

# **MEDICAL LABORATORY EVALUATION**

## **PARTICIPANT SUMMARY**

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

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## EVALUATION CRITERIA

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

### Qualitative/Semi-Quantitative

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

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

### Quantitative

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

Activated Partial Thromboplastin Time	$\pm 15\%$	Hemoglobin	$\pm 7\%$
Automated Differential	$\pm 3$ SD	International Normalized Ratio (INR)	$\pm 15\%$
Bilirubin, Neonatal (Total)	$\pm 0.4$ mg/dL or $20\% *$	Platelet Count	$\pm 25\%$
Bilirubin, Direct	$\pm 2$ SD	Prothrombin Time	$\pm 15\%$
CK-MB (U/L)	$\pm 3$ SD	Red Blood Cell Count	$\pm 6\%$
Cytomegalovirus	$\pm 3$ SD	Rubella	$\pm 3$ SD
Fibrinogen	$\pm 20\%$	Sedimentation Rate	$\pm 3$ SD
Folate	$\pm 1$ ng/mL or $\pm 30\%*$	Specific Gravity	$\pm 0.010$
Glucose, Whole Blood	$\pm 6$ mg/dL or $\pm 20%*$	Toxoplasma	$\pm 3$ SD
Glycohemoglobin	$\pm 5\%$	White Blood Cell Count	$\pm 15\%$
Hematocrit	$\pm 6\%$		

\*Whichever is greater

**SEDIMENTATION RATE (MM/HR)**

<u>Instrument</u>	<b>Specimen ES-5</b>						<b>Specimen ES-6</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	149	11.7	3.7	31.3	11	0 - 23	148	56.8	13.0	22.8	58	17 - 96
All Automated Methods	33	13.3	3.6	27.1	12	2 - 25	33	70.2	13.8	19.6	69	28 - 112
All Diesse Methods	13	12.5	3.7	29.8	11	1 - 24	12	79.6	13.0	16.3	81	40 - 119
All Manual Methods	112	11.3	3.6	31.4	11	0 - 22	112	53.2	10.4	19.5	54	22 - 85
All Vital Diagnostics Methods	13	10.7	3.9	36.1	11	0 - 23	13	60.9	8.8	14.4	62	34 - 88
Ves-Matic Easy Diesse	5	11.8	1.8	15.2	11	6 - 18	5	89.0	9.4	10.5	86	60 - 118
Vital Diagnostics Excyte M/10	7	11.9	2.3	19.1	12	5 - 19	7	57.1	8.3	14.6	56	32 - 83
Westergren - diluted	90	10.7	3.2	29.4	10	1 - 21	91	53.3	9.2	17.2	55	25 - 81
Westergren - undiluted	19	12.8	3.8	29.7	12	1 - 25	19	52.9	15.5	29.3	48	6 - 100

**HEMATOLOGY W/ 5-PART DIFFERENTIAL–WHITE BLOOD CELL 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	21	6.94	0.75	10.9	6.7	5.8 - 8.0	21	2.62	0.39	14.8	2.5	2.2 - 3.1
All Abbott Cell-Dyn Instruments	11	8.10	0.17	2.1	8.0	6.8 - 9.4	11	3.22	0.15	4.6	3.2	2.7 - 3.8
Abbott Cell-Dyn Emerald 22	6	6.45	0.34	5.3	6.5	5.4 - 7.5	6	2.33	0.10	4.1	2.4	1.9 - 2.7
Abbott Cell-Dyn Ruby	5	8.10	0.17	2.1	8.0	6.8 - 9.4	5	3.22	0.15	4.6	3.2	2.7 - 3.8
Orphee Mythic 22	10	6.55	0.25	3.8	6.6	5.5 - 7.6	10	2.44	0.11	4.4	2.5	2.0 - 2.9

  

<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	2.63	0.38	14.6	2.5	2.2 - 3.1	21	18.11	1.52	8.4	17.4	15.3 - 20.9
All Abbott Cell-Dyn Instruments	11	3.22	0.11	3.4	3.2	2.7 - 3.8	11	20.42	0.56	2.7	20.6	17.3 - 23.5
Abbott Cell-Dyn Emerald 22	6	2.35	0.13	5.5	2.4	1.9 - 2.8	6	17.43	0.45	2.6	17.4	14.8 - 20.1
Abbott Cell-Dyn Ruby	5	3.22	0.11	3.4	3.2	2.7 - 3.8	5	20.42	0.56	2.7	20.6	17.3 - 23.5
Orphee Mythic 22	10	2.45	0.14	5.9	2.4	2.0 - 2.9	10	17.22	0.59	3.4	17.1	14.6 - 19.9

  

<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	21	6.97	0.78	11.1	6.6	5.9 - 8.1
All Abbott Cell-Dyn Instruments	11	8.18	0.08	1.0	8.2	6.9 - 9.5
Abbott Cell-Dyn Emerald 22	6	6.45	0.29	4.5	6.5	5.4 - 7.5
Abbott Cell-Dyn Ruby	5	8.18	0.08	1.0	8.2	6.9 - 9.5
Orphee Mythic 22	10	6.57	0.25	3.7	6.6	5.5 - 7.6

**HEMATOLOGY W/ 5-PART DIFFERENTIAL-RED BLOOD CELL COUNT (x M/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	21	4.788	0.151	3.2	4.76	4.50 - 5.08	21	2.208	0.064	2.9	2.21	2.07 - 2.35
All Abbott Cell-Dyn Instruments	11	4.946	0.093	1.9	4.94	4.64 - 5.25	11	2.266	0.051	2.3	2.27	2.13 - 2.41
Abbott Cell-Dyn Emerald 22	6	4.680	0.161	3.4	4.68	4.39 - 4.97	6	2.208	0.059	2.7	2.22	2.07 - 2.34
Abbott Cell-Dyn Ruby	5	4.946	0.093	1.9	4.94	4.64 - 5.25	5	2.266	0.051	2.3	2.27	2.13 - 2.41
Orphee Mythic 22	10	4.752	0.113	2.4	4.74	4.46 - 5.04	10	2.179	0.055	2.5	2.18	2.04 - 2.31
<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	2.209	0.066	3.0	2.20	2.07 - 2.35	21	5.152	0.120	2.3	5.13	4.84 - 5.47
All Abbott Cell-Dyn Instruments	11	2.262	0.041	1.8	2.28	2.12 - 2.40	11	5.260	0.085	1.6	5.25	4.94 - 5.58
Abbott Cell-Dyn Emerald 22	6	2.220	0.094	4.2	2.23	2.08 - 2.36	6	5.190	0.094	1.8	5.19	4.87 - 5.51
Abbott Cell-Dyn Ruby	5	2.262	0.041	1.8	2.28	2.12 - 2.40	5	5.260	0.085	1.6	5.25	4.94 - 5.58
Orphee Mythic 22	10	2.179	0.049	2.3	2.18	2.04 - 2.31	10	5.083	0.100	2.0	5.09	4.77 - 5.39
<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	4.839	0.168	3.5	4.81	4.54 - 5.13						
All Abbott Cell-Dyn Instruments	11	4.994	0.143	2.9	4.91	4.69 - 5.30						
Abbott Cell-Dyn Emerald 22	6	4.858	0.257	5.3	4.80	4.56 - 5.15						
Abbott Cell-Dyn Ruby	5	4.994	0.143	2.9	4.91	4.69 - 5.30						
Orphee Mythic 22	10	4.755	0.064	1.4	4.76	4.46 - 5.05						

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

<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	12.21	1.05	8.6	11.8	11.3 - 13.1	21	5.10	0.47	9.2	5.0	4.7 - 5.5
All Abbott Cell-Dyn Instruments	11	13.82	0.13	0.9	13.8	12.8 - 14.8	11	5.76	0.05	1.0	5.8	5.3 - 6.2
Abbott Cell-Dyn Emerald 22	6	12.08	0.33	2.7	12.1	11.2 - 13.0	6	5.13	0.21	4.1	5.2	4.7 - 5.5
Abbott Cell-Dyn Ruby	5	13.82	0.13	0.9	13.8	12.8 - 14.8	5	5.76	0.05	1.0	5.8	5.3 - 6.2
Orphee Mythic 22	10	11.46	0.31	2.7	11.4	10.6 - 12.3	10	4.76	0.18	3.7	4.7	4.4 - 5.1
	<b>Specimen CL-13</b>						<b>Specimen CL-14</b>					
All Method	21	5.11	0.43	8.4	5.0	4.7 - 5.5	21	15.51	0.89	5.8	15.3	14.4 - 16.6
All Abbott Cell-Dyn Instruments	11	5.68	0.11	1.9	5.7	5.2 - 6.1	11	16.78	0.33	2.0	16.8	15.6 - 18.0
Abbott Cell-Dyn Emerald 22	6	5.23	0.21	4.0	5.3	4.8 - 5.6	6	15.50	0.37	2.4	15.6	14.4 - 16.6
Abbott Cell-Dyn Ruby	5	5.68	0.11	1.9	5.7	5.2 - 6.1	5	16.78	0.33	2.0	16.8	15.6 - 18.0
Orphee Mythic 22	10	4.79	0.18	3.7	4.8	4.4 - 5.2	10	14.87	0.38	2.5	14.9	13.8 - 16.0
	<b>Specimen CL-15</b>											
All Method	21	12.27	1.04	8.4	11.9	11.4 - 13.2						
All Abbott Cell-Dyn Instruments	11	13.72	0.30	2.2	13.8	12.7 - 14.7						
Abbott Cell-Dyn Emerald 22	6	12.45	0.59	4.8	12.7	11.5 - 13.4						
Abbott Cell-Dyn Ruby	5	13.72	0.30	2.2	13.8	12.7 - 14.7						
Orphee Mythic 22	10	11.47	0.31	2.7	11.4	10.6 - 12.3						

**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	21	39.35	1.59	4.0	39.4	36.9 - 41.8	21	16.20	0.72	4.4	16.3	15.2 - 17.2
All Abbott Cell-Dyn Instruments	11	37.94	1.16	3.1	37.5	35.6 - 40.3	11	15.58	0.36	2.3	15.6	14.6 - 16.6
Abbott Cell-Dyn Emerald 22	6	40.18	1.28	3.2	40.5	37.7 - 42.6	6	16.18	0.51	3.1	16.2	15.2 - 17.2
Abbott Cell-Dyn Ruby	5	37.94	1.16	3.1	37.5	35.6 - 40.3	5	15.58	0.36	2.3	15.6	14.6 - 16.6
Orphee Mythic 22	10	39.73	1.52	3.8	39.5	37.3 - 42.2	10	16.52	0.75	4.5	16.6	15.5 - 17.6
	<b>Specimen CL-13</b>						<b>Specimen CL-14</b>					
All Method	21	16.22	0.72	4.4	16.1	15.2 - 17.2	21	46.02	2.04	4.4	45.8	43.2 - 48.8
All Abbott Cell-Dyn Instruments	11	15.64	0.36	2.3	15.6	14.7 - 16.6	11	43.88	1.28	2.9	43.7	41.2 - 46.6
Abbott Cell-Dyn Emerald 22	6	16.68	0.91	5.4	16.6	15.6 - 17.7	6	47.68	0.85	1.8	47.8	44.8 - 50.6
Abbott Cell-Dyn Ruby	5	15.64	0.36	2.3	15.6	14.7 - 16.6	5	43.88	1.28	2.9	43.7	41.2 - 46.6
Orphee Mythic 22	10	16.33	0.62	3.8	16.2	15.3 - 17.4	10	46.48	1.81	3.9	46.0	43.6 - 49.3
	<b>Specimen CL-15</b>											
All Method	21	39.42	1.32	3.3	39.5	37.0 - 41.8						
All Abbott Cell-Dyn Instruments	11	38.44	1.38	3.6	38.0	36.1 - 40.8						
Abbott Cell-Dyn Emerald 22	6	39.55	1.15	2.9	39.4	37.1 - 42.0						
Abbott Cell-Dyn Ruby	5	38.44	1.38	3.6	38.0	36.1 - 40.8						
Orphee Mythic 22	10	39.85	1.20	3.0	39.7	37.4 - 42.3						



**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	21	267.3	26.8	10.0	264	200 - 335	21	99.9	15.3	15.3	102	74 - 125
All Abbott Cell-Dyn Instruments	11	265.6	14.3	5.4	262	199 - 332	11	78.2	5.0	6.4	79	58 - 98
Abbott Cell-Dyn Emerald 22	6	253.0	9.9	3.9	254	189 - 317	6	103.3	5.3	5.1	102	77 - 130
Abbott Cell-Dyn Ruby	5	265.6	14.3	5.4	262	199 - 332	5	78.2	5.0	6.4	79	58 - 98
Orphee Mythic 22	10	273.8	34.3	12.5	272	205 - 343	10	109.5	8.9	8.1	109	82 - 137
<b>Specimen CL-13</b>												
All Method	21	100.1	16.1	16.1	102	75 - 126	21	513.4	27.2	5.3	503	385 - 642
All Abbott Cell-Dyn Instruments	11	79.4	6.4	8.1	79	59 - 100	11	515.8	34.2	6.6	503	386 - 645
Abbott Cell-Dyn Emerald 22	6	109.8	17.2	15.6	104	82 - 138	6	490.3	15.1	3.1	496	367 - 613
Abbott Cell-Dyn Ruby	5	79.4	6.4	8.1	79	59 - 100	5	515.8	34.2	6.6	503	386 - 645
Orphee Mythic 22	10	106.5	8.7	8.2	104	79 - 134	10	521.4	23.9	4.6	521	391 - 652
<b>Specimen CL-15</b>												
All Method	21	278.5	21.4	7.7	275	208 - 349						
All Abbott Cell-Dyn Instruments	11	277.8	15.0	5.4	284	208 - 348						
Abbott Cell-Dyn Emerald 22	6	265.0	27.3	10.3	257	198 - 332						
Abbott Cell-Dyn Ruby	5	277.8	15.0	5.4	284	208 - 348						
Orphee Mythic 22	10	284.2	21.2	7.5	274	213 - 356						

**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	58.47	2.17	3.7	58.6	51.9 - 65.0	21	44.64	1.64	3.7	44.5	39.7 - 49.6
All Abbott Cell-Dyn Instruments	11	60.90	0.92	1.5	60.9	58.1 - 63.7	11	45.28	1.23	2.7	45.4	41.5 - 49.0
Abbott Cell-Dyn Emerald 22	6	59.40	1.41	2.4	59.6	55.1 - 63.7	6	45.90	1.14	2.5	46.0	42.4 - 49.4
Abbott Cell-Dyn Ruby	5	60.90	0.92	1.5	60.9	58.1 - 63.7	5	45.28	1.23	2.7	45.4	41.5 - 49.0
Orphee Mythic 22	10	56.88	1.36	2.4	56.9	52.7 - 61.0	10	43.82	1.62	3.7	43.9	38.9 - 48.7
<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	44.65	1.80	4.0	44.5	39.2 - 50.1	21	71.12	0.97	1.4	71.0	68.2 - 74.1
All Abbott Cell-Dyn Instruments	11	46.34	0.85	1.8	46.1	43.7 - 48.9	11	72.14	0.64	0.9	72.0	70.2 - 74.1
Abbott Cell-Dyn Emerald 22	6	44.98	2.05	4.5	45.7	38.8 - 51.2	6	70.95	0.58	0.8	70.9	69.2 - 72.7
Abbott Cell-Dyn Ruby	5	46.34	0.85	1.8	46.1	43.7 - 48.9	5	72.14	0.64	0.9	72.0	70.2 - 74.1
Orphee Mythic 22	10	43.67	1.44	3.3	44.2	39.3 - 48.0	10	70.68	0.88	1.2	70.5	68.0 - 73.4
<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	59.24	1.64	2.8	59.2	54.3 - 64.2						
All Abbott Cell-Dyn Instruments	11	61.12	0.73	1.2	60.8	58.9 - 63.3						
Abbott Cell-Dyn Emerald 22	6	59.08	0.75	1.3	59.2	56.8 - 61.4						
Abbott Cell-Dyn Ruby	5	61.12	0.73	1.2	60.8	58.9 - 63.3						
Orphee Mythic 22	10	58.36	1.46	2.5	58.4	53.9 - 62.8						

**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	21	20.96	4.10	19.6	21.0	8.6 - 33.3	21	29.24	6.31	21.6	29.1	10.3 - 48.2
All Abbott Cell-Dyn Instruments	11	25.32	1.10	4.4	25.1	22.0 - 28.7	11	37.56	1.15	3.1	37.6	34.1 - 41.1
Abbott Cell-Dyn Emerald 22	6	15.85	2.03	12.8	16.5	9.7 - 22.0	6	22.33	3.64	16.3	21.9	11.3 - 33.3
Abbott Cell-Dyn Ruby	5	25.32	1.10	4.4	25.1	22.0 - 28.7	5	37.56	1.15	3.1	37.6	34.1 - 41.1
Orphee Mythic 22	10	20.82	3.09	14.8	21.0	11.5 - 30.1	10	27.85	3.57	12.8	28.8	17.1 - 38.6
<b>Specimen CL-13</b>												
All Method	21	29.53	6.36	21.6	28.5	10.4 - 48.7	21	14.52	1.98	13.6	14.2	8.5 - 20.5
All Abbott Cell-Dyn Instruments	11	38.42	0.90	2.4	38.3	35.7 - 41.2	11	15.40	2.06	13.3	14.7	9.2 - 21.6
Abbott Cell-Dyn Emerald 22	6	23.08	2.79	12.1	22.7	14.7 - 31.5	6	12.78	0.54	4.2	12.8	11.1 - 14.4
Abbott Cell-Dyn Ruby	5	38.42	0.90	2.4	38.3	35.7 - 41.2	5	15.40	2.06	13.3	14.7	9.2 - 21.6
Orphee Mythic 22	10	27.66	3.43	12.4	28.5	17.3 - 38.0	10	14.78	2.00	13.5	15.2	8.7 - 20.8
<b>Specimen CL-15</b>												
All Method	21	20.53	3.95	19.2	20.8	8.6 - 32.4						
All Abbott Cell-Dyn Instruments	11	25.40	0.73	2.9	25.3	23.2 - 27.6						
Abbott Cell-Dyn Emerald 22	6	16.93	0.81	4.8	16.7	14.4 - 19.4						
Abbott Cell-Dyn Ruby	5	25.40	0.73	2.9	25.3	23.2 - 27.6						
Orphee Mythic 22	10	19.54	3.27	16.7	19.8	9.7 - 29.4						

**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	21	14.83	4.85	32.7	16.9	0.2 - 29.4	21	20.81	6.85	32.9	22.7	0.2 - 41.4
All Abbott Cell-Dyn Instruments	11	7.26	0.48	6.6	7.4	5.8 - 8.8	11	10.32	0.87	8.4	9.9	7.7 - 13.0
Abbott Cell-Dyn Emerald 22	6	18.48	2.21	12.0	18.6	11.8 - 25.2	6	26.60	2.64	9.9	27.0	18.6 - 34.6
Abbott Cell-Dyn Ruby	5	7.26	0.48	6.6	7.4	5.8 - 8.8	5	10.32	0.87	8.4	9.9	7.7 - 13.0
Orphee Mythic 22	10	17.16	1.22	7.1	17.2	13.4 - 20.9	10	23.74	2.38	10.0	22.9	16.6 - 30.9
<b>Specimen CL-13</b>												
All Method	21	20.38	7.23	35.5	22.0	0.0 - 42.1	21	7.83	2.40	30.7	9.0	0.6 - 15.1
All Abbott Cell-Dyn Instruments	11	9.18	0.62	6.7	9.1	7.3 - 11.1	11	4.06	0.30	7.3	4.1	3.1 - 5.0
Abbott Cell-Dyn Emerald 22	6	26.10	2.16	8.3	25.7	19.6 - 32.6	6	9.43	1.23	13.0	9.4	5.7 - 13.2
Abbott Cell-Dyn Ruby	5	9.18	0.62	6.7	9.1	7.3 - 11.1	5	4.06	0.30	7.3	4.1	3.1 - 5.0
Orphee Mythic 22	10	23.70	2.52	10.6	23.0	16.1 - 31.3	10	9.07	0.48	5.3	9.1	7.6 - 10.6
<b>Specimen CL-15</b>												
All Method	21	14.51	4.98	34.3	16.5	0.0 - 29.5						
All Abbott Cell-Dyn Instruments	11	6.72	0.76	11.4	7.1	4.4 - 9.1						
Abbott Cell-Dyn Emerald 22	6	18.53	1.42	7.7	18.7	14.2 - 22.8						
Abbott Cell-Dyn Ruby	5	6.72	0.76	11.4	7.1	4.4 - 9.1						
Orphee Mythic 22	10	16.80	1.41	8.4	16.6	12.5 - 21.1						

**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	21	5.51	1.04	18.8	5.8	2.3 - 8.7	21	4.96	0.98	19.7	5.0	2.0 - 7.9	
All Abbott Cell-Dyn Instruments	11	6.22	0.26	4.2	6.3	5.4 - 7.0	11	6.02	0.66	11.0	6.1	4.0 - 8.1	
Abbott Cell-Dyn Emerald 22	6	6.23	0.68	10.8	6.1	4.1 - 8.3	6	4.98	0.30	6.0	5.0	4.0 - 5.9	
Abbott Cell-Dyn Ruby	5	6.22	0.26	4.2	6.3	5.4 - 7.0	5	6.02	0.66	11.0	6.1	4.0 - 8.1	
Orphee Mythic 22	10	4.79	0.96	20.0	4.6	1.9 - 7.7	10	4.37	0.83	19.0	4.9	1.8 - 6.9	
	<b>Specimen CL-13</b>						<b>Specimen CL-14</b>						
All Method	21	4.93	0.65	13.1	5.0	2.9 - 6.9	21	6.80	1.67	24.5	7.4	1.8 - 11.8	
All Abbott Cell-Dyn Instruments	11	5.26	0.52	9.8	5.1	3.7 - 6.9	11	8.64	0.45	5.2	8.5	7.2 - 10.0	
Abbott Cell-Dyn Emerald 22	6	5.33	0.55	10.3	5.2	3.6 - 7.0	6	7.40	0.08	1.1	7.4	7.1 - 7.7	
Abbott Cell-Dyn Ruby	5	5.26	0.52	9.8	5.1	3.7 - 6.9	5	8.64	0.45	5.2	8.5	7.2 - 10.0	
Orphee Mythic 22	10	4.58	0.59	13.0	4.3	2.7 - 6.4	10	5.51	1.27	23.1	5.3	1.6 - 9.4	
	<b>Specimen CL-15</b>												
All Method	21	5.67	1.07	18.9	6.2	2.4 - 8.9							
All Abbott Cell-Dyn Instruments	11	6.50	0.19	2.9	6.5	5.9 - 7.1							
Abbott Cell-Dyn Emerald 22	6	6.20	0.35	5.6	6.3	5.1 - 7.3							
Abbott Cell-Dyn Ruby	5	6.50	0.19	2.9	6.5	5.9 - 7.1							
Orphee Mythic 22	10	4.97	1.11	22.4	4.7	1.6 - 8.4							

**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	21	0.59	0.38	63.8	0.5	0.0 - 1.8	21	0.52	0.32	60.9	0.4	0.0 - 1.5
All Abbott Cell-Dyn Instruments	11	0.42	0.28	66.1	0.3	0.0 - 1.3	11	0.80	0.20	25.0	0.7	0.2 - 1.4
Abbott Cell-Dyn Emerald 22	6	0.45	0.39	86.1	0.4	0.0 - 1.7	6	0.30	0.22	72.0	0.4	0.0 - 1.0
Abbott Cell-Dyn Ruby	5	0.42	0.28	66.1	0.3	0.0 - 1.3	5	0.80	0.20	25.0	0.7	0.2 - 1.4
Orphee Mythic 22	10	0.74	0.39	53.0	0.7	0.0 - 2.0	10	0.47	0.32	67.3	0.4	0.0 - 1.5
<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	21	0.62	0.39	62.5	0.6	0.0 - 1.8	21	0.37	0.26	68.8	0.3	0.0 - 1.2
All Abbott Cell-Dyn Instruments	11	0.82	0.43	52.7	0.6	0.0 - 2.2	11	0.52	0.29	56.7	0.5	0.0 - 1.5
Abbott Cell-Dyn Emerald 22	6	0.40	0.32	79.1	0.5	0.0 - 1.4	6	0.23	0.10	42.6	0.3	0.0 - 0.6
Abbott Cell-Dyn Ruby	5	0.82	0.43	52.7	0.6	0.0 - 2.2	5	0.52	0.29	56.7	0.5	0.0 - 1.5
Orphee Mythic 22	10	0.61	0.38	61.6	0.7	0.0 - 1.8	10	0.36	0.26	73.2	0.3	0.0 - 1.2
<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	21	0.56	0.42	74.5	0.5	0.0 - 1.9						
All Abbott Cell-Dyn Instruments	11	0.24	0.17	69.7	0.2	0.0 - 0.8						
Abbott Cell-Dyn Emerald 22	6	0.55	0.53	95.6	0.4	0.0 - 2.2						
Abbott Cell-Dyn Ruby	5	0.24	0.17	69.7	0.2	0.0 - 0.8						
Orphee Mythic 22	10	0.72	0.39	54.7	0.7	0.0 - 2.0						

## BLOOD BANK

### ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Group O	18	94.74%	Acceptable
	Group AB	1	5.26%	
BB-12	Group A	18	94.74%	Acceptable
	Group AB	1	5.26%	
BB-13	Group A	18	94.74%	Acceptable
	Group AB	1	5.26%	
BB-14	Group O	18	94.74%	Acceptable
	Group AB	1	5.26%	
BB-15	Group B	18	94.74%	Acceptable
	Group AB	1	5.26%	

### RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Rh Negative	18	94.74%	Acceptable
	Rh Positive	1	5.26%	
BB-12	Rh Positive	19	100.00%	Acceptable
BB-13	Rh Negative	18	94.74%	Acceptable
	Rh Positive	1	5.26%	
BB-14	Rh Positive	19	100.00%	Acceptable
BB-15	Rh Positive	19	100.00%	Acceptable

### UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	No unexpected antibody detected	16	100.00%	Acceptable
AB-12	Unexpected antibody detected	15	93.75%	Acceptable
	No unexpected antibody detected	1	6.25%	
AB-13	No unexpected antibody detected	16	100.00%	Acceptable
AB-14	Unexpected antibody detected	16	100.00%	Acceptable
AB-15	No unexpected antibody detected	16	100.00%	Acceptable

## BLOOD BANK

### ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	No antibody detected	8	100.00%	Acceptable
AB-12	Anti-E	8	100.00%	Acceptable
AB-13	No antibody detected	8	100.00%	Acceptable
AB-14	Anti-c	8	100.00%	Acceptable
AB-15	No antibody detected	8	100.00%	Acceptable

### COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	Compatible	13	100.00%	Acceptable
AB-12	Compatible	11	84.62%	Acceptable
	Not Compatible	2	15.38%	
AB-13	Compatible	13	100.00%	Acceptable
AB-14	Not Compatible	12	92.31%	Acceptable
	Compatible	1	7.69%	
AB-15	Compatible	12	92.31%	Acceptable
	Not Compatible	1	7.69%	



# Coagulation

## PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	53	11.57	1.23	10.6	11.1	9.8 - 13.4	53	14.78	1.66	11.3	14.4	12.5 - 17.1
Dade Innovin												
Dade Behring BFT II	5	9.60	0.28	2.9	9.6	8.1 - 11.1	5	12.75	0.21	1.7	12.8	10.8 - 14.7
Sysmex CA-500/600 series	14	10.50	0.39	3.7	10.5	8.9 - 12.1	14	13.24	0.58	4.4	13.1	11.2 - 15.3
All Coagulation Instruments	21	10.43	0.51	4.9	10.4	8.8 - 12.0	21	13.17	0.55	4.1	13.1	11.1 - 15.2
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	6	12.87	0.26	2.0	12.9	10.9 - 14.8	6	16.42	0.16	1.0	16.4	13.9 - 18.9
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	10	12.95	0.33	2.6	13.0	11.0 - 14.9	10	16.64	0.40	2.4	16.7	14.1 - 19.2
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	12.95	0.21	1.6	13.0	11.0 - 14.9	5	17.70	0.14	0.8	17.7	15.0 - 20.4
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	10.83	0.25	2.3	10.9	9.2 - 12.5	6	14.33	0.33	2.3	14.4	12.1 - 16.5
<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	52	11.88	1.43	12.0	11.3	10.0 - 13.7	53	33.47	4.69	14.0	34.1	28.4 - 38.5
Dade Innovin												
Dade Behring BFT II	5	9.90	0.28	2.9	9.9	8.4 - 11.4	5	30.60	0.57	1.8	30.6	26.0 - 35.2
Sysmex CA-500/600 series	14	10.70	0.30	2.8	10.7	9.0 - 12.4	14	29.75	1.84	6.2	29.3	25.2 - 34.3
All Coagulation Instruments	21	10.61	0.40	3.8	10.6	9.0 - 12.3	21	29.44	1.03	3.5	29.3	25.0 - 33.9
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	6	13.43	0.30	2.2	13.4	11.4 - 15.5	6	35.73	0.59	1.6	35.6	30.3 - 41.1
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	10	13.55	0.44	3.2	13.5	11.5 - 15.6	10	35.63	1.71	4.8	35.6	30.2 - 41.0
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	4	-	-	-	13.4	10.0 - 13.7	5	45.75	0.07	0.2	45.8	38.8 - 52.7
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	10.88	0.35	3.3	10.9	9.2 - 12.6	6	35.27	1.83	5.2	35.2	29.9 - 40.6

**PROTHROMBIN TIME (seconds)****Specimen CG-15**

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	53	20.77	2.62	12.6	21.2	17.6 - 23.9
Dade Innovin						
Dade Behring BFT II	5	18.80	0.71	3.8	18.8	15.9 - 21.7
Sysmex CA-500/600 series	14	18.39	0.65	3.5	18.3	15.6 - 21.2
All Coagulation Instruments	21	18.38	0.67	3.6	18.3	15.6 - 21.2
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	6	22.40	0.76	3.4	22.5	19.0 - 25.8
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STart Max	10	22.59	0.79	3.5	22.5	19.2 - 26.0
Diagnostica Stago STA NeoPTimal						
Diagnostica Stago STA Compact / Max	5	26.90	0.71	2.6	26.9	22.8 - 31.0
HemosIL RecombiPlasTin 2G						
IL ACL, all models	6	21.07	0.70	3.3	21.2	17.9 - 24.3

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

<u>Reagent/Instrument</u>	<b>Specimen CG-11</b>						<b>Specimen CG-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	53	0.99	0.06	5.9	1.0	0.8 - 1.2	53	1.30	0.07	5.6	1.3	1.1 - 1.6
Dade Innovin												
Dade Behring BFT II	5	1.00	0.01	0.0	1.0	0.8 - 1.2	5	1.35	0.07	5.2	1.4	1.1 - 1.6
Sysmex CA-500/600 series	14	1.03	0.05	4.6	1.0	0.8 - 1.2	14	1.29	0.07	5.6	1.3	1.0 - 1.5
All Coagulation Instruments	21	1.02	0.04	4.2	1.0	0.8 - 1.2	21	1.29	0.07	5.6	1.3	1.1 - 1.5
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	6	0.97	0.05	5.0	1.0	0.8 - 1.2	6	1.30	0.01	0.0	1.3	1.1 - 1.5
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	10	0.99	0.04	3.6	1.0	0.8 - 1.2	10	1.36	0.05	3.9	1.4	1.1 - 1.6
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	1.00	0.01	0.0	1.0	0.8 - 1.2	5	1.40	0.01	0.0	1.4	1.1 - 1.7
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	0.92	0.04	4.5	0.9	0.7 - 1.1	6	1.27	0.08	6.4	1.3	1.0 - 1.5
<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	52	1.02	0.06	6.3	1.0	0.8 - 1.2	53	3.25	0.41	12.7	3.3	2.7 - 3.8
Dade Innovin												
Dade Behring BFT II	5	1.10	0.01	0.0	1.1	0.9 - 1.3	5	2.85	0.21	7.4	2.9	2.4 - 3.3
Sysmex CA-500/600 series	14	1.06	0.09	8.1	1.0	0.8 - 1.3	14	2.96	0.21	7.2	2.9	2.5 - 3.5
All Coagulation Instruments	21	1.04	0.05	4.9	1.0	0.8 - 1.2	21	2.93	0.21	7.0	2.9	2.4 - 3.4
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	6	1.01	0.04	3.7	1.0	0.8 - 1.2	6	3.59	0.09	2.5	3.6	3.0 - 4.2
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	10	1.04	0.05	5.0	1.0	0.8 - 1.3	10	3.62	0.23	6.4	3.6	3.0 - 4.2
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	4	-	-	-	1.0	0.8 - 1.2	5	3.95	0.07	1.8	4.0	3.3 - 4.6
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	0.92	0.04	4.9	0.9	0.7 - 1.1	6	3.25	0.34	10.4	3.3	2.7 - 3.8

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

**Specimen CG-15**

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	53	1.90	0.16	8.5	1.9	1.6 - 2.2
Dade Innovin						
Dade Behring BFT II	5	1.90	0.14	7.4	1.9	1.6 - 2.2
Sysmex CA-500/600 series	14	1.81	0.08	4.2	1.8	1.5 - 2.1
All Coagulation Instruments	21	1.81	0.09	5.0	1.8	1.5 - 2.1
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	6	1.96	0.08	4.0	2.0	1.6 - 2.3
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STart Max	10	2.01	0.11	5.2	2.0	1.7 - 2.4
Diagnostica Stago STA NeoPTimal						
Diagnostica Stago STA Compact / Max	5	2.25	0.07	3.1	2.3	1.9 - 2.6
HemosIL RecombiPlasTin 2G						
IL ACL, all models	6	1.87	0.14	7.3	1.9	1.5 - 2.2

**ACTIVATED PARTIAL THROMBOPLASTIN (seconds)**

Specimen CG-11							Specimen CG-12					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	32	27.7	3.5	12.5	27	23 - 32	32	32.9	4.8	14.7	32	27 - 38
Dade Actin FSL												
Sysmex CA-500/600 series	9	24.8	1.0	3.9	25	21 - 29	9	30.4	5.9	19.5	28	25 - 36
All Coagulation Instruments	10	25.0	1.2	4.6	25	21 - 29	10	30.3	5.6	18.5	29	25 - 35
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	5	30.0	1.4	4.7	30	25 - 35	5	36.0	1.4	3.9	36	30 - 42
HemosIL APTT-SP												
IL ACL, all models	5	28.3	1.9	6.7	28	24 - 33	5	33.0	2.6	7.8	33	28 - 38
IL TEST APTT-SP												
IL ACL, all models	5	29.0	1.4	4.9	29	24 - 34	5	36.5	0.7	1.9	37	31 - 42
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	31	28.6	6.5	22.6	25	24 - 33	32	61.0	12.5	20.5	58	51 - 71
Dade Actin FSL												
Sysmex CA-500/600 series	9	24.6	0.5	2.1	25	20 - 29	9	49.2	1.7	3.5	50	41 - 57
All Coagulation Instruments	10	24.6	0.5	2.1	25	20 - 29	10	49.7	2.2	4.5	50	42 - 58
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	4	-	-	-	30	24 - 33	5	67.5	2.1	3.1	68	57 - 78
HemosIL APTT-SP												
IL ACL, all models	5	29.0	1.4	4.9	29	24 - 34	5	68.8	8.3	12.0	69	58 - 80
IL TEST APTT-SP												
IL ACL, all models	5	31.0	0.1	0.0	31	26 - 36	5	67.5	2.1	3.1	68	57 - 78
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	32	37.6	6.0	16.0	39	31 - 44						
Dade Actin FSL												
Sysmex CA-500/600 series	9	32.9	3.1	9.3	32	27 - 38						
All Coagulation Instruments	10	32.9	2.9	8.8	32	27 - 38						
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	5	42.0	0.1	0.0	42	35 - 49						
HemosIL APTT-SP												
IL ACL, all models	5	42.8	3.5	8.2	43	36 - 50						
IL TEST APTT-SP												
IL ACL, all models	5	41.0	1.4	3.4	41	34 - 48						

**FIBRINOGEN (mg/dL)**

<b>Specimen CG-11</b>							<b>Specimen CG-12</b>					
<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>	<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	11	266.6	38.9	14.6	285	213 - 320	11	167.9	19.2	11.4	173	134 - 202
IL Fibrinogen-C IL ACL, all models	6	282.0	34.8	12.3	287	225 - 339	6	169.0	20.4	12.1	176	135 - 203
<b>Specimen CG-13</b>							<b>Specimen CG-14</b>					
<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>	<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	11	453.7	35.9	7.9	460	362 - 545	11	258.1	29.4	11.4	260	206 - 310
IL Fibrinogen-C IL ACL, all models	6	452.3	50.4	11.1	468	361 - 543	6	262.7	40.1	15.3	260	210 - 316
<b>Specimen CG-15</b>												
<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	11	251.3	25.3	10.1	250	201 - 302						
IL Fibrinogen-C IL ACL, all models	6	245.3	25.4	10.4	260	196 - 295						

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

<u>Reagent/Instrument</u>	<b>Specimen XS-11</b>						<b>Specimen XS-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	27	14.98	0.24	1.6	15.0	12.7 - 17.3	27	24.27	0.94	3.9	24.3	20.6 - 28.0
All Roche CoaguChek XS Plus Instruments	12	14.95	0.28	1.9	15.0	12.7 - 17.2	12	23.93	0.78	3.3	24.1	20.3 - 27.6
Roche CoaguChek Pro II	14	14.99	0.21	1.4	15.0	12.7 - 17.3	14	24.36	0.75	3.1	24.4	20.7 - 28.1
Roche CoaguChek XS Plus - Waived	8	16.19	3.37	20.8	15.1	13.7 - 18.7	8	22.64	3.18	14.0	23.5	19.2 - 26.1
Roche CoaguChek XS Plus	5	14.88	0.33	2.2	15.0	12.6 - 17.2	5	24.24	0.23	0.9	24.3	20.6 - 27.9

<u>Reagent/Instrument</u>	<b>Specimen XS-13</b>						<b>Specimen XS-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	6	32.75	0.70	2.2	32.8	27.8 - 37.7	6	14.96	0.11	0.8	15.0	12.7 - 17.3
All Roche CoaguChek XS Plus Instruments	5	32.47	0.51	1.6	32.6	27.5 - 37.4	5	14.98	0.13	0.8	15.0	12.7 - 17.3
Roche CoaguChek Pro II	1	-	-	-	33.6	27.8 - 37.7	1	-	-	-	14.9	12.7 - 17.3
Roche CoaguChek XS Plus - Waived	2	-	-	-	32.6	27.7 - 37.5	2	-	-	-	15.1	12.7 - 17.4
Roche CoaguChek XS Plus	3	-	-	-	32.4	27.5 - 37.3	3	-	-	-	14.9	12.6 - 17.2

<u>Reagent/Instrument</u>	<b>Specimen XS-15</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	6	24.42	1.01	4.1	24.7	20.7 - 28.1
All Roche CoaguChek XS Plus Instruments	5	24.25	1.08	4.5	24.6	20.6 - 27.9
Roche CoaguChek Pro II	1	-	-	-	25.1	20.7 - 28.1
Roche CoaguChek XS Plus - Waived	2	-	-	-	24.0	20.3 - 27.6
Roche CoaguChek XS Plus	3	-	-	-	24.6	20.8 - 28.3

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

<u>Reagent/Instrument</u>	<b>Specimen XS-11</b>						<b>Specimen XS-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	57	1.25	0.05	4.0	1.3	1.0 - 1.5	55	2.02	0.06	3.2	2.0	1.7 - 2.4
All Roche CoaguChek XS Plus Instruments	30	1.26	0.05	4.0	1.3	1.0 - 1.5	29	2.00	0.07	3.3	2.0	1.7 - 2.3
Roche CoaguChek Pro II	26	1.24	0.05	4.1	1.2	1.0 - 1.5	26	2.04	0.06	2.8	2.0	1.7 - 2.4
Roche CoaguChek XS Plus - Waived	22	1.26	0.05	4.0	1.3	1.0 - 1.5	21	2.00	0.07	3.3	2.0	1.7 - 2.4
Roche CoaguChek XS Plus	8	1.25	0.05	4.3	1.3	1.0 - 1.5	8	1.99	0.06	3.2	2.0	1.6 - 2.3

<u>Reagent/Instrument</u>	<b>Specimen XS-13</b>						<b>Specimen XS-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	2.74	0.06	2.3	2.7	2.3 - 3.2	19	1.22	0.04	3.5	1.2	1.0 - 1.5
All Roche CoaguChek XS Plus Instruments	7	2.72	0.04	1.6	2.7	2.3 - 3.2	7	1.23	0.05	4.2	1.2	1.0 - 1.5
Roche CoaguChek Pro II	12	2.75	0.07	2.5	2.7	2.3 - 3.2	12	1.22	0.04	3.2	1.2	1.0 - 1.4
Roche CoaguChek XS Plus - Waived	5	2.73	0.06	2.1	2.7	2.3 - 3.2	5	1.25	0.06	4.6	1.3	1.0 - 1.5
Roche CoaguChek XS Plus	2	-	-	-	2.7	2.2 - 3.2	2	-	-	-	1.2	1.0 - 1.4

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	19	2.04	0.07	3.4	2.0	1.7 - 2.4
All Roche CoaguChek XS Plus Instruments	7	2.05	0.08	4.1	2.1	1.7 - 2.4
Roche CoaguChek Pro II	12	2.03	0.07	3.2	2.0	1.7 - 2.4
Roche CoaguChek XS Plus - Waived	5	2.05	0.10	4.9	2.1	1.7 - 2.4
Roche CoaguChek XS Plus	2	-	-	-	2.1	1.7 - 2.4



## 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	125	1.0238	0.0056	0.5	1.025	1.013 - 1.034
All Iris Diagnostics Methods	6	1.0272	0.0010	0.1	1.028	1.017 - 1.038
All Refractive Index Methods	11	1.0271	0.0038	0.4	1.028	1.017 - 1.038
All Roche Methods	38	1.0206	0.0056	0.5	1.020	1.010 - 1.031
All Siemens Methods	35	1.0229	0.0028	0.3	1.025	1.012 - 1.033
77 Elektronika LabUMat/2	17	1.0306	0.0048	0.5	1.031	1.020 - 1.041
Acon Laboratories	6	1.0250	0.0045	0.4	1.025	1.015 - 1.035
Roche Chemstrips / Combur	7	1.0193	0.0035	0.3	1.020	1.009 - 1.030
Roche cobas u 411	17	1.0194	0.0015	0.2	1.020	1.009 - 1.030
Roche cobas u 601 / 701	7	1.0291	0.0063	0.6	1.032	1.019 - 1.040
Roche Urisys	14	1.0179	0.0043	0.4	1.015	1.007 - 1.028
Siemens Clinitek Advantus	15	1.0243	0.0025	0.2	1.025	1.014 - 1.035
Siemens Clinitek Status / Status+	20	1.0218	0.0025	0.2	1.020	1.011 - 1.032

## URINALYSIS DIPSTICK-pH

Specimen UA-3

### Participant Results

<u>Method</u>	<u>Labs</u>	<u>≤3.5</u>	<u>4.0</u>	<u>4.5</u>	<u>5.0</u>	<u>5.5</u>	<u>6.0</u>	<u>6.5</u>	<u>7.0</u>	<u>7.5</u>	<u>8.0</u>	<u>8.5</u>	<u>≥9.0</u>
ALL METHODS	150	-	-	-	114	17	19	-	-	-	-	-	-
77 Elektronika LabUMat/2	18	-	-	-	18	-	-	-	-	-	-	-	-
Acon Laboratories	6	-	-	-	2	2	2	-	-	-	-	-	-
Arkray Aution AU-4050	1	-	-	-	1	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	-	-	-	1	-	-	-	-	-	-	-	-
Arkray Aution Sticks	1	-	-	-	1	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	1	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	1	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	4	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	1	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	2	-	-	-	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	1	-	-	-	-	-	-	-
Other Dipstick Method	2	-	-	-	1	-	1	-	-	-	-	-	-
Plasmatec URIPATH	1	-	-	-	1	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	20	-	-	-	20	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	1	-	-	-	-	-	-	-	-
Roche cobas u 411	17	-	-	-	17	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	7	-	-	-	7	-	-	-	-	-	-	-	-
Roche Urisys	14	-	-	-	14	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	15	-	-	-	3	7	5	-	-	-	-	-	-
Siemens Clinitek Status / Status+	20	-	-	-	14	6	-	-	-	-	-	-	-
Siemens Reagent Strips	12	-	-	-	1	-	11	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	1	-	-	-	-	-	-	-	-
Urinometer	1	-	-	-	-	1	-	-	-	-	-	-	-
Uriscan Optima	1	-	-	-	1	-	-	-	-	-	-	-	-
UriScan Pro/II	1	-	-	-	1	-	-	-	-	-	-	-	-

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

**Participant Results**

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>10 - 20</u> <u>mg/dL</u>	<u>30 - 70</u> <u>mg/dL</u>	<u>75</u> <u>mg/dL</u>	<u>100 - 200</u> <u>mg/dL</u>	<u>≥300 - 600</u> <u>mg/dL</u>	<u>&gt;600 or ≥1000</u> <u>mg/dL</u>
ALL METHODS	150	150	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	17	17	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	6	6	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution AU-4050	1	1	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	1	1	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	2	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	2	2	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	20	20	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	17	17	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	7	7	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	14	14	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	15	15	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	20	20	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	12	12	-	-	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-
Uriscan Optima	1	1	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	1	1	-	-	-	-	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK–GLUCOSE

### Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Negative or Normal</u>	<u>Trace</u>	<u>(1+)</u>	<u>Participant Results</u>			<u>30 - 100 mg/dL</u>	<u>150 - 300 mg/dL</u>	<u>500 mg/dL</u>	<u>&gt;500 or ≥1000 or ≥2000 mg/dL</u>
					<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>				
ALL METHODS	149	1	30	15	2	6	58	-	3	3	31
77 Elektronika LabUMat/2	17	-	-	-	-	-	10	-	-	-	7
Acon Laboratories	6	-	-	-	-	1	5	-	-	-	-
Arkray Aution AU-4050	1	-	-	-	-	-	1	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	1	-	-	-	-
Arkray Aution Sticks	1	-	-	-	-	-	1	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	1	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	-	2	1	-	-	1	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	-	1	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	-	1	1	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	1	-
Other Dipstick Method	2	-	-	-	-	1	1	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	20	-	-	-	-	1	19	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	1	-	-	-	-
Roche cobas u 411	17	-	-	-	-	-	9	-	-	-	8
Roche cobas u 601 / 701	7	-	-	-	-	-	-	-	-	-	7
Roche Urisys	14	-	-	-	-	-	6	-	-	-	8
Siemens Clinitek Advantus	15	-	11	3	-	-	-	-	1	-	-
Siemens Clinitek Status / Status+	20	-	8	11	-	-	-	-	1	-	-
Siemens Reagent Strips	12	-	11	1	-	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	-	-	1
Urinometer	1	-	-	-	1	-	-	-	-	-	-
Uriscan Optima	1	-	-	-	1	-	-	-	-	-	-
UriScan Pro/II	1	-	-	-	-	-	-	-	1	-	-

## URINALYSIS DIPSTICK–KETONES

### Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Participant Results</u>													
		<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>5 - 10</u> <u>mg/dL</u>	<u>15 - 25</u> <u>mg/dL</u>	<u>40 - 60</u> <u>mg/dL</u>	<u>≥80 - 100</u> <u>mg/dL</u>	<u>≥150</u> <u>mg/dL</u>
ALL METHODS	150	4	1	-	-	-	12	68	28	2	-	2	23	-	10
77 Elektronika LabUMat/2	18	-	-	-	-	-	1	9	1	-	-	-	7	-	-
Acon Laboratories	6	2	1	-	-	-	2	1	-	-	-	-	-	-	-
Arkray Aution AU-4050	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Arkray Aution Sticks	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	-	-	-	2	1	-	-	-	1	-	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	-	-	-	2	-	-	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Other Dipstick Method	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	20	-	-	-	-	-	-	15	5	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Roche cobas u 411	18	-	-	-	-	-	-	-	8	1	-	-	5	-	4
Roche cobas u 601 / 701	6	-	-	-	-	-	-	-	-	-	-	-	4	-	2
Roche Urisys	14	-	-	-	-	-	1	2	4	-	-	-	3	-	4
Siemens Clinitek Advantus	15	-	-	-	-	-	6	8	-	-	-	-	1	-	-
Siemens Clinitek Status / Status+	20	-	-	-	-	-	-	14	5	-	-	-	1	-	-
Siemens Reagent Strips	12	-	-	-	-	-	-	9	3	-	-	-	-	-	-
Symex UN Series	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Urinometer	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Uriscan Optima	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
UriScan Pro/II	1	-	-	-	-	-	-	-	-	-	-	-	1	-	-

## URINALYSIS DIPSTICK–BILIRUBIN

### Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Positive (Ictotest ONLY)</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Participant Results</u>								
							<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>0.5 - 1.0 mg/dL</u>	<u>2.0 - 4.0 mg/dL</u>	<u>6.0 - 10.0 mg/dL</u>	<u>&gt;10.0 mg/dL</u>
ALL METHODS	126	126	-	-	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	17	17	-	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	6	6	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution AU-4050	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Consult Diagnostics Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	7	7	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	17	17	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	7	7	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	14	14	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	15	15	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	20	20	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Uriscan Optima	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK–UROBILINOGEN

### Specimen UA-3

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>				
		<u>Normal or 0.0 - 0.2 mg/dL or &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	126	124	2	-	-	-
77 Elektronika LabUMat/2	18	18	-	-	-	-
Acon Laboratories	6	6	-	-	-	-
Arkray Aution AU-4050	1	1	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-
Arkray Aution Sticks	1	1	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	1	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	2	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-
Other Dipstick Method	2	2	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-
Roche Chemstrips / Combur	7	7	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-
Roche cobas u 411	17	17	-	-	-	-
Roche cobas u 601 / 701	7	6	1	-	-	-
Roche Urisys	14	14	-	-	-	-
Siemens Clinitek Advantus	15	15	-	-	-	-
Siemens Clinitek Status / Status+	20	20	-	-	-	-
Siemens Reagent Strips	1	1	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-
Urinometer	1	1	-	-	-	-
Uriscan Optima	1	-	1	-	-	-
UriScan Pro/II	1	1	-	-	-	-

**URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN**

Specimen UA-3

**Participant Results**

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>(5+)</u>	<u>5 - 25</u> <u>Ery/uL</u>	<u>50 -</u> <u>100</u> <u>Ery/uL</u>	<u>200 -</u> <u>300</u> <u>Ery/uL</u>	<u>±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>≥ 1.0</u> <u>mg/</u> <u>dL</u>
ALL METHODS	149	145	2	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	17	17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	6	5	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution AU-4050	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	19	19	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	18	17	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	6	6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Mditron Junior/II	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	14	14	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	15	15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	20	20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	12	12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Uriscan Optima	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



## URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-3

### Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>15 or 25 µL</u>	<u>75 or 100 µL</u>	<u>250 or 500 µL</u>
ALL METHODS	137	-	2	2	-	-	24	19	48	2	-	2	38
77 Elektronika LabUMat/2	17	-	-	-	-	-	-	1	9	-	-	-	7
Acon Laboratories	6	-	-	-	-	-	1	5	-	-	-	-	-
Arkray Aution AU-4050	1	-	-	-	-	-	-	-	-	1	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	-	-	-	1	-	-	-
Arkray Aution Sticks	1	-	-	-	-	-	-	-	-	-	-	-	1
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	-	-	1
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	-	-	-	-	2	-	-	-	2
Iris Diagnostics vChem Urine Strips	2	-	-	-	-	-	-	-	2	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	-	-	-	-	-	-	-	1	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	-	-	1
Other Dipstick Method	2	-	-	-	-	-	-	2	-	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche Chemstrips / Combur	20	-	-	-	-	-	-	-	19	-	-	-	1
Roche cobas u 411	18	-	-	-	-	-	-	1	7	-	-	-	10
Roche cobas u 601 / 701	6	-	-	-	-	-	-	-	-	-	-	-	6
Roche Urisys	14	-	-	-	-	-	-	-	6	-	-	-	8
Siemens Clinitek Advantus	15	-	2	-	-	-	12	-	-	-	-	1	-
Siemens Clinitek Status / Status+	20	-	-	2	-	-	10	8	-	-	-	-	-
Siemens Reagent Strips	1	-	-	-	-	-	-	1	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	-	-	-	-	1
Urinometer	1	-	-	-	-	-	-	-	1	-	-	-	-
Uriscan Optima	1	-	-	-	-	-	1	-	-	-	-	-	-
UriScan Pro/II	1	-	-	-	-	-	-	-	-	-	-	1	-

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

<b><u>Method</u></b>	<b><u>Labs</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>
ALL METHODS	139	13	126
77 Elektronika LabUMat/2	18	-	18
Acon Laboratories	6	1	5
Arkray Aution AU-4050	1	-	1
Arkray Aution Jet	1	-	1
Arkray Aution Sticks	1	-	1
DIRUI H-800 Urine Analyzer	1	-	1
Iris Diagnostics Aution Max AX-4280	1	-	1
Iris Diagnostics iChem Velocity Strips	4	-	4
Iris Diagnostics vChem Urine Strips	1	-	1
Iris Ichem VELOCITY Urine Chemistry System	2	-	2
Other Analyzer Method	1	-	1
Other Dipstick Method	2	-	2
Plasmatec URIPATH	1	-	1
Roche Chemstrips / Combur	20	-	20
Roche cobas 6500 / u 601	1	-	1
Roche cobas u 411	18	2	16
Roche cobas u 601 / 701	6	-	6
Roche Urisys	14	9	5
Siemens Clinitek Advantus	15	-	15
Siemens Clinitek Status / Status+	20	-	20
Siemens Reagent Strips	1	-	1
Sysmex UN Series	1	-	1
Urinometer	1	-	1
Uriscan Optima	1	1	-
UriScan Pro/II	1	-	1

**URINALYSIS –MICROALBUMIN (dipstick only)**

**Specimen UA-3**

<u>Method</u>	<i>Participant Results</i>										
	<u>Labs</u>	<u>Negative</u>	<u>10 mg/L</u>	<u>20 mg/L</u>	<u>30 mg/L</u>	<u>50 mg/L</u>	<u>80 mg/L</u>	<u>100 mg/L</u>	<u>150 mg/L</u>	<u>+ (4 - 8 mg/dL)</u>	<u>++ (&gt;8 mg/dL)</u>
ALL METHODS	6	2	3	2	-	-	-	-	-	-	-
Other Dipstick Method	1	1	1	-	-	-	-	-	-	-	-
Roche Micral - 1 minute	3	1	2	2	-	-	-	-	-	-	-

**URINALYSIS –URINE hCG**

**Specimen UA-3**

<u>Method</u>	<i>Participant Results</i>		
	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	89	1	88
77 Elektronika LabUMat/2	1	-	1
Abon (Alere) Biopharm	3	-	3
Acon Laboratories	4	-	4
Alere Clearview hCG Cassette	2	-	2
Alere hCG Combo Cassette	9	-	9
Biosynex	2	-	2
CTK Biotech	5	-	5
JusChek	3	-	3
Other Dipstick Method	1	-	1
SD Bioline hCG	6	1	5
Siemens Clinitek Status / Status+	15	-	15
Stanbio QuStick	1	-	1

## MISCELLANEOUS CULTURES

### Specimen BA-7 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Alcaligenes faecalis	85	76.58%	Acceptable
Alcaligenes sp.	3	2.70%	Acceptable
Gram negative bacilli	7	6.31%	Acceptable
Pseudomonas sp.	6	5.41%	

Organism(s) present: *Alcaligenes faecalis*

### Specimen BA-8 – CSF Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Listeria monocytogenes	93	88.57%	Acceptable
Listeria sp.	6	5.71%	Acceptable
Gram positive bacilli	1	0.95%	Acceptable

Organism(s) present: *Listeria monocytogenes*

### Specimen BA-9 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pseudomonas aeruginosa	105	62.50%	Acceptable
Pseudomonas sp.	2	1.19%	Acceptable
Micrococcus luteus	45	26.79%	Acceptable
Micrococcus sp.	11	6.55%	Acceptable
Gram positive cocci	1	0.60%	Acceptable

Organism(s) present: *Pseudomonas aeruginosa* and *Micrococcus luteus*

**ANTIMICROBIAL SUSCEPTIBILITY TESTING**

**Specimen UC-11, CC-11 (SUS-11)** Organism(s) present: *Enterococcus faecalis* – Vancomycin resistant.

<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	-	-	-	-	5	5	-	-	Inappropriate drug <sup>1</sup>
Amoxicillin/Clavulanate	7	7	-	-	11	11	-	-	100.00%
Ampicillin	29	29	-	-	138	134	-	4	97.60%
Ampicillin/Sulbactam	2	2	-	-	16	13	1	2	83.33%
Aztreonam	-	-	-	-	4	3	-	1	Inappropriate drug <sup>1</sup>
Cefaclor	1	-	-	1	-	-	-	-	100.00%
Cefazolin	-	-	-	-	5	4	-	1	Inappropriate drug <sup>1</sup>
Cefepime	-	-	-	-	8	6	1	1	Inappropriate drug <sup>1</sup>
Cefixime	3	1	-	2	3	2	-	1	Inappropriate drug <sup>1</sup>
Cefoperazone	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Cefotaxime	1	-	-	1	4	3	-	1	Inappropriate drug <sup>1</sup>
Cefoxitin	-	-	-	-	5	1	-	4	80.00%
Cefpodoxime	1	-	-	1	1	-	-	1	100.00%
Ceftaroline	-	-	-	-	4	-	-	4	100.00%
Ceftazidime	-	-	-	-	7	5	-	2	Inappropriate drug <sup>1</sup>
Ceftriaxone	3	1	-	2	5	4	-	1	Inappropriate drug <sup>1</sup>
Cefuroxime	4	-	-	4	5	5	-	-	Inappropriate drug <sup>1</sup>
Ciprofloxacin	27	1	-	26	118	5	-	113	95.86%
Daptomycin	-	-	-	-	44	41	1	2	93.18%
Doxycycline	3	-	1	2	-	-	-	-	100.00%
Ertapenem	-	-	-	-	5	5	-	-	Inappropriate drug <sup>1</sup>
Fosfomycin	10	10	-	-	5	5	-	-	100.00%
Gentamicin	9	-	-	9	51	10	-	41	83.33%
Imipenem	-	-	-	-	8	8	-	-	100.00%
Levofloxacin	19	2	-	17	89	4	-	85	94.44%
Linezolid	16	16	-	-	104	103	1	-	99.17%
Lomefloxacin	-	-	-	-	1	-	-	1	Inappropriate drug <sup>1</sup>

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

**ANTIMICROBIAL SUSCEPTIBILITY TESTING (continued)**

**Specimen UC-11, CC-11 (SUS-11)** Organism(s) present *Enterococcus faecalis* – Vancomycin resistant.

<b><u>Antimicrobial</u></b>	<b>-----Disk Diffusion-----</b>				<b>-----MIC-----</b>				<b><u>Acceptable (%)</u></b>
	<b><u>Interpretative category data</u></b>				<b><u>Interpretative category data</u></b>				
	<b><u>Labs</u></b>	<b><u>S</u></b>	<b><u>I</u></b>	<b><u>R</u></b>	<b><u>Labs</u></b>	<b><u>S</u></b>	<b><u>I</u></b>	<b><u>R</u></b>	
Meropenem	-	-	-	-	6	6	-	-	Inappropriate drug <sup>1</sup>
Minocycline	-	-	-	-	20	-	4	16	100.00%
Moxifloxacin	-	-	-	-	4	1	-	3	Inappropriate drug <sup>1</sup>
Nalidixic Acid	1	-	-	1	1	1	-	-	Inappropriate drug <sup>1</sup>
Nitrofurantoin	25	25	-	-	129	128	-	1	99.35%
Norfloxacin	7	1	-	6	9	5	-	4	Not graded <sup>2</sup>
Oxacillin	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Penicillin	17	16	-	1	52	51	-	1	97.10%
Piperacillin	-	-	-	-	2	2	-	-	Inappropriate drug <sup>1</sup>
Piperacillin/Tazobactam	2	2	-	-	8	6	1	1	80.00%
Quinupristin/Dalfopristin	-	-	-	-	17	-	-	17	100.00%
Rifampin	5	5	-	-	7	7	-	-	100.00%
Streptomycin	-	-	-	-	22	22	-	-	100.00%
Teicoplanin	2	-	-	2	32	-	-	32	100.00%
Tetracycline	13	2	-	11	75	-	-	75	97.73%
Tobramycin	-	-	-	-	2	1	-	1	Inappropriate drug <sup>1</sup>
Trimethoprim/Sulfamethoxazole	2	-	-	2	14	8	-	6	Inappropriate drug <sup>1</sup>
Vancomycin	21	1	-	20	137	6	-	131	95.57%

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

<sup>2</sup> This drug is not graded due to lack of participant consensus.

## PARASITOLOGY

### Specimen FP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis larvae	208	48.71%	Acceptable
Blastocystis hominis	116	27.17%	Acceptable
Endolimax nana	58	13.58%	Acceptable
Parasite egg or larva seen – no ID	2	0.47%	Acceptable
No parasite seen	21	4.92%	
Hookworm	6	1.41%	

Parasite(s) present: *Strongyloides stercoralis*, *Blastocystis hominis*, and *Endolimax nana*

### Specimen FP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	246	66.67%	Acceptable
Trichuris trichiura eggs	1	0.27%	Acceptable
Parasite egg or larva seen – no ID	5	1.36%	Acceptable
Giardia lamblia	48	13.01%	
Entamoeba coli	19	5.15%	
No parasite seen	11	2.98%	
Other parasite found	8	2.17%	
Entamoeba histolytica	6	1.63%	
Trichostrongylus sp. eggs	5	1.36%	
Blastocystis hominis	5	1.36%	

Parasite(s) present: Hookworm and *Trichuris trichiura* eggs. This challenge was graded by referee consensus.

## PARASITOLOGY (continued)

### Specimen FP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	264	49.53%	Acceptable
Cystoisospora belli oocysts	72	13.51%	Acceptable
Entamoeba histolytica	61	11.44%	Acceptable
Protozoan cyst or trophozoite seen – no ID	1	0.19%	Acceptable
Entamoeba coli	62	11.63%	
Ascaris lumbricoides eggs	23	4.32%	
No parasite seen	12	2.25%	
Endolimax nana	11	2.06%	
Trichuris trichiura eggs	6	1.13%	
Iodamoeba buetschlii	6	1.13%	

Parasite(s) present: *Giardia lamblia*, *Cystoisospora belli* oocysts, and *Entamoeba histolytica*. This challenge was graded by referee consensus.

### Specimen FP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	241	47.16%	Acceptable
Entamoeba coli	190	37.18%	Acceptable
Entamoeba histolytica	19	3.72%	
Enterobius vermicularis eggs	10	1.96%	
No parasite seen	9	1.76%	
Diphyllobothrium latum	9	1.76%	
Paragonimus westermani eggs	8	1.57%	
Strongyloides stercoralis larvae	5	0.98%	

Parasite(s) present: *Ascaris lumbricoides* eggs and *Entamoeba coli*.



**PARASITOLOGY (continued)**

**Specimen FP-15**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium malariae	33	9.43%	Acceptable
Plasmodium falciparum	152	43.43%	Acceptable
Plasmodium sp.	64	18.29%	Acceptable
Plasmodium vivax	83	23.71%	
No parasite seen	6	1.71%	
Plasmodium ovale	5	1.43%	

Parasite(s) present: *Plasmodium malariae* and *Plasmodium falciparum*. This challenge was graded by referee consensus.

**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	3	21	24	-	22	2
Bio-Rad	-	1	1	-	1	-
BioSystems	1	1	2	-	2	-
Human	-	1	1	-	1	-
Immuno Concepts	-	3	3	-	3	-
INOVA Diagnostics	1	10	11	-	9	2
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	1	23	3	21
Bio-Rad	-	1	-	1
BioSystems	-	2	-	2
Human	-	1	-	1
Immuno Concepts	-	3	1	2
INOVA Diagnostics	-	11	1	10
Kallestad	-	1	-	1

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

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

ALL METHODS	16	-	-	2	-	1	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	9	-	-	1	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

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

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

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

**Specimen AE-13**

ALL METHODS	2	-	-	1	-	-	1	7	2	6	-	-
Bio-Rad	-	-	-	-	-	-	-	1	-	-	-	-
Immuno Concepts	-	-	-	1	-	-	-	-	2	-	-	-
INOVA Diagnostics	2	-	-	-	-	-	1	2	-	5	-	-
Kallestad	-	-	-	-	-	-	-	1	-	-	-	-

**Specimen AE-14**

ALL METHODS	18	-	-	1	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	10	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

**Specimen AE-15**

ALL METHODS	17	-	-	1	1	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	9	-	-	-	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	1	22	23	-	-	23
BioSystems	-	2	2	-	-	2
Human	-	1	1	-	-	1
Immuno Concepts	-	1	1	-	-	1
INOVA Diagnostics	-	10	10	-	-	10
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	1	22
BioSystems	-	2	-	2
Human	-	1	-	1
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	10	-	10
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	-	15	-	14	11	3
INOVA Diagnostics	-	9	-	8	7	1

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

### Anti-RNP/Sm

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	4	2	2	4	-
INOVA Diagnostics	-	1	-	1	1	-

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

### Anti-SSA

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	20	19	-	-	19
INOVA Diagnostics	-	10	9	-	-	9

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	20	-	20
INOVA Diagnostics	-	10	-	10

**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	-	20	-	19	1	18
INOVA Diagnostics	-	10	-	9	-	9

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	20	-	20
INOVA Diagnostics	-	10	-	10

**Anti-SSA/SSB**

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

<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	-	20	1	18	5	14
INOVA Diagnostics	-	11	1	9	2	8

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	20	-	20
INOVA Diagnostics	-	11	-	11

**Rubella—Qualitative**

<u>Method</u>	Specimen RU-11		Specimen RU-12		Specimen RU-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	1	16	1	-	17
Abbott Architect	12	1	12	1	-	13
DiaSorin	1	-	1	-	-	1
Roche cobas 6000 / e 601	1	-	1	-	-	1
Roche cobas e 411	1	-	1	-	-	1
Siemens Atellica	1	-	1	-	-	1

<u>Method</u>	Specimen RU-14		Specimen RU-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	1	-	17
Abbott Architect	12	1	-	13
DiaSorin	1	-	-	1
Roche cobas 6000 / e 601	1	-	-	1
Roche cobas e 411	1	-	-	1
Siemens Atellica	1	-	-	1

## Rubella—Quantitative (IU/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
<b>Specimen RU-11</b>						
All Method	17	37.46	19.02	50.8	26.4	0.0 - 94.6
All Roche Methods	6	65.76	3.69	5.6	66.1	54.7 - 76.9
Abbott Architect	11	25.60	2.50	9.8	25.7	18.1 - 33.1
<b>Specimen RU-12</b>						
All Method	19	43.21	21.60	50.0	31.6	0.0 - 108.1
All Roche Methods	6	73.67	4.24	5.8	74.0	60.9 - 86.4
Abbott Architect	12	28.99	3.96	13.7	29.6	17.1 - 40.9
<b>Specimen RU-13</b>						
All Method	20	0.14	0.20	148.7	0.0	0.0 - 0.8
All Roche Methods	6	0.40	0.15	38.7	0.5	0.0 - 0.9
Abbott Architect	11	0.00	0.01	0.0	0.0	0.0 - 0.1
<b>Specimen RU-14</b>						
All Method	19	38.03	19.50	51.3	26.2	0.0 - 96.6
All Roche Methods	6	65.82	2.96	4.5	65.5	56.9 - 74.7
Abbott Architect	12	25.23	1.56	6.2	25.5	20.5 - 29.9
<b>Specimen RU-15</b>						
All Method	20	0.14	0.21	150.9	0.0	0.0 - 0.8
All Roche Methods	6	0.42	0.17	41.3	0.5	0.0 - 1.0
Abbott Architect	11	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	2	-	47	46	-	3	45	1	3
BioSystems	-	-	1	1	-	-	1	-	-
CTK Biotech	-	-	1	1	-	-	1	-	-
Human	-	-	2	1	-	1	1	-	1
Lorne Laboratories	-	-	1	1	-	-	1	-	-
Roche cobas 6000 / e 601	-	-	1	1	-	-	1	-	-
SPINREACT	-	-	1	1	-	-	1	-	-
Wiener Lab	2	-	35	35	-	2	34	1	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	1	-	48	45	-	4
BioSystems	-	-	1	1	-	-
CTK Biotech	-	-	1	1	-	-
Human	-	-	2	1	-	1
Lorne Laboratories	-	-	1	1	-	-
Roche cobas 6000 / e 601	-	-	1	1	-	-
SPINREACT	-	-	1	1	-	-
Wiener Lab	1	-	36	34	-	3

**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	45	-	-	-	-	1	-	-	-
BioSystems	1	-	-	-	-	-	-	-	-
Lorne Laboratories	1	-	-	-	-	-	-	-	-
Wiener Lab	37	-	-	-	-	1	-	-	-
<b>Specimen SY-12</b>									
ALL METHODS	2	1	4	8	16	12	-	1	2
BioSystems	-	-	-	1	-	-	-	-	-
Lorne Laboratories	-	-	-	-	-	-	-	1	-
Wiener Lab	2	1	4	6	13	10	-	-	2
<b>Specimen SY-13</b>									
ALL METHODS	2	2	7	18	12	1	1	2	1
BioSystems	-	-	-	1	-	-	-	-	-
Lorne Laboratories	-	-	-	-	-	-	-	1	-
Wiener Lab	2	2	6	16	8	1	1	1	1
<b>Specimen SY-14</b>									
ALL METHODS	45	-	-	1	-	-	-	-	-
BioSystems	1	-	-	-	-	-	-	-	-
Lorne Laboratories	1	-	-	-	-	-	-	-	-
Wiener Lab	37	-	-	1	-	-	-	-	-
<b>Specimen SY-15</b>									
ALL METHODS	3	2	4	19	11	4	2	-	1
BioSystems	-	-	-	1	-	-	-	-	-
Lorne Laboratories	-	-	-	-	-	-	1	-	-
Wiener Lab	3	2	4	16	9	2	1	-	1

**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	-	11	11	-	11	-
Abbott Architect	-	1	1	-	1	-
Atlas Medical	-	1	1	-	1	-
Bio-Rad Evolis	-	1	1	-	1	-
Plasmatec	-	1	1	-	1	-
Serodia	-	3	3	-	3	-
Standard Diagnostics	-	3	3	-	3	-

  

	<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	-	11	11	-
Abbott Architect	-	1	1	-
Atlas Medical	-	1	1	-
Bio-Rad Evolis	-	1	1	-
Plasmatec	-	1	1	-
Serodia	-	3	3	-
Standard Diagnostics	-	3	3	-

**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	-	48	48	-	48	-
Abbott Alinity	-	3	3	-	3	-
Abbott Architect	-	9	9	-	9	-
Abon (Alere) Biopharm	-	1	1	-	1	-
DiaSorin	-	1	1	-	1	-
Human	-	1	1	-	1	-
Roche cobas 6000 / c 501	-	1	1	-	1	-
Roche cobas 8000/e801	-	2	2	-	2	-
Roche cobas e 411	-	1	1	-	1	-
SD Bioline	-	5	5	-	5	-
Serodia	-	8	8	-	8	-
Siemens Immulite 2000	-	1	1	-	1	-
Standard Diagnostics	-	4	4	-	4	-
Wiener Lab	-	1	1	-	1	-
Zeus	-	2	2	-	2	-

	<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	-	48	48	-
Abbott Architect	-	3	3	-
Bio-Rad Evolis	-	9	9	-
bioMerieux	-	1	1	-
DiaSorin	-	1	1	-
Human	-	1	1	-
Plasmatec	-	1	1	-
Roche cobas 6000 / c 501	-	2	2	-
Roche cobas 8000/e801	-	1	1	-
Roche cobas e 411	-	5	5	-
SD Bioline	-	8	8	-
Serodia	-	1	1	-
Siemens Immulite 2000	-	4	4	-
Standard Diagnostics	-	1	1	-
Zeus	-	2	2	-

**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	-	51	50	1	51	-
Atlas Medical	-	2	2	-	2	-
Becton Dickinson	-	4	4	-	4	-
bioMerieux	-	2	2	-	2	-
BioSystems	-	13	12	1	13	-
Human	-	3	3	-	3	-
Lorne Laboratories	-	3	3	-	3	-
Omega Diagnostics	-	2	2	-	2	-
Plasmatec	-	3	3	-	3	-
Pulse Scientific	-	1	1	-	1	-
SPINREACT	-	14	14	-	14	-

  

	<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	-	51	51	-
Atlas Medical	-	2	2	-
Becton Dickinson	-	4	4	-
bioMerieux	-	2	2	-
BioSystems	-	13	13	-
Human	-	3	3	-
Lorne Laboratories	-	3	3	-
Omega Diagnostics	-	2	2	-
Plasmatec	-	3	3	-
Pulse Scientific	-	1	1	-
SPINREACT	-	14	14	-

**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	45	-	-	-	-	-	-	-	-
Atlas Medical	1	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-
BioSystems	13	-	-	-	-	-	-	-	-
Human	3	-	-	-	-	-	-	-	-
Lorne Laboratories	2	-	-	-	-	-	-	-	-
Omega Diagnostics	2	-	-	-	-	-	-	-	-
Plasmatec	2	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	14	-	-	-	-	-	-	-	-
<b>Specimen SY-12</b>									
ALL METHODS	1	-	4	17	19	2	1	-	1
Atlas Medical	-	-	-	1	-	-	-	-	-
Becton Dickinson	-	-	-	-	3	1	-	-	-
BioSystems	1	-	1	2	8	-	-	-	1
Human	-	-	-	1	2	-	-	-	-
Lorne Laboratories	-	-	1	-	1	-	-	-	-
Omega Diagnostics	-	-	-	-	-	1	1	-	-
Plasmatec	-	-	1	1	-	-	-	-	-
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	-	-	9	5	-	-	-	-

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

<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-13</b>									
ALL METHODS	-	-	19	14	8	1	3	-	-
Atlas Medical	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	1	1	2	-	-	-	-
BioSystems	-	-	3	5	3	1	1	-	-
Human	-	-	-	1	1	-	1	-	-
Lorne Laboratories	-	-	1	-	1	-	-	-	-
Omega Diagnostics	-	-	-	1	-	-	1	-	-
Plasmatec	-	-	2	-	-	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	-	8	5	1	-	-	-	-
<b>Specimen SY-14</b>									
ALL METHODS	45	-	-	-	-	-	-	-	-
Atlas Medical	1	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-
BioSystems	13	-	-	-	-	-	-	-	-
Human	3	-	-	-	-	-	-	-	-
Lorne Laboratories	2	-	-	-	-	-	-	-	-
Omega Diagnostics	2	-	-	-	-	-	-	-	-
Plasmatec	2	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	14	-	-	-	-	-	-	-	-

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

<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-15</b>									
ALL METHODS	-	-	22	12	5	5	1	-	-
Atlas Medical	-	-	-	1	-	-	-	-	-
Becton Dickinson	-	-	1	3	-	-	-	-	-
BioSystems	-	-	3	3	3	3	1	-	-
Human	-	-	-	2	-	1	-	-	-
Lorne Laboratories	-	-	1	1	-	-	-	-	-
Omega Diagnostics	-	-	-	-	1	1	-	-	-
Plasmatec	-	-	1	-	1	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	-	12	2	-	-	-	-	-



**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	-	39	-	39	-	-	-	39	-
Abbott Alinity	-	2	-	2	-	-	-	2	-
Abbott Architect	-	20	-	20	-	-	-	20	-
Beckman ACCESS / 2 / DxI	-	1	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	7	-	7	-	-	-	7	-
Roche cobas 8000/e801	-	4	-	4	-	-	-	4	-
Siemens ADVIA	-	2	-	2	-	-	-	2	-
VITROS									
3600/4600/5600/7600	-	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	-	39	-	1	38	-
Abbott Alinity	-	2	-	-	2	-
Abbott Architect	-	20	-	1	19	-
Beckman ACCESS / 2 / DxI	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	7	-	-	7	-
Roche cobas 8000/e801	-	4	-	-	4	-
Siemens ADVIA Centaur	-	2	-	-	2	-
VITROS						
3600/4600/5600/7600	-	3	-	-	3	-

**Viral Markers – Anti-HBc (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	-	60	-	60	-	-	-	60	-
Abbott Alinity	-	7	-	7	-	-	-	7	-
Abbott Architect	-	27	-	27	-	-	-	27	-
Beckman ACCESS / 2 / Dxl	-	1	-	1	-	-	-	1	-
DiaSorin	-	2	-	2	-	-	-	2	-
Roche cobas 6000 / e 601	-	9	-	9	-	-	-	9	-
Roche cobas 8000/e801	-	4	-	4	-	-	-	4	-
Roche cobas e 411	-	2	-	2	-	-	-	2	-
Siemens ADVIA	-	3	-	3	-	-	-	3	-
Siemens Atellica	-	1	-	1	-	-	-	1	-
VITROS									
3600/4600/5600/7600	-	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	-	60	-	60	-	-
Abbott Alinity	-	7	-	7	-	-
Abbott Architect	-	27	-	27	-	-
Beckman ACCESS / 2 / Dxl	-	1	-	1	-	-
DiaSorin	-	2	-	2	-	-
Roche cobas 6000 / e 601	-	9	-	9	-	-
Roche cobas 8000/e801	-	4	-	4	-	-
Roche cobas e 411	-	2	-	2	-	-
Siemens ADVIA	-	3	-	3	-	-
Siemens Atellica	-	1	-	1	-	-
VITROS						
3600/4600/5600/7600	-	3	-	3	-	-

**Viral Markers – Anti-HIV**

<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	-	129	-	-	129	-	-	129	-
Abbott Alinity	-	9	-	-	9	-	-	9	-
Abbott Architect	-	51	-	-	51	-	-	51	-
Alere Clearview HIV1/2 STAT-PAK	-	1	-	-	1	-	-	1	-
Alere Determine - moderate	-	3	-	-	3	-	-	3	-
Alere Determine - waived	-	1	-	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-	-	3	-
CTK Biotech	-	2	-	-	2	-	-	2	-
DiaSorin	-	1	-	-	1	-	-	1	-
Human	-	3	-	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	14	-	-	14	-	-	14	-
Roche cobas 8000/e801	-	7	-	-	7	-	-	7	-
Roche cobas e 411	-	9	-	-	9	-	-	9	-
Roche Modular Analytics	-	1	-	-	1	-	-	1	-
SD Biline	-	1	-	-	1	-	-	1	-
Siemens ADVIA	-	4	-	-	4	-	-	4	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
Standard Diagnostics	-	5	-	-	5	-	-	5	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-	-	4	-

**Viral Markers – Anti-HIV- (continued)**

<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	129	-	-	1	128	-
Abbott Alinity	9	-	-	-	9	-
Abbott Architect	51	-	-	1	50	-
Alere Clearview HIV1/2 STAT-PAK	1	-	-	-	1	-
Alere Determine - moderate	3	-	-	-	3	-
Alere Determine - waived	1	-	-	-	1	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	3	-	-	-	3	-
CTK Biotech	2	-	-	-	2	-
DiaSorin	2	-	-	-	2	-
Human	1	-	-	-	1	-
Roche cobas 6000 / e 601	3	-	-	-	3	-
Roche cobas 8000/e801	14	-	-	-	14	-
Roche cobas e 411	7	-	-	-	7	-
Roche Modular Analytics	9	-	-	-	9	-
SD Bioline	1	-	-	-	1	-
Siemens ADVIA	4	-	-	-	4	-
Siemens Atellica	1	-	-	-	1	-
Standard Diagnostics VITROS	5	-	-	-	5	-
3600/4600/5600/7600	4	-	-	-	4	-

**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	-	51	-	-	51	-	-	51	-
Abbott Alinity	-	1	-	-	1	-	-	1	-
Abbott Architect	-	27	-	-	27	-	-	27	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	11	-	-	11	-	-	11	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
Siemens ADVIA	-	2	-	-	2	-	-	2	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
Standard Diagnostics	-	4	-	-	4	-	-	4	-

<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	-	51	-	-	51	-
Abbott Alinity	-	1	-	-	1	-
Abbott Architect	-	27	-	-	27	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	11	-	-	11	-
Roche cobas 8000/e801	-	4	-	-	4	-
Siemens ADVIA	-	2	-	-	2	-
Siemens Atellica	-	1	-	-	1	-
Standard Diagnostics	-	4	-	-	4	-

**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	37	2	-	2	37	-	9	30	-
Abbott Alinity	1	-	-	-	1	-	-	1	-
Abbott Architect	21	-	-	-	21	-	6	15	-
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	1	-	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	2	2	-	1	3	-	1	3	-
Roche cobas 8000/e801	4	-	-	-	4	-	-	4	-
Roche cobas e 411	2	-	-	-	2	-	1	1	-
Roche Elecsys	1	-	-	-	1	-	-	1	-
Siemens ADVIA	2	-	-	1	1	-	1	1	-
Siemens Atellica	1	-	-	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	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	37	2	-	2	37	-
Abbott Alinity	1	-	-	-	1	-
Abbott Architect	21	-	-	-	21	-
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-
bioMerieux Vidas, Mini Vidas	1	-	-	-	1	-
Roche cobas 6000 / e 601	2	2	-	1	3	-
Roche cobas 8000/e801	4	-	-	-	4	-
Roche cobas e 411	2	-	-	-	2	-
SD Bioline	1	-	-	-	1	-
Siemens ADVIA	2	-	-	1	1	-
Siemens Atellica	1	-	-	-	1	-
VITROS 3600/4600/5600/7600	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	-	32	-	2	30	-	-	32	-
Abbott Architect	-	16	-	-	16	-	-	16	-
Roche cobas 6000 / e 601	-	8	-	-	8	-	-	8	-
Roche cobas 8000/e801	-	5	-	-	5	-	-	5	-
Siemens ADVIA	-	1	-	1	-	-	-	1	-
Siemens Atellica	-	1	-	1	-	-	-	1	-
VITROS 3600/4600/5600/7600	-	1	-	-	1	-	-	1	-

<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	-	32	-	-	32	-
Abbott Architect	-	16	-	-	16	-
Roche cobas 6000 / e 601	-	8	-	-	8	-
Roche cobas 8000/e801	-	5	-	-	5	-
Siemens ADVIA	-	1	-	-	1	-
Siemens Atellica	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	-	1	-	-	1	-

**Viral Markers – Anti-HBs**

<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	77	3	-	3	77	-	3	77	-
Abbott Alinity	6	-	-	-	6	-	-	6	-
Abbott Architect	35	-	-	-	35	-	-	35	-
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	8	-	-	-	8	-	-	8	-
Roche cobas 8000/e801	7	-	-	-	7	-	1	6	-
Roche cobas e 411	7	-	-	-	7	-	2	5	-
Roche Elecsys	1	-	-	-	1	-	-	1	-
SD Bioline	-	2	-	2	-	-	-	2	-
Siemens ADVIA	4	-	-	-	4	-	-	4	-
Siemens Atellica	1	-	-	-	1	-	-	1	-
Siemens Immulite 2000	1	-	-	-	1	-	-	1	-
Standard Diagnostics	1	1	-	1	1	-	-	2	-
VITROS									
3600/4600/5600/7600	3	-	-	-	3	-	-	3	-
VITROS Eci	1	-	-	-	1	-	-	1	-



**Viral Markers – Anti-HBs**

<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	77	3	-	4	76	-
Abbott Alinity	6	-	-	-	6	-
Abbott Architect	35	-	-	-	35	-
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-
Roche cobas 6000 / e 601	8	-	-	-	8	-
Roche cobas 8000/e801	7	-	-	-	7	-
Roche cobas e 411	7	-	-	-	7	-
Roche Elecsys	1	-	-	-	1	-
SD Bioline	-	2	-	2	-	-
Siemens ADVIA	4	-	-	1	3	-
Siemens Atellica	1	-	-	-	1	-
Siemens Immulite 2000	1	-	-	-	1	-
Standard Diagnostics	1	1	-	1	1	-
VITROS						
3600/4600/5600/7600	3	-	-	-	3	-
VITROS Eci	1	-	-	-	1	-

**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	3	123	-	125	1	-	7	117	2
Abbott Alinity	-	12	-	12	-	-	-	12	-
Abbott Architect	1	48	-	49	-	-	1	48	-
Advanced Biotech	-	1	-	1	-	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	3	-	3	-	-	-	3	-
CTK Biotech	-	2	-	2	-	-	-	2	-
DiaSorin	-	2	-	2	-	-	1	1	-
Roche cobas 6000 / e 601	1	14	-	14	1	-	4	11	-
Roche cobas 8000/e801	-	6	-	6	-	-	1	3	2
Roche cobas e 411	-	9	-	9	-	-	-	9	-
Roche Elecsys	-	1	-	1	-	-	-	1	-
Roche Modular Analytics	-	1	-	1	-	-	-	1	-
SD Biotec	-	5	-	5	-	-	-	5	-
Siemens ADVIA	1	4	-	5	-	-	-	5	-
Siemens Atellica	-	1	-	1	-	-	-	1	-
Standard Diagnostics	-	5	-	5	-	-	-	5	-
VITROS									
3600/4600/5600/7600	-	4	-	4	-	-	-	4	-

**Viral Markers – HBsAg (continued)**

<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	3	123	-	124	2	-
Abbott Alinity	-	12	-	12	-	-
Abbott Architect	1	48	-	48	1	-
Advanced Biotech	-	1	-	1	-	-
Beckman ACCESS / 2 / Dxl	-	3	-	3	-	-
CTK Biotech	-	2	-	2	-	-
DiaSorin	-	2	-	2	-	-
Roche cobas 6000 / e 601	1	14	-	14	1	-
Roche cobas 8000/e801	1	5	-	6	-	-
Roche cobas e 411	-	9	-	9	-	-
Roche Elecsys	-	1	-	1	-	-
Roche Modular Analytics	-	1	-	1	-	-
SD Bioline	-	5	-	5	-	-
Siemens ADVIA	-	5	-	5	-	-
Siemens Atellica	-	1	-	1	-	-
Standard Diagnostics	-	5	-	5	-	-
VITROS						
3600/4600/5600/7600	-	4	-	4	-	-

**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	26	84	-	1	109	-	-	110	-
Abbott Alinity	-	10	-	-	10	-	-	10	-
Abbott Architect	1	44	-	-	45	-	-	45	-
Abon (Alere) Biopharm	-	1	-	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-	-	2	-
DiaSorin	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	10	-	-	-	10	-	-	10	-
Roche cobas 8000/e801	5	-	-	-	5	-	-	5	-
Roche cobas e 411	8	1	-	1	8	-	-	9	-
Roche Modular Analytics	1	-	-	-	1	-	-	1	-
SD Bioline	-	1	-	-	1	-	-	1	-
Siemens ADVIA	-	4	-	-	4	-	-	4	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
Standard Diagnostics	-	9	-	-	9	-	-	9	-
VITROS									
3600/4600/5600/7600	-	4	-	-	4	-	-	4	-
VITROS Eci	-	1	-	-	1	-	-	1	-
Wantai BioPharm	1	-	-	-	1	-	-	1	-

**Viral Markers – Anti-HCV**

<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	-	110	-	-	110	-
Abbott Alinity	-	10	-	-	10	-
Abbott Architect	-	45	-	-	45	-
Abon (Alere) Biopharm	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-
DiaSorin	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	10	-	-	10	-
Roche cobas 8000/e801	-	5	-	-	5	-
Roche cobas e 411	-	9	-	-	9	-
Roche Modular Analytics	-	1	-	-	1	-
SD Bioline	-	1	-	-	1	-
Siemens ADVIA	-	4	-	-	4	-
Siemens Atellica	-	1	-	-	1	-
Standard Diagnostics	-	9	-	-	9	-
VITROS						
3600/4600/5600/7600	-	4	-	-	4	-
VITROS Eci	-	1	-	-	1	-
Wantai BioPharm	-	1	-	-	1	-

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

<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	12	-	-	-	12	-
bioMerieux Vidas, Mini Vidas	2	-	-	-	2	-
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	1	-	-	-	1	-
Roche cobas e 411	1	-	-	-	1	-
VITROS 3600/4600/5600/7600	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	88.225	37.387	42.4	71.60	0.00 - 200.39
All Roche Instruments	7	151.080	21.973	14.5	145.50	85.15 - 217.01
Abbott Architect	15	64.307	6.870	10.7	64.30	43.69 - 84.92
Roche cobas 6000 / e 601	5	153.900	16.671	10.8	145.50	103.88 - 203.92
<b>Specimen TOX-6</b>						
All Method	26	0.467	0.304	65.2	0.53	0.00 - 1.39
All Roche Instruments	7	0.130	0.001	0.0	0.13	0.12 - 0.14
Abbott Architect	15	0.667	0.150	22.4	0.70	0.21 - 1.12
Roche cobas 6000 / e 601	5	0.130	0.001	0.0	0.13	0.12 - 0.14

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

<b><u>Method</u></b>	<b>Specimen TOX-5</b>			<b>Specimen TOX-6</b>		
	<b><u>Positiv e</u></b>	<b><u>Negati ve</u></b>	<b><u>Equivoc al</u></b>	<b><u>Positiv e</u></b>	<b><u>Negativ e</u></b>	<b><u>Equivoc al</u></b>
ALL METHODS	21	-	-	-	21	-
Abbott Architect	14	-	-	-	14	-
bioMerieux Vidas, Mini Vidas	2	-	-	-	2	-
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	2	-	-	-	2	-
Roche cobas e 411	1	-	-	-	1	-
VITROS 3600/4600/5600/7600	1	-	-	-	1	-

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

<b><u>Specimen/Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
<b>Specimen TOX-5</b>						
All Method	22	18.548	9.064	48.9	13.88	0.00 - 45.74
All Roche Instruments	6	35.153	1.941	5.5	34.94	29.33 - 40.98
Abbott Architect	13	13.497	1.317	9.8	13.21	9.54 - 17.45
Roche cobas 6000 / e 601	4	-	-	-	36.66	29.33 - 40.98
<b>Specimen TOX-6</b>						
All Method	23	0.136	0.056	41.3	0.12	0.00 - 0.31
All Roche Instruments	7	0.224	0.028	12.5	0.21	0.14 - 0.31
Abbott Architect	13	0.108	0.017	15.5	0.11	0.05 - 0.16
Roche cobas 6000 / e 601	5	0.213	0.015	7.2	0.21	0.16 - 0.26

**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	2	13	-	14	1	-
Abbott Architect	1	11	-	12	-	-
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	-	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	1.074	0.567	52.8	1.10	0.00 - 2.78
Abbott Architect	14	1.271	0.391	30.8	1.10	0.09 - 2.45
<b>Specimen CMV-6</b>						
All Method	16	344.944	147.028	42.6	250.00	0.00 - 786.03
Abbott Architect	13	300.369	124.656	41.5	250.00	0.00 - 674.34



**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	15	3	-	2	16	-
Abbott Architect	15	-	-	2	13	-
Roche cobas 6000 / e 601	-	2	-	-	2	-
VITROS 3600/4600/5600/7600	-	1	-	-	1	-

**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	15	1.818	0.696	38.3	1.74	0.00 - 3.91
Abbott Architect	13	2.045	0.376	18.4	2.11	0.91 - 3.18
<b>Specimen CMV-6</b>						
All Method	15	0.575	0.225	39.1	0.63	0.00 - 1.25
Abbott Architect	13	0.632	0.178	28.2	0.67	0.09 - 1.17

**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	45	0.01	0.03	286.0	0.0	0.0 - 0.5	48	6.84	0.34	4.9	6.9	5.4 - 8.3
No Reagent Required												
Bilirubinometer / Unistat	40	0.00	0.01	0.0	0.0	0.0 - 0.4	39	6.88	0.30	4.3	6.9	5.5 - 8.3
All Chemistry Instruments	40	0.00	0.01	0.0	0.0	0.0 - 0.4	43	6.89	0.30	4.3	6.9	5.5 - 8.3
	<b>Specimen NB-13</b>						<b>Specimen NB-14</b>					
All Method	49	12.03	0.59	4.9	12.0	9.6 - 14.5	47	17.39	0.90	5.2	17.5	13.9 - 20.9
No Reagent Required												
Bilirubinometer / Unistat	40	12.11	0.55	4.5	12.2	9.6 - 14.6	38	17.58	0.83	4.7	17.6	14.0 - 21.1
All Chemistry Instruments	44	12.08	0.56	4.6	12.1	9.6 - 14.5	42	17.46	0.88	5.1	17.5	13.9 - 21.0
	<b>Specimen NB-15</b>											
All Method	49	18.67	0.96	5.1	18.8	14.9 - 22.5						
No Reagent Required												
Bilirubinometer / Unistat	40	18.84	0.87	4.6	18.9	15.0 - 22.7						
All Chemistry Instruments	44	18.67	1.01	5.4	18.9	14.9 - 22.5						

**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	10	0.13	0.16	120.5	0.1	0.0 - 0.5	10	1.68	0.49	29.4	1.6	0.6 - 2.7
	<b>Specimen NB-13</b>						<b>Specimen NB-14</b>					
All Method	10	5.02	0.96	19.2	4.7	3.0 - 7.0	10	5.86	0.89	15.2	5.6	4.0 - 7.7
	<b>Specimen NB-15</b>											
All Method	10	4.13	0.86	20.7	3.9	2.4 - 5.9						

**Glycohemoglobin (percent)**

<u>Method</u>	Specimen GH-5						Specimen GH-6					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	117	10.26	0.59	5.7	10.3	9.7 - 10.8	117	5.48	0.22	3.9	5.5	5.2 - 5.8
All Bio-Rad Methods	6	10.25	0.26	2.6	10.3	9.7 - 10.8	6	5.75	0.13	2.2	5.8	5.4 - 6.1
All Enzymatic A1c Methods	5	9.58	0.62	6.5	9.9	9.1 - 10.1	5	5.24	0.32	6.1	5.1	4.9 - 5.6
All Hemoglobin A1c Methods	109	10.29	0.57	5.5	10.3	9.7 - 10.9	109	5.50	0.20	3.7	5.5	5.2 - 5.8
All Roche Methods	11	9.90	0.45	4.6	9.8	9.4 - 10.4	11	5.25	0.26	4.9	5.3	4.9 - 5.6
All TOSOH Methods	13	9.68	0.22	2.3	9.7	9.1 - 10.2	13	5.59	0.08	1.4	5.6	5.3 - 5.9
Beckman AU A1c	7	9.63	0.31	3.3	9.7	9.1 - 10.2	7	5.21	0.07	1.3	5.2	4.9 - 5.5
Bio-Rad D-10 HbA1C	5	10.25	0.26	2.6	10.3	9.7 - 10.8	5	5.75	0.13	2.2	5.8	5.4 - 6.1
Roche cobas c501 HbA1c	5	9.78	0.46	4.7	9.7	9.2 - 10.3	5	5.20	0.19	3.6	5.2	4.9 - 5.5
Roche Integra A1C	5	10.23	0.33	3.2	10.3	9.7 - 10.8	5	5.45	0.13	2.4	5.5	5.1 - 5.8
Siemens DCA Vantage	53	10.66	0.33	3.1	10.7	10.1 - 11.2	53	5.57	0.16	2.8	5.6	5.2 - 5.9
Siemens Dimension HA1C	10	9.86	0.23	2.3	9.9	9.3 - 10.4	10	5.39	0.10	1.8	5.4	5.1 - 5.7
Siemens Dimension HB1C	5	9.70	0.24	2.5	9.8	9.2 - 10.2	5	5.30	0.08	1.5	5.3	5.0 - 5.6
TOSOH G8	13	9.68	0.22	2.3	9.7	9.1 - 10.2	13	5.59	0.08	1.4	5.6	5.3 - 5.9

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

<u>Method</u>	Specimen WBG-11						Specimen WBG-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	867	417.5	25.5	6.1	423	334 - 502	884	66.2	9.9	14.9	68	52 - 80
All Abbott Methods	46	401.7	30.8	7.7	402	321 - 482	46	54.6	5.2	9.4	55	43 - 66
All Arkray Methods	6	423.0	13.7	3.2	423	338 - 508	8	78.3	7.9	10.1	83	62 - 94
All Bayer Methods	17	346.0	36.5	10.6	346	276 - 416	17	48.4	5.2	10.7	46	38 - 59
All Hemocue Methods	46	424.0	11.4	2.7	427	339 - 509	49	89.5	7.3	8.2	91	71 - 108
All Lifescan Methods	9	443.2	35.6	8.0	457	354 - 532	9	58.1	4.5	7.7	57	46 - 70
All Roche Methods	535	427.0	10.1	2.4	427	341 - 513	535	68.6	1.9	2.8	68	54 - 83
Abbott FreeStyle Freedom	10	406.9	27.5	6.8	403	325 - 489	10	52.4	4.9	9.4	51	41 - 63
Abbott FreeStyle Lite/Freedom Lite	7	412.9	19.9	4.8	410	330 - 496	7	61.6	1.6	2.6	61	49 - 74
Abbott FreeStyle Precision Pro	23	400.7	33.1	8.3	405	320 - 481	23	53.6	4.6	8.5	52	42 - 65
Abbott Precision XceedPro	13	383.8	22.7	5.9	384	307 - 461	13	53.0	3.0	5.7	52	42 - 64
Acon On Call	7	367.0	8.1	2.2	370	293 - 441	7	56.1	1.7	3.0	57	44 - 68
Arkray Platinum	23	409.6	21.0	5.1	409	327 - 492	25	81.8	5.3	6.5	82	65 - 99
Bayer Contour	21	343.8	33.2	9.6	336	275 - 413	20	48.2	4.8	9.9	46	38 - 58
CareSens	11	407.5	47.0	11.5	396	325 - 489	11	69.1	4.5	6.5	69	55 - 83
HemoCue Glucose 201	48	423.8	11.1	2.6	426	339 - 509	51	88.6	8.5	9.6	90	70 - 107
Home Diagnostics True Balance / TrueTrack	6	583.5	40.4	6.9	600	466 - 701	10	171.2	10.1	5.9	172	136 - 206
Lifescan One Touch Ultra	23	442.6	25.1	5.7	457	354 - 532	21	58.2	0.9	1.5	58	46 - 70
Medline EvenCare G2 / G3	18	386.4	52.3	13.5	368	309 - 464	18	69.8	4.7	6.7	71	55 - 84
NOVA Biomedical StatStrip	50	364.3	14.7	4.0	366	291 - 438	51	53.2	3.2	6.0	53	42 - 64
Quintet / AC	29	433.3	14.9	3.4	436	346 - 520	29	54.0	4.4	8.1	52	43 - 65
Roche Accu-Chek Inform	10	421.0	9.8	2.3	422	336 - 506	10	65.9	1.7	2.6	67	52 - 80
Roche Accu-Chek Inform II	355	427.4	8.9	2.1	427	341 - 513	354	68.5	1.6	2.3	68	54 - 83
Roche Accu-Chek Performa	164	426.7	12.3	2.9	425	341 - 513	162	69.1	2.0	2.9	69	55 - 83
True Metrix Pro	38	400.4	16.6	4.1	398	320 - 481	38	52.2	2.4	4.6	51	41 - 63

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

<b><u>Method</u></b>	<b>Specimen WBG-13</b>						<b>Specimen WBG-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	189	65.1	7.8	12.0	68	52 - 79	189	102.8	11.7	11.3	108	82 - 124
All Abbott Methods	10	54.3	4.6	8.5	55	43 - 66	10	91.6	6.7	7.4	92	73 - 110
All Lifescan Methods	3	-	-	-	64	49 - 75	3	-	-	-	112	88 - 132
All Roche Methods	91	70.5	1.7	2.5	70	56 - 85	91	109.0	2.1	2.0	109	87 - 131
Abbott FreeStyle Freedom	10	54.3	4.6	8.5	55	43 - 66	10	91.6	6.7	7.4	92	73 - 110
Acon On Call	7	58.7	1.5	2.5	59	46 - 71	7	91.9	1.9	2.0	92	73 - 111
CareSens	11	74.8	5.3	7.0	73	59 - 90	11	126.1	6.3	5.0	126	100 - 152
Lifescan One Touch Ultra	17	65.5	0.6	1.0	66	52 - 79	18	106.7	7.4	6.9	112	85 - 129
NOVA Biomedical StatStrip	31	56.0	2.5	4.4	56	44 - 68	31	90.5	3.2	3.5	90	72 - 109
Roche Accu-Chek Inform	10	69.8	1.5	2.2	69	55 - 84	10	108.3	2.4	2.2	109	86 - 130
Roche Accu-Chek Inform II	76	70.6	1.8	2.5	70	56 - 85	75	109.2	2.0	1.8	109	87 - 132
Roche Accu-Chek Performa	11	64.5	6.4	9.9	63	51 - 78	11	96.3	12.8	13.3	93	77 - 116
True Metrix Pro	11	54.0	1.2	2.2	54	43 - 65	11	85.5	2.2	2.5	86	68 - 103

**Specimen WBG-15**

<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	189	323.7	33.3	10.3	329	258 - 389
All Abbott Methods	10	314.5	22.1	7.0	312	251 - 378
All Lifescan Methods	3	-	-	-	379	302 - 454
All Roche Methods	93	333.9	7.5	2.2	334	267 - 401
Abbott FreeStyle Freedom	10	314.5	22.1	7.0	312	251 - 378
Acon On Call	7	267.4	4.0	1.5	267	213 - 321
CareSens	11	365.6	29.0	7.9	372	292 - 439
Lifescan One Touch Ultra	18	373.5	33.7	9.0	401	298 - 449
NOVA Biomedical StatStrip	32	285.2	8.9	3.1	284	228 - 343
Roche Accu-Chek Inform	10	335.4	6.9	2.1	335	268 - 403
Roche Accu-Chek Inform II	77	333.8	7.5	2.2	333	267 - 401
Roche Accu-Chek Performa	11	310.6	28.8	9.3	316	248 - 373
True Metrix Pro	11	297.3	7.6	2.6	297	237 - 357

**Folate (ng/mL)**

<u>Method</u>	<b>Specimen SC-5</b>						<b>Specimen SC-6</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	25	1.78	0.65	36.2	2.0	0.7 - 2.8	24	2.95	1.01	34.3	4.0	1.9 - 4.0
All Roche Instruments	9	1.74	0.49	28.0	2.0	0.7 - 2.8	9	2.50	0.71	28.5	2.4	1.5 - 3.5
All Siemens Dimension Instruments	5	1.54	0.66	42.7	1.5	0.5 - 2.6	5	2.00	0.37	18.4	2.0	1.0 - 3.0
All TOSOH Instruments	8	1.26	0.43	33.9	1.3	0.2 - 2.3	8	2.23	0.35	15.7	2.3	1.2 - 3.3
Abbott Architect	5	1.96	0.49	25.2	2.1	0.9 - 3.0	5	4.32	0.32	7.4	4.3	3.0 - 5.7
Beckman ACCESS / 2 / Dxl	23	2.17	0.25	11.6	2.2	1.1 - 3.2	23	4.46	0.39	8.7	4.3	3.1 - 5.8
Roche cobas e 601/ e 602	5	1.58	0.63	39.6	2.0	0.5 - 2.6	5	2.50	0.51	20.6	2.6	1.5 - 3.5

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

<u>Method</u>	<b>Specimen CK-11</b>						<b>Specimen CK-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	6	22.35	6.15	27.5	22.4	3.8 - 40.9	6	13.55	3.61	26.6	13.6	2.7 - 24.4
<u>Method</u>	<b>Specimen CK-13</b>						<b>Specimen CK-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	6	5.90	1.27	21.6	5.9	2.0 - 9.8	6	39.70	9.48	23.9	39.7	11.2 - 68.2
<u>Method</u>	<b>Specimen CK-15</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	6	72.20	20.08	27.8	72.2	11.9 - 132.5						

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