

# **MEDICAL LABORATORY EVALUATION**

## **PARTICIPANT SUMMARY**

# **2 • 0 • 1 • 9**

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

**International Data Supplement  
2019 MLE-M3**



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

# Table of Contents

<b>Evaluation Criteria</b> .....	4
<b>Hematology</b>	
<b>Sedimentation Rate</b> .....	5
<b>Hematology with 5-part Automated Differential (CL Samples – Module 223)</b> .....	5
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) .....	17
<b>Activated Partial Thromboplastin Time</b> .....	20
<b>Fibrinogen</b> .....	22
<b>Urinalysis</b>	
<b>Urinalysis Dipstick</b> .....	23
Specific Gravity .....	23
pH .....	24
Protein .....	25
Glucose.....	26
Ketones.....	27
Bilirubin .....	28
Urobilinogen.....	29
Blood or Hemoglobin .....	30
Leukocyte Esterase .....	31
Nitrite .....	32
Microalbumin (Dipstick Only) .....	33
<b>Urine hCG</b> .....	33
<b>Microbiology</b>	
<b>Miscellaneous Cultures</b> .....	34
<b>Antimicrobial Susceptibility Testing</b> .....	36
<b>Parasitology (PA Specimens)</b> .....	38
<b>Parasitology (FP Specimens)</b> .....	40
<b>Immunology</b>	
<b>Antinuclear Antibody</b> .....	45
Qualitative .....	45
Semi-Quantitative .....	45

# Table of Contents (cont'd)

## Immunology

Anti-dsDNA.....	47
Anti-RNP .....	47
Anti-RNP/Sm .....	48
Anti-SSA .....	48
Anti-SSB .....	49
Anti-SSA/SSB .....	49
Anti-Sm .....	50
Rubella.....	51
Qualitative.....	51
Quantitative.....	52
Syphilis Serology.....	53
VDRL Slide .....	53
VDRL Slide (Titer).....	54
MHA-TP .....	56
TPA.....	57
RPR .....	58
RPR (Titer).....	59
Viral Markers .....	62
Anti-HBc (IgM) .....	62
Anti-HBc (Total/IgG) .....	63
Anti-HIV .....	64
Anti-HAV (IgM).....	66
Anti-HAV (Total/IgG).....	67
HBeAg .....	68
Anti-HBs .....	69
HBsAg .....	70
Anti-HCV.....	71
Toxoplasma gondii .....	72
Qualitative (IgG).....	72
Quantitative (IgG) .....	72
Qualitative (IgM) .....	73
Quantitative (IgM) .....	73
Cytomegalovirus (CMV) .....	74
Qualitative (IgG).....	74
Quantitative (IgG) .....	74
Qualitative (IgM) .....	75
Quantitative (IgM) .....	75

## Chemistry

Bilirubin, Neonatal (Total) .....	76
Bilirubin, Direct (NB Specimens).....	76
Glycohemoglobin (GH Specimens).....	77
Glucose, Whole Blood (WBG Specimens).....	77
CK-MB .....	79

## EVALUATION CRITERIA

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

### Qualitative/Semi-Quantitative

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

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

### Quantitative

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

Activated Partial Thromboplastin Time	$\pm 15\%$	International Normalized Ratio (INR)	$\pm 20\%$
Automated Differential	$\pm 3$ SD	Platelet Count	$\pm 25\%$
Bilirubin, Neonatal (Total)	$\pm 0.4$ mg/dL or $20\%$ *	Prothrombin Time	$\pm 15\%$
Bilirubin, Direct	$\pm 2$ SD	Red Blood Cell Count	$\pm 6\%$
CK-MB (U/L)	$\pm 3$ SD	Rubella	$\pm 3$ SD
Cytomegalovirus	$\pm 2$ SD	Sedimentation Rate	$\pm 2$ SD
Fibrinogen	$\pm 20\%$	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	$\pm 6\%$		
Hemoglobin	$\pm 7\%$		

**SEDIMENTATION RATE (MM/HR)**

<u>Instrument</u>	Specimen ES-5						Specimen ES-6					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	170	53.2	12.5	23.4	50	28 - 79	170	10.3	3.2	30.8	10	3 - 17
All Automated Methods	37	67.1	10.6	15.8	66	45 - 89	37	12.1	3.3	27.0	12	5 - 19
All Diese Methods	11	71.2	11.1	15.6	72	48 - 94	11	12.5	3.5	27.9	12	5 - 20
All Manual Methods	117	47.8	8.0	16.7	47	31 - 64	117	9.6	2.6	27.6	9	4 - 15
All Vital Diagnostics Methods	18	66.5	10.6	16.0	64	45 - 88	18	11.3	3.3	29.5	11	4 - 19
Westergren - diluted	94	47.6	7.8	16.3	47	32 - 64	91	9.2	2.0	22.3	9	5 - 14
Westergren - undiluted	20	51.2	10.5	20.6	50	30 - 73	22	13.0	3.9	30.2	12	5 - 21

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

<u>Instrument</u>	Specimen CL-11						Specimen CL-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	24	6.89	0.71	10.3	6.6	5.8 - 8.0	23	2.60	0.34	13.2	2.5	2.2 - 3.0
All Abbott Cell-Dyn Instruments	9	7.51	0.19	2.5	7.4	6.3 - 8.7	9	2.91	0.13	4.4	2.9	2.4 - 3.4
Abbott Cell-Dyn Ruby	9	7.51	0.19	2.5	7.4	6.3 - 8.7	9	2.91	0.13	4.4	2.9	2.4 - 3.4
Orphee Mythic 22	11	6.30	0.26	4.1	6.4	5.3 - 7.3	11	2.30	0.14	6.1	2.3	1.9 - 2.7

  

<u>Instrument</u>	Specimen CL-13						Specimen CL-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	23	6.84	0.67	9.7	6.6	5.8 - 7.9	24	18.32	1.75	9.6	17.6	15.5 - 21.1
All Abbott Cell-Dyn Instruments	9	7.38	0.10	1.3	7.4	6.2 - 8.5	9	19.68	0.55	2.8	19.6	16.7 - 22.7
Abbott Cell-Dyn Ruby	9	7.38	0.10	1.3	7.4	6.2 - 8.5	9	19.68	0.55	2.8	19.6	16.7 - 22.7
Orphee Mythic 22	11	6.25	0.28	4.4	6.3	5.3 - 7.2	11	16.81	0.73	4.4	17.0	14.2 - 19.4

  

<u>Instrument</u>	Specimen CL-15					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	23	2.63	0.36	13.6	2.5	2.2 - 3.1
All Abbott Cell-Dyn Instruments	9	2.98	0.13	4.4	3.0	2.5 - 3.5
Abbott Cell-Dyn Ruby	9	2.98	0.13	4.4	3.0	2.5 - 3.5
Orphee Mythic 22	11	2.31	0.11	4.9	2.3	1.9 - 2.7

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

<i><u>Instrument</u></i>	<b>Specimen CL-11</b>						<b>Specimen CL-12</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	23	4.644	0.161	3.5	4.64	4.36 - 4.93	24	2.326	0.062	2.7	2.33	2.18 - 2.47
All Abbott Cell-Dyn Instruments	9	4.782	0.116	2.4	4.81	4.49 - 5.07	9	2.370	0.042	1.8	2.37	2.22 - 2.52
Abbott Cell-Dyn Ruby	9	4.782	0.116	2.4	4.81	4.49 - 5.07	9	2.370	0.042	1.8	2.37	2.22 - 2.52
Orphee Mythic 22	10	4.553	0.130	2.9	4.56	4.27 - 4.83	11	2.293	0.061	2.7	2.27	2.15 - 2.44
<i><u>Instrument</u></i>	<b>Specimen CL-13</b>						<b>Specimen CL-14</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	24	4.612	0.145	3.1	4.63	4.33 - 4.89	24	5.108	0.169	3.3	5.09	4.80 - 5.42
All Abbott Cell-Dyn Instruments	9	4.746	0.075	1.6	4.75	4.46 - 5.04	9	5.237	0.133	2.5	5.22	4.92 - 5.56
Abbott Cell-Dyn Ruby	9	4.746	0.075	1.6	4.75	4.46 - 5.04	9	5.237	0.133	2.5	5.22	4.92 - 5.56
Orphee Mythic 22	11	4.511	0.118	2.6	4.51	4.24 - 4.79	11	5.014	0.150	3.0	4.97	4.71 - 5.32
<i><u>Instrument</u></i>	<b>Specimen CL-15</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	23	2.330	0.062	2.7	2.32	2.18 - 2.47						
All Abbott Cell-Dyn Instruments	9	2.361	0.056	2.4	2.35	2.21 - 2.51						
Abbott Cell-Dyn Ruby	9	2.361	0.056	2.4	2.35	2.21 - 2.51						
Orphee Mythic 22	11	2.305	0.062	2.7	2.29	2.16 - 2.45						

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

<i><u>Instrument</u></i>	<b>Specimen CL-11</b>						<b>Specimen CL-12</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	24	12.63	0.83	6.6	12.3	11.7 - 13.6	23	5.28	0.44	8.3	5.0	4.9 - 5.7
All Abbott Cell-Dyn Instruments	9	13.52	0.29	2.2	13.4	12.5 - 14.5	9	5.72	0.16	2.9	5.7	5.3 - 6.2
Abbott Cell-Dyn Ruby	9	13.52	0.29	2.2	13.4	12.5 - 14.5	9	5.72	0.16	2.9	5.7	5.3 - 6.2
Orphee Mythic 22	11	11.90	0.20	1.7	11.9	11.0 - 12.8	11	4.87	0.08	1.6	4.9	4.5 - 5.3
<i><u>Instrument</u></i>	<b>Specimen CL-13</b>						<b>Specimen CL-14</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	24	12.52	0.78	6.2	12.2	11.6 - 13.4	24	15.85	0.62	3.9	15.7	14.7 - 17.0
All Abbott Cell-Dyn Instruments	9	13.33	0.34	2.5	13.4	12.3 - 14.3	9	16.50	0.38	2.3	16.5	15.3 - 17.7
Abbott Cell-Dyn Ruby	9	13.33	0.34	2.5	13.4	12.3 - 14.3	9	16.50	0.38	2.3	16.5	15.3 - 17.7
Orphee Mythic 22	11	11.84	0.18	1.5	11.8	11.0 - 12.7	11	15.36	0.20	1.3	15.4	14.2 - 16.5
<i><u>Instrument</u></i>	<b>Specimen CL-15</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	23	5.27	0.42	7.9	5.1	4.9 - 5.7						
All Abbott Cell-Dyn Instruments	9	5.69	0.17	3.0	5.6	5.2 - 6.1						
Abbott Cell-Dyn Ruby	9	5.69	0.17	3.0	5.6	5.2 - 6.1						
Orphee Mythic 22	11	4.89	0.13	2.7	4.9	4.5 - 5.3						

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

<u>Instrument</u>	<b>Specimen CL-11</b>						<b>Specimen CL-12</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	39.22	1.67	4.2	38.9	36.8 - 41.6	24	16.73	0.92	5.5	16.5	15.7 - 17.8
All Abbott Cell-Dyn Instruments	9	37.97	0.99	2.6	38.0	35.6 - 40.3	9	15.96	0.30	1.9	16.0	14.9 - 17.0
Abbott Cell-Dyn Ruby	9	37.97	0.99	2.6	38.0	35.6 - 40.3	9	15.96	0.30	1.9	16.0	14.9 - 17.0
Orphee Mythic 22	11	39.86	1.18	3.0	39.6	37.4 - 42.3	11	17.15	0.64	3.7	16.9	16.1 - 18.2
<u>Instrument</u>	<b>Specimen CL-13</b>						<b>Specimen CL-14</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	38.97	1.69	4.3	38.7	36.6 - 41.4	22	45.91	1.96	4.3	46.0	43.1 - 48.7
All Abbott Cell-Dyn Instruments	9	37.63	0.85	2.3	37.2	35.3 - 39.9	9	44.23	1.17	2.7	44.0	41.5 - 46.9
Abbott Cell-Dyn Ruby	9	37.63	0.85	2.3	37.2	35.3 - 39.9	9	44.23	1.17	2.7	44.0	41.5 - 46.9
Orphee Mythic 22	11	39.56	1.11	2.8	39.4	37.1 - 42.0	10	47.07	1.42	3.0	46.7	44.2 - 49.9
<u>Instrument</u>	<b>Specimen CL-15</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	23	16.72	0.96	5.7	16.5	15.7 - 17.8						
All Abbott Cell-Dyn Instruments	9	15.93	0.38	2.4	16.0	14.9 - 16.9						
Abbott Cell-Dyn Ruby	9	15.93	0.38	2.4	16.0	14.9 - 16.9						
Orphee Mythic 22	11	17.13	0.63	3.7	17.1	16.0 - 18.2						

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

<u>Instrument</u>	<b>Specimen CL-11</b>						<b>Specimen CL-12</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	23	266.3	12.3	4.6	267	199 - 333	24	94.6	15.3	16.1	91	70 - 119
All Abbott Cell-Dyn Instruments	9	258.7	9.6	3.7	260	194 - 324	9	80.9	3.3	4.0	82	60 - 102
Abbott Cell-Dyn Ruby	9	258.7	9.6	3.7	260	194 - 324	9	80.9	3.3	4.0	82	60 - 102
Orphee Mythic 22	11	272.5	11.3	4.2	272	204 - 341	11	104.4	7.8	7.5	105	78 - 131
<u>Instrument</u>	<b>Specimen CL-13</b>						<b>Specimen CL-14</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	261.1	17.9	6.9	261	195 - 327	24	485.1	29.4	6.1	487	363 - 607
All Abbott Cell-Dyn Instruments	9	253.1	10.8	4.3	255	189 - 317	9	496.7	18.6	3.7	488	372 - 621
Abbott Cell-Dyn Ruby	9	253.1	10.8	4.3	255	189 - 317	9	496.7	18.6	3.7	488	372 - 621
Orphee Mythic 22	11	269.9	16.2	6.0	276	202 - 338	11	485.8	25.3	5.2	491	364 - 608
<u>Instrument</u>	<b>Specimen CL-15</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	23	92.7	13.7	14.8	97	69 - 116						
All Abbott Cell-Dyn Instruments	9	80.9	4.4	5.5	80	60 - 102						
Abbott Cell-Dyn Ruby	9	80.9	4.4	5.5	80	60 - 102						
Orphee Mythic 22	11	102.8	5.0	4.8	101	77 - 129						

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

<u>Instrument</u>	<b>Specimen CL-11</b>						<b>Specimen CL-12</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	21	61.28	1.73	2.8	61.3	56.0 - 66.5	21	50.44	1.94	3.8	51.3	44.6 - 56.3
All Abbott Cell-Dyn Instruments	9	61.57	0.85	1.4	61.4	59.0 - 64.2	9	51.26	0.56	1.1	51.4	49.5 - 53.0
Abbott Cell-Dyn Ruby	9	61.57	0.85	1.4	61.4	59.0 - 64.2	9	51.26	0.56	1.1	51.4	49.5 - 53.0
Orphee Mythic 22	10	60.78	1.95	3.2	61.1	54.9 - 66.7	10	49.65	2.57	5.2	50.5	41.9 - 57.4
<u>Instrument</u>	<b>Specimen CL-13</b>						<b>Specimen CL-14</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	21	61.39	2.01	3.3	61.8	55.3 - 67.5	19	74.31	0.78	1.0	74.2	71.9 - 76.7
All Abbott Cell-Dyn Instruments	9	62.34	0.85	1.4	62.3	59.8 - 64.9	9	74.66	0.76	1.0	74.8	72.3 - 77.0
Abbott Cell-Dyn Ruby	9	62.34	0.85	1.4	62.3	59.8 - 64.9	9	74.66	0.76	1.0	74.8	72.3 - 77.0
Orphee Mythic 22	10	60.29	2.19	3.6	60.8	53.7 - 66.9	9	74.08	0.68	0.9	74.0	72.0 - 76.2
<u>Instrument</u>	<b>Specimen CL-15</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	20	50.60	1.98	3.9	51.0	44.6 - 56.6						
All Abbott Cell-Dyn Instruments	9	51.07	1.61	3.2	51.4	46.2 - 56.0						
Abbott Cell-Dyn Ruby	9	51.07	1.61	3.2	51.4	46.2 - 56.0						
Orphee Mythic 22	9	50.34	2.39	4.7	50.9	43.1 - 57.6						

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

<u>Instrument</u>	<b>Specimen CL-11</b>						<b>Specimen CL-12</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	18	22.81	5.24	23.0	24.7	7.0 - 38.6	18	32.04	6.06	18.9	34.9	13.8 - 50.3
All Abbott Cell-Dyn Instruments	9	26.20	1.40	5.3	26.3	22.0 - 30.4	9	35.92	3.73	10.4	36.4	24.7 - 47.2
Abbott Cell-Dyn Ruby	9	26.20	1.40	5.3	26.3	22.0 - 30.4	9	35.92	3.73	10.4	36.4	24.7 - 47.2
Orphee Mythic 22	7	18.70	5.75	30.7	16.2	1.4 - 36.0	7	27.03	5.11	18.9	28.4	11.7 - 42.4
<u>Instrument</u>	<b>Specimen CL-13</b>						<b>Specimen CL-14</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	17	23.54	4.66	19.8	25.4	9.5 - 37.6	21	12.71	2.79	22.0	14.0	4.3 - 21.1
All Abbott Cell-Dyn Instruments	9	26.18	0.85	3.3	26.2	23.6 - 28.8	9	14.97	0.70	4.7	15.0	12.8 - 17.1
Abbott Cell-Dyn Ruby	9	26.18	0.85	3.3	26.2	23.6 - 28.8	9	14.97	0.70	4.7	15.0	12.8 - 17.1
Orphee Mythic 22	6	20.07	5.83	29.0	18.2	2.5 - 37.6	9	10.74	2.09	19.5	10.2	4.4 - 17.1
<u>Instrument</u>	<b>Specimen CL-15</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	18	34.92	6.01	17.2	36.5	16.8 - 53.0						
All Abbott Cell-Dyn Instruments	9	37.18	1.81	4.9	37.0	31.7 - 42.7						
Abbott Cell-Dyn Ruby	9	37.18	1.81	4.9	37.0	31.7 - 42.7						
Orphee Mythic 22	7	32.53	8.82	27.1	30.2	6.0 - 59.0						



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

<u>Instrument</u>	<b>Specimen CL-11</b>						<b>Specimen CL-12</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	20	12.62	5.73	45.4	11.6	0.0 - 29.9	20	16.47	7.59	46.1	17.6	0.0 - 39.3
All Abbott Cell-Dyn Instruments	9	7.66	1.31	17.1	7.1	3.7 - 11.6	9	9.78	3.05	31.2	8.9	0.6 - 19.0
Abbott Cell-Dyn Ruby	9	7.66	1.31	17.1	7.1	3.7 - 11.6	9	9.78	3.05	31.2	8.9	0.6 - 19.0
Orphee Mythic 22	9	17.61	3.33	18.9	18.3	7.6 - 27.6	9	23.60	3.27	13.9	23.9	13.7 - 33.5
<u>Instrument</u>	<b>Specimen CL-13</b>						<b>Specimen CL-14</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	20	13.44	7.03	52.3	11.2	0.0 - 34.6	22	7.06	3.29	46.7	8.3	0.0 - 17.0
All Abbott Cell-Dyn Instruments	9	6.92	0.43	6.2	6.9	5.6 - 8.3	9	3.81	0.54	14.2	3.8	2.1 - 5.5
Abbott Cell-Dyn Ruby	9	6.92	0.43	6.2	6.9	5.6 - 8.3	9	3.81	0.54	14.2	3.8	2.1 - 5.5
Orphee Mythic 22	9	20.21	3.03	15.0	21.2	11.1 - 29.4	11	9.95	1.42	14.3	9.8	5.6 - 14.3
<u>Instrument</u>	<b>Specimen CL-15</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	20	14.92	7.14	47.9	12.4	0.0 - 36.4						
All Abbott Cell-Dyn Instruments	9	8.70	1.07	12.3	8.6	5.4 - 12.0						
Abbott Cell-Dyn Ruby	9	8.70	1.07	12.3	8.6	5.4 - 12.0						
Orphee Mythic 22	9	21.38	4.71	22.0	22.9	7.2 - 35.5						

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

<u>Instrument</u>	<b>Specimen CL-11</b>						<b>Specimen CL-12</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	20	4.04	0.75	18.5	4.1	1.7 - 6.3	21	2.40	0.56	23.4	2.5	0.7 - 4.1
All Abbott Cell-Dyn Instruments	9	4.30	0.27	6.3	4.4	3.4 - 5.2	9	2.56	0.41	16.1	2.5	1.3 - 3.8
Abbott Cell-Dyn Ruby	9	4.30	0.27	6.3	4.4	3.4 - 5.2	9	2.56	0.41	16.1	2.5	1.3 - 3.8
Orphee Mythic 22	9	4.10	0.71	17.3	4.0	1.9 - 6.3	10	2.40	0.65	26.9	2.4	0.4 - 4.4
<u>Instrument</u>	<b>Specimen CL-13</b>						<b>Specimen CL-14</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	20	3.76	0.77	20.4	4.0	1.4 - 6.1	20	5.28	1.09	20.7	5.4	2.0 - 8.6
All Abbott Cell-Dyn Instruments	9	4.31	0.25	5.9	4.2	3.5 - 5.1	9	6.16	0.27	4.4	6.2	5.3 - 7.0
Abbott Cell-Dyn Ruby	9	4.31	0.25	5.9	4.2	3.5 - 5.1	9	6.16	0.27	4.4	6.2	5.3 - 7.0
Orphee Mythic 22	9	3.46	0.68	19.7	3.5	1.4 - 5.5	9	4.80	0.87	18.2	4.8	2.1 - 7.5
<u>Instrument</u>	<b>Specimen CL-15</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	19	2.48	0.76	30.5	2.4	0.2 - 4.8						
All Abbott Cell-Dyn Instruments	9	2.52	0.92	36.5	2.8	0.0 - 5.3						
Abbott Cell-Dyn Ruby	9	2.52	0.92	36.5	2.8	0.0 - 5.3						
Orphee Mythic 22	8	2.43	0.68	28.2	2.2	0.3 - 4.5						

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

<u>Instrument</u>	<b>Specimen CL-11</b>						<b>Specimen CL-12</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	20	0.32	0.29	93.4	0.2	0.0 - 1.2	21	0.54	0.47	86.7	0.4	0.0 - 2.0
All Abbott Cell-Dyn Instruments	9	0.27	0.34	128.5	0.1	0.0 - 1.3	9	0.54	0.59	108.7	0.3	0.0 - 2.4
Abbott Cell-Dyn Ruby	9	0.27	0.34	128.5	0.1	0.0 - 1.3	9	0.54	0.59	108.7	0.3	0.0 - 2.4
Orphee Mythic 22	10	0.43	0.45	105.8	0.3	0.0 - 1.8	10	0.46	0.24	51.4	0.5	0.0 - 1.2
<u>Instrument</u>	<b>Specimen CL-13</b>						<b>Specimen CL-14</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	19	0.31	0.20	65.2	0.3	0.0 - 1.0	21	0.34	0.18	52.5	0.3	0.0 - 0.9
All Abbott Cell-Dyn Instruments	9	0.22	0.14	62.7	0.2	0.0 - 0.7	9	0.36	0.21	59.8	0.3	0.0 - 1.0
Abbott Cell-Dyn Ruby	9	0.22	0.14	62.7	0.2	0.0 - 0.7	9	0.36	0.21	59.8	0.3	0.0 - 1.0
Orphee Mythic 22	10	0.60	0.59	98.8	0.5	0.0 - 2.4	10	0.30	0.16	52.1	0.3	0.0 - 0.8
<u>Instrument</u>	<b>Specimen CL-15</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	21	0.40	0.35	86.6	0.3	0.0 - 1.5						
All Abbott Cell-Dyn Instruments	9	0.27	0.24	91.9	0.3	0.0 - 1.1						
Abbott Cell-Dyn Ruby	9	0.27	0.24	91.9	0.3	0.0 - 1.1						
Orphee Mythic 22	10	0.40	0.28	70.7	0.3	0.0 - 1.3						

## BLOOD BANK

### ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Group O	27	100%	Acceptable
BB-12	Group A	27	100%	Acceptable
BB-13	Group AB	27	100%	Acceptable
BB-14	Group A	27	100%	Acceptable
BB-15	Group O	27	100%	Acceptable

### RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Rh Positive	27	100%	Acceptable
BB-12	Rh Negative	27	100%	Acceptable
BB-13	Rh Positive	27	100%	Acceptable
BB-14	Rh Positive	27	100%	Acceptable
BB-15	Rh Negative	27	100%	Acceptable

## BLOOD BANK

### UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	Unexpected antibody detected	20	100%	Acceptable
AB-12	No unexpected antibody detected	20	100%	Acceptable
AB-13	No unexpected antibody detected	20	100%	Acceptable
AB-14	Unexpected antibody detected	20	100%	Acceptable
AB-15	No unexpected antibody detected	20	100%	Acceptable

### ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	Anti-E	12	100%	Acceptable
AB-12	No antibody detected	12	100%	Acceptable
AB-13	No antibody detected	12	100%	Acceptable
AB-14	Anti-K	12	100%	Acceptable
AB-15	No antibody detected	12	100%	Acceptable

## BLOOD BANK

### COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	Compatible	19	95.00%	Acceptable
	Not Compatible	1	5.00%	
AB-12	Compatible	20	100%	Acceptable
AB-13	Compatible	20	100%	Acceptable
AB-14	Not Compatible	20	100%	Acceptable
AB-15	Compatible	20	100%	Acceptable

# Coagulation

## PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	67	36.46	5.68	15.6	37.8	30.9 - 42.0	67	12.86	1.60	12.4	12.6	10.9 - 14.8
Dade Innovin												
Dade Behring BFT II	5	34.65	2.97	8.6	34.6	29.4 - 39.9	5	10.90	0.59	5.4	10.8	9.2 - 12.6
Sysmex CA-500/600 series	13	32.32	1.51	4.7	32.0	27.4 - 37.2	13	11.14	0.27	2.4	11.0	9.4 - 12.9
All Coagulation Instruments	20	32.74	1.97	6.0	32.2	27.8 - 37.7	20	11.10	0.38	3.5	11.0	9.4 - 12.8
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	8	40.53	2.35	5.8	40.8	34.4 - 46.7	8	14.30	0.42	3.0	14.3	12.1 - 16.5
RAL Clot-SP	7	41.01	2.14	5.2	40.0	34.8 - 47.2	7	14.79	0.23	1.6	14.8	12.5 - 17.1
All Coagulation Instruments	16	40.69	2.13	5.2	40.1	34.5 - 46.8	16	14.48	0.44	3.1	14.5	12.3 - 16.7
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	38.87	1.37	3.5	39.1	33.0 - 44.7	5	14.40	0.20	1.4	14.4	12.2 - 16.6
Diagnostica Stago STart Max	5	42.66	2.13	5.0	42.6	36.2 - 49.1	5	14.50	0.23	1.6	14.6	12.3 - 16.7
All Coagulation Instruments	10	41.24	2.64	6.4	40.9	35.0 - 47.5	10	14.46	0.21	1.5	14.5	12.2 - 16.7
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	42.38	2.63	6.2	43.1	36.0 - 48.8	5	11.92	0.19	1.6	11.9	10.1 - 13.8
IL TEST PT Fibrinogen												
IL ACL, all models	5	25.97	1.70	6.6	26.1	22.0 - 29.9	5	13.00	0.62	4.8	12.8	11.0 - 15.0

**PROTHROMBIN TIME (seconds)**

<u>Reagent/Instrument</u>	Specimen CG-13						Specimen CG-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	67	12.17	1.50	12.3	12.1	10.3 - 14.0	67	24.72	3.53	14.3	25.8	21.0 - 28.5
Dade Innovin												
Dade Behring BFT II	5	9.55	0.06	0.6	9.6	8.1 - 11.0	5	22.68	1.79	7.9	22.2	19.2 - 26.1
Sysmex CA-500/600 series	13	10.53	0.21	2.0	10.5	8.9 - 12.2	13	21.55	0.74	3.5	21.5	18.3 - 24.8
All Coagulation Instruments	20	10.37	0.48	4.6	10.5	8.8 - 12.0	20	21.65	0.68	3.1	21.8	18.4 - 25.0
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	8	13.59	0.38	2.8	13.5	11.5 - 15.7	8	27.98	1.29	4.6	28.6	23.7 - 32.2
RAL Clot-SP	7	13.96	0.25	1.8	13.9	11.8 - 16.1	7	28.06	1.02	3.6	28.2	23.8 - 32.3
All Coagulation Instruments	16	13.73	0.38	2.8	13.8	11.6 - 15.8	16	27.99	1.10	3.9	28.3	23.7 - 32.2
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	13.53	0.47	3.5	13.7	11.5 - 15.6	5	26.73	0.68	2.5	26.5	22.7 - 30.8
Diagnostica Stago STart Max	5	13.56	0.13	1.0	13.5	11.5 - 15.6	5	28.92	0.74	2.6	28.9	24.5 - 33.3
All Coagulation Instruments	10	13.55	0.27	2.0	13.6	11.5 - 15.6	10	28.10	1.31	4.7	28.2	23.8 - 32.4
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	11.90	0.29	2.4	11.9	10.1 - 13.7	5	27.14	0.76	2.8	26.9	23.0 - 31.3
IL TEST PT Fibrinogen												
IL ACL, all models	5	12.57	0.60	4.8	12.5	10.6 - 14.5	5	19.47	0.21	1.1	19.4	16.5 - 22.4

**PROTHROMBIN TIME (seconds)**

<u>Reagent/Instrument</u>	Specimen CG-15					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	67	15.65	1.67	10.7	16.1	13.2 - 18.0
Dade Innovin						
Dade Behring BFT II	5	13.85	0.44	3.2	13.9	11.7 - 16.0
Sysmex CA-500/600 series	13	13.78	0.56	4.1	13.6	11.7 - 15.9
All Coagulation Instruments	20	13.73	0.36	2.6	13.7	11.6 - 15.8
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	8	17.45	0.61	3.5	17.1	14.8 - 20.1
RAL Clot-SP	7	17.63	0.24	1.3	17.6	14.9 - 20.3
All Coagulation Instruments	16	17.45	0.56	3.2	17.6	14.8 - 20.1
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STA Compact	5	16.83	0.61	3.6	16.7	14.3 - 19.4
Diagnostica Stago STart Max	5	17.12	0.56	3.3	17.0	14.5 - 19.7
All Coagulation Instruments	10	17.01	0.56	3.3	17.0	14.4 - 19.6
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	15.78	0.56	3.5	15.8	13.4 - 18.2
IL TEST PT Fibrinogen						
IL ACL, all models	5	15.83	0.60	3.8	15.9	13.4 - 18.3



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

<b><u>Reagent/Instrument</u></b>	<b>Specimen CG-11</b>						<b>Specimen CG-12</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	64	3.75	0.60	16.0	3.8	2.9 - 4.5	64	1.11	0.08	7.5	1.1	0.8 - 1.4
Dade Innovin												
Dade Behring BFT II	5	3.33	0.13	3.8	3.3	2.6 - 4.0	5	1.20	0.08	6.8	1.2	0.9 - 1.5
Sysmex CA-500/600 series	13	3.22	0.11	3.4	3.2	2.5 - 3.9	13	1.09	0.05	4.5	1.1	0.8 - 1.4
All Coagulation Instruments	20	3.24	0.14	4.3	3.2	2.5 - 3.9	20	1.11	0.07	6.5	1.1	0.8 - 1.4
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	8	4.40	0.36	8.1	4.6	3.5 - 5.3	8	1.14	0.05	4.5	1.1	0.9 - 1.4
RAL Clot-SP	6	4.13	0.43	10.3	4.0	3.3 - 5.0	6	1.18	0.04	3.5	1.2	0.9 - 1.5
All Coagulation Instruments	15	4.26	0.40	9.3	4.2	3.4 - 5.2	15	1.15	0.06	5.6	1.2	0.9 - 1.4
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	3.87	0.25	6.5	3.9	3.0 - 4.7	5	1.03	0.12	11.2	1.1	0.8 - 1.3
Diagnostica Stago STart Max	5	4.54	0.35	7.7	4.5	3.6 - 5.5	5	1.14	0.05	4.8	1.1	0.9 - 1.4
All Coagulation Instruments	8	4.29	0.46	10.7	4.3	3.4 - 5.2	8	1.10	0.09	8.4	1.1	0.8 - 1.4
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	3.66	0.27	7.4	3.7	2.9 - 4.4	5	1.00	0.07	7.1	1.0	0.8 - 1.2
IL TEST PT Fibrinogen												
IL ACL, all models	5	4.10	0.44	10.6	3.9	3.2 - 5.0	5	1.20	0.10	8.3	1.2	0.9 - 1.5

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

<b><u>Reagent/Instrument</u></b>	<b>Specimen CG-13</b>						<b>Specimen CG-14</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	64	1.04	0.07	6.3	1.0	0.8 - 1.3	64	2.41	0.26	11.0	2.4	1.9 - 2.9
Dade Innovin												
Dade Behring BFT II	5	1.08	0.05	4.7	1.1	0.8 - 1.3	5	2.30	0.14	6.1	2.3	1.8 - 2.8
Sysmex CA-500/600 series	13	1.02	0.04	4.3	1.0	0.8 - 1.3	13	2.12	0.08	3.9	2.1	1.6 - 2.6
All Coagulation Instruments	20	1.04	0.05	4.7	1.0	0.8 - 1.3	20	2.17	0.12	5.7	2.2	1.7 - 2.6
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	8	1.06	0.05	4.9	1.1	0.8 - 1.3	8	2.73	0.18	6.7	2.8	2.1 - 3.3
RAL Clot-SP	6	1.10	0.01	0.0	1.1	0.8 - 1.4	6	2.63	0.14	5.2	2.6	2.1 - 3.2
All Coagulation Instruments	15	1.07	0.05	4.3	1.1	0.8 - 1.3	15	2.67	0.17	6.2	2.6	2.1 - 3.3
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	0.97	0.06	6.0	1.0	0.7 - 1.2	5	2.40	0.10	4.2	2.4	1.9 - 2.9
Diagnostica Stago STart Max	5	1.02	0.04	4.4	1.0	0.8 - 1.3	5	2.72	0.15	5.5	2.7	2.1 - 3.3
All Coagulation Instruments	8	1.00	0.05	5.3	1.0	0.8 - 1.2	8	2.60	0.21	8.0	2.6	2.0 - 3.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	1.00	0.07	7.1	1.0	0.8 - 1.2	5	2.34	0.11	4.9	2.3	1.8 - 2.9
IL TEST PT Fibrinogen												
IL ACL, all models	5	1.13	0.12	10.2	1.2	0.9 - 1.4	5	2.43	0.12	4.7	2.5	1.9 - 3.0

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

**Specimen CG-15**

<b><u>Reagent/Instrument</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	64	1.40	0.09	6.7	1.4	1.1 - 1.7
Dade Innovin						
Dade Behring BFT II	5	1.48	0.05	3.4	1.5	1.1 - 1.8
Sysmex CA-500/600 series	13	1.35	0.07	4.9	1.3	1.0 - 1.7
All Coagulation Instruments	20	1.38	0.08	5.6	1.4	1.1 - 1.7
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	8	1.44	0.09	6.4	1.4	1.1 - 1.8
RAL Clot-SP	6	1.48	0.04	2.8	1.5	1.1 - 1.8
All Coagulation Instruments	15	1.45	0.08	5.8	1.5	1.1 - 1.8
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STA Compact	5	1.30	0.01	0.0	1.3	1.0 - 1.6
Diagnostica Stago STart Max	5	1.44	0.05	3.8	1.4	1.1 - 1.8
All Coagulation Instruments	8	1.39	0.08	6.0	1.4	1.1 - 1.7
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	1.36	0.11	8.4	1.4	1.0 - 1.7
IL TEST PT Fibrinogen						
IL ACL, all models	5	1.70	0.17	10.2	1.8	1.3 - 2.1

**ACTIVATED PARTIAL THROMBOPLASTIN (seconds)**

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	42	49.0	5.3	10.7	49	41 - 57	42	31.2	5.9	18.8	31	26 - 36
Dade Actin FSL												
Sysmex CA-500/600 series	7	43.6	1.9	4.4	43	37 - 51	7	24.9	0.9	3.6	25	21 - 29
All Coagulation Instruments	9	44.3	2.3	5.2	44	37 - 51	9	25.2	1.3	5.2	25	21 - 30
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	5	55.3	1.2	2.1	56	47 - 64	5	34.0	1.7	5.1	35	28 - 40
Hemoliance SynthASil												
IL ACL, all models	5	50.0	0.1	0.0	50	42 - 58	5	40.0	1.4	3.5	40	34 - 46
HemosIL APTT-SP												
IL ACL, all models	5	47.5	3.5	7.4	48	40 - 55	5	36.3	5.6	15.3	36	30 - 42
IL TEST APTT-SP												
IL ACL, all models	5	47.5	2.1	4.5	48	40 - 55	5	33.0	1.4	4.3	33	28 - 38

**ACTIVATED PARTIAL THROMBOPLASTIN (seconds)**

<u>Reagent/Instrument</u>	<b>Specimen CG-13</b>						<b>Specimen CG-14</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	42	26.9	2.9	10.7	27	22 - 31	42	40.0	5.1	12.6	39	34 - 47
Dade Actin FSL												
Sysmex CA-500/600 series	7	23.3	1.1	4.8	24	19 - 27	7	35.6	1.5	4.3	36	30 - 41
All Coagulation Instruments	9	23.7	1.2	5.2	24	20 - 28	9	36.2	1.9	5.1	36	30 - 42
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	5	30.7	1.5	5.0	31	26 - 36	5	44.7	0.6	1.3	45	37 - 52
Hemoliance SynthASil												
IL ACL, all models	5	27.0	0.1	0.0	27	22 - 32	5	39.5	0.7	1.8	40	33 - 46
HemosIL APTT-SP												
IL ACL, all models	5	27.3	0.5	1.8	27	23 - 32	5	37.5	1.9	5.1	37	31 - 44
IL TEST APTT-SP												
IL ACL, all models	5	29.5	0.7	2.4	30	25 - 34	5	38.0	1.4	3.7	38	32 - 44

**Specimen CG-15**

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	42	36.4	5.9	16.1	37	30 - 42
Dade Actin FSL						
Sysmex CA-500/600 series	7	29.1	1.9	6.4	29	24 - 34
All Coagulation Instruments	9	29.6	1.9	6.4	30	25 - 34
Diagnostica Stago STA C.K. Prest						
Diagnostica Stago STA Compact	5	42.3	2.9	6.8	44	35 - 49
Hemoliance SynthASil						
IL ACL, all models	5	37.5	0.7	1.9	38	31 - 44
HemosIL APTT-SP						
IL ACL, all models	5	37.5	4.0	10.8	39	31 - 44
IL TEST APTT-SP						
IL ACL, all models	5	44.0	1.4	3.2	44	37 - 51

**FIBRINOGEN (mg/dL)**

Specimen CG-11							Specimen CG-12					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	256.3	25.3	9.9	247	205 - 308	17	401.9	28.2	7.0	411	321 - 483
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	5	257.8	27.2	10.6	257	206 - 310	5	413.3	8.1	2.0	417	330 - 496
Specimen CG-13							Specimen CG-14					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	287.1	20.4	7.1	289	229 - 345	17	261.5	23.2	8.9	254	209 - 314
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	5	281.0	22.0	7.8	279	224 - 338	5	265.0	24.5	9.2	265	212 - 318
Specimen CG-15												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	17	135.3	6.2	4.6	135	108 - 163						
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	5	136.0	5.4	3.9	136	108 - 164						

**URINALYSIS DIPSTICK–SPECIFIC GRAVITY**

**Specimen UA-3**

<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	128	1.0177	0.0082	0.8	1.015	1.007 - 1.028
All Arkray Methods	10	1.0300	0.0001	0.0	1.030	1.020 - 1.040
All Iris Diagnostics Methods	7	1.0230	0.0063	0.6	1.026	1.013 - 1.033
All Refractive Index Methods	21	1.0267	0.0061	0.6	1.030	1.016 - 1.037
All Roche Methods	38	1.0177	0.0069	0.7	1.015	1.007 - 1.028
All Siemens Methods	21	1.0155	0.0031	0.3	1.015	1.005 - 1.026
77 Elektronika LabUMat/2	10	1.0268	0.0076	0.7	1.031	1.016 - 1.037
Acon Laboratories	6	1.0092	0.0021	0.2	1.010	0.999 - 1.020
Arkray Aution Sticks	10	1.0300	0.0001	0.0	1.030	1.020 - 1.040
Roche Chemstrips / Combur	9	1.0089	0.0033	0.3	1.010	0.998 - 1.019
Roche cobas u 411	21	1.0155	0.0031	0.3	1.015	1.005 - 1.026
Roche Urisys	17	1.0205	0.0093	0.9	1.015	1.010 - 1.031
SD UroColor Reagent Strips	6	1.0125	0.0027	0.3	1.013	1.002 - 1.023
Siemens Clinitek Status / Status+	16	1.0166	0.0023	0.2	1.015	1.006 - 1.027
UriScan Reagent Strips	5	1.0110	0.0022	0.2	1.010	1.001 - 1.021

## URINALYSIS DIPSTICK-pH

Specimen UA-3

### Participant Results

<u>Method</u>	<u>Labs</u>	<u>≤3.5</u>	<u>4.0</u>	<u>4.5</u>	<u>5.0</u>	<u>5.5</u>	<u>6.0</u>	<u>6.5</u>	<u>7.0</u>	<u>7.5</u>	<u>8.0</u>	<u>8.5</u>	<u>≥9.0</u>
ALL METHODS	155	-	-	-	-	1	-	-	6	18	106	22	2
77 Elektronika LabUMat/2	11	-	-	-	-	-	-	-	3	7	1	-	-
Acon Laboratories	6	-	-	-	-	-	-	-	1	-	4	1	-
Arkray Aution Jet	1	-	-	-	-	-	-	-	-	1	-	-	-
Arkray Aution Sticks	10	-	-	-	-	-	-	-	-	-	10	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	1	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	-	-	1	-	-
Iris Diagnostics iChem Velocity Strips	5	-	-	-	-	-	-	-	-	2	3	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	-	-	-	-	-	2	-	-	-
Other Analyzer Method	3	-	-	-	-	-	-	-	-	1	2	-	-
Other Dipstick Method	3	-	-	-	-	-	-	-	-	-	3	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	-	-	-	1	-	-
Roche Chemstrips / Combur	23	-	-	-	-	1	-	-	1	-	18	1	2
Roche cobas 6500 / u 601	2	-	-	-	-	-	-	-	-	-	2	-	-
Roche cobas u 411	20	-	-	-	-	-	-	-	1	-	19	-	-
Roche Urisys	18	-	-	-	-	-	-	-	-	-	18	-	-
SD UroColor Reagent Strips	8	-	-	-	-	-	-	-	-	3	5	-	-
Siemens Clinitek Advantus	4	-	-	-	-	-	-	-	-	-	1	3	-
Siemens Clinitek Atlas	1	-	-	-	-	-	-	-	-	-	1	-	-
Siemens Clinitek Status / Status+	17	-	-	-	-	-	-	-	-	-	1	16	-
Siemens Reagent Strips	12	-	-	-	-	-	-	-	-	-	11	1	-
Urinometer	1	-	-	-	-	-	-	-	-	-	1	-	-
UriScan Pro/II	1	-	-	-	-	-	-	-	-	-	1	-	-
UriScan Reagent Strips	4	-	-	-	-	-	-	-	-	1	3	-	-



**URINALYSIS DIPSTICK–PROTEIN QUALITATIVE**  
**Specimen UA-3**

<u>Method</u>	<i>Participant Results</i>												
	<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	156	1	-	5	82	40	-	-	-	1	27	-	-
77 Elektronika LabUMat/2	11	-	-	2	5	-	-	-	-	-	4	-	-
Acon Laboratories	6	-	-	-	6	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	1	-	-	-	-	-	-	-
Arkray Aution Sticks	10	-	-	-	10	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	1	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	5	-	-	-	2	-	-	-	-	-	3	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	1	-	-	-	-	-	1	-	-
Other Analyzer Method	3	-	-	-	2	-	-	-	-	-	1	-	-
Other Dipstick Method	3	-	-	-	1	2	-	-	-	-	-	-	-
Plasmatec URIPATH	1	-	-	-	1	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	23	1	-	1	18	3	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	2	-	-	-	-	1	-	-	-	-	1	-	-
Roche cobas u 411	20	-	-	-	1	10	-	-	-	1	8	-	-
Roche Urisys	18	-	-	-	2	8	-	-	-	-	8	-	-
SD UroColor Reagent Strips	8	-	-	1	7	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	4	-	-	-	4	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	-	-	-	1	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	-	-	-	3	14	-	-	-	-	1	-	-
Siemens Reagent Strips	12	-	-	-	12	-	-	-	-	-	-	-	-
Urinometer	1	-	-	-	1	-	-	-	-	-	-	-	-
UriScan Pro/II	1	-	-	-	1	-	-	-	-	-	-	-	-
UriScan Reagent Strips	4	-	-	-	4	-	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Negative or Normal</u>	<u>Trace</u>	<u>(1+)</u>	<u>Participant Results</u>			<u>30 - 100 mg/dL</u>	<u>150 - 300 mg/dL</u>	<u>500 mg/dL</u>	<u>&gt;500 or ≥1000 or ≥2000 mg/dL</u>
					<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>				
ALL METHODS	155	154	-	-	-	1	-	-	-	-	-
77 Elektronika LabUMat/2	11	11	-	-	-	-	-	-	-	-	-
Acon Laboratories	6	6	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	10	10	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	5	5	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	2	-	-	-	-	-	-	-	-	-
Other Analyzer Method	3	3	-	-	-	-	-	-	-	-	-
Other Dipstick Method	3	3	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	23	22	-	-	-	1	-	-	-	-	-
Roche cobas 6500 / u 601	2	2	-	-	-	-	-	-	-	-	-
Roche cobas u 411	20	20	-	-	-	-	-	-	-	-	-
Roche Urisys	18	18	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	8	8	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	4	4	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	17	17	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	12	12	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-
UriScan Pro/II	1	1	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	4	4	-	-	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK–KETONES

### Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>Participant Results</u>					<u>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	156	-	-	-	-	-	1	12	60	56	-	-	-	3	24	
77 Elektronika LabUMat/2	11	-	-	-	-	-	-	-	7	-	-	-	-	-	4	
Acon Laboratories	6	-	-	-	-	-	-	-	5	1	-	-	-	-	-	
Arkray Aution Jet	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	
Arkray Aution Sticks	10	-	-	-	-	-	-	-	-	10	-	-	-	-	-	
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	
Iris Diagnostics iChem Velocity Strips	5	-	-	-	-	-	-	-	1	1	-	-	-	2	1	
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	-	-	-	-	-	1	-	-	-	-	1	
Other Analyzer Method	3	-	-	-	-	-	-	-	-	2	-	-	-	1	-	
Other Dipstick Method	3	-	-	-	-	-	-	-	3	-	-	-	-	-	-	
Plasmatec URIPATH	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	
Roche Chemstrips / Combur	23	-	-	-	-	-	1	3	18	1	-	-	-	-	-	
Roche cobas 6500 / u 601	2	-	-	-	-	-	-	-	-	1	-	-	-	-	1	
Roche cobas u 411	20	-	-	-	-	-	-	1	-	10	-	-	-	-	9	
Roche Urisys	18	-	-	-	-	-	-	1	4	5	-	-	-	-	8	
SD UroColor Reagent Strips	8	-	-	-	-	-	-	4	4	-	-	-	-	-	-	
Siemens Clinitek Advantus	4	-	-	-	-	-	-	-	4	-	-	-	-	-	-	
Siemens Clinitek Atlas	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	
Siemens Clinitek Status / Status+	18	-	-	-	-	-	-	-	-	18	-	-	-	-	-	
Siemens Reagent Strips	12	-	-	-	-	-	-	-	8	4	-	-	-	-	-	
Urinometer	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	
UriScan Pro/II	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	
UriScan Reagent Strips	4	-	-	-	-	-	-	1	3	-	-	-	-	-	-	

**URINALYSIS DIPSTICK–BILIRUBIN**

**Specimen UA-3**

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Participant Results</u>					<u>0.5 - 1.0 mg/dL</u>	<u>2.0 - 4.0 mg/dL</u>	<u>6.0 - 10.0 mg/dL</u>	<u>&gt;10.0 mg/dL</u>
						<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>				
ALL METHODS	131	21	3	-	3	-	37	45	2	-	11	8	-	1
77 Elektronika LabUMat/2	11	1	-	-	-	-	6	-	-	-	2	2	-	-
Acon Laboratories	6	3	-	-	-	-	1	2	-	-	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	-	1	-	-	-	-	-	-
Arkray Aution Sticks	10	1	-	-	-	-	-	9	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	1	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	5	4	-	-	-	-	1	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	3	-	-	-	-	-	-	2	1	-	-	-	-	-
Other Dipstick Method	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	10	-	1	-	-	-	1	7	-	-	-	-	-	1
Roche cobas 6500 / u 601	2	-	-	-	-	-	2	-	-	-	-	-	-	-
Roche cobas u 411	20	1	-	-	-	-	7	3	-	-	5	4	-	-
Roche Urisys	18	-	1	-	-	-	6	5	-	-	4	2	-	-
SD UroColor Reagent Strips	8	3	1	-	-	-	4	-	-	-	-	-	-	-
Siemens Clinitek Advantus	4	-	-	-	-	-	-	4	-	-	-	-	-	-
Siemens Clinitek Atlas	1	-	-	-	-	-	1	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	16	-	-	-	3	-	4	9	-	-	-	-	-	-
Siemens Reagent Strips	2	-	-	-	-	-	-	1	1	-	-	-	-	-
Urinometer	1	-	-	-	-	-	1	-	-	-	-	-	-	-
UriScan Pro/II	1	1	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	4	1	-	-	-	-	3	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK–UROBILINOGEN

### Specimen UA-3

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>				
		<u>Normal or 0.0 - 0.2 mg/dL or &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	130	43	37	18	24	8
77 Elektronika LabUMat/2	11	1	-	-	6	4
Acon Laboratories	6	5	1	-	-	-
Arkray Aution Jet	1	-	-	1	-	-
Arkray Aution Sticks	10	1	2	7	-	-
Arkray PocketChem UA	1	1	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	1	-	-	-
Iris Diagnostics Aution Max AX-4280	5	-	3	2	-	-
Iris Diagnostics iChem Velocity Strips	2	-	1	1	-	-
Iris Ichem VELOCITY Urine Chemistry System	3	-	1	2	-	-
Other Analyzer Method	3	2	1	-	-	-
Other Dipstick Method	1	1	-	-	-	-
Plasmatec URIPATH	10	2	6	-	1	1
Roche Chemstrips / Combur	2	-	2	-	-	-
Roche cobas 6500 / u 601	19	7	12	-	-	-
Roche cobas u 411	18	14	4	-	-	-
Roche Urisys	8	5	2	1	-	-
SD UroColor Reagent Strips	4	-	-	2	2	-
Siemens Clinitek Advantus	1	1	-	-	-	-
Siemens Clinitek Status / Status+	16	-	-	-	13	3
Siemens Reagent Strips	2	-	-	2	-	-
Urinometer	1	1	-	-	-	-
UriScan Pro/II	1	1	-	-	-	-
UriScan Reagent Strips	4	1	1	-	2	-

**URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN**

Specimen UA-3

**Participant Results**

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>(5+)</u>	<u>5 - 25</u> <u>Ery/<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	156	1	-	-	1	2	1	22	55	34	14	-	1	23	-	1	1	-
77 Elektronika LabUMat/2	11	1	-	-	-	-	-	-	7	-	-	-	1	2	-	-	-	-
Acon Laboratories	6	-	-	-	-	-	-	-	-	6	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	10	-	-	-	-	-	-	9	1	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	5	-	-	-	-	-	-	2	1	-	-	-	-	-	-	1	1	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	3	-	-	-	-	-	-	2	-	-	-	-	-	1	-	-	-	-
Other Dipstick Method	3	-	-	-	-	-	-	1	1	1	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	-	-	-	-	-	-	-	2	19	-	-	-	1	-	-	-	-
Roche cobas 6500 / u 601	2	-	-	-	-	-	-	-	-	-	1	-	-	1	-	-	-	-
Roche cobas u 411	20	-	-	-	-	-	-	1	-	-	10	-	-	9	-	-	-	-
Roche Mditron Junior/II	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Roche Urisys	18	-	-	-	-	-	-	-	1	5	3	-	-	9	-	-	-	-
SD UroColor Reagent Strips	8	-	-	-	-	-	-	-	6	2	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	4	-	-	-	-	-	-	-	4	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	-	-	-	1	2	-	2	13	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	12	-	-	-	-	-	-	-	12	-	-	-	-	-	-	-	-	-
Urinometer	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
UriScan Pro/II	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	4	-	-	-	-	-	-	1	3	-	-	-	-	-	-	-	-	-

**URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE**

**Specimen UA-3**

**Participant Results**

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>15 or 25 µL</u>	<u>75 or 100 µL</u>	<u>250 or 500 µL</u>
ALL METHODS	143	143	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	11	11	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	6	6	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	9	9	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	5	5	-	-	-	-	-	-	-	-	-	-	-
Iris iChem VELOCITY Urine Chemistry System	2	2	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	3	3	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	3	3	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	22	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	2	2	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	21	21	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	18	18	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	8	8	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	4	4	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	16	16	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	2	2	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	1	1	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	4	4	-	-	-	-	-	-	-	-	-	-	-

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

<b><u>Method</u></b>	<b><u>Labs</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	144	144	-
77 Elektronika LabUMat/2	11	11	-
Acon Laboratories	6	6	-
Arkray Aution Jet	1	1	-
Arkray Aution Sticks	10	10	-
DIRUI H-800 Urine Analyzer	1	1	-
Iris Diagnostics Aution Max AX-4280	1	1	-
Iris Diagnostics iChem Velocity Strips	5	5	-
Iris Ichem VELOCITY Urine Chemistry System	2	2	-
Other Analyzer Method	3	3	-
Other Dipstick Method	3	3	-
Plasmatec URIPATH	1	1	-
Roche Chemstrips / Combur	23	23	-
Roche cobas 6500 / u 601	2	2	-
Roche cobas u 411	20	20	-
Roche Urisys	18	18	-
SD UroColor Reagent Strips	8	8	-
Siemens Clinitek Advantus	4	4	-
Siemens Clinitek Atlas	1	1	-
Siemens Clinitek Status / Status+	16	16	-
Siemens Reagent Strips	2	2	-
Urinometer	1	1	-
UriScan Pro/II	1	1	-
UriScan Reagent Strips	4	4	-



**URINALYSIS –MICROALBUMIN (dipstick only)**

**Specimen UA-3**

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>										
		<u>Negative</u>	<u>10 mg/L</u>	<u>20 mg/L</u>	<u>30 mg/L</u>	<u>50 mg/L</u>	<u>80 mg/L</u>	<u>100 mg/L</u>	<u>150 mg/L</u>	<u>+(4 - 8 mg/dL)</u>	<u>++ (&gt;8 mg/dL)</u>	
ALL METHODS	10	1	-	-	-	-	-	-	1	3	-	5
Arkray Aution Sticks	1	-	-	-	-	-	-	-	-	1	-	-
Other Analyzer Method	2	-	-	-	-	-	-	-	-	1	-	1
Other Dipstick Method	1	-	-	-	-	-	-	-	-	-	-	1
Roche Micral - 1 minute	2	-	-	-	-	-	-	1	-	-	-	1
Roche Urisys	1	1	-	-	-	-	-	-	-	-	-	-

**URINALYSIS –URINE hCG**

**Specimen UA-3**

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>	
		<u>Positive</u>	<u>Negative</u>
ALL METHODS	86	86	-
Acon Laboratories	4	4	-
Alere Aceava hCG-Urine	1	1	-
Alere Clearview hCG Cassette	3	3	-
Alere hCG Cassette	21	21	-
Other Dipstick Method	1	1	-
SD Bioline hCG	11	11	-
Siemens Clinitek Status / Status+	10	10	-
Stanbio QuStick	1	1	-

## MISCELLANEOUS CULTURES

### Specimen BA-7 – CSF (Spinal Fluid) Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pseudomonas stutzeri	88	75.86%	Acceptable
Pseudomonas sp.	17	14.66%	Acceptable
Gram negative bacilli	2	1.72%	Acceptable
Growth, referred for identification	1	0.86%	Acceptable

Organism(s) present: *Pseudomonas stutzeri*.

### Specimen BA-8 – Ear Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Moraxella catarrhalis	79	64.23%	Acceptable
Moraxella sp.	16	13.01%	Acceptable
Gram negative diplococci	6	4.88%	Acceptable
Growth, referred for identification	1	0.81%	Acceptable
Gram negative coccobacilli	1	0.81%	Acceptable
Micrococcus sp.	5	4.07%	

Organism(s) present: *Moraxella catarrhalis*.

## MISCELLANEOUS CULTURES

### Specimen BA-9 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus simulans	95	50.26%	Acceptable
Anaerococcus prevotii	27	14.29%	Acceptable
Anaerobe present – no ID	15	7.94%	Acceptable
Staphylococcus sp.	12	6.35%	Acceptable
Staph – coagulase negative	8	4.23%	Acceptable
Anaerobe present – would refer	7	3.70%	Acceptable
Anaerobic cultures not perform	5	2.65%	Acceptable
Anaerococcus sp.	2	1.06%	Acceptable
Growth, referred for identification	1	0.53%	Acceptable
Gram positive cocci	1	0.53%	Acceptable
Aerococcus viridans	10	5.29%	

Organism(s) present: *Staphylococcus simulans* and *Anaerococcus prevotii*.

**ANTIMICROBIAL SUSCEPTIBILITY TESTING**

Specimen UC-11, CC-11 (SUS-11) Organism(s) present: *Stenotrophomonas maltophilia*.

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>
	<u>Interpretative category data</u>				<u>Interpretative category data</u>				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Amikacin	8	8	-	-	10	5	-	5	Inappropriate drug <sup>1</sup>
Amoxicillin/Clavulanate	4	-	-	4	4	1	-	3	Inappropriate drug <sup>1</sup>
Ampicillin	1	-	-	1	2	-	-	2	Inappropriate drug <sup>1</sup>
Ampicillin/Sulbactam	1	-	-	1	4	1	-	3	Inappropriate drug <sup>1</sup>
Aztreonam	7	4	-	3	3	-	-	3	Inappropriate drug <sup>1</sup>
Cefazolin	1	-	-	1	3	-	-	3	Inappropriate drug <sup>1</sup>
Cefdinir	1	-	-	1	-	-	-	-	Inappropriate drug <sup>1</sup>
Cefepime	6	2	1	3	7	1	-	6	Inappropriate drug <sup>1</sup>
Cefixime	4	1	-	3	3	1	-	2	Inappropriate drug <sup>1</sup>
Cefoperazone	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Cefotaxime	2	-	-	2	7	1	-	6	Inappropriate drug <sup>1</sup>
Cefoxitin	2	-	-	2	3	-	-	3	Inappropriate drug <sup>1</sup>
Ceftazidime	17	10	1	6	65	32	17	16	Ungraded <sup>2</sup>
Ceftolozane/Tazobactam	-	-	-	-	2	-	1	1	Inappropriate drug <sup>1</sup>
Ceftriaxone	6	-	1	5	10	-	-	10	Inappropriate drug <sup>1</sup>
Cefuroxime	4	-	-	4	7	-	-	7	Inappropriate drug <sup>1</sup>
Chloramphenicol	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Ciprofloxacin	12	12	-	-	10	5	-	5	Inappropriate drug <sup>1</sup>
Colistin	-	-	-	-	1	-	-	1	Inappropriate drug <sup>1</sup>
Doripenem	1	-	-	1	-	-	-	-	Inappropriate drug <sup>1</sup>
Doxycycline	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Ertapenem	-	-	-	-	8	1	-	7	Inappropriate drug <sup>1</sup>
Fosfomycin	1	1	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Gentamicin	9	9	-	-	10	2	-	8	Inappropriate drug <sup>1</sup>
Imipenem	4	-	-	4	9	1	-	8	Inappropriate drug <sup>1</sup>
Levofloxacin	33	33	-	-	79	79	-	-	100.00%
Meropenem	5	-	-	5	10	2	-	8	Inappropriate drug <sup>1</sup>
Minocycline	10	10	-	-	4	4	-	-	100.00%
Moxifloxacin	1	1	-	-	-	-	-	-	Inappropriate drug <sup>1</sup>
Nalidixic Acid	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>

<sup>1</sup> Inappropriate drug for organism and/or source.

<sup>2</sup> This is an ungraded challenge due to lack of comparison group.

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

**Specimen UC-11, CC-11 (SUS-11)** Organism(s) present: *Stenotrophomonas maltophilia*.

<u>Antimicrobial</u>	-----Disk Diffusion----- <i>Interpretative category data</i>				-----MIC----- <i>Interpretative category data</i>				<u>Acceptable (%)</u>
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Nitrofurantoin	4	-	-	4	6	1	-	5	Inappropriate drug <sup>1</sup>
Norfloxacin	6	6	-	-	3	1	-	2	Inappropriate drug <sup>1</sup>
Ofloxacin	3	3	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Oxacillin	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Piperacillin	1	-	-	1	1	-	-	1	Inappropriate drug <sup>1</sup>
Piperacillin/Tazobactam	4	1	-	3	10	1	2	7	Inappropriate drug <sup>1</sup>
Polymyxin B	1	1	-	-	1	-	-	1	Inappropriate drug <sup>1</sup>
Tetracycline	-	-	-	-	1	-	-	1	Inappropriate drug <sup>1</sup>
Ticarcillin/Clavulanate	1	-	-	1	5	1	2	2	83.33%
Tobramycin	2	1	-	1	1	-	-	1	Inappropriate drug <sup>1</sup>
Trimethoprim	-	-	-	-	6	6	-	-	100.00%
Trimethoprim/Sulfamethoxazole	33	32	-	1	169	158	-	11	93.24%

<sup>1</sup> Inappropriate drug for organism and/or source.

<sup>2</sup> This is an ungraded challenge due to lack of comparison group.

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

## PARASITOLOGY (PA Specimens)

### Specimen PA-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Protozoan cyst or trophozoite	1	25.00%	Acceptable
No parasite seen	2	50.00%	
Entamoeba histolytica	1	25.00%	

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

### Specimen PA-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	4	80.00%	Acceptable
Endolimax nana	1	25.00%	

Parasite(s) present: No parasite present.

### Specimen PA-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis larvae	19	95.00%	Acceptable
No parasite seen	1	5.00%	

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

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

**Specimen PA-14**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Diphyllobothrium latum	19	90.00%	Acceptable
Fasciola hepatica eggs	1	5.00%	
Parasite(s) present: <i>Diphyllobothrium latum</i> .			

**Specimen PA-15**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium ovale	7	41.18%	Acceptable
Plasmodium sp.	6	35.29%	Acceptable
Plasmodium malariae	3	17.65%	
Babesia sp.	1	5.88%	
Parasite(s) present: <i>Plasmodium ovale</i> . This specimen is graded to US statistics.			

## PARASITOLOGY (FP Specimens)

### Specimen FP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Endolimax nana	149	50.00%	Acceptable
Protozoan cyst or trophozoite	2	0.62%	Acceptable
Nonpathogenic protozoan present	1	0.34%	Acceptable
No parasite seen	39	13.09%	
Pollen artifact	21	7.05%	
Blastocystis hominis	20	6.71%	
Entamoeba histolytica	11	3.69%	
Taenia sp. eggs	10	3.36%	
Cryptosporidium sp., oocysts	9	3.02%	
Cryptosporidium parvum	6	2.01%	
Hymenolepis nana eggs	6	2.01%	
Ascaris lumbricoides eggs	5	1.68%	

Parasite(s) present: *Endolimax nana*. This challenge is graded by referee consensus.



## PARASITOLOGY (FP Specimens)

### Specimen FP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	231	92.40%	Acceptable
Strongyloides stercoralis larvae	5	2.00%	
Endolimax nana	2	0.80%	
Hookworm	2	0.80%	
Nonpathogenic protozoan present	2	0.80%	
Cryptosporidium sp., oocysts	2	0.80%	
Nematode-like artifact	1	0.40%	
Root hair artifact	1	0.40%	
Ascaris lumbricoides eggs	1	0.40%	
Cryptosporidium eggs	1	0.40%	
Blastocystis hominis	1	0.40%	
Balantidium coli	1	0.40%	

Parasite(s) present: No parasite seen.

## PARASITOLOGY (FP Specimens) cont'd

### Specimen FP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Diphyllobothrium latum	173	57.48%	Acceptable
Parasite egg or larvae seen – no	3	1.00%	Acceptable
Endolimax nana	27	8.97%	
Hookworm	23	7.64%	
Paragonimus westermani eggs	17	5.65%	
Ascaris lumbricoides eggs	12	3.99%	
Blastocystis hominis	11	3.65%	
Entamoeba histolytica	11	3.65%	
Fasciola hepatica eggs	8	2.66%	
Entamoeba coli	4	1.33%	
Clonorchis sinensis	3	1.00%	
Trichostrongylus sp. Eggs	2	0.66%	
Trichuris trichiura eggs	1	0.33%	
Strongyloides stercoralis larvae	1	0.33%	
Nematode like artifact	1	0.33%	
Taenia sp. eggs	1	0.33%	
No parasite seen	1	0.33%	
Chilomastix mesnili	1	0.33%	
Entamoeba hartmanni	1	0.33%	

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

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

**Specimen FP-14**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	241	73.70%	Acceptable
Protozoan cyst or trophozoite	1	0.31%	Acceptable
Blastocystis hominis	68	20.80%	
Entamoeba coli	8	2.45%	
Endolimax nana	4	1.22%	
Entamoeba histolytica	2	0.61%	
No parasite seen	1	0.31%	
Chilomastix mesnili	1	0.31%	
Diphyllobothrium latum	1	0.31%	

Parasite(s) present: *Giardia lamblia* and *Blastocystis hominis*. This challenge is graded by referee consensus.

## PARASITOLOGY (FP Specimens) cont'd

### Specimen FP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Babesia sp.	40	16.13%	Acceptable
Plasmodium falciparum	96	38.76%	
Plasmodium vivax	55	22.18%	
Plasmodium sp.	45	18.15%	
Plasmodium malariae	7	2.82%	
Plasmodium knowlesi	4	1.61%	
Plasmodium ovale	1	0.40%	

Parasite(s) present: *Babesia sp.* This is an ungraded challenge due to lack of referee consensus.

This peripheral blood smear contains red blood cells infected with *Babesia sp.*, the causative agent of Babesiosis. Babesiosis is a tick born disease that clinically mimics symptoms of malaria, (a mosquito borne disease caused by *Plasmodium sp.*), and treatment is significantly different. This distinction is even more relevant when the infection is asymptomatic. Unlike Babesia, Plasmodium species like *P. falciparum* and *P.ovale* become more pathogenic as the disease progresses. It is therefore important to correctly identify the organism in the laboratory.

A common mistake is to misidentify *Babesia* as *Plasmodium* based on their similar blood smear presentation. A few distinguishing features that can help determine which organism is present include red blood cell size, location of parasite on smear, and chromatin pigmentation of rings.

With Babesia species, infected red cells are not enlarged as typically seen with Plasmodium species. Organisms are seen both within the red cell (intracellular) and extracellularly, unlike Plasmodium species, which are only intra-cellular. The chromatin ring structure of Babesia appears vacuolated, pleomorphic and do not produce pigment.

Specimen FP-15 contains both intracellular and extracellular forms of Babesia, with intracellular vacuoles seen. Please review the following links for further information on Babesia sp. and Babesiosis.

<https://camlt.org/microbiology-case-studies-babesia-vs-malaria>

[https://www.cdc.gov/dpdx/resources/pdf/benchAids/Babesia\\_benchaid.pdf](https://www.cdc.gov/dpdx/resources/pdf/benchAids/Babesia_benchaid.pdf)

**Antinuclear Antibody (ANA) - Qualitative**

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	23	2	21	21	2
Bio-Rad	-	3	-	3	3	-
BioSystems	-	2	-	2	2	-
Immuno Concepts	-	3	1	2	2	1
INOVA Diagnostics	-	9	-	9	9	-
Kallestad	-	1	-	1	1	-

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	23	21	2
Bio-Rad	-	3	3	-
BioSystems	-	2	2	-
Immuno Concepts	-	3	2	1
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-11**

ALL METHODS	16	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	7	-	-	-	-	-	-	-	-	-	-	-
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-12**

ALL METHODS	14	-	-	-	-	1	1	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	1	-	-	-	-	1	-	-	-	-	-	-
INOVA Diagnostics	7	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

**Specimen AE-13**

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

**Specimen AE-14**

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

**Specimen AE-15**

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

## Anti-dsDNA

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	20	-	20	-	20
BioSystems	-	2	-	2	-	2
Immuno Concepts	-	2	-	2	-	2
INOVA Diagnostics	-	9	-	9	-	9
Kallestad	-	1	-	1	-	1

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	20	5	15
BioSystems	-	2	1	1
Immuno Concepts	-	2	1	1
INOVA Diagnostics	-	9	2	7
Kallestad	-	1	-	1

## Anti-RNP

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

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	12	11	2
INOVA Diagnostics	-	10	10	-

**Anti-RNP/Sm**

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	1	4	4	1
Immuno Concepts	-	1	-	1	1	-

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	4	4	1
Immuno Concepts	1	-	1	-

**Anti-SSA**

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	-	18	-	18
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	11	-	11	-	11

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	-	18
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	11	-	11



**Anti-SSB**

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	-	18	-	18
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	11	-	11	-	11

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	-	18
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	11	-	11

**Anti-SSA/SSB**

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

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

**Anti-Sm**

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	1	17	9	9
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	11	-	11	9	2

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	-	18
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	11	-	11

**Rubella—Qualitative**

<b><u>Method</u></b>	<b>Specimen RU-11</b>		<b>Specimen RU-12</b>		<b>Specimen RU-13</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	15	1
Abbott Architect	-	13	12	1	12	1
Roche cobas e 411	-	2	2	-	2	-
Siemens ADVIA Centaur	-	1	1	-	1	-

  

<b><u>Method</u></b>	<b>Specimen RU-14</b>		<b>Specimen RU-15</b>	
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	-	16	-	16
Abbott Architect	-	13	-	13
Roche cobas e 411	-	2	-	2
Siemens ADVIA Centaur	-	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-11</b>						
All Method	20	0.07	0.12	167.8	0.0	0.0 - 0.5
Abbott Architect	12	0.00	0.01	0.0	0.0	0.0 - 0.1
<b>Specimen RU-12</b>						
All Method	21	42.54	23.68	55.7	29.1	0.0 - 113.6
Abbott Architect	13	27.33	2.56	9.4	28.1	19.6 - 35.1
<b>Specimen RU-13</b>						
All Method	21	25.30	15.71	62.1	16.0	0.0 - 72.5
Abbott Architect	13	15.25	1.10	7.2	15.4	11.9 - 18.6
<b>Specimen RU-14</b>						
All Method	20	0.09	0.16	179.9	0.0	0.0 - 0.6
Abbott Architect	13	0.00	0.01	0.0	0.0	0.0 - 0.1
<b>Specimen RU-15</b>						
All Method	20	0.08	0.15	184.1	0.0	0.0 - 0.6
Abbott Architect	13	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-11</b>			<b>Specimen SY-12</b>			<b>Specimen SY-13</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	-	52	45	5	3	47	4	2
Abbott Architect	1	-	-	-	-	1	1	-	-
Acon Laboratories	-	-	2	2	-	-	2	-	-
BioSystems	-	-	1	1	-	-	1	-	-
Omega Diagnostics	-	-	1	1	-	-	1	-	-
Plasmatec	-	-	1	1	-	-	1	-	-
SPINREACT	-	-	2	2	-	-	2	-	-
Standard Diagnostics	-	-	2	2	-	-	2	-	-
Wiener Lab	-	-	38	33	3	2	34	2	2

<b><u>Method</u></b>	<b>Specimen SY-14</b>			<b>Specimen SY-15</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	-	51	51	1	1
Abbott Architect	1	-	-	-	-	1
Acon Laboratories	-	-	2	2	-	-
BioSystems	-	-	1	1	-	-
Omega Diagnostics	-	-	1	1	-	-
Plasmatec	-	-	1	1	-	-
SPINREACT	-	-	2	2	-	-
Standard Diagnostics	-	-	2	2	-	-
Wiener Lab	1	-	37	38	-	-

**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-11</b>									
ALL METHODS	47	-	-	-	-	-	-	-	-
BioSystems	1	-	-	-	-	-	-	-	-
Human	1	-	-	-	-	-	-	-	-
Plasmatec	1	-	-	-	-	-	-	-	-
Wiener Lab	40	-	-	-	-	-	-	-	-
<b>Specimen SY-12</b>									
ALL METHODS	2	3	11	14	9	6	2	-	-
BioSystems	-	-	1	-	-	-	-	-	-
Human	-	-	1	-	-	-	-	-	-
Plasmatec	-	-	-	1	-	-	-	-	-
Wiener Lab	2	3	9	10	9	5	2	-	-
<b>Specimen SY-13</b>									
ALL METHODS	2	3	9	14	17	1	-	1	-
BioSystems	-	-	1	-	-	-	-	-	-
Human	-	-	1	-	-	-	-	-	-
Plasmatec	-	-	-	1	-	-	-	-	-
Wiener Lab	2	3	7	11	15	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-14</b>									
ALL METHODS	46	-	-	-	1	-	-	-	-
BioSystems	1	-	-	-	-	-	-	-	-
Human	1	-	-	-	-	-	-	-	-
Plasmatec	1	-	-	-	-	-	-	-	-
Wiener Lab	39	-	-	-	1	-	-	-	-
<b>Specimen SY-15</b>									
ALL METHODS	-	1	3	12	14	13	2	2	-
BioSystems	-	-	-	1	-	-	-	-	-
Human	-	-	1	-	-	-	-	-	-
Plasmatec	-	-	-	1	-	-	-	-	-
Wiener Lab	-	1	2	10	12	11	2	2	-

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

<b><u>Method</u></b>	<b>Specimen SY-11</b>		<b>Specimen SY-12</b>		<b>Specimen SY-13</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	-	14	14	-	13	1
Abbott Architect	-	2	2	-	2	-
Biokit	-	1	1	-	1	-
Plasmatec	-	5	5	-	5	-
Serodia	-	3	3	-	2	1
Standard Diagnostics	-	1	1	-	1	-

  

	<b>Specimen SY-14</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	-	14	13	1
Abbott Architect	-	2	2	-
Biokit	-	1	1	-
Plasmatec	-	5	5	-
Serodia	-	3	2	1
Standard Diagnostics	-	1	1	-



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

<b><u>Method</u></b>	<b>Specimen SY-11</b>		<b>Specimen SY-12</b>		<b>Specimen SY-13</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	-	47	47	-	47	-
Abbott Architect	-	8	8	-	8	-
bioMerieux	-	1	1	-	1	-
DiaSorin	-	1	1	-	1	-
Human	-	2	2	-	2	-
Plasmatec	-	3	3	-	3	-
Roche cobas 6000 / c 501	-	2	2	-	2	-
Roche cobas 8000/e801	-	1	1	-	1	-
Roche cobas e 411	-	1	1	-	1	-
Serodia	-	8	8	-	8	-
Standard Diagnostics	-	9	9	-	9	-

	<b>Specimen SY-14</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	-	47	47	-
Abbott Architect	-	8	8	-
bioMerieux	-	1	1	-
DiaSorin	-	1	1	-
Human	-	2	2	-
Plasmatec	-	3	3	-
Roche cobas 6000 / c 501	-	2	2	-
Roche cobas 8000/e801	-	1	1	-
Roche cobas e 411	-	1	1	-
Serodia	-	8	8	-
Standard Diagnostics	-	9	9	-

**Syphilis Serology—Qualitative: RPR**

<b><u>Method</u></b>	<b>Specimen SY-11</b>		<b>Specimen SY-12</b>		<b>Specimen SY-13</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	-	75	75	-	75	-
Abbott Architect	-	1	1	-	1	-
Becton Dickinson	-	2	2	-	2	-
bioMerieux	-	4	4	-	4	-
BioSystems	-	17	17	-	17	-
Human	-	4	4	-	4	-
Omega Diagnostics	-	7	7	-	7	-
Plasmatec	-	10	10	-	10	-
Pulse Scientific	-	1	1	-	1	-
SPINREACT	-	21	21	-	21	-
Wiener Lab	-	1	1	-	1	-

  

	<b>Specimen SY-14</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	-	75	75	-
Abbott Architect	-	1	1	-
Becton Dickinson	-	2	2	-
bioMerieux	-	4	4	-
BioSystems	-	17	17	-
Human	-	4	4	-
Omega Diagnostics	-	7	7	-
Plasmatec	-	10	10	-
Pulse Scientific	-	1	1	-
SPINREACT	-	21	21	-
Wiener Lab	-	1	1	-

**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-11</b>									
ALL METHODS	64	-	-	-	-	-	-	-	-
Becton Dickinson	2	-	-	-	-	-	-	-	-
bioMerieux	3	-	-	-	-	-	-	-	-
BioSystems	15	-	-	-	-	-	-	-	-
Human	3	-	-	-	-	-	-	-	-
Omega Diagnostics	6	-	-	-	-	-	-	-	-
Plasmatec	7	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	19	-	-	-	-	-	-	-	-
Wiener Lab	1	-	-	-	-	-	-	-	-
<b>Specimen SY-12</b>									
ALL METHODS	1	8	29	20	4	1	-	1	-
Becton Dickinson	-	-	1	1	-	-	-	-	-
bioMerieux	-	-	2	1	-	-	-	-	-
BioSystems	-	4	4	5	1	1	-	-	-
Human	-	-	2	1	-	-	-	-	-
Omega Diagnostics	1	1	2	1	-	-	-	1	-
Plasmatec	-	-	6	1	-	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	1	6	9	3	-	-	-	-
Wiener Lab	-	1	-	-	-	-	-	-	-
	1	8	29	20	4	1	-	1	-

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

<u>Specimen/Method</u>	<u>N/A</u> <u>(Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>&gt;64</u>
------------------------	----------------------------	----------	----------	----------	----------	-----------	-----------	-----------	---------------

**Specimen SY-13**

ALL METHODS	1	8	32	18	3	2	-	-	-
Becton Dickinson	-	-	1	1	-	-	-	-	-
bioMerieux	-	-	1	2	-	-	-	-	-
BioSystems	-	3	4	5	2	1	-	-	-
Human	-	-	3	-	-	-	-	-	-
Omega Diagnostics	1	-	3	1	-	1	-	-	-
Plasmatec	-	2	4	1	-	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	-	11	7	1	-	-	-	-
Wiener Lab	-	1	-	-	-	-	-	-	-

**Specimen SY-14**

ALL METHODS	64	-	-	-	-	-	-	-	-
Becton Dickinson	2	-	-	-	-	-	-	-	-
bioMerieux	3	-	-	-	-	-	-	-	-
BioSystems	15	-	-	-	-	-	-	-	-
Human	3	-	-	-	-	-	-	-	-
Omega Diagnostics	6	-	-	-	-	-	-	-	-
Plasmatec	7	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	19	-	-	-	-	-	-	-	-
Wiener Lab	1	-	-	-	-	-	-	-	-

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

<u>Specimen/Method</u>	<u>N/A</u> <u>(Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>&gt;64</u>
<b>Specimen SY-15</b>									
ALL METHODS	1	-	16	26	15	5	1	-	-
Becton Dickinson	-	-	1	1	-	-	-	-	-
bioMerieux	-	-	-	3	-	-	-	-	-
BioSystems	-	-	5	3	5	1	1	-	-
Human	-	-	-	2	1	-	-	-	-
Omega Diagnostics	1	-	2	2	1	-	-	-	-
Plasmatec	-	-	5	-	2	-	-	-	-
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	-	-	11	5	3	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-	-

**Viral Markers – Anti-HBc (IgM)**

<b><u>Method</u></b>	<b>Specimen VM-11</b>			<b>Specimen VM-12</b>			<b>Specimen VM-13</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	-	48	-	-	48	-	-	48	-
Abbott Architect	-	25	-	-	25	-	-	25	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	7	-	-	7	-	-	7	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
Roche cobas e 411	-	1	-	-	1	-	-	1	-
Roche Modular Analytics	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	1	-	-	1	-	-	1	-
VITROS 3600/4600/5600	-	4	-	-	4	-	-	4	-
VITROS Eci	-	1	-	-	1	-	-	1	-

<b><u>Method</u></b>	<b>Specimen VM-14</b>			<b>Specimen VM-15</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	-	47	-	-	48	-
Abbott Architect	-	25	-	-	25	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	6	-	-	7	-
Roche cobas 8000/e801	-	4	-	-	4	-
Roche cobas e 411	-	1	-	-	1	-
Roche Modular Analytics	-	1	-	-	1	-
Siemens ADVIA Centaur	-	1	-	-	1	-
VITROS 3600/4600/5600	-	4	-	-	4	-
VITROS Eci	-	1	-	-	1	-

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

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	74	-	-	74	-	-	74	-
Abbott Architect	-	42	-	-	42	-	-	42	-
Beckman ACCESS / 2 / DxI	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	10	-	-	10	-	-	10	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
Roche cobas e 411	-	4	-	-	4	-	-	4	-
Siemens ADVIA Centaur	-	3	-	-	3	-	-	3	-
VITROS 3600/4600/5600	-	4	-	-	4	-	-	4	-
VITROS Eci	-	1	-	-	1	-	-	1	-

  

	Specimen VM-14			Specimen VM-15		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	73	1	-	-	74	-
Abbott Architect	42	-	-	-	42	-
Beckman ACCESS / 2 / DxI	2	-	-	-	2	-
Roche cobas 6000 / e 601	9	1	-	-	10	-
Roche cobas 8000/e801	4	-	-	-	4	-
Roche cobas e 411	4	-	-	-	4	-
Siemens ADVIA Centaur	3	-	-	-	3	-
VITROS 3600/4600/5600	4	-	-	-	4	-
VITROS Eci	1	-	-	-	1	-

## Viral Markers – Anti-HIV

<u>Method</u>	<b>Specimen VM-11</b>			<b>Specimen VM-12</b>			<b>Specimen VM-13</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	142	2	-	2	142	-	143	1	-
Abbott Alinity	1	-	-	-	1	-	1	-	-
Abbott Architect	66	1	-	-	67	-	67	-	-
Acon Laboratories	1	-	-	-	1	-	1	-	-
Alere Clearview HIV1/2 STAT-PAK	1	-	-	-	1	-	1	-	-
Alere Determine HIV - moderate	4	-	-	-	4	-	4	-	-
Alere Determine HIV - waived	1	-	-	-	1	-	1	-	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	4	-	-	1	3	-	4	-	-
DiaSorin	1	-	-	-	1	-	1	-	-
Human	3	-	-	-	3	-	3	-	-
Roche cobas 6000 / e 601	16	1	-	-	17	-	16	1	-
Roche cobas 8000/e801	3	-	-	-	3	-	3	-	-
Roche cobas e 411	8	-	-	1	7	-	8	-	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-	1	-	-
Roche Modular Analytics	2	-	-	-	2	-	2	-	-
Siemens ADVIA Centaur	5	-	-	-	5	-	5	-	-
Standard Diagnostics	4	-	-	-	4	-	4	-	-
VITROS 3600/4600/5600	6	-	-	-	6	-	6	-	-
VITROS Eci	2	-	-	-	2	-	2	-	-



**Viral Markers – Anti-HIV- cont'd**

<b><u>Method</u></b>	<b>Specimen VM-14</b>			<b>Specimen VM-15</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	130	14	-	-	144	-
Abbott Alinity	1	-	-	-	1	-
Abbott Architect	67	-	-	-	67	-
Acon Laboratories	1	-	-	-	1	-
Alere Clearview HIV1/2 STAT-PAK	1	-	-	-	1	-
Alere Determine HIV - moderate	1	3	-	-	4	-
Alere Determine HIV - waived	1	-	-	-	1	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	4	-	-	-	4	-
DiaSorin	-	1	-	-	1	-
Human	2	1	-	-	3	-
Roche cobas 6000 / e 601	15	2	-	-	17	-
Roche cobas 8000/e801	3	-	-	-	3	-
Roche cobas e 411	8	-	-	-	8	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-
Roche Modular Analytics	2	-	-	-	2	-
Siemens ADVIA Centaur	5	-	-	-	5	-
Standard Diagnostics	1	3	-	-	4	-
VITROS 3600/4600/5600	6	-	-	-	6	-
VITROS Eci	2	-	-	-	2	-

**Viral Markers – Anti-HAV (IgM)**

<b><u>Method</u></b>	<b>Specimen VM-11</b>			<b>Specimen VM-12</b>			<b>Specimen VM-13</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	-	57	-	-	57	-	-	57	-
Abbott Architect	-	28	-	-	28	-	-	28	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	10	-	-	10	-	-	10	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
Roche cobas e 411	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	4	-	-	4	-	-	4	-
Standard Diagnostics	-	3	-	-	3	-	-	3	-
VITROS 3600/4600/5600	-	2	-	-	2	-	-	2	-
VITROS ECI	-	1	-	-	1	-	-	1	-

<b><u>Method</u></b>	<b>Specimen VM-14</b>			<b>Specimen VM-15</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	-	56	-	52	5	-
Abbott Architect	-	28	-	27	1	-
bioMerieux Vidas, Mini Vidas	-	3	-	3	-	-
Roche cobas 6000 / e 601	-	9	-	9	1	-
Roche cobas 8000/e801	-	4	-	4	-	-
Roche cobas e 411	-	1	-	1	-	-
Siemens ADVIA Centaur	-	4	-	4	-	-
Standard Diagnostics	-	3	-	-	3	-
VITROS 3600/4600/5600	-	2	-	2	-	-
VITROS ECI	-	1	-	1	-	-

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

<b><u>Method</u></b>	<b>Specimen VM-11</b>			<b>Specimen VM-12</b>			<b>Specimen VM-13</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	43	1	-	43	1	-	43	1	-
Abbott Architect	24	-	-	24	-	-	24	-	-
bioMerieux Vidas, Mini Vidas	3	-	-	3	-	-	3	-	-
Roche cobas 6000 / e 601	5	-	-	5	-	-	5	-	-
Roche cobas 8000/e801	3	-	-	3	-	-	3	-	-
Roche cobas e 411	2	-	-	2	-	-	2	-	-
Roche Elecsys 1010 / 2010	1	-	-	1	-	-	1	-	-
Roche Modular Analytics	1	-	-	1	-	-	1	-	-
Siemens ADVIA Centaur	3	-	-	3	-	-	3	-	-
Standard Diagnostics	-	1	-	-	1	-	-	1	-

<b><u>Method</u></b>	<b>Specimen VM-14</b>			<b>Specimen VM-15</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	43	1	-	43	1	-
Abbott Architect	24	-	-	24	-	-
bioMerieux Vidas, Mini Vidas	3	-	-	3	-	-
Roche cobas 6000 / e 601	5	-	-	5	-	-
Roche cobas 8000/e801	3	-	-	3	-	-
Roche cobas e 411	2	-	-	2	-	-
Roche Elecsys 1010 / 2010	1	-	-	1	-	-
Roche Modular Analytics	1	-	-	1	-	-
Siemens ADVIA Centaur	3	-	-	3	-	-
Standard Diagnostics	-	1	-	-	1	-

**Viral Markers – HBeAg**

<b><u>Method</u></b>	<b>Specimen VM-11</b>			<b>Specimen VM-12</b>			<b>Specimen VM-13</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	-	34	-	-	34	-	-	34	-
Abbott Architect	-	14	-	-	14	-	-	14	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	-	1	-
DiaSorin	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	9	-	-	9	-	-	9	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
Roche Modular Analytics	-	1	-	-	1	-	-	1	-
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-14</b>			<b>Specimen VM-15</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	-	-	34	-
Abbott Architect	-	14	-	-	14	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-
DiaSorin	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	8	-	-	9	-
Roche cobas 8000/e801	-	4	-	-	4	-
Roche Modular Analytics	-	1	-	-	1	-
Siemens ADVIA Centaur	-	1	-	-	1	-
VITROS 3600/4600/5600	-	1	-	-	1	-
VITROS ECI	-	1	-	-	1	-

**Viral Markers – Anti-HBs**

<b><u>Method</u></b>	<b>Specimen VM-11</b>			<b>Specimen VM-12</b>			<b>Specimen VM-13</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	11	82	-	93	-	-	92	1	-
Abbott Alinity	-	1	-	1	-	-	1	-	-
Abbott Architect	8	39	-	47	-	-	46	1	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	-	3	-	3	-	-	3	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-	1	-	-
Roche cobas 8000/e801	3	9	-	12	-	-	12	-	-
Roche cobas e 411	-	4	-	4	-	-	4	-	-
Roche Elecsys 1010 / 2010	-	5	-	5	-	-	5	-	-
Roche Modular Analytics	-	2	-	2	-	-	2	-	-
Siemens ADVIA Centaur	-	1	-	1	-	-	1	-	-
Standard Diagnostics	-	6	-	6	-	-	6	-	-
VITROS 3600/4600/5600	-	1	-	1	-	-	1	-	-
VITROS Eci	-	6	-	6	-	-	6	-	-
	-	3	-	3	-	-	3	-	-

<b><u>Method</u></b>	<b>Specimen VM-14</b>			<b>Specimen VM-15</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	91	-	1	92	-
Abbott Alinity	-	1	-	-	1	-
Abbott Architect	1	46	-	-	47	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	1	-	-	1	-
Roche cobas 8000/e801	1	11	-	1	11	-
Roche cobas e 411	-	4	-	-	4	-
Roche Elecsys 1010 / 2010	-	5	-	-	5	-
Roche Modular Analytics	-	2	-	-	2	-
Siemens ADVIA Centaur	-	1	-	-	1	-
Standard Diagnostics	-	6	-	-	6	-
VITROS 3600/4600/5600	-	1	-	-	1	-
VITROS Eci	-	6	-	-	6	-
	-	3	-	-	3	-

**Viral Markers – HBsAg**

<b><u>Method</u></b>	<b>Specimen VM-11</b>			<b>Specimen VM-12</b>			<b>Specimen VM-13</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	148	-	-	149	-	1	147	1
Abbott Alinity	-	1	-	-	1	-	-	1	-
Abbott Architect	-	66	-	-	66	-	-	65	1
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	-	4	-	-	4	-	-	4	-
Human	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	1	-	-	1	-	-	1	-
Roche cobas 8000/e801	1	17	-	-	18	-	-	18	-
Roche cobas e 411	-	4	-	-	4	-	-	4	-
Roche Elecsys 1010 / 2010	-	12	-	-	12	-	-	12	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	-	1	-
Roche Modular Analytics	-	2	-	-	2	-	-	2	-
Siemens ADVIA Centaur	-	8	-	-	8	-	1	7	-
Standard Diagnostics	-	12	-	-	12	-	-	12	-
VITROS 3600/4600/5600	-	6	-	-	6	-	-	6	-
VITROS Eci	-	2	-	-	2	-	-	2	-

<b><u>Method</u></b>	<b>Specimen VM-14</b>			<b>Specimen VM-15</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	148	1	-	125	22	2
Abbott Alinity	1	-	-	1	-	-
Abbott Architect	66	-	-	65	-	1
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	4	-	-	4	-	-
Human	2	-	-	2	-	-
Roche cobas 6000 / e 601	1	-	-	-	1	-
Roche cobas 8000/e801	17	1	-	16	1	1
Roche cobas e 411	4	-	-	4	-	-
Roche Elecsys 1010 / 2010	12	-	-	12	-	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-
Roche Modular Analytics	2	-	-	1	1	-
Siemens ADVIA Centaur	8	-	-	7	1	-
Standard Diagnostics	12	-	-	-	12	-
VITROS 3600/4600/5600	6	-	-	6	-	-
VITROS Eci	2	-	-	2	-	-

## Viral Markers – Anti-HCV

<b><u>Method</u></b>	<b>Specimen VM-11</b>			<b>Specimen VM-12</b>			<b>Specimen VM-13</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	131	1	-	-	132	-	-	132	-
Abbott Alinity	1	-	-	-	1	-	-	1	-
Abbott Architect	67	-	-	-	67	-	-	67	-
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-	-	2	-
bioMerieux Vidas, Mini Vidas	2	-	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	12	1	-	-	13	-	-	13	-
Roche cobas 8000/e801	3	-	-	-	3	-	-	3	-
Roche cobas e 411	10	-	-	-	10	-	-	10	-
Roche Modular Analytics	2	-	-	-	2	-	-	2	-
Siemens ADVIA Centaur	5	-	-	-	5	-	-	5	-
Standard Diagnostics	8	-	-	-	8	-	-	8	-
VITROS 3600/4600/5600	6	-	-	-	6	-	-	6	-
VITROS ECI	3	-	-	-	3	-	-	3	-

<b><u>Method</u></b>	<b>Specimen VM-14</b>			<b>Specimen VM-15</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	1	-	23	106	3
Abbott Alinity	1	-	-	-	1	-
Abbott Architect	67	-	-	1	66	-
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-
bioMerieux Vidas, Mini Vidas	2	-	-	-	2	-
Roche cobas 6000 / e 601	12	1	-	11	1	1
Roche cobas 8000/e801	3	-	-	3	-	-
Roche cobas e 411	10	-	-	7	1	2
Roche Modular Analytics	2	-	-	1	1	-
Siemens ADVIA Centaur	5	-	-	-	5	-
Standard Diagnostics	8	-	-	-	8	-
VITROS 3600/4600/5600	6	-	-	-	6	-
VITROS ECI	3	-	-	-	3	-

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

<b><u>Method</u></b>	<b>Specimen TOX-5</b>			<b>Specimen TOX-6</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	-	2	-	2	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas e 411	-	2	-	2	-	-

**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-5</b>						
All Method	26	0.213	0.176	82.5	0.20	0.00 - 0.57
All Roche Instruments	5	0.953	1.426	149.6	0.13	0.00 - 3.81
Abbott Architect	16	0.313	0.245	78.3	0.20	0.00 - 0.81
<b>Specimen TOX-6</b>						
All Method	26	683.905	705.556	103.2	372.00	0.00 - 2095.02
All Roche Instruments	5	2307.000	65.818	2.9	2269.00	2175.36 - 2438.64
Abbott Architect	16	442.556	290.134	65.6	200.00	0.00 - 1022.83



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

<b><u>Method</u></b>	<b>Specimen TOX-5</b>			<b>Specimen TOX-6</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	-	21	-	21	-	-
Abbott Architect	-	14	-	14	-	-
bioMerieux Vidas, Mini Vidas	-	2	-	2	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
Roche cobas e 411	-	2	-	2	-	-

**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-5</b>						
All Method	22	0.177	0.059	33.2	0.17	0.05 - 0.30
All Roche Instruments	5	0.213	0.015	7.2	0.21	0.18 - 0.25
Abbott Architect	13	0.178	0.063	35.5	0.15	0.05 - 0.31
<b>Specimen TOX-6</b>						
All Method	22	9.048	3.989	44.1	7.59	1.06 - 17.03
All Roche Instruments	5	17.183	2.108	12.3	18.05	12.96 - 21.40
Abbott Architect	13	7.337	0.855	11.6	7.36	5.62 - 9.05

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

<b><u>Method</u></b>	<b>Specimen CMV-5</b>			<b>Specimen CMV-6</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	-	15	-	15	-	-
Abbott Architect	-	14	-	14	-	-
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-5</b>						
All Method	17	1.280	0.731	57.1	1.30	0.00 - 2.75
Abbott Architect	14	1.471	0.649	44.1	1.40	0.17 - 2.77
<b>Specimen CMV-6</b>						
All Method	17	70.384	32.979	46.9	80.80	4.42 - 136.35
Abbott Architect	14	83.979	14.297	17.0	87.25	55.38 - 112.58

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

<b><u>Method</u></b>	<b>Specimen CMV-5</b>			<b>Specimen CMV-6</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	15	-	17	-	-
Abbott Architect	2	13	-	15	-	-
Roche cobas 6000 / e 601	-	2	-	2	-	-

**Cytomegalovirus (CMV) Antibodies (IgM) —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-5</b>						
All Method	14	0.542	0.264	48.7	0.53	0.01 - 1.07
Abbott Architect	12	0.607	0.224	36.9	0.64	0.15 - 1.06
<b>Specimen CMV-6</b>						
All Method	14	6.114	0.984	16.1	6.03	4.14 - 8.09
Abbott Architect	12	6.139	0.627	10.2	6.03	4.88 - 7.40

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

<u>Method</u>	<b>Specimen NB-11</b>						<b>Specimen NB-12</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	47	10.77	0.68	6.3	11.0	8.6 - 13.0	46	6.95	0.39	5.6	7.0	5.5 - 8.4
No Reagent Required												
Bilirubinometer / Unistat	35	10.98	0.43	3.9	11.0	8.7 - 13.2	35	7.00	0.34	4.8	7.0	5.6 - 8.5
All Chemistry Instruments	39	10.96	0.43	3.9	11.0	8.7 - 13.2	39	7.01	0.32	4.6	7.0	5.6 - 8.5
<u>Method</u>	<b>Specimen NB-13</b>						<b>Specimen NB-14</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	47	15.95	0.95	5.9	16.1	12.7 - 19.2	43	0.02	0.04	293.5	0.0	0.0 - 0.5
No Reagent Required												
Bilirubinometer / Unistat	35	16.29	0.58	3.5	16.3	13.0 - 19.6	35	0.00	0.01	0.0	0.0	0.0 - 0.4
All Chemistry Instruments	39	16.25	0.57	3.5	16.2	12.9 - 19.5	35	0.00	0.01	0.0	0.0	0.0 - 0.4
<u>Method</u>	<b>Specimen NB-15</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	45	6.97	0.37	5.3	7.0	5.5 - 8.4						
No Reagent Required												
Bilirubinometer / Unistat	34	7.02	0.31	4.4	7.1	5.6 - 8.5						
All Chemistry Instruments	38	7.04	0.31	4.4	7.1	5.6 - 8.5						

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

<u>Method</u>	<b>Specimen NB-11</b>						<b>Specimen NB-12</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	4.74	0.52	11.0	4.5	3.6 - 5.8	11	1.73	0.29	16.8	1.6	1.1 - 2.4
<u>Method</u>	<b>Specimen NB-13</b>						<b>Specimen NB-14</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	6.05	0.67	11.0	5.9	4.7 - 7.4	10	0.07	0.07	102.9	0.1	0.0 - 0.2
<u>Method</u>	<b>Specimen NB-15</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	11	2.18	1.69	77.4	1.6	0.0 - 5.6						

**Glycohemoglobin (percent)**

<u>Method</u>	<u>Specimen GH-5</u>						<u>Specimen GH-6</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	159	7.52	0.37	4.9	7.5	7.0 - 8.0	159	10.79	0.45	4.2	10.7	10.1 - 11.5
All Bio-Rad Methods	20	8.16	0.26	3.2	8.2	7.6 - 8.7	20	11.31	0.27	2.4	11.4	10.6 - 12.0
All Hemoglobin A1c Methods	158	7.52	0.36	4.8	7.5	7.0 - 8.0	159	10.79	0.45	4.2	10.7	10.1 - 11.5
All Roche Methods	15	7.26	0.15	2.0	7.2	6.8 - 7.7	15	10.77	0.22	2.0	10.9	10.1 - 11.5
All TOSOH Methods	19	7.23	0.16	2.3	7.2	6.7 - 7.7	19	10.36	0.22	2.1	10.3	9.7 - 11.0
Beckman AU A1c	10	7.36	0.34	4.7	7.4	6.9 - 7.9	10	10.52	0.62	5.9	10.4	9.8 - 11.2
Bio-Rad D-10 HbA1C	7	8.00	0.32	4.0	7.8	7.5 - 8.5	7	11.16	0.30	2.7	11.1	10.4 - 11.9
Bio-Rad D-100	13	8.25	0.19	2.2	8.2	7.7 - 8.8	13	11.38	0.23	2.1	11.5	10.7 - 12.1
Roche cobas c 501 HbA1c	7	7.29	0.17	2.3	7.2	6.8 - 7.8	7	10.67	0.22	2.1	10.7	10.0 - 11.4
Roche Integra A1C	7	7.24	0.14	1.9	7.2	6.8 - 7.7	7	10.86	0.20	1.8	10.9	10.2 - 11.6
Siemens DCA Vantage	65	7.53	0.19	2.5	7.5	7.0 - 8.0	66	10.82	0.40	3.7	10.7	10.1 - 11.5
Siemens Dimension HB1C	14	7.40	0.21	2.8	7.4	6.9 - 7.9	14	10.57	0.24	2.3	10.5	9.9 - 11.3
TOSOH G8	19	7.23	0.16	2.3	7.2	6.7 - 7.7	19	10.36	0.22	2.1	10.3	9.7 - 11.0

**Whole Blood Glucose (mg/dL)**

<u>Method</u>	<u>Specimen WBG-11</u>						<u>Specimen WBG-12</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	795	70.7	9.7	13.7	72	56 - 85	777	280.7	19.1	6.8	285	224 - 337
All Abbott Methods	50	58.9	5.1	8.6	59	46 - 71	50	267.5	15.0	5.6	267	213 - 321
All Arkray Methods	7	79.6	11.4	14.3	82	63 - 96	3	-	-	-	282	192 - 288
All Bayer Methods	24	47.9	4.3	8.9	48	35 - 60	25	220.3	11.9	5.4	218	176 - 265
All Hemocue Methods	58	88.5	6.4	7.2	90	70 - 107	57	292.2	7.3	2.5	293	233 - 351
All Lifescan Methods	13	61.3	3.8	6.3	61	49 - 74	14	316.3	84.4	26.7	319	253 - 380
All Roche Methods	497	73.1	2.3	3.1	74	58 - 88	496	285.9	6.1	2.1	286	228 - 344
Abbott FreeStyle Lite/Freedom Lite	7	64.9	3.4	5.3	64	51 - 78	7	272.9	8.5	3.1	273	218 - 328
Abbott FreeStyle Precision Pro	23	56.2	3.8	6.8	57	44 - 69	24	263.0	16.1	6.1	261	210 - 316
Abbott Precision XceedPro	19	59.3	3.4	5.7	60	47 - 72	19	271.2	14.2	5.2	270	216 - 326
Arkray Platinum	24	85.9	4.2	4.8	87	68 - 104	20	277.5	9.6	3.5	278	221 - 333
Bayer Contour	26	47.8	4.1	8.6	48	35 - 60	27	220.2	11.5	5.2	218	176 - 265
HemoCue Glucose 201	58	87.8	7.1	8.0	90	70 - 106	56	292.3	7.3	2.5	293	233 - 351
Home Diagnostics True Balance / TrueTrack	13	176.6	8.9	5.0	176	141 - 212	13	555.4	23.7	4.3	561	444 - 667
Lifescan One Touch Ultra	11	60.5	3.6	6.0	61	48 - 73	11	315.7	10.5	3.3	319	252 - 379
Medline EvenCare G2 / G3	15	68.6	6.0	8.8	70	54 - 83	16	268.6	42.8	15.9	276	214 - 323
Nipro True Result	10	53.0	3.1	5.9	53	41 - 65	10	178.9	14.3	8.0	178	143 - 215
NOVA Biomedical StatStrip	30	57.8	3.7	6.4	57	45 - 70	30	246.4	10.6	4.3	248	197 - 296
Quintet / AC	25	57.6	4.8	8.3	59	45 - 70	25	298.7	13.9	4.7	298	238 - 359
Roche Accu-Chek Active	9	60.0	1.6	2.6	60	48 - 72	9	237.9	3.8	1.6	237	190 - 286
Roche Accu-Chek Aviva	5	71.2	3.3	4.6	71	56 - 86	5	281.4	7.0	2.5	280	225 - 338
Roche Accu-Chek Inform	10	70.5	2.1	2.9	71	56 - 85	10	282.1	6.4	2.3	282	225 - 339
Roche Accu-Chek Inform II	319	73.0	2.1	2.9	74	58 - 88	317	286.6	5.5	1.9	286	229 - 344
Roche Accu-Chek Performa	165	73.4	2.4	3.3	74	58 - 89	162	284.6	6.5	2.3	284	227 - 342
True MetrPro	17	56.2	2.9	5.2	56	44 - 69	17	262.6	20.7	7.9	261	210 - 316

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

**Specimen WBG-13**

<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	131	109.6	7.9	7.2	111	87 - 132
All Abbott Methods	18	103.7	4.1	4.0	103	82 - 125
All Bayer Methods	1	-	-	-	137	109 - 165
All Lifescan Methods	5	116.2	3.8	3.3	117	92 - 140
All Roche Methods	89	112.5	2.5	2.3	112	90 - 136
Abbott FreeStyle Precision Pro	10	102.4	3.4	3.3	103	81 - 123
Abbott Precision XceedPro	8	105.3	4.6	4.4	105	84 - 127
Bayer Contour	1	-	-	-	137	109 - 165
Lifescan One Touch Ultra	5	116.2	3.8	3.3	117	92 - 140
Medline EvenCare G2 / G3	1	-	-	-	109	87 - 131
Nipro True Result	10	82.9	5.4	6.6	82	66 - 100
NOVA Biomedical StatStrip	9	94.9	2.4	2.5	95	75 - 114
Roche Accu-Chek Inform	10	112.4	4.1	3.6	112	89 - 135
Roche Accu-Chek Inform II	59	112.9	2.4	2.1	113	90 - 136
Roche Accu-Chek Performa	21	111.9	2.7	2.4	112	89 - 135
True Metrix Pro	1	-	-	-	110	88 - 132

**Specimen WBG-14**

<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
131	198.4	13.0	6.5	200	158 - 239
18	192.1	4.6	2.4	192	153 - 231
1	-	-	-	197	157 - 237
5	222.0	7.1	3.2	225	177 - 267
89	201.8	4.9	2.4	202	161 - 243
10	190.4	4.3	2.3	191	152 - 229
8	194.3	4.3	2.2	195	155 - 234
1	-	-	-	197	157 - 237
5	222.0	7.1	3.2	225	177 - 267
1	-	-	-	187	149 - 225
10	149.6	12.6	8.5	151	119 - 180
9	172.9	7.1	4.1	169	138 - 208
10	200.8	4.6	2.3	200	160 - 241
59	202.7	4.7	2.3	202	162 - 244
21	199.0	5.6	2.8	200	159 - 239
1	-	-	-	225	180 - 270

**Specimen WBG-15**

<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	136	66.8	7.5	11.2	70	53 - 81
All Abbott Methods	18	56.9	2.9	5.1	57	44 - 69
All Bayer Methods	1	-	-	-	118	94 - 142
All Lifescan Methods	5	60.6	2.1	3.4	61	48 - 73
All Roche Methods	90	71.7	2.0	2.8	71	57 - 87
Abbott FreeStyle Precision Pro	10	55.2	2.1	3.9	56	43 - 68
Abbott Precision XceedPro	8	59.0	2.3	3.9	59	47 - 71
Bayer Contour	1	-	-	-	118	94 - 142
Lifescan One Touch Ultra	5	60.6	2.1	3.4	61	48 - 73
Medline EvenCare G2 / G3	1	-	-	-	62	49 - 75
Nipro True Result	10	53.6	4.0	7.4	52	41 - 66
NOVA Biomedical StatStrip	9	57.0	2.5	4.4	58	45 - 69
Roche Accu-Chek Inform	10	71.5	1.3	1.8	71	57 - 86
Roche Accu-Chek Inform II	59	71.7	2.1	2.9	71	57 - 87
Roche Accu-Chek Performa	21	71.7	2.1	3.0	71	57 - 87
True Metrix Pro	1	-	-	-	57	45 - 69

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
<b>Specimen CK-11</b>						
All Method	5	5.53	0.50	9.1	5.6	4.0 - 7.1
<b>Specimen CK-12</b>						
All Method	5	85.83	15.47	18.0	93.9	39.4 - 132.3
<b>Specimen CK-13</b>						
All Method	5	26.13	4.46	17.0	28.4	12.7 - 39.6
<b>Specimen CK-14</b>						
All Method	5	45.90	7.72	16.8	50.0	22.7 - 69.1
<b>Specimen CK-15</b>						
All Method	5	15.10	1.85	12.3	15.8	9.5 - 20.7

**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)