0</u>	<u>8.5</u>	<u>≥9.0</u>
ALL METHODS	144	-	-	-	-	-	1	-	3	12	99	29	-
77 Elektronika LabUMat/2	8	-	-	-	-	-	-	-	2	5	1	-	-
Acon Laboratories	7	-	-	-	-	-	-	-	-	1	6	-	-
Arkray Aution Jet	1	-	-	-	-	-	1	-	-	-	-	-	-
Arkray Aution Sticks	8	-	-	-	-	-	-	-	-	3	5	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	-	-	1	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	-	-	-	-	-	-	4	-	-
Iris iChem VELOCITY Urine Chemistry System	1	-	-	-	-	-	-	-	-	-	1	-	-
Other Analyzer Method	3	-	-	-	-	-	-	-	-	2	1	-	-
Other Dipstick Method	4	-	-	-	-	-	-	-	-	-	2	2	-
Plasmatec URIPATH	2	-	-	-	-	-	-	-	-	-	1	1	-
Roche Chemstrips / Combur	23	-	-	-	-	-	-	-	-	1	21	1	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	-	-	1	-	-
Roche cobas u 411	16	-	-	-	-	-	-	-	1	-	15	-	-
Roche cobas u 601 / 701	4	-	-	-	-	-	-	-	-	-	4	-	-
Roche SuperUA/ChemstripUA	1	-	-	-	-	-	-	-	-	-	1	-	-
Roche Urisys	20	-	-	-	-	-	-	-	-	-	20	-	-
SD UroColor Reagent Strips	4	-	-	-	-	-	-	-	-	-	3	1	-
Siemens Clinitek Advantus	4	-	-	-	-	-	-	-	-	-	1	3	-
Siemens Clinitek Atlas	1	-	-	-	-	-	-	-	-	-	1	-	-
Siemens Clinitek Status / Status+	18	-	-	-	-	-	-	-	-	-	-	18	-
Siemens Reagent Strips	12	-	-	-	-	-	-	-	-	-	9	3	-
UriScan Reagent Strips	1	-	-	-	-	-	-	-	-	-	1	-	-

**URINALYSIS DIPSTICK–PROTEIN QUALITATIVE**  
**Specimen UA-1**

**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>&gt;600 or ≥1000</u> <u>mg/dL</u>
ALL METHODS	143	136	4	2	1	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	8	8	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	7	5	2	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	8	7	1	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	3	3	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	4	4	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	2	1	1	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	23	23	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	16	15	-	1	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	4	3	-	-	1	-	-	-	-	-	-	-	-
Roche SuperUA/ChemstripUA	1	-	-	1	-	-	-	-	-	-	-	-	-
Roche Urisys	19	19	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	4	4	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	4	4	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	18	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	12	12	-	-	-	-	-	-	-	-	-	-	-



## URINALYSIS DIPSTICK–GLUCOSE

### Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Negative or Normal</u>	<u>Trace</u>	<u>(1+)</u>	<u>Participant Results</u>			<u>30 - 100 mg/dL</u>	<u>150 - 300 mg/dL</u>	<u>500 mg/dL</u>	<u>&gt;500 or ≥1000 or ≥2000 mg/dL</u>
					<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>				
ALL METHODS	144	2	-	1	14	30	68	-	2	2	25
77 Elektronika LabUMat/2	8	-	-	-	-	-	5	-	-	-	3
Acon Laboratories	7	-	-	-	-	1	5	-	-	-	1
Arkray Aution Jet	1	-	-	-	-	-	1	-	-	-	-
Arkray Aution Sticks	8	-	-	-	-	-	8	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	-	1	1	-	-	1	1
Iris Ichem VELOCITY Urine Chemistry System	1	-	-	-	-	-	1	-	-	-	-
Other Analyzer Method	3	-	-	-	-	1	1	-	-	1	-
Other Dipstick Method	4	-	-	-	-	2	2	-	-	-	-
Plasmatec URIPATH	2	-	-	-	-	2	-	-	-	-	-
Roche Chemstrips / Combur	23	-	-	-	-	2	20	-	-	-	1
Roche cobas 6500 / u 601	1	-	-	-	-	-	1	-	-	-	-
Roche cobas u 411	16	-	-	-	-	2	7	-	-	-	7
Roche cobas u 601 / 701	4	-	-	-	-	-	-	-	-	-	4
Roche SuperUA/ChemstripUA	1	1	-	-	-	-	-	-	-	-	-
Roche Urisys	20	1	-	-	-	2	8	-	2	-	7
SD UroColor Reagent Strips	4	-	-	-	1	2	1	-	-	-	-
Siemens Clinitek Advantus	4	-	-	-	-	4	-	-	-	-	-
Siemens Clinitek Atlas	1	-	-	-	1	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	-	-	1	12	4	-	-	-	-	1
Siemens Reagent Strips	12	-	-	-	-	7	5	-	-	-	-
UriScan Reagent Strips	1	-	-	-	-	-	1	-	-	-	-

## URINALYSIS DIPSTICK–KETONES

### Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>Participant Results</u>					<u>5 - 10</u> <u>mg/dL</u>	<u>15 - 25</u> <u>mg/dL</u>	<u>40 - 60</u> <u>mg/dL</u>	<u>≥80 - 100</u> <u>mg/dL</u>	<u>≥150</u> <u>mg/dL</u>
							<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>						
ALL METHODS	144	144	-	-	-	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	8	8	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	7	7	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	8	8	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	23	23	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche SuperUA/ChemstripUA	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	20	20	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	18	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	12	12	-	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK–BILIRUBIN

### Specimen UA-1

<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>&gt;10.0 mg/dL</u>
						<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>				
ALL METHODS	119	119	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	8	8	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	7	7	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	8	8	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	3	3	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	4	4	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	2	2	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	10	10	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	16	16	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	4	4	-	-	-	-	-	-	-	-	-	-	-
Roche SuperUA/ChemstripUA	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	20	20	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	4	4	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	4	4	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	16	16	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	2	2	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK–UROBILINOGEN

### Specimen UA-1

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>				
		<u>Normal or 0.0 - 0.2 mg/dL or &lt;3.2 μmol/L</u>	<u>1.0 or &lt;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	119	118	1	-	-	-
77 Elektronika LabUMat/2	8	8	-	-	-	-
Acon Laboratories	7	7	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-
Arkray Aution Sticks	8	8	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-	-	-	-
Other Analyzer Method	3	3	-	-	-	-
Other Dipstick Method	4	4	-	-	-	-
Plasmatec URIPATH	2	2	-	-	-	-
Roche Chemstrips / Combur	10	10	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-
Roche cobas u 411	16	16	-	-	-	-
Roche cobas u 601 / 701	4	3	1	-	-	-
Roche SuperUA/ChemstripUA	1	1	-	-	-	-
Roche Urisys	20	20	-	-	-	-
SD UroColor Reagent Strips	4	4	-	-	-	-
Siemens Clinitek Advantus	4	4	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-
Siemens Clinitek Status / Status+	16	16	-	-	-	-
Siemens Reagent Strips	2	2	-	-	-	-

**URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN**

Specimen UA-1

**Participant Results**

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>(5+)</u>	<u>5 - 25</u> <u>Ery/<math>\mu</math>L</u>	<u>50 -</u> <u>100</u> <u>Ery/<math>\mu</math>L</u>	<u>200 -</u> <u>250</u> <u>Ery/<math>\mu</math>L</u>	<u><math>\pm</math>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><math>\geq</math>1.0</u> <u>mg/</u> <u>dL</u>
ALL METHODS	144	143	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	8	8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	7	7	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	8	8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	22	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Mditron Junior/II	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche SuperUA/ChemstripUA	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	20	20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	17	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	12	12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-1

### Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>15 or 25 µL</u>	<u>75 or 100 µL</u>	<u>250 or 500 µL</u>
ALL METHODS	130	130	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	8	8	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	7	7	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	8	8	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	3	3	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	4	4	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	2	2	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	22	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	16	16	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	4	4	-	-	-	-	-	-	-	-	-	-	-
Roche SuperUA/ChemstripUA	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	20	20	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	4	4	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	4	4	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	16	16	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	2	2	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-

**URINALYSIS DIPSTICK–NITRITE****Specimen UA-1*****Participant Results***

<b><u>Method</u></b>	<b><u>Labs</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	131	131	-
77 Elektronika LabUMat/2	8	8	-
Acon Laboratories	7	7	-
Arkray Aution Jet	1	1	-
Arkray Aution Sticks	8	8	-
Iris Diagnostics Aution Max AX-4280	1	1	-
Iris Diagnostics iChem Velocity Strips	4	4	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-
Other Analyzer Method	3	3	-
Other Dipstick Method	4	4	-
Plasmatec URIPATH	2	2	-
Roche Chemstrips / Combur	23	23	-
Roche cobas 6500 / u 601	1	1	-
Roche cobas u 411	16	16	-
Roche cobas u 601 / 701	4	4	-
Roche SuperUA/ChemstripUA	1	1	-
Roche Urisys	19	19	-
SD UroColor Reagent Strips	4	4	-
Siemens Clinitek Advantus	4	4	-
Siemens Clinitek Atlas	1	1	-
Siemens Clinitek Status / Status+	16	16	-
Siemens Reagent Strips	2	2	-
UriScan Reagent Strips	1	1	-

**URINALYSIS –MICROALBUMIN (dipstick only)**

**Specimen UA-1**

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>									
		<u>Negative</u>	<u>10 mg/L</u>	<u>20 mg/L</u>	<u>30 mg/L</u>	<u>50 mg/L</u>	<u>80 mg/L</u>	<u>100 mg/L</u>	<u>150 mg/L</u>	<u>+(4 - 8 mg/dL)</u>	<u>++ (&gt;8 mg/dL)</u>
ALL METHODS	9	7	1	1	-	-	-	-	-	-	-
Other Analyzer Method	2	2	-	-	-	-	-	-	-	-	-
Other Dipstick Method	1	1	-	-	-	-	-	-	-	-	-
Roche cobas u 411	1	1	-	-	-	-	-	-	-	-	-
Roche Micral - 1 minute	1	-	-	1	-	-	-	-	-	-	-
Roche Urisys	1	1	-	-	-	-	-	-	-	-	-

**URINALYSIS –URINE hCG**

**Specimen UA-1**

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>	
		<u>Positive</u>	<u>Negative</u>
ALL METHODS	91	-	91
Acon Laboratories	5	-	5
Alere Acceava hCG-Urine	1	-	1
Alere Clearview hCG Cassette	4	-	4
Alere hCG Combo Cassette	21	-	21
bioMerieux VIKIA hCG-D	2	-	2
Other Dipstick Method	1	-	1
SD Bioline hCG	10	-	10
Siemens Clinitek Status / Status+	10	-	10
Stanbio QuStick	1	-	1



## MISCELLANEOUS CULTURES

### Specimen BA-1 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Citrobacter braakii	65	73.03%	Acceptable
Citrobacter sp.	11	12.36%	Acceptable
Citrobacter freundii	8	8.99%	

Organism(s) present: *Citrobacter braakii*

### Specimen BA-2 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Erysipelothrix rhusiopathiae	57	47.11%	Acceptable
Erysipelothrix sp.	4	3.31%	Acceptable
Cutibacterium acnes	12	9.92%	Acceptable
Gram positive bacilli	11	9.09%	Acceptable
Anaerobe present – no ID	7	5.79%	Acceptable
Anaerobic cultures not performed	5	4.13%	Acceptable
Anaerobe present – would refer	3	2.48%	Acceptable

Organism(s) present: *Erysipelothrix rhusiopathiae* and *Cutibacterium acnes*

## MISCELLANEOUS CULTURES

### Specimen BA-3 – Stool Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Enterococcus faecalis	65	57.52%	Acceptable
Enterococcus sp.	18	15.93%	Acceptable
Gram positive cocci	1	0.88%	Acceptable
Normal flora	1	0.88%	Acceptable
Campylobacter coli	4	3.54%	Acceptable
Campylobacter sp.	18	15.93%	Acceptable
Gram negative bacilli	1	0.88%	Acceptable
No enteric pathogens isolated	5	4.42%	

Organism(s) present: *Campylobacter coli* and *Enterococcus faecalis*

**ANTIMICROBIAL SUSCEPTIBILIY TESTING**

**Specimen UC-1, CC-1 (SUS-1)** Organism(s) present: *Streptococcus anginosus*

<u>Antimicrobial</u>	<u>-----Disk Diffusion-----</u>				<u>-----MIC-----</u>				<u>Acceptable (%)</u>
	<u>Interpretative category data</u>				<u>Interpretative category data</u>				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Amikacin	1	1	-	-	6	6	-	-	Inappropriate <sup>1</sup>
Amoxicillin/Clavulanate	12	12	-	-	9	8	-	1	Inappropriate <sup>1</sup>
Ampicillin	20	19	-	1	71	68	1	2	95.65%
Ampicillin/Sulbactam	2	2	-	-	6	4	1	1	Inappropriate <sup>1</sup>
Aztreonam	-	-	-	-	2	1	-	1	Inappropriate <sup>1</sup>
Cefaclor	1	1	-	-	1	1	-	-	Inappropriate <sup>1</sup>
Cefazolin	-	-	-	-	1	1	-	-	Inappropriate <sup>1</sup>
Cefepime	12	11	1	-	33	33	-	-	97.78%
Cefixime	1	1	-	-	2	1	1	-	Inappropriate <sup>1</sup>
Cefoperazone	1	1	-	-	-	-	-	-	Inappropriate <sup>1</sup>
Cefotaxime	22	21	-	1	66	64	1	1	96.59%
Cefoxitin	1	1	-	-	3	2	1	-	Inappropriate <sup>1</sup>
Cefpodoxime	1	1	-	-	-	-	-	-	Inappropriate <sup>1</sup>
Ceftaroline	-	-	-	-	1	1	-	-	Inappropriate <sup>1</sup>
Ceftazidime	3	2	1	-	5	5	-	-	Inappropriate <sup>1</sup>
Ceftriaxone	30	30	-	-	43	42	-	1	98.65%
Cefuroxime	9	9	-	-	8	5	-	3	Inappropriate <sup>1</sup>
Ciprofloxacin	7	7	-	-	11	11	-	-	Inappropriate <sup>1</sup>
Daptomycin	-	-	-	-	11	11	-	-	100.00%
Doxycycline	1	-	1	-	3	3	-	-	100.00%
Ertapenem	-	-	-	-	4	4	-	-	100.00%
Fosfomycin	-	-	-	-	3	3	-	-	Inappropriate <sup>1</sup>
Gentamicin	4	4	-	-	11	9	-	2	Inappropriate <sup>1</sup>
Imipenem	1	1	-	-	1	1	-	-	Inappropriate <sup>1</sup>
Levofloxacin	15	15	-	-	50	50	-	-	100.00%
Linezolid	10	10	-	-	42	42	-	-	100.00%
Meropenem	3	3	-	-	7	7	-	-	100.00%
Minocycline	-	-	-	-	1	1	-	-	100.00%
Moxifloxacin	1	1	-	-	28	28	-	-	Inappropriate <sup>1</sup>
Nitrofurantoin	3	2	-	1	9	8	-	1	Inappropriate <sup>1</sup>

<sup>1</sup> This is an inappropriate drug for the organism and/or source

**ANTIMICROBIAL SUSCEPTIBILITY TESTING (cont'd)**

**Specimen UC-1, CC-1 (SUS-1)** Organism(s) present: *Streptococcus anginosus*

<u>Antimicrobial</u>	<u>-----Disk Diffusion-----</u>				<u>-----MIC-----</u>				<u>Acceptable (%)</u>
	<u>Interpretative category data</u>				<u>Interpretative category data</u>				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Norfloxacin	2	2	-	-	3	3	-	-	Inappropriate <sup>1</sup>
Ofloxacin	6	6	-	-	1	1	-	-	100.00%
Oxacillin	1	1	-	-	6	6	-	-	Inappropriate <sup>1</sup>
Penicillin	22	19	-	3	65	63	1	1	93.26%
Piperacillin	-	-	-	-	1	1	-	-	Inappropriate <sup>1</sup>
Piperacillin/Tazobactam	1	1	-	-	2	2	-	-	Inappropriate <sup>1</sup>
Quinupristin/Dalfopristin	-	-	-	-	2	2	-	-	100.00%
Rifampin	-	-	-	-	6	5	1	-	Inappropriate <sup>1</sup>
Streptomycin	-	-	-	-	1	1	-	-	Inappropriate <sup>1</sup>
Teicoplanin	2	2	-	-	5	5	-	-	Inappropriate <sup>1</sup>
Tetracycline	9	4	2	3	35	26	2	7	Not graded <sup>2</sup>
Tobramycin	-	-	-	-	2	2	-	-	Inappropriate <sup>1</sup>
Trimethoprim	1	-	-	1	-	-	-	-	Inappropriate <sup>1</sup>
Trimethoprim/Sulfamethoxazole	8	3	-	5	17	17	-	-	Inappropriate <sup>1</sup>
Vancomycin	19	19	-	-	72	70	1	1	97.83%

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.

<sup>2</sup> This is an ungraded drug due to lack of participant consensus

## PARASITOLOGY (PA Specimens)

### Specimen PA-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	1	100%	Unacceptable

Parasite(s) present: *Dientamoeba fragilis*. This specimen is graded by US consensus/

### Specimen PA-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Protozoan cyst or trophozoite seen	1	100%	Acceptable

Parasite(s) present: *Entamoeba coli*

### Specimen PA-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	15	93.75%	Acceptable
Pollen artifact	1	6.25%	Acceptable

Parasite(s) present: Negative for parasites. Pollen artifact present.

## PARASITOLOGY (PA Specimens) cont'd

### Specimen PA-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	17	48.57%	Acceptable
Trichuris trichiura eggs	9	25.71%	Acceptable
Entamoeba coli	9	25.71%	Acceptable

Parasite(s) present: *Ascaris lumbricoides* eggs, *Trichuris trichiura* eggs, *Entamoeba coli*, and *Entamoeba histolytica*

### Specimen PA-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium falciparum	8	50.00%	Acceptable
Plasmodium sp.	7	43.75%	Acceptable

Parasite(s) present: *Plasmodium falciparum*

## PARASITOLOGY (FP Specimens)

### Specimen FP-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	211	76.45%	Acceptable
Parasite egg or larva seen - no ID	4	1.45%	Acceptable
Entamoeba coli	27	9.78%	
No parasite seen	11	3.99%	
Trichostrongylus sp. eggs	6	2.17%	

Parasite(s) present: Hookworm. This specimen is graded by referee consensus.

## PARASITOLOGY (FP Specimens)

### Specimen FP-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hymenolepis nana eggs	207	80.54%	Acceptable
Parasite egg or larva seen – no ID	2	0.78%	Acceptable
Hymenolepis diminuta eggs	19	7.39%	
Taenia sp. eggs	8	3.11%	
No parasite seen	5	1.95%	
Endolimax nana	5	1.95%	

Parasite(s) present: *Hymenolepis nana* eggs



**PARASITOLOGY (FP Specimens) cont'd**

**Specimen FP-3**

<b><u>Identification</u></b>	<b><u>Labs</u></b>	<b><u>Percent</u></b>	<b><u>Performance</u></b>
Trichuris trichiura eggs	214	60.45%	Acceptable
Endolimax nana	95	26.84%	Acceptable
Parasite egg or larva seen – no ID	1	0.28%	Acceptable
Blastocystis hominis	32	9.04%	

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

**PARASITOLOGY (FP Specimens) cont'd**

**Specimen FP-4**

<b><u>Identification</u></b>	<b><u>Labs</u></b>	<b><u>Percent</u></b>	<b><u>Performance</u></b>
No parasite seen	226	91.13%	Acceptable
Trichuris trichiura eggs	4	1.61%	
Blastocystis hominis	4	1.61%	
Giardia lamblia	3	1.21%	

Parasite(s) present: Negative for parasites

**PARASITOLOGY (FP Specimens) cont'd**

**Specimen FP-5**

<b><u>Identification</u></b>	<b><u>Labs</u></b>	<b><u>Percent</u></b>	<b><u>Performance</u></b>
Plasmodium falciparum	114	47.11%	Acceptable
Plasmodium sp.	48	19.83%	Acceptable
Plasmodium vivax	58	23.97%	
Plasmodium malariae	14	5.79%	
Plasmodium ovale	4	1.65%	

Parasite(s) present: *Plasmodium falciparum*. This specimen is graded by referee consensus.

**Antinuclear Antibody (ANA) - Qualitative**

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	22	1	2	21	22	1
Bio-Rad	2	-	-	2	2	-
BioSystems	2	-	1	1	2	-
Human	1	-	-	1	1	-
Immuno Concepts	4	-	-	4	4	-
INOVA Diagnostics	8	1	1	8	8	1
Kallestad	1	-	-	1	1	-

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	22	1	21
Bio-Rad	-	2	-	1
BioSystems	1	1	1	1
Human	-	1	-	1
Immuno Concepts	-	4	-	4
INOVA Diagnostics	-	9	-	9
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>&gt;640</u>	<u>1024/</u> <u>1280</u>	<u>2048/</u> <u>2560</u>	<u>≥2560</u>
------------------------	----------------------------	------------------------	-------------------------	-------------------------	-------------------------	---------------------------	---------------------------	---------------------------	----------------	-----------------------------	-----------------------------	--------------

**Specimen AE-1**

ALL METHODS	1	-	-	1	3	6	5	2	-	-	-	-
Bio-Rad	-	-	-	-	-	-	2	-	-	-	-	-
Immuno Concepts	-	-	-	1	2	-	-	1	-	-	-	-
INOVA Diagnostics	1	-	-	-	1	4	2	-	-	-	-	-
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>&gt;640</u>	<u>1024/</u> <u>1280</u>	<u>2048/</u> <u>2560</u>	<u>≥2560</u>
------------------------	----------------------------	------------------------	-------------------------	-------------------------	-------------------------	---------------------------	---------------------------	---------------------------	----------------	-----------------------------	-----------------------------	--------------

**Specimen AE-2**

ALL METHODS	16	-	-	1	-	1	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	7	-	-	-	-	1	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

**Specimen AE-3**

ALL METHODS	1	-	-	1	-	2	4	4	-	5	1	-
Bio-Rad	-	-	-	-	-	-	1	1	-	-	-	-
Immuno Concepts	-	-	-	1	-	-	2	1	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	1	1	2	-	2	1	-
Kallestad	-	-	-	-	-	1	-	-	-	-	-	-

**Specimen AE-4**

ALL METHODS	17	-	-	1	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	8	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

**Specimen AE-5**

ALL METHODS	17	-	-	1	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	8	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

## Anti-dsDNA

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	21	2	-	23	-	23
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-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	23	-	23
BioSystems	-	2	-	2
Human	-	1	-	1
Immuno Concepts	-	2	-	2
INOVA Diagnostics	-	9	-	9
Kallestad	-	1	-	1

## Anti-RNP

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	15	-	15	15	-
INOVA Diagnostics	-	11	-	11	11	-

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	15	-	15
INOVA Diagnostics	-	11	-	11

**Anti-RNP/Sm**

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	5	-	6	6	-
Immuno Concepts	-	1	-	1	1	-
INOVA Diagnostics	-	1	-	1	1	-

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	-	6
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	1	-	1

**Anti-SSA**

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	21	-	-	21	-	21
Immuno Concepts	1	-	-	1	-	1
INOVA Diagnostics	13	-	-	13	-	13

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	-	21
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	13	-	13

**Anti-SSB**

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	-	21	-	21
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	13	-	13	-	13

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	-	21
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	13	-	13

**Anti-SSA/SSB**

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

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



**Anti-Sm**

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	-	21	3	18
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	13	-	13	2	11

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	-	21
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	13	-	13

**Rubella—Qualitative**

<b><u>Method</u></b>	<b>Specimen RU-1</b>		<b>Specimen RU-2</b>		<b>Specimen RU-3</b>	
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	-	16	15	1	-	16
Abbott Architect	-	12	11	1	-	12
Roche cobas 6000 / e 601	-	2	2	-	-	2
Roche cobas e 411	-	1	1	-	-	1
Siemens Atellica	-	1	1	-	-	1

<b><u>Method</u></b>	<b>Specimen RU-4</b>		<b>Specimen RU-5</b>	
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	15	1	-	16
Abbott Architect	11	1	-	12
Roche cobas 6000 / e 601	2	-	-	2
Roche cobas e 411	1	-	-	1
Siemens Atellica	1	-	-	1

**Rubella—Quantitative (IU/mL)**

<b><u>Specimen/Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
<b>Specimen RU-1</b>						
All Method	23	0.10	0.15	156.0	0.0	0.0 - 0.6
Abbott Architect	13	0.00	0.01	0.0	0.0	0.0 - 0.1
<b>Specimen RU-2</b>						
All Method	23	41.46	24.03	58.0	27.0	0.0 - 113.6
Abbott Architect	14	26.09	1.68	6.4	26.2	21.0 - 31.2
<b>Specimen RU-3</b>						
All Method	23	0.10	0.17	165.1	0.0	0.0 - 0.6
Abbott Architect	14	0.00	0.01	0.0	0.0	0.0 - 0.1
<b>Specimen RU-4</b>						
All Method	23	40.99	24.45	59.6	26.6	0.0 - 114.4
Abbott Architect	14	25.33	2.46	9.7	24.8	17.9 - 32.8
<b>Specimen RU-5</b>						
All Method	23	0.10	0.16	165.2	0.0	0.0 - 0.6
Abbott Architect	14	0.00	0.01	0.0	0.0	0.0 - 0.1

**Syphilis Serology—Qualitative: VDRL Slide**

<b><u>Method</u></b>	<b>Specimen SY-1</b>			<b>Specimen SY-2</b>			<b>Specimen SY-3</b>		
	<b><u>Reactive</u></b>	<b><u>Weakly Reactive</u></b>	<b><u>Non- Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Weakly Reactive</u></b>	<b><u>Non- Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Weakly Reactive</u></b>	<b><u>Non- Reactive</u></b>
ALL METHODS	1	-	51	52	-	-	51	-	1
Abbott Architect	-	-	1	1	-	-	1	-	-
Acon Laboratories	-	-	2	2	-	-	2	-	-
BioSystems	-	-	1	1	-	-	1	-	-
Omega Diagnostics	-	-	1	1	-	-	1	-	-
Other Total Method	-	-	1	1	-	-	1	-	-
SPINREACT	-	-	2	2	-	-	2	-	-
Standard Diagnostics	-	-	1	1	-	-	1	-	-
Wiener Lab	1	-	38	39	-	-	38	-	1

<b><u>Method</u></b>	<b>Specimen SY-4</b>			<b>Specimen SY-5</b>		
	<b><u>Reactive</u></b>	<b><u>Weakly Reactive</u></b>	<b><u>Non- Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Weakly Reactive</u></b>	<b><u>Non- Reactive</u></b>
ALL METHODS	2	-	49	-	-	52
Abbott Architect	-	-	1	-	-	1
Acon Laboratories	-	-	2	-	-	2
BioSystems	-	-	1	-	-	1
Omega Diagnostics	-	-	1	-	-	1
Other Total Method	-	-	1	-	-	1
SPINREACT	-	-	1	-	-	2
Standard Diagnostics	-	-	1	-	-	1
Wiener Lab	2	-	37	-	-	39

**Syphilis Serology—Semi-Quantitative: VDRL Slide Titer**

<b><u>Specimen/Method</u></b>	<b><u>N/A (Neg)</u></b>	<b><u>0 dils</u></b>	<b><u>1 dil</u></b>	<b><u>2 dils</u></b>	<b><u>4 dils</u></b>	<b><u>8 dils</u></b>	<b><u>16 dils</u></b>	<b><u>32 dils</u></b>	<b><u>&gt;32 dils</u></b>
<b>Specimen SY-1</b>									
ALL METHODS	47	-	1	-	-	-	-	-	-
BioSystems	1	-	-	-	-	-	-	-	-
Wiener Lab	41	-	1	-	-	-	-	-	-
<b>Specimen SY-2</b>									
ALL METHODS	1	-	-	9	28	7	2	1	1
BioSystems	1	-	-	-	-	-	-	-	-
Wiener Lab	-	-	-	9	25	6	2	-	1
<b>Specimen SY-3</b>									
ALL METHODS	1	1	7	22	15	1	1	-	1
BioSystems	-	-	-	-	1	-	-	-	-
Wiener Lab	1	1	7	19	12	1	1	-	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>&gt;32 dils</u>
<b>Specimen SY-4</b>									
ALL METHODS	45	-	2	1	-	-	-	-	-
BioSystems	-	-	-	1	-	-	-	-	-
Wiener Lab	40	-	2	-	-	-	-	-	-
<b>Specimen SY-5</b>									
ALL METHODS	48	-	-	-	-	-	-	-	-
BioSystems	1	-	-	-	-	-	-	-	-
Wiener Lab	42	-	-	-	-	-	-	-	-

**Syphilis Serology—Qualitative: MHA-TP**

<b><u>Method</u></b>	<b>Specimen SY-1</b>		<b>Specimen SY-2</b>		<b>Specimen SY-3</b>	
	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>
ALL METHODS	-	9	8	1	8	1
Abbott Architect	-	1	-	1	-	1
Biokit	-	1	1	-	1	-
Human	-	1	1	-	1	-
Plasmatec	-	2	2	-	2	-
Serodia	-	2	2	-	2	-
Standard Diagnostics	-	2	2	-	2	-

  

	<b>Specimen SY-4</b>		<b>Specimen SY-5</b>	
	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>
ALL METHODS	-	9	-	9
Abbott Architect	-	1	-	1
Biokit	-	1	-	1
Human	-	1	-	1
Plasmatec	-	2	-	2
Serodia	-	2	-	2
Standard Diagnostics	-	2	-	2

**Syphilis Serology—Qualitative: *Treponema pallidum* Antibodies**

<b><u>Method</u></b>	<b>Specimen SY-1</b>		<b>Specimen SY-2</b>		<b>Specimen SY-3</b>	
	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>
ALL METHODS	-	52	51	1	51	1
Abbott Architect	-	9	8	1	8	1
bioMerieux	-	1	1	-	1	-
BioSystems	-	1	1	-	1	-
DiaSorin	-	2	2	-	2	-
Human	-	2	2	-	2	-
Plasmatec	-	2	2	-	2	-
Roche cobas 6000 / c 501	-	3	3	-	3	-
Roche cobas 8000/e801	-	1	1	-	1	-
Roche cobas e 411	-	1	1	-	1	-
Serodia	-	9	9	-	9	-
Siemens Immulite 2000	-	1	1	-	1	-
Standard Diagnostics	-	7	7	-	7	-
Zeus	-	1	1	-	1	-

  

	<b>Specimen SY-4</b>		<b>Specimen SY-5</b>	
	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>
ALL METHODS	-	52	-	52
Abbott Architect	-	9	-	9
bioMerieux	-	1	-	1
BioSystems	-	1	-	1
DiaSorin	-	2	-	2
Human	-	2	-	2
Plasmatec	-	2	-	2
Roche cobas 6000 / c 501	-	3	-	3
Roche cobas 8000/e801	-	1	-	1
Roche cobas e 411	-	1	-	1
Serodia	-	9	-	9
Siemens Immulite 2000	-	1	-	1
Standard Diagnostics	-	7	-	7
Zeus	-	1	-	1



**Syphilis Serology—Qualitative: RPR**

<b><u>Method</u></b>	<b>Specimen SY-1</b>		<b>Specimen SY-2</b>		<b>Specimen SY-3</b>	
	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>
ALL METHODS	-	72	72	-	72	-
Abbott Architect	-	1	1	-	1	-
Becton Dickinson	-	2	2	-	2	-
bioMerieux	-	5	5	-	5	-
BioSystems	-	17	17	-	17	-
Human	-	6	6	-	6	-
Omega Diagnostics	-	8	8	-	8	-
Plasmatec	-	7	7	-	7	-
Pulse Scientific	-	1	1	-	1	-
SPINREACT	-	18	18	-	18	-

	<b>Specimen SY-4</b>		<b>Specimen SY-15</b>	
	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>	<b><u>Reactive</u></b>	<b><u>Non-Reactive</u></b>
ALL METHODS	-	72	-	72
Abbott Architect	-	1	-	1
Becton Dickinson	-	2	-	2
bioMerieux	-	5	-	5
BioSystems	-	17	-	17
Human	-	6	-	6
Omega Diagnostics	-	8	-	8
Plasmatec	-	7	-	7
Pulse Scientific	-	1	-	1
SPINREACT	-	18	-	18

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

<b><u>Specimen/Method</u></b>	<b><u>N/A</u></b> <b><u>(Neg)</u></b>	<b><u>1</u></b>	<b><u>2</u></b>	<b><u>4</u></b>	<b><u>8</u></b>	<b><u>16</u></b>	<b><u>32</u></b>	<b><u>64</u></b>	<b><u>&gt;64</u></b>
<b>Specimen SY-1</b>									
ALL METHODS	62	-	-	-	-	-	-	-	-
Becton Dickinson	2	-	-	-	-	-	-	-	-
bioMerieux	3	-	-	-	-	-	-	-	-
BioSystems	17	-	-	-	-	-	-	-	-
Human	6	-	-	-	-	-	-	-	-
Omega Diagnostics	7	-	-	-	-	-	-	-	-
Plasmatec	3	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	18	-	-	-	-	-	-	-	-
<b>Specimen SY-2</b>									
ALL METHODS	-	1	10	24	19	4	2	3	-
Becton Dickinson	-	-	1	1	-	-	-	-	-
bioMerieux	-	-	-	2	-	1	-	-	-
BioSystems	-	-	1	8	5	-	1	2	-
Human	-	-	2	1	2	1	-	-	-
Omega Diagnostics	-	-	3	-	3	-	1	-	-
Plasmatec	-	1	-	1	-	1	-	-	-
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	-	1	8	8	1	-	1	-

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

<b><u>Specimen/Method</u></b>	<b><u>N/A</u></b> <b><u>(Neg)</u></b>	<b><u>1</u></b>	<b><u>2</u></b>	<b><u>4</u></b>	<b><u>8</u></b>	<b><u>16</u></b>	<b><u>32</u></b>	<b><u>64</u></b>	<b><u>&gt;64</u></b>
<b>Specimen SY-3</b>									
ALL METHODS	-	9	26	21	3	2	1	-	1
Becton Dickinson	-	-	2	-	-	-	-	-	-
bioMerieux	-	-	2	1	-	-	-	-	-
BioSystems	-	3	6	6	1	-	-	-	1
Human	-	1	3	2	-	-	-	-	-
Omega Diagnostics	-	3	1	1	1	1	-	-	-
Plasmatec	-	1	1	-	-	-	1	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	-	8	9	1	1	-	-	-
<b>Specimen SY-4</b>									
ALL METHODS	62	-	-	-	-	-	-	-	-
Becton Dickinson	2	-	-	-	-	-	-	-	-
bioMerieux	3	-	-	-	-	-	-	-	-
BioSystems	17	-	-	-	-	-	-	-	-
Human	6	-	-	-	-	-	-	-	-
Omega Diagnostics	7	-	-	-	-	-	-	-	-
Plasmatec	3	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	18	-	-	-	-	-	-	-	-

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>&gt;64</u>
<b>Specimen SY-5</b>									
ALL METHODS	62	-	-	-	-	-	-	-	-
Becton Dickinson	2	-	-	-	-	-	-	-	-
bioMerieux	3	-	-	-	-	-	-	-	-
BioSystems	17	-	-	-	-	-	-	-	-
Human	6	-	-	-	-	-	-	-	-
Omega Diagnostics	7	-	-	-	-	-	-	-	-
Plasmatec	3	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	18	-	-	-	-	-	-	-	-

**Viral Markers – Anti-HBc (IgM)**

<u>Method</u>	<b>Specimen VM-1</b>			<b>Specimen VM-2</b>			<b>Specimen VM-3</b>		
	<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	-	48	-	1	47	-	1	47	-
Abbott Alinity	-	1	-	1	-	-	1	-	-
Abbott Architect	-	26	-	-	26	-	-	26	-
Beckman ACCESS / 2 / DxI	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	9	-	-	9	-	-	9	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
Roche cobas e 411	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	1	-	-	1	-	-	1	-
VITROS 3600/4600/5600	-	3	-	-	3	-	-	3	-
VITROS ECI	-	1	-	-	1	-	-	1	-

  

<u>Method</u>	<b>Specimen VM-4</b>			<b>Specimen VM-5</b>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	48	-	1	47	-
Abbott Alinity	-	1	-	1	-	-
Abbott Architect	-	26	-	-	26	-
Beckman ACCESS / 2 / DxI	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	9	-	-	9	-
Roche cobas 8000/e801	-	4	-	-	4	-
Roche cobas e 411	-	1	-	-	1	-
Siemens ADVIA Centaur	-	1	-	-	1	-
VITROS 3600/4600/5600	-	3	-	-	3	-
VITROS ECI	-	1	-	-	1	-

**Viral Markers – Anti-HBc (Total / IgG)**

<b><u>Method</u></b>	<b>Specimen VM-1</b>			<b>Specimen VM-2</b>			<b>Specimen VM-3</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	1	70	-	71	-	-	70	1	-
Abbott Alinity	-	2	-	2	-	-	2	-	-
Abbott Architect	1	41	-	42	-	-	41	1	-
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	-	2	-	-
DiaSorin	-	1	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	-	11	-	11	-	-	11	-	-
Roche cobas 8000/e801	-	4	-	4	-	-	4	-	-
Roche cobas e 411	-	3	-	3	-	-	3	-	-
Siemens ADVIA Centaur	-	2	-	2	-	-	2	-	-
VITROS 3600/4600/5600	-	3	-	3	-	-	3	-	-

<b><u>Method</u></b>	<b>Specimen VM-4</b>			<b>Specimen VM-5</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	2	69	-	70	1	-
Abbott Alinity	-	2	-	2	-	-
Abbott Architect	-	42	-	42	-	-
Beckman ACCESS / 2 / Dxl	2	-	-	2	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	11	-	11	-	-
Roche cobas 8000/e801	-	4	-	4	-	-
Roche cobas e 411	-	3	-	3	-	-
Siemens ADVIA Centaur	-	2	-	2	-	-
VITROS 3600/4600/5600	-	3	-	2	1	-

## Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	141	-	-	121	18	2	3	137	1
Abbott Alinity	5	-	-	5	-	-	-	5	-
Abbott Architect	65	-	-	64	-	1	-	65	-
Acon Laboratories	1	-	-	1	-	-	1	-	-
Alere Clearview HIV1/2 STAT-PAK	3	-	-	-	3	-	-	3	-
Alere Determine HIV - moderate	4	-	-	-	4	-	-	4	-
Alere Determine HIV - waived	1	-	-	1	-	-	-	1	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	3	-	-	1	2	-	-	3	-
DiaSorin	4	-	-	4	-	-	-	4	-
Human	2	-	-	1	1	-	-	2	-
Roche cobas 6000 / e 601	2	-	-	1	1	-	-	2	-
Roche cobas 8000/e801	18	-	-	17	-	1	-	18	-
Roche cobas e 411	3	-	-	3	-	-	-	3	-
Roche Elecsys 1010 / 2010	7	-	-	7	-	-	2	4	1
Roche Elecsys 1010 / 2010	1	-	-	1	-	-	-	1	-
Roche Modular Analytics	2	-	-	1	1	-	-	2	-
Siemens ADVIA Centaur	3	-	-	3	-	-	-	3	-
Standard Diagnostics	6	-	-	3	3	-	-	6	-
VITROS 3600/4600/5600	4	-	-	4	-	-	-	4	-
VITROS Eci	2	-	-	2	-	-	-	2	-

**Viral Markers – Anti-HIV- cont'd**

<u>Method</u>	<b>Specimen VM-4</b>			<b>Specimen VM-5</b>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	16	120	4	4	136	1
Abbott Alinity	-	5	-	-	5	-
Abbott Architect	-	65	-	1	63	1
Acon Laboratories	-	1	-	-	1	-
Alere Clearview HIV1/2 STAT-PAK	-	3	-	-	3	-
Alere Determine HIV - moderate	-	4	-	-	4	-
Alere Determine HIV - waived	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	1	3	-	-	4	-
DiaSorin	1	1	-	-	2	-
Human	-	2	-	-	2	-
Roche cobas 6000 / e 601	7	6	4	-	18	-
Roche cobas 8000/e801	-	3	-	-	3	-
Roche cobas e 411	4	3	-	3	4	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-
Roche Modular Analytics	-	2	-	-	2	-
Siemens ADVIA Centaur	1	2	-	-	3	-
Standard Diagnostics	-	6	-	-	6	-
VITROS 3600/4600/5600	1	3	-	-	4	-
VITROS Eci	-	2	-	-	2	-



**Viral Markers – Anti-HAV (IgM)**

<u>Method</u>	<b>Specimen VM-1</b>			<b>Specimen VM-2</b>			<b>Specimen VM-3</b>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	58	-	-	58	-	-	58	-
Abbott Architect	-	31	-	-	31	-	-	31	-
bioMerieux Vidas, Mini Vidas	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	11	-	-	11	-	-	11	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
Roche cobas e 411	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	2	-	-	2	-	-	2	-
Standard Diagnostics	-	4	-	-	4	-	-	4	-
VITROS 3600/4600/5600	-	1	-	-	1	-	-	1	-
VITROS ECI	-	1	-	-	1	-	-	1	-

<u>Method</u>	<b>Specimen VM-4</b>			<b>Specimen VM-5</b>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	58	-	-	57	-
Abbott Architect	-	31	-	-	30	-
bioMerieux Vidas, Mini Vidas	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	11	-	-	11	-
Roche cobas 8000/e801	-	4	-	-	4	-
Roche cobas e 411	-	1	-	-	1	-
Siemens ADVIA Centaur	-	2	-	-	2	-
Standard Diagnostics	-	4	-	-	4	-
VITROS 3600/4600/5600	-	1	-	-	1	-
VITROS ECI	-	1	-	-	1	-

**Viral Markers – Anti-HAV (Total/IgG)**

<b><u>Method</u></b>	<b>Specimen VM-1</b>			<b>Specimen VM-2</b>			<b>Specimen VM-3</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	40	1	-	-	41	-	2	39	-
Abbott Architect	25	-	-	-	25	-	-	25	-
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	1	-	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	3	-	-	-	3	-	1	2	-
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	-
Standard Diagnostics	-	1	-	-	1	-	-	1	-
VITROS ECI	1	-	-	-	1	-	-	1	-

<b><u>Method</u></b>	<b>Specimen VM-4</b>			<b>Specimen VM-5</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	6	35	-	40	1	-
Abbott Architect	6	19	-	25	-	-
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	-	-
Standard Diagnostics	-	1	-	-	1	-
VITROS ECI	-	1	-	1	-	-

**Viral Markers – HBeAg**

<b><u>Method</u></b>	<b>Specimen VM-1</b>			<b>Specimen VM-2</b>			<b>Specimen VM-3</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	-	33	-	33	-	-	-	33	-
Abbott Architect	-	17	-	17	-	-	-	17	-
DiaSorin	-	1	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	8	-	8	-	-	-	8	-
Roche cobas 8000/e801	-	4	-	4	-	-	-	4	-
Siemens ADVIA Centaur	-	1	-	1	-	-	-	1	-
VITROS 3600/4600/5600	-	1	-	1	-	-	-	1	-
VITROS ECI	-	1	-	1	-	-	-	1	-

<b><u>Method</u></b>	<b>Specimen VM-4</b>			<b>Specimen VM-5</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	-	33	-	-	33	-
Abbott Architect	-	17	-	-	17	-
DiaSorin	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	8	-	-	8	-
Roche cobas 8000/e801	-	4	-	-	4	-
Siemens ADVIA Centaur	-	1	-	-	1	-
VITROS 3600/4600/5600	-	1	-	-	1	-
VITROS ECI	-	1	-	-	1	-

**Viral Markers – Anti-HBs**

<u>Method</u>	<b>Specimen VM-1</b>			<b>Specimen VM-2</b>			<b>Specimen VM-3</b>		
	<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	87	4	-	18	71	2	90	1	-
Abbott Alinity	3	-	-	-	3	-	3	-	-
Abbott Architect	46	1	-	-	47	-	47	-	-
Beckman ACCESS / 2 / Dxl	3	-	-	1	2	-	3	-	-
Roche cobas 6000 / e 601	11	-	-	9	2	-	11	-	-
Roche cobas 8000/e801	4	-	-	4	-	-	4	-	-
Roche cobas e 411	5	1	-	3	2	1	6	-	-
Roche Elecsys 1010 / 2010	2	-	-	-	1	1	2	-	-
Roche Modular Analytics	1	-	-	-	1	-	1	-	-
Siemens ADVIA Centaur	4	-	-	1	3	-	4	-	-
Standard Diagnostics	1	1	-	-	2	-	2	-	-
VITROS 3600/4600/5600	4	-	-	-	4	-	4	-	-
VITROS ECI	3	-	-	-	3	-	3	-	-

<u>Method</u>	<b>Specimen VM-4</b>			<b>Specimen VM-5</b>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	89	2	-	3	88	-
Abbott Alinity	3	-	-	-	3	-
Abbott Architect	47	-	-	-	47	-
Beckman ACCESS / 2 / Dxl	3	-	-	1	2	-
Roche cobas 6000 / e 601	11	-	-	-	11	-
Roche cobas 8000/e801	4	-	-	-	4	-
Roche cobas e 411	6	-	-	2	4	-
Roche Elecsys 1010 / 2010	2	-	-	-	2	-
Roche Modular Analytics	1	-	-	-	1	-
Siemens ADVIA Centaur	4	-	-	-	4	-
Standard Diagnostics	1	1	-	-	2	-
VITROS 3600/4600/5600	4	-	-	-	4	-
VITROS ECI	3	-	-	-	3	-

**Viral Markers – HBsAg**

<b><u>Method</u></b>	<b>Specimen VM-1</b>			<b>Specimen VM-2</b>			<b>Specimen VM-3</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	-	141	-	141	1	-	1	141	-
Abbott Alinity	-	5	-	5	-	-	-	5	-
Abbott Architect	-	63	-	63	-	-	-	63	-
Beckman ACCESS / 2 / Dxl	-	4	-	4	-	-	-	4	-
DiaSorin	-	1	-	1	-	-	-	1	-
Human	-	1	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	17	-	17	-	-	-	17	-
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	-
Siemens ADVIA Centaur	-	5	-	5	-	-	1	4	-
Standard Diagnostics	-	15	-	14	1	-	-	15	-
VITROS 3600/4600/5600	-	4	-	4	-	-	-	4	-
VITROS ECI	-	1	-	2	-	-	-	2	-

<b><u>Method</u></b>	<b>Specimen VM-4</b>			<b>Specimen VM-5</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	2	138	2	141	1	-
Abbott Alinity	-	5	-	5	-	-
Abbott Architect	1	62	-	63	-	-
Beckman ACCESS / 2 / Dxl	-	4	-	4	-	-
DiaSorin	-	1	-	1	-	-
Human	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	15	2	17	-	-
Roche cobas 8000/e801	-	4	-	4	-	-
Roche cobas e 411	-	10	-	10	-	-
Roche Elecsys 1010 / 2010	-	1	-	1	-	-
Roche Modular Analytics	-	2	-	2	-	-
Siemens ADVIA Centaur	-	5	-	4	1	-
Standard Diagnostics	-	15	-	15	-	-
VITROS 3600/4600/5600	-	4	-	4	-	-
VITROS ECI	1	1	-	2	-	-

**Viral Markers – Anti-HCV**

<b><u>Method</u></b>	<b>Specimen VM-1</b>			<b>Specimen VM-2</b>			<b>Specimen VM-3</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	2	129	-	1	130	-	1	130	-
Abbott Alinity	-	5	-	-	5	-	-	5	-
Abbott Architect	-	64	-	-	64	-	-	64	-
Beckman ACCESS / 2 / Dxl	-	3	-	-	3	-	-	3	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	-	1	-
DiaSorin	-	1	-	-	1	-	-	1	-
Human	1	-	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	-	11	-	-	11	-	-	11	-
Roche cobas 8000/e801	-	3	-	-	3	-	-	3	-
Roche cobas e 411	-	9	-	-	9	-	-	9	-
Roche Modular Analytics	-	2	-	-	2	-	-	2	-
Siemens ADVIA Centaur	-	4	-	-	4	-	-	4	-
Standard Diagnostics	1	10	-	-	11	-	-	11	-
VITROS 3600/4600/5600	-	4	-	-	4	-	-	4	-
VITROS ECI	-	3	-	-	3	-	-	3	-

<b><u>Method</u></b>	<b>Specimen VM-4</b>			<b>Specimen VM-5</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	131	-	-	129	2	-
Abbott Alinity	5	-	-	5	-	-
Abbott Architect	64	-	-	62	2	-
Beckman ACCESS / 2 / Dxl	3	-	-	3	-	-
bioMerieux Vidas, Mini Vidas	1	-	-	1	-	-
DiaSorin	1	-	-	1	-	-
Human	1	-	-	1	-	-
Roche cobas 6000 / e 601	11	-	-	11	-	-
Roche cobas 8000/e801	3	-	-	3	-	-
Roche cobas e 411	9	-	-	9	-	-
Roche Modular Analytics	2	-	-	2	-	-
Siemens ADVIA Centaur	4	-	-	4	-	-
Standard Diagnostics	11	-	-	11	-	-
VITROS 3600/4600/5600	4	-	-	4	-	-
VITROS ECI	3	-	-	3	-	-

## Toxoplasma gondii Antibody (IgG) - Qualitative

<b><u>Method</u></b>	<b>Specimen TOX-1</b>			<b>Specimen TOX-2</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	17	-	-	-	17	-
Abbott Architect	12	-	-	-	12	-
bioMerieux Vidas, Mini Vidas	3	-	-	-	3	-
DiaSorin	1	-	-	-	1	-
Roche cobas e 411	1	-	-	-	1	-

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

<b><u>Specimen/Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
<b>Specimen TOX-1</b>						
All Method	20	60.711	14.665	24.2	53.70	16.71 - 104.71
Abbott Architect	14	52.050	2.920	5.6	53.00	43.28 - 60.82
bioMerieux Vidas, Mini Vidas	3	85.000	11.533	13.6	81.00	50.40 - 119.60
<b>Specimen TOX-2</b>						
All Method	20	0.342	0.224	65.6	0.40	0.00 - 1.02
Abbott Architect	15	0.447	0.141	31.5	0.50	0.02 - 0.87
bioMerieux Vidas, Mini Vidas	3	0.000	0.001	0.0	0.00	0.00 - 0.01

**Toxoplasma gondii Antibody (IgM) - Qualitative**

<b><u>Method</u></b>	<b>Specimen TOX-1</b>			<b>Specimen TOX-2</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	19	-	-	-	19	-
Abbott Architect	13	-	-	-	13	-
bioMerieux Vidas, Mini Vidas	3	-	-	-	3	-
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	1	-	-	-	1	-
Roche cobas e 411	1	-	-	-	1	-

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

<b><u>Specimen/Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
<b>Specimen TOX-1</b>						
All Method	17	15.827	7.858	49.6	14.53	0.00 - 39.40
Abbott Architect	12	14.183	0.895	6.3	14.26	11.49 - 16.87
<b>Specimen TOX-2</b>						
All Method	17	0.159	0.034	21.2	0.16	0.05 - 0.27
Abbott Architect	12	0.156	0.024	15.3	0.16	0.08 - 0.23



**Cytomegalovirus (CMV) Antibodies (IgG) - Qualitative**

<b><u>Method</u></b>	<b>Specimen CMV-1</b>			<b>Specimen CMV-2</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	12	2	-	14	-	-
Abbott Architect	11	1	-	12	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas 6000 / e 601	1	-	-	1	-	-

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

<b><u>Specimen/Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
<b>Specimen CMV-1</b>						
All Method	16	45.659	15.170	33.2	51.50	0.14 - 91.17
Abbott Architect	12	51.967	5.737	11.0	53.50	34.75 - 69.18
<b>Specimen CMV-2</b>						
All Method	16	64.349	29.343	45.6	76.90	0.00 - 152.38
Abbott Architect	13	77.348	9.593	12.4	78.60	48.56 - 106.13

**Cytomegalovirus (CMV) Antibodies (IgM) - Qualitative**

<u>Method</u>	<u>Specimen CMV-1</u>			<u>Specimen CMV-2</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	14	-	15	-	-
Abbott Architect	1	13	-	14	-	-
Roche cobas 6000 / e 601	-	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>
<b>Specimen CMV-1</b>						
All Method	11	0.205	0.039	19.1	0.21	0.08 - 0.33
Abbott Architect	10	0.213	0.029	13.5	0.22	0.12 - 0.30
<b>Specimen CMV-2</b>						
All Method	12	4.678	0.681	14.6	4.62	2.63 - 6.73
Abbott Architect	11	4.720	0.698	14.8	4.64	2.62 - 6.82

**Neonatal Bilirubin, Total (mg/dL)**

<u>Method</u>	<b>Specimen NB-1</b>						<b>Specimen NB-2</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	44	0.01	0.03	319.9	0.0	0.0 - 0.5	48	15.51	0.64	4.1	15.8	12.4 - 18.7
No Reagent Required												
Bilirubinometer / Unistat	37	0.00	0.01	0.0	0.0	0.0 - 0.4	37	15.74	0.45	2.8	15.8	12.5 - 18.9
All Chemistry Instruments	38	0.00	0.02	616.5	0.0	0.0 - 0.5	41	15.67	0.49	3.1	15.8	12.5 - 18.9
<u>Method</u>	<b>Specimen NB-3</b>						<b>Specimen NB-4</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	49	5.93	0.26	4.5	6.0	4.7 - 7.2	48	17.14	0.59	3.4	17.3	13.7 - 20.6
No Reagent Required												
Bilirubinometer / Unistat	38	5.92	0.27	4.5	6.0	4.7 - 7.1	37	17.29	0.45	2.6	17.3	13.8 - 20.8
All Chemistry Instruments	42	5.93	0.26	4.4	6.0	4.7 - 7.2	41	17.22	0.51	3.0	17.3	13.7 - 20.7
<u>Method</u>	<b>Specimen NB-5</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	47	10.77	0.45	4.1	10.8	8.6 - 13.0						
No Reagent Required												
Bilirubinometer / Unistat	37	10.94	0.28	2.5	11.0	8.7 - 13.2						
All Chemistry Instruments	41	10.90	0.30	2.8	10.9	8.7 - 13.1						

**Bilirubin, Direct (mg/dL)**

<u>Method</u>	<b>Specimen NB-1</b>						<b>Specimen NB-2</b>					
	<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	0.05	0.07	143.0	0.0	0.0 - 0.2	11	5.58	0.70	12.5	5.4	4.1 - 7.0
<u>Method</u>	<b>Specimen NB-3</b>						<b>Specimen NB-4</b>					
	<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	1.64	0.30	18.4	1.6	1.0 - 2.3	11	4.06	0.58	14.3	3.8	2.9 - 5.3
<u>Method</u>	<b>Specimen NB-5</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	11	5.07	0.52	10.3	4.8	4.0 - 6.2						

## Glycohemoglobin (percent)

<u>Method</u>	<u>Specimen GH-1</u>						<u>Specimen GH-2</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	131	6.07	0.24	4.0	6.1	5.7 - 6.4	132	7.29	0.28	3.8	7.3	6.9 - 7.7
All Bio-Rad Methods	5	6.50	0.19	2.9	6.5	6.1 - 6.9	5	7.54	0.15	2.0	7.6	7.1 - 8.0
All Enzymatic A1c Methods	6	5.43	0.23	4.1	5.5	5.1 - 5.8	6	6.75	0.08	1.2	6.8	6.4 - 7.1
All Hemoglobin A1c Methods	124	6.10	0.21	3.4	6.1	5.7 - 6.5	126	7.32	0.26	3.5	7.3	6.9 - 7.7
All Roche Methods	11	5.80	0.19	3.4	5.9	5.5 - 6.1	11	7.02	0.13	1.9	7.0	6.6 - 7.4
All TOSOH Methods	16	5.94	0.12	2.0	5.9	5.6 - 6.3	16	6.94	0.12	1.7	7.0	6.5 - 7.3
Beckman AU A1c	9	6.11	0.14	2.2	6.2	5.8 - 6.5	9	7.30	0.16	2.2	7.3	6.9 - 7.7
Bio-Rad D-10 HbA1C	5	6.50	0.19	2.9	6.5	6.1 - 6.9	5	7.54	0.15	2.0	7.6	7.1 - 8.0
Roche cobas c 501 HbA1c	5	5.66	0.21	3.7	5.7	5.3 - 6.0	5	6.94	0.09	1.3	7.0	6.5 - 7.3
Roche Integra A1C	5	5.92	0.08	1.4	5.9	5.6 - 6.3	5	7.06	0.13	1.9	7.0	6.7 - 7.5
Siemens DCA Vantage	62	6.15	0.17	2.8	6.1	5.8 - 6.5	61	7.40	0.16	2.2	7.4	7.0 - 7.8
Siemens Dimension HB1C	13	6.14	0.43	7.0	6.1	5.8 - 6.5	13	7.35	0.48	6.5	7.4	6.9 - 7.8
TOSOH G8	16	5.94	0.12	2.0	5.9	5.6 - 6.3	16	6.94	0.12	1.7	7.0	6.5 - 7.3

## Whole Blood Glucose (mg/dL)

<u>Method</u>	<u>Specimen WBG-1</u>						<u>Specimen WBG-2</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	760	279.8	19.6	7.0	284	223 - 336	755	418.0	29.6	7.1	427	334 - 502
All Abbott Methods	37	253.8	18.6	7.3	255	203 - 305	37	384.8	24.5	6.4	384	307 - 462
All Arkray Methods	10	278.7	39.6	14.2	267	222 - 335	10	385.6	68.3	17.7	366	308 - 463
All Bayer Methods	22	219.7	13.1	5.9	219	175 - 264	22	335.0	26.0	7.8	332	268 - 402
All Hemocue Methods	56	291.8	8.4	2.9	291	233 - 351	53	414.9	19.5	4.7	418	331 - 498
All Lifescan Methods	9	308.7	14.2	4.6	310	246 - 371	9	439.2	22.6	5.1	440	351 - 528
All Roche Methods	496	285.3	6.4	2.2	284	228 - 343	495	430.8	9.5	2.2	430	344 - 517
Abbott FreeStyle Lite/Freedom Lite	7	267.9	12.3	4.6	264	214 - 322	7	392.9	20.9	5.3	384	314 - 472
Abbott FreeStyle Precision Pro	18	261.5	57.9	22.1	239	209 - 314	16	382.7	28.6	7.5	387	306 - 460
Abbott Precision XceedPro	14	259.8	14.7	5.7	264	207 - 312	14	383.1	21.8	5.7	382	306 - 460
Arkray Platinum	27	269.1	8.3	3.1	269	215 - 323	26	372.5	14.4	3.9	369	297 - 447
Bayer Contour	24	219.3	12.7	5.8	219	175 - 264	24	335.3	25.1	7.5	332	268 - 403
HemoCue Glucose 201	56	291.9	8.2	2.8	291	233 - 351	51	417.3	15.8	3.8	422	333 - 501
Home Diagnostics True Balance / TrueTrack	14	557.4	19.2	3.4	559	445 - 669	4	-	-	-	596	476 - 714
Lifescan One Touch Ultra	9	308.7	14.2	4.6	310	246 - 371	9	439.2	22.6	5.1	440	351 - 528
Medline EvenCare G2 / G3	15	256.1	32.0	12.5	259	204 - 308	14	335.4	19.4	5.8	333	268 - 403
NOVA Biomedical StatStrip	34	237.4	8.3	3.5	238	189 - 285	34	362.3	12.6	3.5	365	289 - 435
Quintet / AC	29	298.0	12.3	4.1	297	238 - 358	28	420.4	19.0	4.5	426	336 - 505
Roche Accu-Chek Aviva	5	276.8	4.8	1.7	279	221 - 333	5	421.6	3.5	0.8	422	337 - 506
Roche Accu-Chek Inform	11	280.2	7.9	2.8	281	224 - 337	11	429.2	7.5	1.7	432	343 - 516
Roche Accu-Chek Inform II	335	285.4	5.8	2.0	285	228 - 343	332	430.9	8.7	2.0	430	344 - 518
Roche Accu-Chek Performa	145	285.5	7.1	2.5	284	228 - 343	147	431.1	11.0	2.6	430	344 - 518
True Metrix Pro	16	248.6	18.1	7.3	253	198 - 299	17	421.4	19.1	4.5	417	337 - 506

**Whole Blood Glucose (mg/dL) cont'd**

<u>Method</u>	<b>Specimen WBG-3</b>						<b>Specimen WBG-4</b>					
	<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	123	67.1	6.8	10.1	70	53 - 81	122	171.1	11.5	6.7	174	136 - 206
All Abbott Methods	5	54.6	1.8	3.3	55	42 - 67	5	163.2	5.0	3.0	164	130 - 196
All Lifescan Methods	3	-	-	-	60	49 - 75	3	-	-	-	193	151 - 228
All Roche Methods	94	70.5	1.4	2.0	71	56 - 85	95	174.6	3.5	2.0	175	139 - 210
Abbott Precision XceedPro	5	54.6	1.8	3.3	55	42 - 67	5	163.2	5.0	3.0	164	130 - 196
Lifescan One Touch Ultra	3	-	-	-	60	49 - 75	3	-	-	-	193	151 - 228
Medline EvenCare G2 / G3	1	-	-	-	63	50 - 76	1	-	-	-	174	139 - 209
NOVA Biomedical StatStrip	15	53.3	2.3	4.2	53	41 - 66	15	144.1	4.2	2.9	144	115 - 173
Roche Accu-Chek Inform	10	70.6	1.8	2.6	71	56 - 85	10	174.5	3.9	2.2	176	139 - 210
Roche Accu-Chek Inform II	77	70.4	1.3	1.9	70	56 - 85	77	174.6	3.2	1.9	175	139 - 210
Roche Accu-Chek Performa	7	70.7	1.5	2.1	71	56 - 85	7	173.0	4.5	2.6	174	138 - 208
True Metrix Pro	1	-	-	-	53	41 - 65	1	-	-	-	151	120 - 182

<u>Method</u>	<b>Specimen WBG-5</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	123	419.4	23.7	5.7	428	335 - 504
All Abbott Methods	5	388.0	7.8	2.0	385	310 - 466
All Lifescan Methods	3	-	-	-	436	353 - 531
All Roche Methods	95	429.5	7.6	1.8	430	343 - 516
Abbott Precision XceedPro	5	388.0	7.8	2.0	385	310 - 466
Lifescan One Touch Ultra	3	-	-	-	436	353 - 531
Medline EvenCare G2 / G3	1	-	-	-	399	319 - 479
NOVA Biomedical StatStrip	15	367.7	8.9	2.4	368	294 - 442
Roche Accu-Chek Inform	10	430.4	6.8	1.6	431	344 - 517
Roche Accu-Chek Inform II	78	429.9	7.5	1.8	430	343 - 516
Roche Accu-Chek Performa	7	423.7	8.0	1.9	426	338 - 509
True Metrix Pro	1	-	-	-	418	334 - 502

**Folate (ng/mL)**

<u>Method</u>	<b>Specimen SC-1</b>						<b>Specimen SC-2</b>					
	<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	1.10	0.86	77.7	0.5	0.1 - 2.2	23	9.44	3.89	41.3	10.6	6.6 - 12.3
All Roche Instruments	7	1.81	0.54	29.6	2.0	0.8 - 2.9	7	9.37	0.68	7.3	9.8	6.5 - 12.2
All Siemens Dimension Instruments	8	0.61	0.21	34.3	0.6	0.0 - 1.7	8	6.29	0.56	8.9	6.5	4.4 - 8.2
All TOSOH Instruments	9	0.52	0.07	12.8	0.5	0.0 - 1.6	9	6.10	0.81	13.3	6.4	4.2 - 8.0
Abbott Architect	6	0.70	0.71	101.4	0.4	0.0 - 1.7	5	15.50	2.71	17.5	16.6	10.8 - 20.2
Beckman ACCESS / 2 / Dxl	25	0.42	0.41	98.5	0.3	0.0 - 1.5	25	12.49	0.99	7.9	12.8	8.7 - 16.3
Siemens Dimension	6	0.63	0.24	38.2	0.6	0.0 - 1.7	6	6.25	0.58	9.2	6.5	4.3 - 8.2
TOSOH AIA PACK	5	0.54	0.09	16.6	0.5	0.0 - 1.6	5	6.28	1.01	16.1	6.4	4.3 - 8.2

**CK-MB - Quantitative (U/L)**

<u>Method</u>	<b>Specimen CK-1</b>						<b>Specimen CK-2</b>					
	<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	46.00	11.31	24.6	46.0	12.0 - 80.0	5	5.50	0.71	12.9	5.5	3.3 - 7.7
<u>Method</u>	<b>Specimen CK-3</b>						<b>Specimen CK-4</b>					
	<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	25.75	6.72	26.1	25.8	5.5 - 46.0	5	15.95	2.76	17.3	16.0	7.6 - 24.3
<u>Method</u>	<b>Specimen CK-5</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	5	85.80	23.76	27.7	85.8	14.5 - 157.1						

**Medical Laboratory Evaluation**  
 25 Massachusetts Ave NW Ste 700  
 Washington, DC 20001-7401  
 800-338-2746 • 202-261-4500 • Fax: 202-835-0440  
[www.acponline.org/mle](http://www.acponline.org/mle)