

# **MEDICAL LABORATORY EVALUATION**

## **PARTICIPANT SUMMARY**

**2 • 0 • 2 • 0**

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

**International Data Supplement  
2020 MLE-M2**



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

\*Whichever is greater

**SEDIMENTATION RATE (MM/HR)**

<u>Instrument</u>	Specimen ES-3						Specimen ES-4					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	145	8.8	2.6	29.9	9	3 - 14	146	44.4	12.6	28.5	41	19 - 70
All Automated Methods	34	10.3	2.9	28.1	10	4 - 17	34	58.6	14.1	24.2	61	30 - 87
All Diesse Methods	10	11.7	2.9	24.9	11	5 - 18	10	62.2	14.3	23.0	69	33 - 91
All Manual Methods	103	8.2	2.3	28.8	8	3 - 13	105	40.4	8.7	21.5	39	23 - 58
All Vital Diagnostics Methods	17	9.2	1.8	20.1	9	5 - 13	17	58.5	14.4	24.7	58	29 - 88
Westergren - diluted	86	7.8	2.2	28.1	7	3 - 13	87	40.2	8.7	21.6	38	22 - 58
Westergren - undiluted	14	9.6	1.6	16.8	10	6 - 13	14	42.1	9.2	21.8	42	23 - 61

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	23	2.55	0.33	12.8	2.4	2.1 - 3.0	23	6.62	0.56	8.4	6.4	5.6 - 7.7
All Abbott Cell-Dyn Instruments	7	2.99	0.13	4.5	3.0	2.5 - 3.5	7	7.39	0.18	2.4	7.4	6.2 - 8.5
Abbott Cell-Dyn Ruby	7	2.99	0.13	4.5	3.0	2.5 - 3.5	7	7.39	0.18	2.4	7.4	6.2 - 8.5
Orphee Mythic 22	14	2.37	0.15	6.3	2.4	2.0 - 2.8	14	6.26	0.22	3.5	6.2	5.3 - 7.2

  

<u>Instrument</u>	Specimen CL-8						Specimen CL-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	23	22.58	1.55	6.8	22.0	19.1 - 26.0	23	18.51	1.35	7.3	18.2	15.7 - 21.3
All Abbott Cell-Dyn Instruments	7	24.66	0.49	2.0	24.6	20.9 - 28.4	7	20.24	0.31	1.5	20.2	17.2 - 23.3
Abbott Cell-Dyn Ruby	7	24.66	0.49	2.0	24.6	20.9 - 28.4	7	20.24	0.31	1.5	20.2	17.2 - 23.3
Orphee Mythic 22	14	21.59	0.73	3.4	21.7	18.3 - 24.9	14	17.67	0.81	4.6	17.8	15.0 - 20.4

  

<u>Instrument</u>	Specimen CL-10					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	23	2.61	0.39	15.0	2.5	2.2 - 3.1
All Abbott Cell-Dyn Instruments	7	3.16	0.08	2.5	3.1	2.6 - 3.7
Abbott Cell-Dyn Ruby	7	3.16	0.08	2.5	3.1	2.6 - 3.7
Orphee Mythic 22	14	2.39	0.16	6.8	2.4	2.0 - 2.8

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

<i><u>Instrument</u></i>	<b>Specimen CL-6</b>						<b>Specimen CL-7</b>					
	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>
All Method	23	2.266	0.052	2.3	2.26	2.13 - 2.41	23	4.737	0.099	2.1	4.73	4.45 - 5.03
All Abbott Cell-Dyn Instruments	7	2.283	0.038	1.7	2.27	2.14 - 2.42	7	4.776	0.094	2.0	4.78	4.48 - 5.07
Abbott Cell-Dyn Ruby	7	2.283	0.038	1.7	2.27	2.14 - 2.42	7	4.776	0.094	2.0	4.78	4.48 - 5.07
Orphee Mythic 22	14	2.263	0.058	2.6	2.26	2.12 - 2.40	14	4.722	0.100	2.1	4.72	4.43 - 5.01
<i><u>Instrument</u></i>	<b>Specimen CL-8</b>						<b>Specimen CL-9</b>					
	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>
All Method	23	6.169	0.138	2.2	6.16	5.79 - 6.54	23	5.011	0.108	2.2	5.05	4.71 - 5.32
All Abbott Cell-Dyn Instruments	7	6.276	0.125	2.0	6.32	5.89 - 6.66	7	5.074	0.089	1.8	5.08	4.76 - 5.38
Abbott Cell-Dyn Ruby	7	6.276	0.125	2.0	6.32	5.89 - 6.66	7	5.074	0.089	1.8	5.08	4.76 - 5.38
Orphee Mythic 22	14	6.121	0.120	2.0	6.11	5.75 - 6.49	14	4.979	0.107	2.1	4.98	4.67 - 5.28
<i><u>Instrument</u></i>	<b>Specimen CL-10</b>											
	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>						
All Method	23	2.255	0.051	2.3	2.25	2.11 - 2.40						
All Abbott Cell-Dyn Instruments	7	2.264	0.026	1.2	2.26	2.12 - 2.41						
Abbott Cell-Dyn Ruby	7	2.264	0.026	1.2	2.26	2.12 - 2.41						
Orphee Mythic 22	14	2.254	0.063	2.8	2.26	2.11 - 2.39						

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

<i><u>Instrument</u></i>	<b>Specimen CL-6</b>						<b>Specimen CL-7</b>					
	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>
All Method	23	4.85	0.51	10.5	4.6	4.5 - 5.2	23	12.29	0.82	6.7	12.0	11.4 - 13.2
All Abbott Cell-Dyn Instruments	7	5.57	0.08	1.4	5.6	5.1 - 6.0	7	13.43	0.37	2.7	13.4	12.4 - 14.4
Abbott Cell-Dyn Ruby	7	5.57	0.08	1.4	5.6	5.1 - 6.0	7	13.43	0.37	2.7	13.4	12.4 - 14.4
Orphee Mythic 22	14	4.50	0.10	2.1	4.5	4.1 - 4.9	14	11.77	0.26	2.2	11.9	10.9 - 12.6
<i><u>Instrument</u></i>	<b>Specimen CL-8</b>						<b>Specimen CL-9</b>					
	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>
All Method	23	18.98	0.70	3.7	18.8	17.6 - 20.4	23	15.54	0.61	3.9	15.4	14.4 - 16.7
All Abbott Cell-Dyn Instruments	7	19.89	0.38	1.9	19.9	18.4 - 21.3	7	16.33	0.35	2.1	16.2	15.1 - 17.5
Abbott Cell-Dyn Ruby	7	19.89	0.38	1.9	19.9	18.4 - 21.3	7	16.33	0.35	2.1	16.2	15.1 - 17.5
Orphee Mythic 22	14	18.57	0.35	1.9	18.6	17.2 - 19.9	14	15.17	0.30	2.0	15.1	14.1 - 16.3
<i><u>Instrument</u></i>	<b>Specimen CL-10</b>											
	<i><u>Labs</u></i>	<i><u>Mean</u></i>	<i><u>SD</u></i>	<i><u>CV</u></i>	<i><u>Median</u></i>	<i><u>Range</u></i>						
All Method	23	4.84	0.49	10.0	4.6	4.5 - 5.2						
All Abbott Cell-Dyn Instruments	7	5.53	0.05	0.9	5.5	5.1 - 6.0						
Abbott Cell-Dyn Ruby	7	5.53	0.05	0.9	5.5	5.1 - 6.0						
Orphee Mythic 22	14	4.50	0.11	2.5	4.5	4.1 - 4.9						

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

<u>Instrument</u>	<b>Specimen CL-6</b>						<b>Specimen CL-7</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	23	17.06	1.00	5.9	17.2	16.0 - 18.1	23	39.80	1.58	4.0	40.2	37.4 - 42.2
All Abbott Cell-Dyn Instruments	7	15.77	0.39	2.5	15.9	14.8 - 16.8	7	37.81	0.36	1.0	37.8	35.5 - 40.1
Abbott Cell-Dyn Ruby	7	15.77	0.39	2.5	15.9	14.8 - 16.8	7	37.81	0.36	1.0	37.8	35.5 - 40.1
Orphee Mythic 22	14	17.73	0.49	2.8	17.7	16.6 - 18.8	14	40.60	0.98	2.4	40.7	38.1 - 43.1
<b>Specimen CL-8</b>												
All Method	23	55.62	2.18	3.9	55.7	52.2 - 59.0	23	45.41	1.99	4.4	45.7	42.6 - 48.2
All Abbott Cell-Dyn Instruments	7	52.97	1.37	2.6	53.1	49.7 - 56.2	7	42.86	0.66	1.5	42.9	40.2 - 45.5
Abbott Cell-Dyn Ruby	7	52.97	1.37	2.6	53.1	49.7 - 56.2	7	42.86	0.66	1.5	42.9	40.2 - 45.5
Orphee Mythic 22	14	56.63	1.20	2.1	56.6	53.2 - 60.1	14	46.36	1.03	2.2	46.1	43.5 - 49.2
<b>Specimen CL-10</b>												
All Method	23	16.95	0.97	5.7	17.1	15.9 - 18.0						
All Abbott Cell-Dyn Instruments	7	15.70	0.28	1.8	15.9	14.7 - 16.7						
Abbott Cell-Dyn Ruby	7	15.70	0.28	1.8	15.9	14.7 - 16.7						
Orphee Mythic 22	14	17.59	0.52	2.9	17.7	16.5 - 18.7						

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

<u>Instrument</u>	<b>Specimen CL-6</b>						<b>Specimen CL-7</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	22	95.9	11.3	11.8	97	71 - 120	23	270.7	16.1	5.9	268	203 - 339
All Abbott Cell-Dyn Instruments	7	85.7	6.0	7.0	86	64 - 108	7	270.1	18.2	6.7	269	202 - 338
Abbott Cell-Dyn Ruby	7	85.7	6.0	7.0	86	64 - 108	7	270.1	18.2	6.7	269	202 - 338
Orphee Mythic 22	13	102.1	9.6	9.4	103	76 - 128	14	272.8	15.6	5.7	267	204 - 341
<b>Specimen CL-8</b>												
All Method	23	527.7	36.6	6.9	517	395 - 660	23	505.2	22.2	4.4	503	378 - 632
All Abbott Cell-Dyn Instruments	7	573.9	21.3	3.7	562	430 - 718	7	505.3	19.9	3.9	499	378 - 632
Abbott Cell-Dyn Ruby	7	573.9	21.3	3.7	562	430 - 718	7	505.3	19.9	3.9	499	378 - 632
Orphee Mythic 22	14	509.0	17.7	3.5	510	381 - 637	14	507.1	22.7	4.5	504	380 - 634
<b>Specimen CL-10</b>												
All Method	23	95.3	12.1	12.7	94	71 - 120						
All Abbott Cell-Dyn Instruments	7	83.0	5.4	6.6	83	62 - 104						
Abbott Cell-Dyn Ruby	7	83.0	5.4	6.6	83	62 - 104						
Orphee Mythic 22	14	101.4	10.5	10.4	102	76 - 127						

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

<u>Instrument</u>	<b>Specimen CL-6</b>						<b>Specimen CL-7</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	23	42.91	2.33	5.4	43.2	35.9 - 50.0	22	61.37	2.20	3.6	61.3	54.7 - 68.0
All Abbott Cell-Dyn Instruments	7	44.97	1.53	3.4	44.0	40.3 - 49.6	7	63.56	0.53	0.8	63.6	61.9 - 65.2
Abbott Cell-Dyn Ruby	7	44.97	1.53	3.4	44.0	40.3 - 49.6	7	63.56	0.53	0.8	63.6	61.9 - 65.2
Orphee Mythic 22	14	41.93	2.03	4.8	42.1	35.8 - 48.1	13	60.32	2.02	3.3	59.9	54.2 - 66.4
<u>Instrument</u>	<b>Specimen CL-8</b>						<b>Specimen CL-9</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	23	73.80	1.59	2.2	73.1	69.0 - 78.6	23	73.40	1.62	2.2	72.8	68.5 - 78.3
All Abbott Cell-Dyn Instruments	7	75.77	0.91	1.2	75.9	73.0 - 78.6	7	75.50	0.46	0.6	75.6	74.1 - 76.9
Abbott Cell-Dyn Ruby	7	75.77	0.91	1.2	75.9	73.0 - 78.6	7	75.50	0.46	0.6	75.6	74.1 - 76.9
Orphee Mythic 22	14	72.93	0.90	1.2	72.9	70.2 - 75.7	14	72.39	0.91	1.3	72.4	69.6 - 75.2
<u>Instrument</u>	<b>Specimen CL-10</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	21	43.26	2.51	5.8	43.5	35.7 - 50.9						
All Abbott Cell-Dyn Instruments	7	45.47	0.90	2.0	45.6	42.7 - 48.2						
Abbott Cell-Dyn Ruby	7	45.47	0.90	2.0	45.6	42.7 - 48.2						
Orphee Mythic 22	12	41.85	2.36	5.6	41.4	34.7 - 49.0						

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

<u>Instrument</u>	<b>Specimen CL-6</b>						<b>Specimen CL-7</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	22	35.20	6.44	18.3	35.3	15.8 - 54.6	22	19.98	4.18	20.9	20.1	7.4 - 32.6
All Abbott Cell-Dyn Instruments	7	42.47	1.66	3.9	43.0	37.4 - 47.5	7	24.09	0.89	3.7	24.1	21.4 - 26.8
Abbott Cell-Dyn Ruby	7	42.47	1.66	3.9	43.0	37.4 - 47.5	7	24.09	0.89	3.7	24.1	21.4 - 26.8
Orphee Mythic 22	13	31.28	4.84	15.5	30.1	16.7 - 45.9	13	17.58	3.70	21.1	17.5	6.4 - 28.7
<u>Instrument</u>	<b>Specimen CL-8</b>						<b>Specimen CL-9</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	23	13.52	1.88	13.9	13.5	7.8 - 19.2	23	13.83	2.07	14.9	13.9	7.6 - 20.1
All Abbott Cell-Dyn Instruments	7	14.79	1.06	7.1	14.3	11.6 - 18.0	7	15.64	0.52	3.3	15.5	14.0 - 17.3
Abbott Cell-Dyn Ruby	7	14.79	1.06	7.1	14.3	11.6 - 18.0	7	15.64	0.52	3.3	15.5	14.0 - 17.3
Orphee Mythic 22	14	12.74	1.93	15.1	12.9	6.9 - 18.6	14	12.89	2.04	15.8	12.9	6.7 - 19.0
<u>Instrument</u>	<b>Specimen CL-10</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	20	34.83	6.50	18.7	34.5	15.3 - 54.4						
All Abbott Cell-Dyn Instruments	7	41.54	1.56	3.8	41.2	36.8 - 46.3						
Abbott Cell-Dyn Ruby	7	41.54	1.56	3.8	41.2	36.8 - 46.3						
Orphee Mythic 22	11	30.78	5.11	16.6	30.2	15.4 - 46.2						



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

<u>Instrument</u>	<b>Specimen CL-6</b>						<b>Specimen CL-7</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	16.63	6.89	41.4	18.5	0.0 - 37.4	23	12.82	4.53	35.3	15.1	0.0 - 26.5
All Abbott Cell-Dyn Instruments	7	7.84	0.97	12.4	7.8	4.9 - 10.8	7	6.46	0.69	10.8	6.3	4.3 - 8.6
Abbott Cell-Dyn Ruby	7	7.84	0.97	12.4	7.8	4.9 - 10.8	7	6.46	0.69	10.8	6.3	4.3 - 8.6
Orphee Mythic 22	12	21.58	2.88	13.3	22.1	12.9 - 30.3	14	15.98	1.29	8.1	16.4	12.0 - 19.9
<b>Specimen CL-8</b>												
All Method	23	9.80	2.93	29.9	11.2	1.0 - 18.6	23	9.91	3.27	33.0	11.4	0.1 - 19.8
All Abbott Cell-Dyn Instruments	7	5.64	0.31	5.5	5.6	4.7 - 6.6	7	5.27	0.24	4.6	5.3	4.5 - 6.1
Abbott Cell-Dyn Ruby	7	5.64	0.31	5.5	5.6	4.7 - 6.6	7	5.27	0.24	4.6	5.3	4.5 - 6.1
Orphee Mythic 22	14	11.83	0.85	7.2	11.9	9.2 - 14.4	14	12.19	0.89	7.3	12.1	9.5 - 14.9
<b>Specimen CL-10</b>												
All Method	22	16.19	7.14	44.1	17.2	0.0 - 37.7						
All Abbott Cell-Dyn Instruments	7	8.26	1.68	20.3	7.7	3.2 - 13.3						
Abbott Cell-Dyn Ruby	7	8.26	1.68	20.3	7.7	3.2 - 13.3						
Orphee Mythic 22	13	20.25	5.64	27.9	22.5	3.3 - 37.2						

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

<u>Instrument</u>	<b>Specimen CL-6</b>						<b>Specimen CL-7</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	23	4.56	1.26	27.7	4.2	0.7 - 8.4	21	5.45	1.21	22.3	5.4	1.8 - 9.1
All Abbott Cell-Dyn Instruments	7	4.66	0.72	15.5	4.3	2.4 - 6.9	7	5.76	0.33	5.7	5.8	4.7 - 6.8
Abbott Cell-Dyn Ruby	7	4.66	0.72	15.5	4.3	2.4 - 6.9	7	5.76	0.33	5.7	5.8	4.7 - 6.8
Orphee Mythic 22	14	4.60	1.55	33.7	4.0	0.0 - 9.3	12	5.34	1.55	28.9	5.1	0.7 - 10.0
<b>Specimen CL-8</b>												
All Method	23	2.46	1.02	41.3	2.4	0.0 - 5.6	22	2.61	0.89	34.2	2.7	0.0 - 5.3
All Abbott Cell-Dyn Instruments	7	3.41	0.15	4.3	3.4	2.9 - 3.9	7	3.29	0.21	6.4	3.3	2.6 - 4.0
Abbott Cell-Dyn Ruby	7	3.41	0.15	4.3	3.4	2.9 - 3.9	7	3.29	0.21	6.4	3.3	2.6 - 4.0
Orphee Mythic 22	14	2.09	1.00	48.0	2.2	0.0 - 5.2	13	2.35	0.97	41.3	2.2	0.0 - 5.3
<b>Specimen CL-10</b>												
All Method	23	4.46	1.66	37.2	4.7	0.0 - 9.5						
All Abbott Cell-Dyn Instruments	7	4.70	0.13	2.7	4.7	4.3 - 5.1						
Abbott Cell-Dyn Ruby	7	4.70	0.13	2.7	4.7	4.3 - 5.1						
Orphee Mythic 22	14	4.37	2.14	49.0	4.0	0.0 - 10.8						

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

<u>Instrument</u>	<b>Specimen CL-6</b>						<b>Specimen CL-7</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	23	0.41	0.36	87.0	0.4	0.0 - 1.5	23	0.29	0.24	83.4	0.3	0.0 - 1.1
All Abbott Cell-Dyn Instruments	7	0.04	0.05	124.7	0.0	0.0 - 0.3	7	0.07	0.15	209.4	0.0	0.0 - 0.6
Abbott Cell-Dyn Ruby	7	0.04	0.05	124.7	0.0	0.0 - 0.3	7	0.07	0.15	209.4	0.0	0.0 - 0.6
Orphee Mythic 22	14	0.58	0.33	56.4	0.5	0.0 - 1.6	14	0.41	0.22	54.0	0.4	0.0 - 1.1
	<b>Specimen CL-8</b>						<b>Specimen CL-9</b>					
All Method	23	0.42	0.23	55.3	0.4	0.0 - 1.2	22	0.29	0.16	55.3	0.2	0.0 - 0.8
All Abbott Cell-Dyn Instruments	7	0.37	0.08	20.4	0.4	0.1 - 0.6	7	0.26	0.08	30.6	0.2	0.0 - 0.5
Abbott Cell-Dyn Ruby	7	0.37	0.08	20.4	0.4	0.1 - 0.6	7	0.26	0.08	30.6	0.2	0.0 - 0.5
Orphee Mythic 22	14	0.41	0.24	59.7	0.4	0.0 - 1.2	14	0.31	0.19	61.9	0.3	0.0 - 0.9
	<b>Specimen CL-10</b>											
All Method	23	0.42	0.34	80.3	0.4	0.0 - 1.5						
All Abbott Cell-Dyn Instruments	7	0.01	0.04	264.6	0.0	0.0 - 0.2						
Abbott Cell-Dyn Ruby	7	0.01	0.04	264.6	0.0	0.0 - 0.2						
Orphee Mythic 22	14	0.59	0.25	42.6	0.6	0.0 - 1.4						

## BLOOD BANK

### ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-6	Group O	16	100%	Acceptable
BB-7	Group O	15	100%	Acceptable
BB-8	Group A	15	100%	Acceptable
BB-9	Group A	13	92.86%	Acceptable
	Group O	1	7.14%	
BB-10	Group B	16	100%	Acceptable

### RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-6	Rh Negative	16	94.12%	Acceptable
	Rh Positive	1	5.88%	
BB-7	Rh Positive	15	93.75%	Acceptable
	Rh Negative	1	6.25%	
BB-8	Rh Negative	15	93.75%	Acceptable
	Rh Positive	1	6.25%	
BB-9	Rh Positive	14	93.33%	Acceptable
	Rh Negative	1	6.67%	
BB-10	Rh Positive	16	94.12%	Acceptable
	Rh Negative	1	5.88%	

## BLOOD BANK

### UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	No unexpected antibody detected	15	100%	Acceptable
AB-7	Unexpected antibody detected	16	100%	Acceptable
AB-8	No unexpected antibody detected	16	100%	Acceptable
AB-9	Unexpected antibody detected	16	100%	Acceptable
AB-10	No unexpected antibody detected	16	100%	Acceptable

### ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	No antibody detected	9	100%	Acceptable
AB-7	Anti-Fy <sup>a</sup>	8	88.89%	Acceptable
	Anti-E	1	11.11%	
AB-8	No antibody detected	8	88.89%	Acceptable
	Anti-K	1	11.11%	
AB-9	Anti-K	8	88.89%	Acceptable
	No antibody detected	1	11.11%	
AB-10	No antibody detected	9	100%	Acceptable

## BLOOD BANK

### COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	Compatible	12	92.31%	Acceptable
	Not Compatible	1	7.69%	
AB-7	Compatible	14	100%	Acceptable
AB-8	Compatible	14	100%	Acceptable
AB-9	Not Compatible	14	100%	Acceptable
AB-10	Compatible	14	100%	Acceptable

## Coagulation

### PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-6						Specimen CG-7					
	<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	51	20.51	2.76	13.4	20.1	17.4 - 23.6	51	14.73	2.06	14.0	14.6	12.5 - 17.0
Dade Innovin												
Dade Behring BFT II	5	18.15	1.79	9.9	17.8	15.4 - 20.9	5	12.43	0.50	4.0	12.4	10.5 - 14.3
Sysmex CA-500/600 series	14	18.01	0.72	4.0	17.9	15.3 - 20.8	14	12.72	0.69	5.5	12.8	10.8 - 14.7
All Coagulation Instruments	20	17.97	0.98	5.4	17.8	15.2 - 20.7	20	12.66	0.64	5.0	12.7	10.7 - 14.6
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	7	23.99	0.61	2.6	23.9	20.3 - 27.6	7	17.30	0.39	2.3	17.2	14.7 - 19.9
All Coagulation Instruments	8	23.84	0.70	3.0	23.8	20.2 - 27.5	8	17.20	0.46	2.7	17.2	14.6 - 19.8
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	23.23	0.32	1.4	23.1	19.7 - 26.8	5	16.93	0.25	1.5	16.9	14.3 - 19.5
Diagnostica Stago STart Max	7	22.90	1.51	6.6	23.0	19.4 - 26.4	7	17.30	0.50	2.9	17.3	14.7 - 19.9
All Coagulation Instruments	12	23.00	1.25	5.5	23.1	19.5 - 26.5	12	17.19	0.46	2.7	17.1	14.6 - 19.8
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	22.32	1.12	5.0	21.9	18.9 - 25.7	5	14.88	0.33	2.2	14.8	12.6 - 17.2

**PROTHROMBIN TIME (seconds)**

<u>Reagent/Instrument</u>	<b>Specimen CG-8</b>						<b>Specimen CG-9</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	51	33.47	5.17	15.5	33.7	28.4 - 38.5	51	11.80	1.67	14.1	11.0	10.0 - 13.6
Dade Innovin												
Dade Behring BFT II	5	29.90	1.76	5.9	30.0	25.4 - 34.4	5	9.55	0.26	2.8	9.6	8.1 - 11.0
Sysmex CA-500/600 series	14	29.10	1.28	4.4	28.7	24.7 - 33.5	14	10.43	0.28	2.6	10.4	8.8 - 12.0
All Coagulation Instruments	20	29.17	1.35	4.6	28.7	24.7 - 33.6	20	10.23	0.47	4.6	10.3	8.6 - 11.8
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	7	39.49	1.51	3.8	39.5	33.5 - 45.5	7	13.80	0.26	1.9	13.7	11.7 - 15.9
All Coagulation Instruments	8	39.13	1.73	4.4	39.0	33.2 - 45.0	8	13.75	0.28	2.1	13.7	11.6 - 15.9
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	37.07	1.63	4.4	36.5	31.5 - 42.7	5	13.73	0.49	3.6	13.5	11.6 - 15.8
Diagnostica Stago STart Max	7	38.84	1.67	4.3	39.3	33.0 - 44.7	7	13.87	0.30	2.2	13.8	11.7 - 16.0
All Coagulation Instruments	12	38.31	1.78	4.7	38.6	32.5 - 44.1	12	13.83	0.35	2.5	13.8	11.7 - 16.0
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	37.02	2.64	7.1	36.2	31.4 - 42.6	5	10.92	0.16	1.5	11.0	9.2 - 12.6

<u>Reagent/Instrument</u>	<b>Specimen CG-10</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	51	11.55	1.55	13.4	11.2	9.8 - 13.3
Dade Innovin						
Dade Behring BFT II	5	9.35	0.29	3.1	9.4	7.9 - 10.8
Sysmex CA-500/600 series	14	10.12	0.25	2.5	10.1	8.6 - 11.7
All Coagulation Instruments	20	9.96	0.43	4.3	9.9	8.4 - 11.5
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	7	13.50	0.33	2.5	13.4	11.4 - 15.6
All Coagulation Instruments	8	13.46	0.32	2.4	13.4	11.4 - 15.5
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STA Compact	5	13.33	0.42	3.1	13.2	11.3 - 15.4
Diagnostica Stago STart Max	7	13.30	0.40	3.0	13.3	11.3 - 15.3
All Coagulation Instruments	12	13.31	0.38	2.8	13.3	11.3 - 15.4
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	11.04	0.19	1.8	11.1	9.3 - 12.7

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

<u>Reagent/Instrument</u>	<u>Specimen CG-6</u>						<u>Specimen CG-7</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	51	1.86	0.16	8.6	1.9	1.4 - 2.3	51	1.30	0.10	7.8	1.3	1.0 - 1.6
Dade Innovin												
Dade Behring BFT II	5	1.83	0.17	9.4	1.9	1.4 - 2.2	5	1.33	0.05	3.8	1.3	1.0 - 1.6
Sysmex CA-500/600 series	14	1.80	0.07	3.9	1.8	1.4 - 2.2	14	1.26	0.09	6.8	1.3	1.0 - 1.6
All Coagulation Instruments	20	1.79	0.10	5.9	1.8	1.4 - 2.2	20	1.27	0.08	6.4	1.3	1.0 - 1.6
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	7	2.03	0.07	3.5	2.0	1.6 - 2.5	7	1.38	0.07	5.1	1.4	1.1 - 1.7
All Coagulation Instruments	8	2.02	0.07	3.3	2.0	1.6 - 2.5	8	1.38	0.07	4.8	1.4	1.1 - 1.7
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	2.00	0.10	5.0	2.0	1.6 - 2.4	5	1.37	0.06	4.2	1.4	1.0 - 1.7
Diagnostica Stago STart Max	7	1.92	0.17	9.0	2.0	1.5 - 2.4	7	1.38	0.08	5.4	1.4	1.1 - 1.7
All Coagulation Instruments	12	1.94	0.15	7.8	2.0	1.5 - 2.4	12	1.38	0.07	4.8	1.4	1.1 - 1.7
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	1.92	0.15	7.7	1.9	1.5 - 2.4	5	1.26	0.09	7.1	1.2	1.0 - 1.6

  

<u>Reagent/Instrument</u>	<u>Specimen CG-8</u>						<u>Specimen CG-9</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	51	3.25	0.42	13.0	3.1	2.6 - 4.0	51	1.00	0.08	7.6	1.0	0.8 - 1.2
Dade Innovin												
Dade Behring BFT II	5	2.83	0.24	8.4	2.9	2.2 - 3.4	5	1.03	0.05	4.9	1.0	0.8 - 1.3
Sysmex CA-500/600 series	14	2.96	0.15	5.1	3.0	2.3 - 3.6	14	1.05	0.09	8.1	1.0	0.8 - 1.3
All Coagulation Instruments	20	2.93	0.17	6.0	3.0	2.3 - 3.6	20	1.02	0.05	5.2	1.0	0.8 - 1.3
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	7	3.79	0.16	4.3	3.8	3.0 - 4.6	7	1.04	0.05	5.0	1.0	0.8 - 1.3
All Coagulation Instruments	8	3.78	0.16	4.1	3.8	3.0 - 4.6	8	1.03	0.05	4.8	1.0	0.8 - 1.3
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	3.67	0.35	9.6	3.7	2.9 - 4.5	5	1.03	0.06	5.6	1.0	0.8 - 1.3
Diagnostica Stago STart Max	7	3.68	0.21	5.8	3.7	2.9 - 4.5	7	1.05	0.05	5.2	1.1	0.8 - 1.3
All Coagulation Instruments	12	3.68	0.24	6.6	3.7	2.9 - 4.5	12	1.04	0.05	5.0	1.0	0.8 - 1.3
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	3.22	0.26	8.0	3.2	2.5 - 3.9	5	0.90	0.07	7.9	0.9	0.7 - 1.1



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

**Specimen CG-10**

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	51	0.98	0.07	6.7	1.0	0.7 - 1.2
Dade Innovin						
Dade Behring BFT II	5	1.00	0.01	0.0	1.0	0.8 - 1.2
Sysmex CA-500/600 series	14	0.98	0.04	4.5	1.0	0.7 - 1.2
All Coagulation Instruments	20	0.98	0.04	4.3	1.0	0.7 - 1.2
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	7	1.01	0.04	3.5	1.0	0.8 - 1.3
All Coagulation Instruments	8	1.01	0.03	3.3	1.0	0.8 - 1.3
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STA Compact	5	1.00	0.01	0.0	1.0	0.8 - 1.2
Diagnostica Stago STart Max	7	1.00	0.06	6.3	1.0	0.8 - 1.2
All Coagulation Instruments	12	1.00	0.05	5.0	1.0	0.8 - 1.2
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	0.94	0.09	9.5	0.9	0.7 - 1.2

**ACTIVATED PARTIAL THROMBOPLASTIN (seconds)**

**Specimen CG-6**

**Specimen CG-7**

<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	27	39.0	7.4	18.9	39	33 - 45	27	32.3	4.2	12.9	32	27 - 38
Dade Actin FSL												
Sysmex CA-500/600 series	8	31.8	4.0	12.5	33	26 - 37	8	29.1	4.2	14.3	28	24 - 34
All Coagulation Instruments	9	32.1	3.9	12.0	33	27 - 37	9	29.2	3.9	13.3	28	24 - 34
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	5	46.5	0.7	1.5	47	39 - 54	5	37.0	0.1	0.0	37	31 - 43
HemosIL APTT-SP												
IL ACL, all models	5	40.3	2.1	5.1	41	34 - 47	5	31.8	3.4	10.7	31	26 - 37
IL TEST APTT-SP												
IL ACL, all models	5	43.0	1.4	3.3	43	36 - 50	5	37.5	0.7	1.9	38	31 - 44

**ACTIVATED PARTIAL THROMBOPLASTIN (seconds)**

<u>Reagent/Instrument</u>	Specimen CG-8						Specimen CG-9					
	<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	57.3	12.4	21.7	57	48 - 66	27	29.8	4.6	15.5	29	25 - 35
Dade Actin FSL												
Sysmex CA-500/600 series	8	47.1	2.9	6.2	48	40 - 55	8	26.4	2.8	10.5	25	22 - 31
All Coagulation Instruments	9	47.9	3.6	7.4	48	40 - 56	9	26.2	2.6	10.0	25	22 - 31
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	5	68.0	0.1	0.0	68	57 - 79	5	30.0	0.1	0.0	30	25 - 35
HemosIL APTT-SP												
IL ACL, all models	5	63.3	4.8	7.6	63	53 - 73	5	32.8	5.0	15.2	33	27 - 38
IL TEST APTT-SP												
IL ACL, all models	5	67.0	0.1	0.0	67	56 - 78	5	30.0	1.4	4.7	30	25 - 35

<u>Reagent/Instrument</u>	Specimen CG-10					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	27	27.2	2.4	8.6	27	23 - 32
Dade Actin FSL						
Sysmex CA-500/600 series	8	27.6	5.9	21.2	25	23 - 32
All Coagulation Instruments	9	27.3	5.5	20.3	25	23 - 32
Diagnostica Stago STA C.K. Prest						
Diagnostica Stago STA Compact	5	29.0	0.1	0.0	29	24 - 34
HemosIL APTT-SP						
IL ACL, all models	5	27.0	0.8	3.0	27	22 - 32
IL TEST APTT-SP						
IL ACL, all models	5	28.5	0.7	2.5	29	24 - 33

**FIBRINOGEN (mg/dL)**

<u>Reagent/Instrument</u>	Specimen CG-6						Specimen CG-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	12	238.3	33.0	13.9	251	190 - 286	12	170.4	17.4	10.2	175	136 - 205

<u>Reagent/Instrument</u>	Specimen CG-8						Specimen CG-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	12	259.4	27.1	10.5	262	207 - 312	12	455.4	43.9	9.6	474	364 - 547

<u>Reagent/Instrument</u>	Specimen CG-10					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	12	266.0	28.4	10.7	266	212 - 320

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

<u>Reagent/Instrument</u>	<b>Specimen XS-6</b>						<b>Specimen XS-7</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	13.96	0.30	2.2	13.9	11.8 - 16.1	25	33.63	0.91	2.7	33.8	28.5 - 38.7
All Roche CoaguChek XS Plus Instruments	14	13.86	0.27	1.9	13.8	11.7 - 16.0	14	33.40	0.81	2.4	33.4	28.3 - 38.5
Roche CoaguChek Pro II	11	14.10	0.30	2.1	14.1	11.9 - 16.3	11	33.92	1.00	2.9	34.4	28.8 - 39.1
Roche CoaguChek XS Plus - Waived	9	13.83	0.30	2.2	13.8	11.7 - 16.0	9	32.69	2.15	6.6	33.3	27.7 - 37.6
Roche CoaguChek XS Plus	6	15.85	4.78	30.2	14.0	13.4 - 18.3	6	33.47	0.78	2.3	33.5	28.4 - 38.5

  

<u>Reagent/Instrument</u>	<b>Specimen XS-8</b>						<b>Specimen XS-9</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	5	23.93	0.21	0.9	23.9	20.3 - 27.6	5	33.25	0.49	1.5	33.3	28.2 - 38.3
All Roche CoaguChek XS Plus Instruments	5	23.93	0.21	0.9	23.9	20.3 - 27.6	5	33.25	0.49	1.5	33.3	28.2 - 38.3
Roche CoaguChek XS Plus - Waived	2	-	-	-	23.8	20.2 - 27.4	2	-	-	-	33.1	28.1 - 38.1
Roche CoaguChek XS Plus	2	-	-	-	24.1	20.4 - 27.7	2	-	-	-	33.4	28.3 - 38.5

  

<u>Reagent/Instrument</u>	<b>Specimen XS-10</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	5	13.73	0.10	0.7	13.8	11.6 - 15.8
All Roche CoaguChek XS Plus Instruments	5	13.73	0.10	0.7	13.8	11.6 - 15.8
Roche CoaguChek XS Plus - Waived	2	-	-	-	13.8	11.6 - 15.9
Roche CoaguChek XS Plus	2	-	-	-	13.7	11.6 - 15.8

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

<b>Specimen XS-6</b>							<b>Specimen XS-7</b>					
<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	50	1.17	0.05	4.0	1.2	0.9 - 1.5	50	2.81	0.09	3.1	2.8	2.2 - 3.4
All Roche CoaguChek XS Plus Instruments	26	1.15	0.05	4.4	1.2	0.9 - 1.4	26	2.77	0.08	3.0	2.8	2.2 - 3.4
Roche CoaguChek Pro II	24	1.19	0.03	2.8	1.2	0.9 - 1.5	24	2.85	0.07	2.3	2.9	2.2 - 3.5
Roche CoaguChek XS Plus - Waived	20	1.16	0.05	4.4	1.2	0.9 - 1.4	19	2.76	0.08	3.0	2.8	2.2 - 3.4
Roche CoaguChek XS Plus	7	1.30	0.40	30.8	1.2	1.0 - 1.6	7	2.79	0.09	3.2	2.8	2.2 - 3.4
<b>Specimen XS-8</b>							<b>Specimen XS-9</b>					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	2.02	0.04	2.2	2.0	1.6 - 2.5	17	2.83	0.08	2.7	2.8	2.2 - 3.4
All Roche CoaguChek XS Plus Instruments	7	2.01	0.04	1.9	2.0	1.6 - 2.5	7	2.77	0.05	1.8	2.8	2.2 - 3.4
Roche CoaguChek Pro II	10	2.03	0.05	2.4	2.0	1.6 - 2.5	10	2.87	0.07	2.4	2.9	2.2 - 3.5
Roche CoaguChek XS Plus - Waived	5	2.02	0.04	2.2	2.0	1.6 - 2.5	5	2.76	0.05	2.0	2.8	2.2 - 3.4
Roche CoaguChek XS Plus	2	-	-	-	2.0	1.6 - 2.4	2	-	-	-	2.8	2.2 - 3.4
<b>Specimen XS-10</b>												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	17	1.14	0.05	4.4	1.1	0.9 - 1.4						
All Roche CoaguChek XS Plus Instruments	7	1.10	0.01	0.0	1.1	0.8 - 1.4						
Roche CoaguChek Pro II	10	1.17	0.05	4.1	1.2	0.9 - 1.5						
Roche CoaguChek XS Plus - Waived	5	1.10	0.01	0.0	1.1	0.8 - 1.4						
Roche CoaguChek XS Plus	2	-	-	-	1.1	0.8 - 1.4						

**URINALYSIS DIPSTICK–SPECIFIC GRAVITY**

**Specimen UA-2**

<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	131	1.0172	0.0068	0.7	1.015	1.007 - 1.028
All Arkray Methods	6	1.0297	0.0008	0.1	1.030	1.019 - 1.040
All Refractive Index Methods	12	1.0285	0.0027	0.3	1.030	1.018 - 1.039
All Roche Methods	41	1.0151	0.0053	0.5	1.015	1.005 - 1.026
All Siemens Methods	33	1.0171	0.0035	0.3	1.020	1.007 - 1.028
77 Elektronika LabUMat/2	8	1.0273	0.0047	0.5	1.029	1.017 - 1.038
Acon Laboratories	7	1.0121	0.0040	0.4	1.010	1.002 - 1.023
Arkray Aution Sticks	5	1.0300	0.0001	0.0	1.030	1.020 - 1.040
Roche Chemstrips / Combur	11	1.0100	0.0022	0.2	1.010	1.000 - 1.020
Roche cobas u 411	21	1.0145	0.0026	0.3	1.015	1.004 - 1.025
Roche Urisys	17	1.0149	0.0066	0.7	1.015	1.004 - 1.025
SD UroColor Reagent Strips	6	1.0133	0.0026	0.3	1.015	1.003 - 1.024
Siemens Clinitek Advantus	15	1.0173	0.0037	0.4	1.020	1.007 - 1.028
Siemens Clinitek Status / Status+	16	1.0178	0.0026	0.3	1.020	1.007 - 1.028

## URINALYSIS DIPSTICK-pH

### Specimen UA-2

### 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	158	-	-	-	-	-	-	1	13	22	104	18	-
77 Elektronika LabUMat/2	8	-	-	-	-	-	-	-	4	4	-	-	-
Acon Laboratories	7	-	-	-	-	-	-	-	-	2	4	1	-
Arkray Aution Jet	1	-	-	-	-	-	-	-	-	-	1	-	-
Arkray Aution Sticks	5	-	-	-	-	-	-	-	-	3	2	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	1	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	-	-	1	-	-
Iris Diagnostics iChem Velocity Strips	2	-	-	-	-	-	-	-	-	2	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	-	-	-	-	-	2	-	-	-
Other Analyzer Method	3	-	-	-	-	-	-	-	-	2	1	-	-
Other Dipstick Method	5	-	-	-	-	-	-	1	-	1	3	-	-
Plasmatec URIPATH	2	-	-	-	-	-	-	-	-	1	1	-	-
Roche Chemstrips / Combur	24	-	-	-	-	-	-	-	-	1	23	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	-	-	1	-	-
Roche cobas u 411	21	-	-	-	-	-	-	-	6	-	15	-	-
Roche cobas u 601 / 701	3	-	-	-	-	-	-	-	1	1	1	-	-
Roche Urisys	17	-	-	-	-	-	-	-	2	-	15	-	-
SD UroColor Reagent Strips	6	-	-	-	-	-	-	-	-	1	5	-	-
Siemens Clinitek Advantus	16	-	-	-	-	-	-	-	-	-	15	1	-
Siemens Clinitek Status / Status+	18	-	-	-	-	-	-	-	-	-	2	16	-
Siemens Reagent Strips	12	-	-	-	-	-	-	-	-	-	12	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	-	1	-	-	-
UriScan Reagent Strips	2	-	-	-	-	-	-	-	-	1	1	-	-

**URINALYSIS DIPSTICK–PROTEIN QUALITATIVE**  
Specimen UA-2

*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	158	3	-	6	89	30	-	1	-	4	21	3	1
77 Elektronika LabUMat/2	8	-	-	-	5	-	-	-	-	-	3	-	-
Acon Laboratories	7	-	-	1	6	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	-	-	-	1	-	-	-	-	-	-	-	-
Arkray Aution Sticks	5	-	-	-	5	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	1	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	1	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	2	-	-	-	1	-	-	-	-	-	1	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	1	1	-	-	-	-	-	-	-
Other Analyzer Method	3	-	-	-	2	-	-	-	-	-	1	-	-
Other Dipstick Method	5	-	-	-	4	-	-	-	-	-	-	-	1
Plasmatec URIPATH	2	-	-	-	2	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	24	-	-	3	16	3	-	1	-	-	1	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	1	-	-	-	-	-	-	-
Roche cobas u 411	21	-	-	-	5	7	-	-	-	1	8	-	-
Roche cobas u 601 / 701	3	1	-	-	-	-	-	-	-	-	2	-	-
Roche Urisys	17	1	-	-	4	5	-	-	-	3	4	-	-
SD UroColor Reagent Strips	6	-	-	2	4	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	16	1	-	-	15	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	-	-	-	2	13	-	-	-	-	-	3	-
Siemens Reagent Strips	12	-	-	-	12	-	-	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	1	-	-	-	-	-	-	-	-
UriScan Reagent Strips	2	-	-	-	2	-	-	-	-	-	-	-	-



## URINALYSIS DIPSTICK–GLUCOSE

### Specimen UA-2

<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	158	155	-	-	-	1	-	1	-	-	1	
77 Elektronika LabUMat/2	8	8	-	-	-	-	-	-	-	-	-	
Acon Laboratories	7	7	-	-	-	-	-	-	-	-	-	
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	
Arkray Aution Sticks	5	5	-	-	-	-	-	-	-	-	-	
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	
Iris Diagnostics iChem Velocity Strips	2	2	-	-	-	-	-	-	-	-	-	
Iris Ichem VELOCITY Urine Chemistry System	2	2	-	-	-	-	-	-	-	-	-	
Other Analyzer Method	3	3	-	-	-	-	-	-	-	-	-	
Other Dipstick Method	5	4	-	-	-	-	-	1	-	-	-	
Plasmatec URIPATH	2	2	-	-	-	-	-	-	-	-	-	
Roche Chemstrips / Combur	24	24	-	-	-	-	-	-	-	-	-	
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	
Roche cobas u 411	21	21	-	-	-	-	-	-	-	-	-	
Roche cobas u 601 / 701	3	3	-	-	-	-	-	-	-	-	-	
Roche Urisys	17	16	-	-	-	-	-	-	-	-	1	
SD UroColor Reagent Strips	6	6	-	-	-	-	-	-	-	-	-	
Siemens Clinitek Advantus	16	15	-	-	-	1	-	-	-	-	-	
Siemens Clinitek Status / Status+	18	18	-	-	-	-	-	-	-	-	-	
Siemens Reagent Strips	12	12	-	-	-	-	-	-	-	-	-	
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	
UriScan Reagent Strips	2	2	-	-	-	-	-	-	-	-	-	

## URINALYSIS DIPSTICK–KETONES

### Specimen UA-2

<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	157	3	-	-	-	-	-	2	74	50	-	1	-	5	22
77 Elektronika LabUMat/2	8	-	-	-	-	-	-	-	5	-	-	-	-	-	3
Acon Laboratories	7	-	-	-	-	-	-	-	6	1	-	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Arkray Aution Sticks	5	-	-	-	-	-	-	-	-	5	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	2	-	-	-	-	-	-	-	-	1	-	-	-	1	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-
Other Analyzer Method	3	-	-	-	-	-	-	-	-	2	-	-	-	1	-
Other Dipstick Method	5	1	-	-	-	-	-	-	4	-	-	-	-	-	-
Plasmatec URIPATH	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-
Roche Chemstrips / Combur	24	-	-	-	-	-	-	-	23	-	-	1	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Roche cobas u 411	21	-	-	-	-	-	-	-	1	11	-	-	-	1	8
Roche cobas u 601 / 701	2	-	-	-	-	-	-	-	-	-	-	-	-	-	2
Roche Urisys	17	1	-	-	-	-	-	1	6	2	-	-	-	-	7
SD UroColor Reagent Strips	6	-	-	-	-	-	-	1	5	-	-	-	-	-	-
Siemens Clinitek Advantus	16	1	-	-	-	-	-	-	15	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	-	-	-	-	-	-	-	1	14	-	-	-	1	2
Siemens Reagent Strips	12	-	-	-	-	-	-	-	1	11	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
UriScan Reagent Strips	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-

**URINALYSIS DIPSTICK–BILIRUBIN**

**Specimen UA-2**

<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	132	23	-	-	1	2	-	41	45	2	1	15	1	-	1
77 Elektronika LabUMat/2	8	-	-	-	-	-	-	4	-	1	-	3	-	-	-
Acon Laboratories	7	6	-	-	-	-	-	1	-	-	-	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Arkray Aution Sticks	5	-	-	-	-	-	-	-	5	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	1	-	-	-	-	-	-	1	-	-	-	-	-	-
Other Analyzer Method	3	-	-	-	-	-	-	1	2	-	-	-	-	-	-
Other Dipstick Method	5	4	-	-	-	-	-	1	-	-	-	-	-	-	-
Plasmatec URIPATH	2	-	-	-	-	-	-	1	1	-	-	-	-	-	-
Roche Chemstrips / Combur	11	-	-	-	-	-	-	5	4	-	-	1	-	-	1
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Roche cobas u 411	21	1	-	-	-	-	-	10	1	-	1	7	1	-	-
Roche cobas u 601 / 701	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	17	2	-	-	-	-	-	10	2	-	-	3	-	-	-
SD UroColor Reagent Strips	6	2	-	-	-	-	-	3	1	-	-	-	-	-	-
Siemens Clinitek Advantus	16	1	-	-	-	-	-	1	14	-	-	-	-	-	-
Siemens Clinitek Status / Status+	16	-	-	-	1	2	-	2	11	-	-	-	-	-	-
Siemens Reagent Strips	2	-	-	-	-	-	-	-	1	1	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	2	1	-	-	-	-	-	1	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK–UROBILINOGEN

### Specimen UA-2

<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	131	42	34	20	26	9
77 Elektronika LabUMat/2	8	-	-	-	3	5
Acon Laboratories	7	7	-	-	-	-
Arkray Aution Sticks	5	-	-	5	-	-
DIRUI H-800 Urine Analyzer	1	-	-	1	-	-
Iris Diagnostics Aution Max AX-4280	1	-	1	-	-	-
Iris Diagnostics iChem Velocity Strips	2	-	1	1	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	1	1	-
Other Analyzer Method	3	-	1	2	-	-
Other Dipstick Method	5	4	-	1	-	-
Plasmatec URIPATH	2	2	-	-	-	-
Roche Chemstrips / Combur	10	6	4	-	-	-
Roche cobas 6500 / u 601	1	-	1	-	-	-
Roche cobas u 411	21	5	16	-	-	-
Roche cobas u 601 / 701	3	1	2	-	-	-
Roche Urisys	17	11	6	-	-	-
SD UroColor Reagent Strips	6	5	-	1	-	-
Siemens Clinitek Advantus	16	1	-	7	8	-
Siemens Clinitek Status / Status+	16	-	-	-	12	4
Siemens Reagent Strips	2	-	1	1	-	-
Sysmex UN Series	1	-	-	-	1	-
UriScan Reagent Strips	2	-	1	-	1	-

**URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN**

Specimen UA-2

**Participant Results**

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>(5+)</u>	<u>5 - 25</u> <u>Ery/<math>\mu</math>L</u>	<u>50 -</u> <u>100</u> <u>Ery/<math>\mu</math>L</u>	<u>200 -</u> <u>300</u> <u>Ery/<math>\mu</math>L</u>	<u><math>\pm</math>0.03</u> <u>mg/dL</u>	<u>0.06</u> <u>-</u> <u>0.10</u> <u>mg/</u> <u>dL</u>	<u>0.2 -</u> <u>0.5</u> <u>mg/</u> <u>dL</u>	<u><math>\geq</math>1.0</u> <u>mg/</u> <u>dL</u>
ALL METHODS	158	2	-	-	1	2	2	10	64	35	12	-	-	29	-	-	1	-
77 Elektronika LabUMat/2	8	-	-	-	-	-	-	1	5	-	-	-	-	2	-	-	-	-
Acon Laboratories	7	-	-	-	-	-	-	-	2	5	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	5	-	-	-	-	-	-	1	4	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	2	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	1	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	-	-	1	1	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	3	-	-	-	-	-	-	1	1	-	-	-	-	1	-	-	-	-
Other Dipstick Method	5	-	-	-	-	-	-	1	1	3	-	-	-	-	-	-	-	-
Plasmatec URIPATH	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	23	-	-	-	-	-	-	-	2	18	-	-	-	3	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Roche cobas u 411	21	-	-	-	-	-	-	-	-	2	9	-	-	10	-	-	-	-
Roche cobas u 601 / 701	3	-	-	-	-	-	-	-	-	-	-	-	-	3	-	-	-	-
Roche Miditron Junior/II	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Roche Urisys	17	1	-	-	-	-	-	-	-	5	2	-	-	9	-	-	-	-
SD UroColor Reagent Strips	6	-	-	-	-	-	-	-	5	1	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	16	1	-	-	-	-	-	2	13	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	-	-	-	1	2	-	1	14	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	12	-	-	-	-	-	-	-	12	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-2

### 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	144	144	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	8	8	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	7	7	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	5	5	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	2	2	-	-	-	-	-	-	-	-	-	-	-
Iris iChem VELOCITY Urine Chemistry System	2	2	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	3	3	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	5	5	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	2	2	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	23	23	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	21	21	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	3	3	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	17	17	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	6	6	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	16	16	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	16	16	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	2	2	-	-	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	2	2	-	-	-	-	-	-	-	-	-	-	-

**URINALYSIS DIPSTICK–NITRITE****Specimen UA-2*****Participant Results***

<b><u>Method</u></b>	<b><u>Labs</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	145	144	1
77 Elektronika LabUMat/2	8	8	-
Acon Laboratories	6	6	-
Arkray Aution Jet	1	1	-
Arkray Aution Sticks	5	5	-
DIRUI H-800 Urine Analyzer	1	1	-
Iris Diagnostics Aution Max AX-4280	1	1	-
Iris Diagnostics iChem Velocity Strips	2	2	-
Iris Ichem VELOCITY Urine Chemistry System	2	2	-
Other Analyzer Method	3	3	-
Other Dipstick Method	5	5	-
Plasmatec URIPATH	2	2	-
Roche Chemstrips / Combur	23	23	-
Roche cobas 6500 / u 601	1	1	-
Roche cobas u 411	21	21	-
Roche cobas u 601 / 701	3	3	-
Roche SuperUA/ChemstripUA	1	1	-
Roche Urisys	16	16	-
SD UroColor Reagent Strips	6	6	-
Siemens Clinitek Advantus	16	16	-
Siemens Clinitek Status / Status+	16	16	-
Siemens Reagent Strips	2	2	-
Sysmex UN Series	1	1	-
UriScan Reagent Strips	2	2	-

**URINALYSIS –MICROALBUMIN (dipstick only)**

**Specimen UA-2**

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

**URINALYSIS –URINE hCG**

**Specimen UA-2**

<u>Method</u>	<i>Participant Results</i>		
	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	105	105	-
Abon (Alere) Biopharm	9	9	-
Acon Laboratories	6	6	-
Alere Acceava hCG-Urine	2	2	-
Alere Clearview hCG Cassette	3	3	-
Alere hCG Combo Cassette	21	21	-
bioMerieux VIKIA hCG-D	1	1	-
Biosynex	1	1	-
Other Dipstick Method	3	3	-
SD Bioline hCG	9	9	-
Siemens Clinitek Status / Status+	10	10	-
Stanbio QuStick	1	1	-



## MISCELLANEOUS CULTURES

### Specimen BA-4 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pediococcus acidilactici	61	68.54%	Acceptable
Pediococcus sp.	10	11.24%	Acceptable
Gram positive cocci	6	6.74%	Acceptable
Streptococcus non-hemolytic	3	3.37%	
Streptococcus alpha-hemolytic	2	2.25%	
Staphylococcus aureus	2	2.25%	

Organism(s) present: *Pediococcus acidilactici*

### Specimen BA-5 – Stool Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Vibrio parahaemolyticus	71	77.17%	Acceptable
Vibrio sp.	4	4.35%	Acceptable
Gram negative bacilli	3	3.26%	Acceptable
Pseudomonas sp.	3	3.26%	
Pasteurella multocida	2	2.17%	
Vibrio vulnificus	2	2.17%	

Organism(s) present: *Vibrio parahaemolyticus*

## MISCELLANEOUS CULTURES

### Specimen BA-6 – Eye Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Haemophilus parainfluenzae	38	29.01%	Acceptable
Corynebacterium sp.	21	16.03%	Acceptable
Haemophilus sp.	20	15.27%	Acceptable
Gram positive bacilli	7	5.34%	Acceptable
Corynebacterium xerosis	4	3.05%	Acceptable
Gram negative bacilli	3	2.29%	Acceptable
Gram negative coccobacilli	2	1.53%	Acceptable
Pasteurella sp.	9	6.87%	
Haemophilus influenzae	7	5.34%	
Gram positive cocci	3	2.29%	
Micrococcus sp.	3	2.29%	
Kocuria rosea	3	2.29%	
Staphylococcus aureus	2	1.53%	
Haemophilus parahaemolyticus	2	1.53%	

Organism(s) present: *Haemophilus parainfluenzae* and *Corynebacterium xerosis*. This challenge was graded by referee consensus.

**ANTIMICROBIAL SUSCEPTIBILIY TESTING**

**Specimen UC-6, CC-6 (SUS-6)** Organism(s) present: *Acinetobacter baumannii*

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>
	<i>Interpretative category data</i>				<i>Interpretative category data</i>				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Amikacin	25	1	-	24	67	15	-	52	82.61%
Amoxicillin/Clavulanate	9	-	-	9	5	-	-	5	100.00%
Ampicillin	6	-	-	6	20	2	-	18	92.31%
Ampicillin/Sulbactam	14	2	3	9	90	3	2	85	90.38%
Aztreonam	3	-	-	3	7	1	-	6	90.00%
Cefazolin	3	-	-	3	15	1	-	14	Inappropriate drug <sup>1</sup>
Cefdinir	2	-	-	2	-	-	-	-	Inappropriate drug <sup>1</sup>
Cefepime	14	-	1	13	121	5	29	87	96.29%
Cefixime	8	-	-	8	3	-	-	3	Inappropriate drug <sup>1</sup>
Cefoperazone	2	-	-	2	1	1	-	-	Inappropriate drug <sup>1</sup>
Cefotaxime	15	-	-	15	30	1	1	28	95.56%
Cefoxitin	2	-	-	2	5	1	-	4	Inappropriate drug <sup>1</sup>
Cefpodoxime	1	-	-	1	-	-	-	-	Inappropriate drug <sup>1</sup>
Ceftaroline	2	-	-	2	1	-	-	1	Inappropriate drug <sup>1</sup>
Ceftazidime	24	-	-	24	123	3	1	119	97.28%
Ceftizoxime	-	-	-	-	2	-	1	1	Inappropriate drug <sup>1</sup>
Ceftolozane/Tazobactam	2	1	-	1	1	1	-	-	Inappropriate drug <sup>1</sup>
Ceftriaxone	24	-	-	24	66	1	-	65	98.89%
Cefuroxime	8	-	-	8	5	1	-	4	Inappropriate drug <sup>1</sup>
Ciprofloxacin	30	-	-	30	131	2	-	129	98.76%
Colistin	1	1	-	-	14	12	2	-	100.00%
Doripenem	3	1	-	2	13	10	3	-	87.50%
Doxycycline	7	7	-	-	-	-	-	-	100.00%
Ertapenem	4	1	-	3	6	-	1	5	80.00%
Fosfomycin	7	-	1	6	3	1	-	2	80.00%
Gentamicin	24	-	-	24	115	2	1	112	97.84%
Imipenem	23	22	-	1	77	72	2	3	94.00%
Levofloxacin	17	-	1	16	60	3	-	57	94.81%
Lomefloxacin	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Meropenem	20	16	1	3	121	119	1	1	95.74%

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

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

**Specimen UC-6, CC-6 (SUS-6)** Organism(s) present: *Acinetobacter baumannii*

<u>Antimicrobial</u>	<u>-----Disk Diffusion-----</u>				<u>-----MIC-----</u>				<u>Acceptable (%)</u>
	<u>Interpretative category data</u>				<u>Interpretative category data</u>				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Minocycline	3	3	-	-	6	6	-	-	100.00%
Moxifloxacin	1	-	-	1	-	-	-	-	Inappropriate drug <sup>1</sup>
Nalidixic Acid	2	-	-	2	2	-	-	2	Inappropriate drug <sup>1</sup>
Netilmicin	4	-	-	4	-	-	-	-	100.00%
Nitrofurantoin	8	-	-	8	7	2	1	4	Inappropriate drug <sup>1</sup>
Norfloxacin	4	-	-	4	10	1	-	9	Inappropriate drug <sup>1</sup>
Ofloxacin	5	-	1	4	-	-	-	-	Inappropriate drug <sup>1</sup>
Penicillin	1	-	-	1	1	1	-	-	Inappropriate drug <sup>1</sup>
Piperacillin	1	-	-	1	3	-	-	3	100.00%
Piperacillin/Tazobactam	21	2	1	18	78	2	10	66	95.96%
Polymyxin B	2	2	-	-	1	1	-	-	100.00%
Sulfonamides	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Teicoplanin	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Tetracycline	5	1	-	4	5	1	-	4	80.00%
Ticarcillin/Clavulanate	1	-	-	1	4	1	-	3	80.00%
Tigecycline	-	-	-	-	7	7	-	-	Inappropriate drug <sup>1</sup>
Tobramycin	6	-	-	6	21	-	-	21	100.00%
Trimethoprim	-	-	-	-	5	1	-	4	80.00%
Trimethoprim/Sulfamethoxazole	23	-	-	23	106	2	-	104	98.45%
Vancomycin	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>

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

## PARASITOLOGY (PA Specimens)

### Specimen PA-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Endolimax nana	2	66.67%	Acceptable
Protozoan cyst or trophozoite seen	1	33.33%	Acceptable

Parasite(s) present: *Endolimax nana*

### Specimen PA-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	3	100%	Acceptable

Parasite(s) present: Negative (Sterile)

### Specimen PA-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	9	52.94%	Acceptable
Trichuris trichiura eggs	7	41.18%	Acceptable

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

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

**Specimen PA-9**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Clonorchis sinensis	12	80.00%	Acceptable
Pollen artifact	2	13.33%	
Taenia sp. eggs	1	6.67%	

Parasite(s) present: *Clonorchis sinensis*

**Specimen PA-10**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	12	92.30%	Acceptable

Parasite(s) present:

## PARASITOLOGY (FP Specimens)

### Specimen FP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. eggs	204	68.23%	Acceptable
Parasite egg or larva seen – no ID	1	0.33%	Acceptable
Blastocystis hominis	35	11.71%	
No parasite seen	28	9.36%	
Ascaris lumbricoides eggs	17	5.69%	
Endolimax nana	5	1.67%	

Parasite(s) present: *Taenia* sp. eggs. This challenge was graded by referee consensus.

**PARASITOLOGY (FP Specimens)**

**Specimen FP-7**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	257	93.12%	Acceptable
Protozoan cyst or trophozoite seen – no ID	1	0.36%	Acceptable
Endolimax nana	5	1.81%	
Blastocystis hominis	3	1.09%	
No parasite seen	3	1.09%	

Parasite(s) present: *Giardia lamblia*



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

**Specimen FP-8**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Paragonimus westermani eggs	108	38.85%	Not graded
No parasite seen	50	17.99%	
Diphyllobothrium latum	46	16.55%	
Fasciola hepatica eggs	42	15.11%	
Clonorchis sinensis	9	3.24%	
Endolimax nana	5	1.80%	
Hookworm	3	1.08%	
Blastocystis hominis	3	1.08%	
Enterobius vermicularis eggs	3	1.08%	

Parasite(s) present: *Paragonimus westermani* eggs. This challenge is not graded due to lack of referee consensus.

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

**Specimen FP-9**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba coli	216	39.78%	Acceptable
Ascaris lumbricoides eggs	174	32.04%	Acceptable
Entamoeba histolytica	49	9.02%	Acceptable
Protozoan cyst or trophozoite seen – no ID	1	0.18%	Acceptable
Iodamoeba buetschlii	52	9.58%	
Endolimax nana	18	3.31%	
Blastocystis hominis	15	2.76%	
Enterobius vermicularis eggs	4	0.74%	
No parasite seen	3	0.55%	

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

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

**Specimen FP-10**

<b><u>Identification</u></b>	<b><u>Labs</u></b>	<b><u>Percent</u></b>	<b><u>Performance</u></b>
No parasite seen	207	82.74%	Acceptable
Plasmodium sp.	17	6.77%	
Plasmodium vivax	10	3.98%	
Plasmodium falciparum			

Parasite(s) present: Negative (Sterile)

**Antinuclear Antibody (ANA) - Qualitative**

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	17	17	1	18	-
Bio-Rad	-	2	2	-	2	-
BioSystems	-	1	-	1	1	-
Human	1	-	1	-	1	-
Immuno Concepts	-	2	2	-	2	-
INOVA Diagnostics	-	7	7	-	7	-
Kallestad	-	1	1	-	1	-

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	18	18	-
Bio-Rad	-	2	2	-
BioSystems	-	1	1	-
Human	-	1	1	-
Immuno Concepts	-	2	2	-
INOVA Diagnostics	-	7	7	-
Kallestad	-	1	1	-

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

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

**Specimen AE-6**

ALL METHODS	15	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	6	-	-	-	-	-	-	-	-	-	-	-
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-7**

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

**Specimen AE-8**

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

**Specimen AE-9**

ALL METHODS	15	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	3	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	6	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

**Specimen AE-10**

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

**Anti-dsDNA**

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	2	19	12	9
BioSystems	-	2	-	2	1	1
Human	-	1	-	1	-	1
Immuno Concepts	-	2	-	2	1	1
INOVA Diagnostics	-	10	2	8	7	3
Kallestad	-	1	-	1	1	-

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	2	19
BioSystems	-	2	-	2
Human	-	1	-	1
Immuno Concepts	-	2	-	2
INOVA Diagnostics	-	10	2	8
Kallestad	-	1	-	1

**Anti-RNP**

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	14	8	6	12	2
INOVA Diagnostics	-	11	8	3	11	-

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	14	14	-
INOVA Diagnostics	-	11	11	-

**Anti-RNP/Sm**

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	4	2	2	4	-
Immuno Concepts	-	1	1	-	1	-

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	4	4	-
Immuno Concepts	-	1	1	-

**Anti-SSA**

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	19	16	3	1	18
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	12	10	2	-	12

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	19	-	19
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	12	-	12

**Anti-SSB**

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	19	19	-	-	19
Immuno Concepts	-	1	1	-	-	1
INOVA Diagnostics	-	12	12	-	-	12

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	19	-	19
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	12	-	12

**Anti-SSA/SSB**

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<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-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	-	-	-



**Anti-Sm**

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	19	-	19	1	18
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	12	-	12	-	12

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	19	10	9
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	12	10	2

**Rubella—Qualitative**

<b><u>Method</u></b>	<b>Specimen RU-6</b>		<b>Specimen RU-7</b>		<b>Specimen RU-8</b>	
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	-	17	16	1	-	17
Abbott Architect	-	12	11	1	-	12
Roche cobas 6000 / e 601	-	2	2	-	-	2
Roche cobas e 411	-	1	1	-	-	1
Siemens Atellica	-	1	1	-	-	1

<b><u>Method</u></b>	<b>Specimen RU-9</b>		<b>Specimen RU-10</b>	
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>
ALL METHODS	16	1	16	1
Abbott Architect	11	1	11	1
Roche cobas 6000 / e 601	2	-	2	-
Roche cobas e 411	1	-	1	-
Siemens Atellica	1	-	1	-

**Rubella—Quantitative (IU/mL)**

<b><u>Specimen/Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
<b>Specimen RU-6</b>						
All Method	19	0.07	0.12	176.0	0.0	0.0 - 0.5
Abbott Architect	12	0.00	0.01	0.0	0.0	0.0 - 0.1
<b>Specimen RU-7</b>						
All Method	21	68.56	39.43	57.5	44.9	0.0 - 186.9
Abbott Architect	13	43.11	2.98	6.9	43.5	34.1 - 52.1
<b>Specimen RU-8</b>						
All Method	20	0.09	0.17	193.8	0.0	0.0 - 0.7
Abbott Architect	13	0.00	0.01	0.0	0.0	0.0 - 0.1
<b>Specimen RU-9</b>						
All Method	21	68.86	38.92	56.5	45.7	0.0 - 185.7
Abbott Architect	13	43.61	3.10	7.1	43.3	34.3 - 53.0
<b>Specimen RU-10</b>						
All Method	21	44.29	27.80	62.8	27.8	0.0 - 127.7
Abbott Architect	13	26.71	1.84	6.9	26.8	21.1 - 32.3

**Syphilis Serology—Qualitative: VDRL Slide**

<b><u>Method</u></b>	<b>Specimen SY-6</b>			<b>Specimen SY-7</b>			<b>Specimen SY-8</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	55	2	-	1	-	56	48	3	6
Abbott Architect	1	-	-	-	-	1	1	-	-
Acon Laboratories	2	-	-	-	-	2	-	-	2
BioSystems	1	-	-	-	-	1	-	-	1
Lorne Laboratories	2	-	-	-	-	2	1	1	-
Omega Diagnostics	4	-	-	-	-	4	4	-	-
Plasmatec	1	1	-	-	-	2	2	-	-
SPINREACT	2	-	-	-	-	2	2	-	-
Standard Diagnostics	1	-	-	-	-	1	1	-	-
Wiener Lab	38	1	-	1	-	38	35	1	3

<b><u>Method</u></b>	<b>Specimen SY-9</b>			<b>Specimen SY-10</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	-	55	56	-	1
Abbott Architect	-	-	1	1	-	-
Acon Laboratories	-	-	2	2	-	-
BioSystems	-	-	1	1	-	-
Lorne Laboratories	-	-	2	2	-	-
Omega Diagnostics	-	-	4	4	-	-
Plasmatec	-	-	2	2	-	-
SPINREACT	-	-	2	2	-	-
Standard Diagnostics	-	-	1	1	-	-
Wiener Lab	2	-	37	38	-	1

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

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>0 dils</u>	<u>1 dil</u>	<u>2 dils</u>	<u>4 dils</u>	<u>8 dils</u>	<u>16 dils</u>	<u>32 dils</u>	<u>&gt;32 dils</u>
<b>Specimen SY-6</b>									
ALL METHODS	-	-	3	8	19	16	6	-	-
Lorne Laboratories	-	-	1	1	-	-	-	-	-
Omega Diagnostics	-	-	-	1	1	-	2	-	-
Plasmatec	-	-	-	1	-	-	-	-	-
Wiener Lab	-	-	2	4	16	15	3	-	-
<b>Specimen SY-7</b>									
ALL METHODS	51	-	-	1	-	-	-	-	-
Lorne Laboratories	2	-	-	-	-	-	-	-	-
Omega Diagnostics	4	-	-	-	-	-	-	-	-
Plasmatec	1	-	-	-	-	-	-	-	-
Wiener Lab	39	-	-	1	-	-	-	-	-
<b>Specimen SY-8</b>									
ALL METHODS	3	3	8	21	15	1	1	-	-
Lorne Laboratories	-	-	2	-	-	-	-	-	-
Omega Diagnostics	-	-	1	1	1	-	1	-	-
Plasmatec	-	-	-	-	1	-	-	-	-
Wiener Lab	3	3	4	18	12	-	-	-	-

**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-9</b>									
ALL METHODS	50	-	-	1	1	-	-	-	-
Lorne Laboratories	2	-	-	-	-	-	-	-	-
Omega Diagnostics	4	-	-	-	-	-	-	-	-
Plasmatec	1	-	-	-	-	-	-	-	-
Wiener Lab	38	-	-	1	1	-	-	-	-
<b>Specimen SY-10</b>									
ALL METHODS	1	-	3	7	15	18	5	3	-
Lorne Laboratories	-	-	1	1	-	-	-	-	-
Omega Diagnostics	-	-	-	-	2	1	-	1	-
Plasmatec	-	-	-	1	-	-	-	-	-
Wiener Lab	1	-	2	4	10	17	4	2	-

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

<b><u>Method</u></b>	<b>Specimen SY-6</b>		<b>Specimen SY-7</b>		<b>Specimen SY-8</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	8	-	1	7	5	3
Abbott Architect	1	-	-	1	1	-
Biokit	1	-	-	1	-	1
Plasmatec	1	-	-	1	-	1
Serodia	3	-	-	3	3	-
Standard Diagnostics	1	-	1	-	-	1

  

	<b>Specimen SY-9</b>		<b>Specimen SY-10</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	1	7	7	1
Abbott Architect	-	1	1	-
Biokit	-	1	1	-
Plasmatec	-	1	1	-
Serodia	-	3	3	-
Standard Diagnostics	1	-	-	1

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

<b><u>Method</u></b>	<b>Specimen SY-6</b>		<b>Specimen SY-7</b>		<b>Specimen SY-8</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	49	-	1	48	43	6
Abbott Architect	8	-	1	7	7	1
Abon (Alere) Biopharm	1	-	-	1	-	1
Atlas Medical	1	-	-	1	1	-
bioMerieux	1	-	-	1	1	-
BioSystems	1	-	-	1	1	-
DiaSorin	2	-	-	2	2	-
Human	2	-	-	2	2	-
Omega Diagnostics	1	-	-	1	1	-
Plasmatec	1	-	-	1	1	-
Roche cobas 6000 / c 501	1	-	-	1	1	-
Roche cobas 8000/e801	1	-	-	1	1	-
Roche cobas e 411	1	-	-	1	1	-
Serodia	8	-	-	8	8	-
Siemens Immulite 2000	1	-	-	1	1	-
Standard Diagnostics	7	-	-	7	6	1
Wiener Lab	1	-	-	1	1	-

	<b>Specimen SY-9</b>		<b>Specimen SY-10</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	1	48	48	1
Abbott Architect	1	7	7	1
Abon (Alere) Biopharm	-	1	1	-
Atlas Medical	-	1	1	-
bioMerieux	-	1	1	-
BioSystems	-	1	1	-
DiaSorin	-	2	2	-
Human	-	2	2	-
Omega Diagnostics	-	1	1	-
Plasmatec	-	1	1	-
Roche cobas 6000 / c 501	-	1	1	-
Roche cobas 8000/e801	-	1	1	-
Roche cobas e 411	-	1	1	-
Serodia	-	8	8	-
Siemens Immulite 2000	-	1	1	-
Standard Diagnostics	-	7	7	-
Wiener Lab	-	1	1	-



**Syphilis Serology—Qualitative: RPR**

<u>Method</u>	<u>Specimen SY-6</u>		<u>Specimen SY-7</u>		<u>Specimen SY-8</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	89	-	2	87	81	8
Atlas Medical	1	-	-	1	1	-
Becton Dickinson	2	-	-	2	2	-
bioMerieux	5	-	-	5	4	1
BioSystems	13	-	-	13	11	2
Human	6	-	-	6	6	-
Lorne Laboratories	11	-	-	11	11	-
Omega Diagnostics	13	-	-	13	12	1
Plasmatec	15	-	1	14	14	1
Pulse Scientific	1	-	-	1	1	-
SPINREACT	16	-	-	16	16	-
Wiener Lab	1	-	1	-	-	1

	<u>Specimen SY-9</u>		<u>Specimen SY-10</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	4	85	87	2
Atlas Medical	-	1	1	-
Becton Dickinson	-	2	2	-
bioMerieux	-	5	5	-
BioSystems	-	13	13	-
Human	-	6	6	-
Lorne Laboratories	-	11	11	-
Omega Diagnostics	2	11	12	1
Plasmatec	-	15	15	-
Pulse Scientific	-	1	1	-
SPINREACT	1	15	16	-
Wiener Lab	1	-	-	1

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

<b><u>Specimen/Method</u></b>	<b><u>N/A (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-6</b>									
ALL METHODS	-	1	9	27	31	9	2	-	-
Atlas Medical	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	1	-	-	-
bioMerieux	-	-	-	2	1	-	-	-	-
BioSystems	-	-	-	2	9	2	1	-	-
Human	-	-	-	4	-	1	1	-	-
Lorne Laboratories	-	-	1	4	3	-	-	-	-
Omega Diagnostics	-	-	2	5	3	2	-	-	-
Plasmatec	-	-	5	2	2	-	-	-	-
Pulse Scientific	-	-	-	-	1	-	-	-	-
SPINREACT	-	-	-	4	12	3	-	-	-
Wiener Lab	-	1	-	-	-	-	-	-	-

**Specimen SY-7**

ALL METHODS	77	1	1	-	-	-	-	-	-
Atlas Medical	1	-	-	-	-	-	-	-	-
Becton Dickinson	2	-	-	-	-	-	-	-	-
bioMerieux	3	-	-	-	-	-	-	-	-
BioSystems	14	-	-	-	-	-	-	-	-
Human	6	-	-	-	-	-	-	-	-
Lorne Laboratories	8	-	-	-	-	-	-	-	-
Omega Diagnostics	12	-	-	-	-	-	-	-	-
Plasmatec	8	1	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	19	-	-	-	-	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-	-

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

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>&gt;64</u>
<b>Specimen SY-8</b>									
ALL METHODS	4	15	31	21	3	4	1	-	-
Atlas Medical	-	1	-	-	-	-	-	-	-
Becton Dickinson	-	-	1	-	1	-	-	-	-
bioMerieux	1	-	2	-	-	-	-	-	-
BioSystems	1	2	2	5	2	2	-	-	-
Human	-	4	1	-	-	1	-	-	-
Lorne Laboratories	-	1	5	2	-	-	-	-	-
Omega Diagnostics	1	4	5	1	-	1	-	-	-
Plasmatec	-	2	1	5	-	-	1	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	-	12	7	-	-	-	-	-
Wiener Lab	1	-	-	-	-	-	-	-	-

**Specimen SY-9**

ALL METHODS	77	-	1	1	-	-	-	-	-
Atlas Medical	1	-	-	-	-	-	-	-	-
Becton Dickinson	2	-	-	-	-	-	-	-	-
bioMerieux	3	-	-	-	-	-	-	-	-
BioSystems	14	-	-	-	-	-	-	-	-
Human	6	-	-	-	-	-	-	-	-
Lorne Laboratories	8	-	-	-	-	-	-	-	-
Omega Diagnostics	12	-	-	-	-	-	-	-	-
Plasmatec	9	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	18	-	-	1	-	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-	-

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

<u>Specimen/Method</u>	<u>N/A</u> <u>(Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>&gt;64</u>
<b>Specimen SY-10</b>									
ALL METHODS	1	-	9	28	28	7	4	1	1
Atlas Medical	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	1	-	-	-
bioMerieux	-	-	-	3	-	-	-	-	-
BioSystems	-	-	1	4	6	2	1	-	-
Human	-	-	-	3	1	-	2	-	-
Lorne Laboratories	-	-	1	4	3	-	-	-	-
Omega Diagnostics	-	-	2	7	2	-	1	-	-
Plasmatec	-	-	4	2	1	-	-	1	1
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	-	-	2	13	4	-	-	-
Wiener Lab	1	-	-	-	-	-	-	-	-

**Viral Markers – Anti-HBc (IgM)**

<b><u>Method</u></b>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	43	1	-	1	43	-	1	43	-
Abbott Alinity	2	-	-	-	2	-	-	2	-
Abbott Architect	24	-	-	-	24	-	-	24	-
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	6	-	-	-	6	-	-	6	-
Roche cobas 8000/e801	5	-	-	-	5	-	-	5	-
Siemens ADVIA Centaur VITROS	2	-	-	-	2	-	-	2	-
3600/4600/5600/7600	3	-	-	-	3	-	-	3	-

<b><u>Method</u></b>	<b>Specimen VM-9</b>			<b>Specimen VM-10</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	41	-	-	44	-
Abbott Alinity	-	2	-	-	2	-
Abbott Architect	1	23	-	-	24	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	6	-	-	6	-
Roche cobas 8000/e801	-	5	-	-	5	-
Siemens ADVIA Centaur VITROS	2	-	-	-	2	-
3600/4600/5600/7600	-	3	-	-	3	-

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

<u>Method</u>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</b>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	66	4	-	3	67	-	3	67	-
Abbott Alinity	5	-	-	-	5	-	-	5	-
Abbott Architect	37	1	-	-	38	-	1	37	-
Beckman ACCESS / 2 / Dxl	2	-	-	1	1	-	-	2	-
DiaSorin	1	-	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	6	-	-	-	6	-	-	6	-
Roche cobas 8000/e801	5	-	-	-	5	-	-	5	-
Roche cobas e 411	4	-	-	-	4	-	-	4	-
Siemens ADVIA Centaur	2	-	-	-	2	-	-	2	-
Siemens Atellica	1	-	-	-	1	-	-	1	-
Siemens Immulite 2000	-	1	-	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	2	1	-	1	2	-	1	2	-

<u>Method</u>	<b>Specimen VM-9</b>			<b>Specimen VM-10</b>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	67	3	-	3	67	-
Abbott Alinity	5	-	-	-	5	-
Abbott Architect	38	-	-	2	36	-
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	6	-	-	-	6	-
Roche cobas 8000/e801	5	-	-	-	5	-
Roche cobas e 411	4	-	-	-	4	-
Siemens ADVIA Centaur	2	-	-	-	2	-
Siemens Atellica	1	-	-	-	1	-
Siemens Immulite 2000	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	2	1	-	1	2	-

## Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	170	-	-	170	-	1	169	-
Abbott Alinity	-	8	-	-	8	-	-	8	-
Abbott Architect	-	68	-	-	68	-	-	68	-
Acon Laboratories	-	1	-	-	1	-	-	1	-
Alere Clearview HIV1/2 STAT-PAK	-	3	-	-	3	-	-	3	-
Alere Determine HIV - moderate	-	3	-	-	3	-	-	3	-
Alere Determine HIV - waived	-	1	-	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	-	4	-	-	4	-	-	4	-
DiaSorin	-	3	-	-	3	-	-	3	-
DiaSorin	-	2	-	-	2	-	-	2	-
Human	-	3	-	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	28	-	-	28	-	-	28	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
Roche cobas e 411	-	14	-	-	14	-	1	13	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	-	1	-
Roche Modular Analytics	-	2	-	-	2	-	-	2	-
Siemens ADVIA Centaur	-	5	-	-	5	-	-	5	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
Standard Diagnostics	-	5	-	-	5	-	-	5	-
VITROS 3600/4600/5600/7600	-	5	-	-	5	-	-	5	-
VITROS ECI	-	1	-	-	1	-	-	1	-

**Viral Markers – Anti-HIV- cont'd**

<b><u>Method</u></b>	<b>Specimen VM-9</b>			<b>Specimen VM-10</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	-	170	-	170	-	-
Abbott Alinity	-	8	-	8	-	-
Abbott Architect	-	68	-	68	-	-
Acon Laboratories	-	1	-	1	-	-
Alere Clearview HIV1/2 STAT-PAK	-	3	-	3	-	-
Alere Determine HIV - moderate	-	3	-	3	-	-
Alere Determine HIV - waived	-	1	-	1	-	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	-	4	-	4	-	-
DiaSorin	-	3	-	3	-	-
Human	-	2	-	2	-	-
Roche cobas 6000 / e 601	-	3	-	3	-	-
Roche cobas 8000/e801	-	28	-	28	-	-
Roche cobas e 411	-	4	-	4	-	-
Roche Elecsys 1010 / 2010	-	14	-	14	-	-
Roche Modular Analytics	-	1	-	1	-	-
Siemens ADVIA Centaur	-	2	-	2	-	-
Siemens Atellica	-	5	-	5	-	-
Standard Diagnostics	-	1	-	1	-	-
VITROS	-	5	-	5	-	-
3600/4600/5600/7600	-	5	-	5	-	-
VITROS Eci	-	1	-	1	-	-



**Viral Markers – Anti-HAV (IgM)**

<u>Method</u>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</b>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	59	-	-	59	-	-	59	-
Abbott Architect	-	33	-	-	33	-	-	33	-
bioMerieux Vidas, Mini Vidas	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	8	-	-	8	-	-	8	-
Roche cobas 8000/e801	-	5	-	-	5	-	-	5	-
Roche cobas e 411	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	2	-	-	2	-	-	2	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
Standard Diagnostics	-	3	-	-	3	-	-	3	-
VITROS 3600/4600/5600/7600	-	2	-	-	2	-	-	2	-

<u>Method</u>	<b>Specimen VM-9</b>			<b>Specimen VM-10</b>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	59	-	-	59	-
Abbott Architect	-	33	-	-	33	-
bioMerieux Vidas, Mini Vidas	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	8	-	-	8	-
Roche cobas 8000/e801	-	5	-	-	5	-
Roche cobas e 411	-	1	-	-	1	-
Siemens ADVIA Centaur	-	2	-	-	2	-
Siemens Atellica	-	1	-	-	1	-
Standard Diagnostics	-	3	-	-	3	-
VITROS 3600/4600/5600/7600	-	2	-	-	2	-

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

<b><u>Method</u></b>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	1	58	-	23	36	-	59	-	-
Abbott Architect	-	31	-	22	9	-	31	-	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-	1	-	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	11	-	-	11	-	11	-	-
Roche cobas 8000/e801	-	3	-	-	3	-	3	-	-
Roche cobas e 411	1	5	-	1	5	-	6	-	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	1	-	-
Siemens ADVIA Centaur	-	4	-	-	4	-	4	-	-
Siemens Atellica	-	1	-	-	1	-	1	-	-

<b><u>Method</u></b>	<b>Specimen VM-9</b>			<b>Specimen VM-10</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	57	2	-	58	1	-
Abbott Architect	31	-	-	31	-	-
Beckman ACCESS / 2 / Dxl	1	-	-	1	-	-
bioMerieux Vidas, Mini Vidas	1	-	-	1	-	-
Roche cobas 6000 / e 601	10	1	-	11	-	-
Roche cobas 8000/e801	3	-	-	3	-	-
Roche cobas e 411	5	1	-	5	1	-
Roche Elecsys 1010 / 2010	1	-	-	1	-	-
Siemens ADVIA Centaur	4	-	-	4	-	-
Siemens Atellica	1	-	-	1	-	-

**Viral Markers – HBeAg**

<b><u>Method</u></b>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</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	29	-	1	31	-	2	30	-
Abbott Architect	-	17	-	-	17	-	-	17	-
DiaSorin	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	1	5	-	1	5	-	1	5	-
Roche cobas 8000/e801	-	5	-	-	5	-	-	5	-
Siemens ADVIA Centaur	1	-	-	-	1	-	1	-	-
Siemens Atellica	1	-	-	-	1	-	-	1	-
VITROS									
3600/4600/5600/7600	-	1	-	-	1	-	-	1	-

<b><u>Method</u></b>	<b>Specimen VM-9</b>			<b>Specimen VM-10</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	29	-	2	30	-
Abbott Architect	-	17	-	-	17	-
DiaSorin	-	1	-	-	1	-
Roche cobas 6000 / e 601	1	5	-	2	4	-
Roche cobas 8000/e801	-	5	-	-	5	-
Siemens ADVIA Centaur	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-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</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	109	1	23	89	1	113	-	-
Abbott Alinity	-	6	-	1	5	-	6	-	-
Abbott Architect	-	45	-	12	33	-	45	-	-
Beckman ACCESS / 2 / DxI	-	3	-	-	3	-	3	-	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	2	18	-	6	14	-	20	-	-
Roche cobas 8000/e801	-	5	-	-	5	-	5	-	-
Roche cobas e 411	-	11	1	3	8	1	12	-	-
Roche Elecsys 1010 / 2010	-	2	-	-	2	-	2	-	-
Roche Modular Analytics	-	1	-	-	1	-	1	-	-
Siemens ADVIA Centaur	1	4	-	-	5	-	5	-	-
Siemens Atellica	-	1	-	-	1	-	1	-	-
Siemens Immulite 2000	-	1	-	-	1	-	1	-	-
Standard Diagnostics	-	3	-	-	3	-	3	-	-
VITROS 3600/4600/5600/7600	-	5	-	-	5	-	5	-	-
VITROS ECI	-	2	-	-	2	-	2	-	-

<b><u>Method</u></b>	<b>Specimen VM-9</b>			<b>Specimen VM-10</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	110	1	113	-	-
Abbott Alinity	-	6	-	6	-	-
Abbott Architect	-	45	-	45	-	-
Beckman ACCESS / 2 / DxI	-	3	-	3	-	-
bioMerieux Vidas, Mini Vidas	-	1	-	1	-	-
Roche cobas 6000 / e 601	2	18	-	20	-	-
Roche cobas 8000/e801	-	5	-	5	-	-
Roche cobas e 411	-	11	1	12	-	-
Roche Elecsys 1010 / 2010	-	2	-	2	-	-
Roche Modular Analytics	-	1	-	1	-	-
Siemens ADVIA Centaur	-	5	-	5	-	-
Siemens Atellica	-	1	-	1	-	-
Siemens Immulite 2000	-	1	-	1	-	-
Standard Diagnostics	-	3	-	3	-	-
VITROS 3600/4600/5600/7600	-	5	-	5	-	-
VITROS ECI	-	2	-	2	-	-

**Viral Markers – HBsAg**

<b><u>Method</u></b>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</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	170	2	-	5	167	-	2	170	-
Abbott Alinity	8	-	-	1	7	-	-	8	-
Abbott Architect	64	1	-	2	63	-	1	64	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	4	-	-	1	3	-	-	4	-
DiaSorin	1	-	-	-	1	-	-	1	-
Human	1	-	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	27	-	-	-	27	-	1	26	-
Roche cobas 8000/e801	5	-	-	1	4	-	-	5	-
Roche cobas e 411	17	-	-	-	17	-	-	17	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-	-	1	-
Roche Modular Analytics	2	-	-	-	2	-	-	2	-
Siemens ADVIA Centaur	7	-	-	-	7	-	-	7	-
Siemens Atellica	1	-	-	-	1	-	-	1	-
Standard Diagnostics	16	-	-	-	16	-	-	16	-
VITROS									
3600/4600/5600/7600	5	-	-	-	5	-	-	5	-
VITROS Eci	1	-	-	-	1	-	-	1	-

**Viral Markers – HBsAg-cont'd**

<b><u>Method</u></b>	<b>Specimen VM-9</b>			<b>Specimen VM-10</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	170	2	-	8	164	-
Abbott Alinity	8	-	-	-	8	-
Abbott Architect	63	2	-	5	60	-
Beckman ACCESS / 2 / Dxl	4	-	-	-	4	-
bioMerieux Vidas, Mini						
Vidas	1	-	-	-	1	-
DiaSorin	1	-	-	-	1	-
Human	1	-	-	-	1	-
Roche cobas 6000 / e 601	27	-	-	-	27	-
Roche cobas 8000/e801	5	-	-	-	5	-
Roche cobas e 411	17	-	-	1	16	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-
Roche Modular Analytics	2	-	-	-	2	-
Siemens ADVIA Centaur	7	-	-	1	6	-
Siemens Atellica	1	-	-	-	1	-
Standard Diagnostics	16	-	-	-	16	-
VITROS						
3600/4600/5600/7600	5	-	-	-	5	-
VITROS Eci	1	-	-	-	1	-

**Viral Markers – Anti-HCV**

<b><u>Method</u></b>	<b>Specimen VM-6</b>			<b>Specimen VM-7</b>			<b>Specimen VM-8</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	38	107	4	-	149	-	-	149	-
Abbott Alinity	-	8	-	-	8	-	-	8	-
Abbott Architect	1	62	-	-	63	-	-	63	-
Beckman ACCESS / 2 / Dxl	-	3	-	-	3	-	-	3	-
DiaSorin	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	20	-	3	-	23	-	-	23	-
Roche cobas 8000/e801	4	-	-	-	4	-	-	4	-
Roche cobas e 411	10	1	1	-	12	-	-	12	-
Roche Modular Analytics	1	-	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	5	-	-	5	-	-	5	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
Standard Diagnostics	-	11	-	-	11	-	-	11	-
VITROS									
3600/4600/5600/7600	-	5	-	-	5	-	-	5	-
VITROS Eci	-	2	-	-	2	-	-	2	-

<b><u>Method</u></b>	<b>Specimen VM-9</b>			<b>Specimen VM-10</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	149	-	-	-	149	-
Abbott Alinity	8	-	-	-	8	-
Abbott Architect	63	-	-	-	63	-
Beckman ACCESS / 2 / Dxl	3	-	-	-	3	-
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	23	-	-	-	23	-
Roche cobas 8000/e801	4	-	-	-	4	-
Roche cobas e 411	12	-	-	-	12	-
Roche Modular Analytics	1	-	-	-	1	-
Siemens ADVIA Centaur	5	-	-	-	5	-
Siemens Atellica	1	-	-	-	1	-
Standard Diagnostics	11	-	-	-	11	-
VITROS						
3600/4600/5600/7600	5	-	-	-	5	-
VITROS Eci	2	-	-	-	2	-

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

<b><u>Method</u></b>	<b>Specimen TOX-3</b>			<b>Specimen TOX-4</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	18	-	-	1	16	1
Abbott Architect	12	-	-	-	12	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	1	-	-	1	-	-
DiaSorin	2	-	-	-	2	-
Roche cobas 6000 / e 601	1	-	-	-	1	-
Roche cobas e 411	1	-	-	-	-	1

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

<b><u>Specimen/Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
<b>Specimen TOX-3</b>						
All Method	20	497.035	302.086	60.8	383.50	0.00 - 1403.30
Abbott Architect	15	487.380	322.656	66.2	200.00	0.00 - 1455.35
<b>Specimen TOX-4</b>						
All Method	19	0.407	0.237	58.3	0.40	0.00 - 1.12
Abbott Architect	15	0.507	0.144	28.4	0.50	0.07 - 0.94



### Toxoplasma gondii Antibody (IgM) - Qualitative

<b><u>Method</u></b>	<b>Specimen TOX-3</b>			<b>Specimen TOX-4</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	21	-	-	-	21	-
Abbott Architect	14	-	-	-	14	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	1	-	-	-	1	-
DiaSorin	2	-	-	-	2	-
Roche cobas 6000 / e 601	1	-	-	-	1	-
Roche cobas e 411	2	-	-	-	2	-
	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-3</b>						
All Method	19	8.705	3.804	43.7	7.59	0.00 - 20.12
All Roche Instruments	3	16.973	0.847	5.0	17.38	14.43 - 19.52
Abbott Architect	13	7.404	0.673	9.1	7.45	5.38 - 9.43
<b>Specimen TOX-4</b>						
All Method	20	0.163	0.063	38.7	0.15	0.00 - 0.36
All Roche Instruments	3	0.240	0.010	4.2	0.24	0.21 - 0.27
Abbott Architect	13	0.132	0.028	21.0	0.14	0.04 - 0.22

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

<b><u>Method</u></b>	<b>Specimen CMV-3</b>			<b>Specimen CMV-4</b>		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	1	14	-	15	-	-
Abbott Architect	1	12	-	13	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-

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

<b><u>Specimen/Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
<b>Specimen CMV-3</b>						
All Method	16	1.361	0.785	57.7	1.55	0.00 - 3.72
Abbott Architect	13	1.654	0.524	31.7	1.70	0.08 - 3.23
<b>Specimen CMV-4</b>						
All Method	16	19.786	8.620	43.6	19.70	0.00 - 45.65
Abbott Architect	13	23.192	5.036	21.7	24.50	8.08 - 38.31

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

<b><u>Method</u></b>	<b>Specimen CMV-3</b>			<b>Specimen CMV-4</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	14	1	17	-	-
Abbott Architect	2	12	1	15	-	-
Roche cobas 6000 / e 601	-	2	-	2	-	-

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

<b><u>Specimen/Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
<b>Specimen CMV-3</b>						
All Method	14	0.711	0.467	65.8	0.77	0.00 - 2.12
Abbott Architect	12	0.804	0.438	54.4	0.82	0.00 - 2.12
<b>Specimen CMV-4</b>						
All Method	14	9.459	1.914	20.2	9.61	3.71 - 15.21
Abbott Architect	12	10.048	1.254	12.5	9.92	6.28 - 13.82

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

<u>Method</u>	<b>Specimen NB-6</b>						<b>Specimen NB-7</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	49	16.71	0.72	4.3	16.7	13.3 - 20.1	49	5.72	0.35	6.1	5.7	4.5 - 6.9
No Reagent Required												
Bilirubinometer / Unistat	38	16.82	0.61	3.6	16.8	13.4 - 20.2	38	5.68	0.31	5.5	5.7	4.5 - 6.9
All Chemistry Instruments	42	16.81	0.60	3.6	16.8	13.4 - 20.2	42	5.73	0.34	6.0	5.7	4.5 - 6.9
<u>Method</u>	<b>Specimen NB-8</b>						<b>Specimen NB-9</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	49	10.35	0.62	6.0	10.4	8.2 - 12.5	45	0.01	0.03	378.3	0.0	0.0 - 0.5
No Reagent Required												
Bilirubinometer / Unistat	39	10.45	0.47	4.5	10.4	8.3 - 12.6	39	0.00	0.01	0.0	0.0	0.0 - 0.4
All Chemistry Instruments	43	10.47	0.47	4.5	10.4	8.3 - 12.6	39	0.00	0.01	0.0	0.0	0.0 - 0.4
<u>Method</u>	<b>Specimen NB-10</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	46	0.02	0.05	308.8	0.0	0.0 - 0.5						
No Reagent Required												
Bilirubinometer / Unistat	38	0.00	0.01	0.0	0.0	0.0 - 0.4						
All Chemistry Instruments	39	0.01	0.03	624.4	0.0	0.0 - 0.5						

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

<u>Method</u>	<b>Specimen NB-6</b>						<b>Specimen NB-7</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	11	4.13	0.70	16.9	3.8	2.7 - 5.6	11	1.70	0.32	18.6	1.6	1.0 - 2.4
<u>Method</u>	<b>Specimen NB-8</b>						<b>Specimen NB-9</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	11	4.91	0.44	8.9	4.8	4.0 - 5.8	11	0.11	0.16	136.5	0.1	0.0 - 0.5
<u>Method</u>	<b>Specimen NB-10</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	11	0.12	0.15	122.7	0.1	0.0 - 0.5						

**Glycohemoglobin (percent)**

<u>Method</u>	<u>Specimen GH-3</u>						<u>Specimen GH-4</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	117	10.74	0.32	3.0	10.7	10.2 - 11.3	120	6.12	0.23	3.8	6.1	5.8 - 6.5
All Bio-Rad Methods	5	10.96	0.38	3.5	11.0	10.4 - 11.6	5	6.38	0.23	3.6	6.3	6.0 - 6.7
All Enzymatic A1c Methods	5	10.14	0.65	6.5	10.4	9.6 - 10.7	6	5.77	0.27	4.7	5.7	5.4 - 6.1
All Hemoglobin A1c Methods	113	10.75	0.32	3.0	10.7	10.2 - 11.3	114	6.14	0.22	3.5	6.1	5.8 - 6.5
All Roche Methods	12	10.71	0.29	2.7	10.7	10.1 - 11.3	12	5.83	0.17	2.9	5.8	5.5 - 6.2
All TOSOH Methods	14	10.80	0.20	1.9	10.8	10.2 - 11.4	14	6.13	0.11	1.9	6.1	5.8 - 6.5
Beckman AU A1c	8	10.51	0.33	3.2	10.6	9.9 - 11.1	8	6.06	0.16	2.6	6.1	5.7 - 6.4
Bio-Rad D-10 HbA1C	5	10.96	0.38	3.5	11.0	10.4 - 11.6	5	6.38	0.23	3.6	6.3	6.0 - 6.7
Roche cobas c 501 HbA1c	6	10.63	0.30	2.8	10.6	10.1 - 11.2	6	5.73	0.12	2.1	5.8	5.4 - 6.1
Roche Integra A1C	5	10.82	0.31	2.9	10.7	10.2 - 11.4	5	5.94	0.18	3.1	5.9	5.6 - 6.3
Siemens DCA Vantage	52	10.83	0.24	2.3	10.9	10.2 - 11.4	53	6.21	0.18	2.9	6.2	5.8 - 6.6
Siemens Dimension HA1C	4	10.63	0.68	6.4	10.4	10.0 - 11.2	4	6.10	0.22	3.5	6.2	5.7 - 6.5
Siemens Dimension HB1C	11	10.39	0.29	2.8	10.4	9.8 - 11.0	11	6.17	0.25	4.0	6.2	5.8 - 6.5
TOSOH G8	14	10.80	0.20	1.9	10.8	10.2 - 11.4	14	6.13	0.11	1.9	6.1	5.8 - 6.5

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

<u>Method</u>	<u>Specimen WBG-6</u>						<u>Specimen WBG-7</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	796	304.8	23.5	7.7	311	243 - 366	816	104.7	10.7	10.2	108	83 - 126
All Abbott Methods	40	283.3	23.2	8.2	282	226 - 340	41	88.1	7.5	8.5	88	70 - 106
All Arkray Methods	6	323.3	66.9	20.7	297	258 - 388	7	116.0	2.9	2.5	116	92 - 140
All Bayer Methods	21	238.0	18.9	7.9	233	190 - 286	21	80.3	6.0	7.5	78	64 - 97
All Hemocue Methods	48	304.5	8.6	2.8	305	243 - 366	47	122.1	7.2	5.9	122	97 - 147
All Lifescan Methods	11	336.5	25.9	7.7	334	269 - 404	10	108.4	8.3	7.7	107	86 - 131
All Roche Methods	493	312.5	6.4	2.0	313	250 - 376	493	107.7	2.4	2.3	108	86 - 130
Abbott FreeStyle Lite/Freedom Lite	7	293.1	7.5	2.6	289	234 - 352	7	96.6	2.4	2.5	97	77 - 116
Abbott FreeStyle Precision Pro	21	275.9	23.7	8.6	272	220 - 332	22	85.1	6.7	7.9	85	68 - 103
Abbott Precision XceedPro	12	290.6	25.0	8.6	286	232 - 349	12	88.7	7.3	8.2	88	70 - 107
Arkray Platinum	22	299.2	11.3	3.8	298	239 - 360	24	116.5	2.4	2.1	117	93 - 140
Bayer Contour	31	233.0	17.2	7.4	227	186 - 280	31	79.1	5.3	6.7	77	63 - 95
HemoCue Glucose 201	58	304.6	7.1	2.3	303	243 - 366	58	120.9	6.5	5.4	120	96 - 146
Home Diagnostics True Balance / TrueTrack	12	581.4	19.4	3.3	584	465 - 698	12	265.3	10.3	3.9	265	212 - 319
Lifescan One Touch Ultra	34	345.3	16.0	4.6	344	276 - 415	32	110.1	3.5	3.2	110	88 - 133
Medline EvenCare G2 / G3	12	299.8	26.6	8.9	306	239 - 360	13	110.4	7.9	7.1	111	88 - 133
NOVA Biomedical StatStrip	56	232.7	79.7	34.2	259	186 - 280	55	87.3	4.3	4.9	86	69 - 105
Quintet / AC	23	324.0	13.0	4.0	321	259 - 389	23	104.7	4.7	4.5	105	83 - 126
Roche Accu-Chek Active	18	248.3	3.7	1.5	249	198 - 298	18	90.4	2.0	2.2	90	72 - 109
Roche Accu-Chek Inform	11	317.5	4.7	1.5	318	253 - 381	11	107.5	2.2	2.0	108	86 - 130
Roche Accu-Chek Inform II	343	312.4	6.4	2.1	312	249 - 375	342	107.6	2.5	2.4	108	86 - 130
Roche Accu-Chek Performa	136	312.6	6.0	1.9	313	250 - 376	136	108.1	2.1	1.9	108	86 - 130
True Metrix Pro	15	282.7	18.7	6.6	286	226 - 340	15	87.8	3.1	3.5	87	70 - 106

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

<u>Method</u>	<u>Specimen WBG-8</u>						<u>Specimen WBG-9</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	189	64.0	7.7	12.0	69	51 - 77	189	57.0	7.4	12.9	61	45 - 70
All Abbott Methods	7	53.7	3.0	5.6	54	41 - 66	7	44.4	3.6	8.1	44	32 - 57
All Lifescan Methods	4	-	-	-	59	46 - 71	4	-	-	-	50	37 - 62
All Roche Methods	100	70.3	1.3	1.9	70	56 - 85	99	62.9	1.5	2.3	63	50 - 76
Abbott FreeStyle Precision Pro	2	-	-	-	55	41 - 66	2	-	-	-	42	32 - 57
Abbott Precision XceedPro	5	53.4	2.6	4.9	54	41 - 66	5	45.6	3.2	7.0	44	33 - 58
Lifescan One Touch Ultra	28	60.3	2.9	4.8	61	48 - 73	28	52.1	2.5	4.7	53	40 - 65
Medline EvenCare G2 / G3	1	-	-	-	63	50 - 76	1	-	-	-	58	46 - 70
NOVA Biomedical StatStrip	30	54.3	3.5	6.4	54	42 - 67	30	47.0	3.8	8.2	47	34 - 59
Roche Accu-Chek Active	18	54.8	2.1	3.9	55	42 - 67	18	53.2	2.6	4.9	53	41 - 66
Roche Accu-Chek Inform	10	70.4	1.0	1.4	71	56 - 85	10	63.6	2.4	3.7	63	50 - 77
Roche Accu-Chek Inform II	80	70.3	1.3	1.9	70	56 - 85	80	62.9	1.5	2.4	63	50 - 76
Roche Accu-Chek Performa	11	69.2	4.3	6.2	70	55 - 84	11	64.2	3.9	6.1	63	51 - 78
True Metrix Pro	1	-	-	-	56	44 - 68	1	-	-	-	49	37 - 61

<u>Method</u>	<u>Specimen WBG-10</u>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	188	411.8	37.7	9.2	429	329 - 495
All Abbott Methods	7	406.3	16.4	4.0	409	325 - 488
All Lifescan Methods	4	-	-	-	435	348 - 523
All Roche Methods	102	430.7	7.5	1.7	432	344 - 517
Abbott FreeStyle Precision Pro	2	-	-	-	397	325 - 488
Abbott Precision XceedPro	5	410.2	18.2	4.4	420	328 - 493
Lifescan One Touch Ultra	28	441.8	9.8	2.2	444	353 - 531
Medline EvenCare G2 / G3	1	-	-	-	389	311 - 467
NOVA Biomedical StatStrip	29	374.8	16.3	4.4	376	299 - 450

**Folate (ng/mL)**

<u>Method</u>	<b>Specimen SC-3</b>						<b>Specimen SC-4</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	23	2.12	0.82	38.9	2.4	1.1 - 3.2	22	3.89	1.72	44.3	4.8	2.7 - 5.1
All Roche Instruments	9	1.78	0.50	28.2	2.0	0.7 - 2.8	8	2.95	0.58	19.6	3.1	1.9 - 4.0
All Siemens Dimension Instruments	7	1.79	0.13	7.5	1.8	0.7 - 2.8	7	3.06	0.35	11.5	3.1	2.0 - 4.1
All TOSOH Instruments	8	1.49	0.56	37.8	1.4	0.4 - 2.5	8	2.74	0.47	17.3	2.7	1.7 - 3.8
Beckman ACCESS / 2 / Dxl	25	2.71	0.32	12.0	2.7	1.7 - 3.8	25	5.71	0.56	9.8	5.7	3.9 - 7.5
Roche cobas e 601/e 602	6	1.67	0.60	35.9	2.0	0.6 - 2.7	6	3.10	0.59	18.9	3.2	2.1 - 4.1
Siemens Dimension	5	1.76	0.15	8.6	1.8	0.7 - 2.8	5	3.02	0.41	13.5	3.1	2.0 - 4.1

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

<u>Method</u>	<b>Specimen CK-6</b>						<b>Specimen CK-7</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	5	79.15	17.18	21.7	79.2	27.6 - 130.7	5	15.40	3.39	22.0	15.4	5.2 - 25.6
<u>Method</u>	<b>Specimen CK-8</b>						<b>Specimen CK-9</b>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	5	43.20	8.77	20.3	43.2	16.8 - 69.6	5	24.85	5.44	21.9	24.9	8.5 - 41.2
<u>Method</u>	<b>Specimen CK-10</b>											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	5	6.10	1.56	25.5	6.1	1.4 - 10.8						

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