

# MEDICAL LABORATORY

# EVALUATION

## PARTICIPANT SUMMARY

# 2 • 0 • 1 • 9

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

International Data Supplement  
2019 MLE-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	$\pm 15\%$	International Normalized Ratio (INR)	$\pm 20\%$
Automated Differential	$\pm 3$ SD	Platelet Count	$\pm 25\%$
Bilirubin, Neonatal (Total)	$\pm 0.4$ mg/dL or $20\%$ *	Prothrombin Time	$\pm 15\%$
Bilirubin, Direct	$\pm 2$ SD	Red Blood Cell Count	$\pm 6\%$
CK-MB (U/L)	$\pm 3$ SD	Rubella	$\pm 3$ SD
Cytomegalovirus	$\pm 2$ SD	Sedimentation Rate	$\pm 2$ SD
Fibrinogen	$\pm 20\%$	Specific Gravity	$\pm 0.010$
Glucose, Whole Blood	$\pm 12$ mg/dL or $\pm 20\%$ *	Toxoplasma	$\pm 2$ SD
Glycohemoglobin	$\pm 6\%$	White Blood Cell Count	$\pm 15\%$
Hematocrit	$\pm 6\%$		
Hemoglobin	$\pm 7\%$		

**SEDIMENTATION RATE (MM/HR)**

<u>Instrument</u>	Specimen ES-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	172	45.6	11.1	24.3	43	23 - 68	173	7.1	2.8	38.9	7	1 - 13
All Automated Methods	39	57.8	10.6	18.3	58	36 - 79	39	7.6	3.6	47.4	7	0 - 15
All Diese Methods	12	65.7	10.5	16.0	66	44 - 87	12	9.2	4.3	47.2	8	0 - 18
All Manual Methods	119	41.1	8.1	19.6	40	25 - 58	118	6.8	2.4	35.2	7	2 - 12
All Vital Diagnostics Methods	15	53.2	4.9	9.2	53	43 - 63	16	6.5	1.8	27.5	7	2 - 11
Vital Diagnostics Excyte M/10	10	53.1	5.3	10.1	53	42 - 64	10	6.4	1.1	16.8	7	4 - 9
Westergren - diluted	91	41.3	7.6	18.4	40	26 - 57	92	6.5	2.4	37.3	7	1 - 12
Westergren - undiluted	22	39.4	8.3	21.2	38	22 - 57	22	8.0	1.8	22.8	8	4 - 12

**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	29	6.58	0.71	10.8	6.4	5.5 - 7.6	29	8.81	0.77	8.7	8.6	7.4 - 10.2
All Abbott Cell-Dyn Instruments	11	7.22	0.22	3.0	7.3	6.1 - 8.4	11	9.52	0.26	2.7	9.5	8.0 - 11.0
Abbott Cell-Dyn Ruby	10	7.21	0.23	3.2	7.3	6.1 - 8.3	10	9.52	0.27	2.8	9.6	8.0 - 11.0
Orphee Mythic 22	14	6.01	0.36	5.9	6.1	5.1 - 7.0	14	8.19	0.39	4.8	8.3	6.9 - 9.5

  

<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	29	2.57	0.38	15.0	2.4	2.1 - 3.0	29	18.04	1.69	9.4	17.6	15.3 - 20.8
All Abbott Cell-Dyn Instruments	11	2.95	0.12	4.1	2.9	2.5 - 3.4	11	19.46	0.54	2.8	19.3	16.5 - 22.4
Abbott Cell-Dyn Ruby	10	2.97	0.12	3.9	3.0	2.5 - 3.5	10	19.53	0.51	2.6	19.4	16.6 - 22.5
Orphee Mythic 22	14	2.24	0.12	5.5	2.3	1.9 - 2.6	14	16.72	0.98	5.8	16.8	14.2 - 19.3

  

<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	29	2.61	0.44	17.0	2.5	2.2 - 3.1
All Abbott Cell-Dyn Instruments	11	3.06	0.16	5.1	3.0	2.6 - 3.6
Abbott Cell-Dyn Ruby	10	3.07	0.16	5.3	3.0	2.6 - 3.6
Orphee Mythic 22	14	2.25	0.15	6.5	2.2	1.9 - 2.6

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

Specimen CL-6							Specimen CL-7					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	29	4.444	0.138	3.1	4.43	4.17 - 4.72	29	6.356	0.212	3.3	6.36	5.97 - 6.74
All Abbott Cell-Dyn Instruments	11	4.584	0.082	1.8	4.60	4.30 - 4.86	11	6.570	0.134	2.0	6.56	6.17 - 6.97
Abbott Cell-Dyn Ruby	10	4.572	0.076	1.7	4.60	4.29 - 4.85	10	6.586	0.130	2.0	6.58	6.19 - 6.99
Orphee Mythic 22	14	4.353	0.086	2.0	4.34	4.09 - 4.62	14	6.214	0.137	2.2	6.19	5.84 - 6.59
Specimen CL-8							Specimen CL-9					
All Method	29	2.229	0.067	3.0	2.21	2.09 - 2.37	29	5.188	0.145	2.8	5.22	4.87 - 5.50
All Abbott Cell-Dyn Instruments	11	2.282	0.064	2.8	2.27	2.14 - 2.42	11	5.293	0.116	2.2	5.33	4.97 - 5.62
Abbott Cell-Dyn Ruby	10	2.272	0.059	2.6	2.27	2.13 - 2.41	10	5.289	0.121	2.3	5.31	4.97 - 5.61
Orphee Mythic 22	14	2.185	0.039	1.8	2.19	2.05 - 2.32	14	5.115	0.133	2.6	5.09	4.80 - 5.43
Specimen CL-10												
All Method	29	2.238	0.064	2.9	2.23	2.10 - 2.38						
All Abbott Cell-Dyn Instruments	11	2.286	0.056	2.4	2.29	2.14 - 2.43						
Abbott Cell-Dyn Ruby	10	2.281	0.056	2.4	2.29	2.14 - 2.42						
Orphee Mythic 22	14	2.201	0.040	1.8	2.20	2.06 - 2.34						

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

Specimen CL-6							Specimen CL-7					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	29	12.38	0.97	7.8	12.0	11.5 - 13.3	29	16.61	1.30	7.8	15.9	15.4 - 17.8
All Abbott Cell-Dyn Instruments	11	13.40	0.32	2.4	13.5	12.4 - 14.4	11	18.00	0.29	1.6	18.0	16.7 - 19.3
Abbott Cell-Dyn Ruby	10	13.36	0.30	2.3	13.5	12.4 - 14.3	10	18.02	0.30	1.7	18.1	16.7 - 19.3
Orphee Mythic 22	14	11.51	0.24	2.1	11.5	10.7 - 12.4	14	15.43	0.29	1.9	15.4	14.3 - 16.6
Specimen CL-8							Specimen CL-9					
All Method	28	5.25	0.46	8.8	5.1	4.8 - 5.7	29	15.76	0.70	4.5	15.6	14.6 - 16.9
All Abbott Cell-Dyn Instruments	11	5.68	0.18	3.2	5.7	5.2 - 6.1	11	16.36	0.48	2.9	16.4	15.2 - 17.6
Abbott Cell-Dyn Ruby	10	5.64	0.13	2.2	5.7	5.2 - 6.1	10	16.37	0.50	3.1	16.5	15.2 - 17.6
Orphee Mythic 22	14	4.85	0.16	3.2	4.8	4.5 - 5.2	14	15.24	0.42	2.7	15.1	14.1 - 16.4
Specimen CL-10												
All Method	28	5.25	0.45	8.6	5.0	4.8 - 5.7						
All Abbott Cell-Dyn Instruments	11	5.66	0.17	3.1	5.7	5.2 - 6.1						
Abbott Cell-Dyn Ruby	10	5.63	0.14	2.5	5.7	5.2 - 6.1						
Orphee Mythic 22	14	4.85	0.15	3.0	4.9	4.5 - 5.2						

**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	28	38.71	1.28	3.3	38.6	36.3 - 41.1	28	53.61	1.55	2.9	53.4	50.3 - 56.9
All Abbott Cell-Dyn Instruments	11	38.33	2.22	5.8	37.8	36.0 - 40.7	11	53.90	2.28	4.2	53.5	50.6 - 57.2
Abbott Cell-Dyn Ruby	10	37.68	0.58	1.5	37.8	35.4 - 40.0	10	53.28	1.03	1.9	53.3	50.0 - 56.5
Orphee Mythic 22	14	39.19	0.77	2.0	38.9	36.8 - 41.6	14	53.48	1.44	2.7	53.4	50.2 - 56.7
<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	29	16.46	0.89	5.4	16.3	15.4 - 17.5	28	47.26	2.20	4.6	46.9	44.4 - 50.1
All Abbott Cell-Dyn Instruments	11	16.04	1.08	6.7	15.8	15.0 - 17.0	11	46.10	2.59	5.6	45.4	43.3 - 48.9
Abbott Cell-Dyn Ruby	10	15.73	0.38	2.4	15.8	14.7 - 16.7	10	45.36	0.88	2.0	45.4	42.6 - 48.1
Orphee Mythic 22	14	16.62	0.40	2.4	16.6	15.6 - 17.7	13	47.66	0.94	2.0	47.5	44.8 - 50.6
<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	29	16.55	0.91	5.5	16.2	15.5 - 17.6						
All Abbott Cell-Dyn Instruments	11	16.07	0.93	5.8	15.9	15.1 - 17.1						
Abbott Cell-Dyn Ruby	10	15.81	0.36	2.3	15.9	14.8 - 16.8						
Orphee Mythic 22	14	16.75	0.50	3.0	16.8	15.7 - 17.8						

**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	28	278.0	20.9	7.5	271	208 - 348	26	121.2	23.5	19.3	120	90 - 152
All Abbott Cell-Dyn Instruments	11	270.6	17.4	6.4	268	202 - 339	8	145.6	17.1	11.8	148	109 - 183
Abbott Cell-Dyn Ruby	10	272.3	17.4	6.4	269	204 - 341	7	149.4	14.4	9.6	148	112 - 187
Orphee Mythic 22	13	286.6	21.2	7.4	293	214 - 359	14	115.6	14.7	12.7	117	86 - 145
<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	29	91.2	17.0	18.6	87	68 - 115	29	493.1	41.9	8.5	481	369 - 617
All Abbott Cell-Dyn Instruments	11	75.8	4.6	6.1	75	56 - 95	11	517.3	50.2	9.7	534	387 - 647
Abbott Cell-Dyn Ruby	10	75.3	4.5	6.0	75	56 - 95	10	526.8	41.1	7.8	540	395 - 659
Orphee Mythic 22	14	104.2	13.4	12.9	103	78 - 131	14	483.6	29.5	6.1	479	362 - 605
<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	28	92.6	18.0	19.4	96	69 - 116						
All Abbott Cell-Dyn Instruments	10	73.5	5.6	7.6	74	55 - 92						
Abbott Cell-Dyn Ruby	10	73.5	5.6	7.6	74	55 - 92						
Orphee Mythic 22	14	106.0	11.9	11.2	105	79 - 133						

**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	28	64.43	2.71	4.2	64.6	56.2 - 72.6	27	67.14	2.98	4.4	67.8	58.2 - 76.1
All Abbott Cell-Dyn Instruments	11	66.61	1.22	1.8	66.7	62.9 - 70.3	11	68.70	0.76	1.1	68.8	66.4 - 71.0
Abbott Cell-Dyn Ruby	10	66.57	1.28	1.9	66.6	62.7 - 70.5	10	68.69	0.80	1.2	68.8	66.2 - 71.2
Orphee Mythic 22	13	62.15	1.95	3.1	62.3	56.2 - 68.1	12	64.95	2.51	3.9	65.0	57.4 - 72.5
<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	28	44.56	2.72	6.1	44.7	36.3 - 52.8	28	71.85	2.79	3.9	71.6	63.4 - 80.3
All Abbott Cell-Dyn Instruments	11	46.16	1.69	3.7	45.9	41.0 - 51.3	11	73.99	0.92	1.2	74.1	71.2 - 76.8
Abbott Cell-Dyn Ruby	10	46.19	1.78	3.8	46.0	40.8 - 51.6	10	73.96	0.96	1.3	74.0	71.0 - 76.9
Orphee Mythic 22	13	42.85	2.22	5.2	43.3	36.1 - 49.6	13	69.53	2.02	2.9	69.5	63.4 - 75.6
<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	28	45.04	3.00	6.7	45.3	36.0 - 54.1						
All Abbott Cell-Dyn Instruments	11	47.25	1.43	3.0	47.0	42.9 - 51.6						
Abbott Cell-Dyn Ruby	10	47.28	1.50	3.2	47.0	42.7 - 51.8						
Orphee Mythic 22	13	42.85	2.43	5.7	42.7	35.5 - 50.2						

**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	28	21.41	5.06	23.6	23.5	6.2 - 36.6	28	18.32	4.83	26.4	20.1	3.8 - 32.9
All Abbott Cell-Dyn Instruments	11	24.85	1.86	7.5	25.0	19.2 - 30.5	11	20.72	1.13	5.4	21.0	17.3 - 24.1
Abbott Cell-Dyn Ruby	10	24.98	1.91	7.6	25.4	19.2 - 30.8	10	20.69	1.18	5.7	21.1	17.1 - 24.3
Orphee Mythic 22	13	19.15	5.14	26.9	19.6	3.7 - 34.6	13	16.98	5.95	35.0	16.5	0.0 - 34.9
<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	28	35.56	7.49	21.1	37.6	13.0 - 58.1	28	15.81	3.70	23.4	17.2	4.7 - 26.9
All Abbott Cell-Dyn Instruments	11	41.15	3.35	8.1	42.2	31.1 - 51.2	11	17.66	0.76	4.3	17.5	15.3 - 20.0
Abbott Cell-Dyn Ruby	10	40.93	3.45	8.4	42.1	30.5 - 51.3	10	17.68	0.79	4.5	17.7	15.2 - 20.1
Orphee Mythic 22	13	31.26	7.12	22.8	30.1	9.9 - 52.7	13	14.62	4.44	30.4	13.9	1.2 - 28.0
<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	28	35.40	7.20	20.3	38.3	13.8 - 57.1						
All Abbott Cell-Dyn Instruments	11	41.11	1.97	4.8	41.7	35.1 - 47.1						
Abbott Cell-Dyn Ruby	10	41.30	1.97	4.8	41.8	35.3 - 47.3						
Orphee Mythic 22	13	31.50	7.05	22.4	31.6	10.3 - 52.7						



**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	28	10.95	5.81	53.1	11.5	0.0 - 28.4	28	10.16	5.09	50.1	11.9	0.0 - 25.5
All Abbott Cell-Dyn Instruments	11	5.40	1.09	20.2	5.0	2.1 - 8.7	11	5.07	0.60	11.8	4.9	3.2 - 6.9
Abbott Cell-Dyn Ruby	10	5.31	1.10	20.8	4.9	2.0 - 8.7	10	5.12	0.61	11.9	5.0	3.2 - 7.0
Orphee Mythic 22	13	15.52	3.25	20.9	16.1	5.7 - 25.3	13	14.35	2.27	15.8	15.0	7.5 - 21.2
<b>Specimen CL-8</b>												
All Method	28	15.75	8.12	51.6	16.0	0.0 - 40.2	28	8.33	4.79	57.6	9.4	0.0 - 22.8
All Abbott Cell-Dyn Instruments	11	8.32	2.75	33.0	7.3	0.0 - 16.6	11	3.65	0.29	8.1	3.7	2.7 - 4.6
Abbott Cell-Dyn Ruby	10	8.48	2.84	33.5	7.3	0.0 - 17.1	10	3.65	0.31	8.5	3.8	2.7 - 4.6
Orphee Mythic 22	13	21.96	5.03	22.9	22.7	6.8 - 37.1	13	12.23	2.48	20.3	12.1	4.7 - 19.7
<b>Specimen CL-10</b>												
All Method	28	16.65	10.22	61.4	16.9	0.0 - 47.3						
All Abbott Cell-Dyn Instruments	11	7.33	1.92	26.3	7.2	1.5 - 13.1						
Abbott Cell-Dyn Ruby	10	7.11	1.88	26.4	7.1	1.4 - 12.8						
Orphee Mythic 22	13	24.45	7.87	32.2	22.8	0.8 - 48.1						

**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	28	2.72	0.97	35.5	2.9	0.0 - 5.7	28	4.44	1.89	42.6	5.1	0.0 - 10.2
All Abbott Cell-Dyn Instruments	11	2.88	0.19	6.7	2.9	2.2 - 3.5	11	5.31	0.25	4.7	5.4	4.5 - 6.1
Abbott Cell-Dyn Ruby	10	2.87	0.20	7.0	2.9	2.2 - 3.5	10	5.30	0.26	5.0	5.4	4.5 - 6.1
Orphee Mythic 22	13	2.49	1.20	48.1	2.9	0.0 - 6.1	13	3.97	2.03	51.0	3.8	0.0 - 10.1
<b>Specimen CL-8</b>												
All Method	28	3.66	1.27	34.7	3.9	0.0 - 7.5	28	3.62	1.15	31.6	4.1	0.1 - 7.1
All Abbott Cell-Dyn Instruments	11	4.17	0.28	6.7	4.1	3.3 - 5.1	11	4.46	0.34	7.6	4.5	3.4 - 5.5
Abbott Cell-Dyn Ruby	10	4.20	0.28	6.6	4.2	3.3 - 5.1	10	4.47	0.36	8.0	4.6	3.3 - 5.6
Orphee Mythic 22	13	3.35	1.31	39.1	3.8	0.0 - 7.3	13	3.10	1.08	35.0	3.0	0.0 - 6.4
<b>Specimen CL-10</b>												
All Method	28	3.49	1.21	34.7	3.7	0.0 - 7.2						
All Abbott Cell-Dyn Instruments	11	4.14	0.66	15.9	4.1	2.1 - 6.2						
Abbott Cell-Dyn Ruby	10	4.14	0.69	16.7	4.1	2.0 - 6.3						
Orphee Mythic 22	13	2.96	1.16	39.1	3.3	0.0 - 6.5						

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

<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	28	0.44	0.35	79.8	0.3	0.0 - 1.6	28	0.32	0.26	81.8	0.3	0.0 - 1.2
All Abbott Cell-Dyn Instruments	11	0.25	0.21	84.2	0.2	0.0 - 0.9	11	0.16	0.09	56.5	0.2	0.0 - 0.5
Abbott Cell-Dyn Ruby	10	0.26	0.21	81.5	0.2	0.0 - 0.9	10	0.16	0.10	60.4	0.2	0.0 - 0.5
Orphee Mythic 22	13	0.56	0.38	67.6	0.5	0.0 - 1.8	13	0.42	0.29	69.0	0.5	0.0 - 1.3
<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	28	0.45	0.51	111.5	0.2	0.0 - 2.0	28	0.41	0.31	75.9	0.3	0.0 - 1.4
All Abbott Cell-Dyn Instruments	11	0.16	0.27	166.9	0.1	0.0 - 1.0	11	0.19	0.12	64.0	0.2	0.0 - 0.6
Abbott Cell-Dyn Ruby	10	0.18	0.28	156.7	0.1	0.0 - 1.1	10	0.19	0.13	67.7	0.2	0.0 - 0.6
Orphee Mythic 22	13	0.58	0.49	84.4	0.5	0.0 - 2.1	13	0.58	0.33	56.7	0.5	0.0 - 1.6
<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	27	0.37	0.45	119.9	0.2	0.0 - 1.8						
All Abbott Cell-Dyn Instruments	11	0.06	0.13	202.1	0.0	0.0 - 0.5						
Abbott Cell-Dyn Ruby	10	0.05	0.13	253.9	0.0	0.0 - 0.5						
Orphee Mythic 22	13	0.55	0.44	79.3	0.5	0.0 - 1.9						

## BLOOD BANK

### ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-6	Group B	27	100%	Acceptable
BB-7	Group A	27	100%	Acceptable
BB-8	Group O	26	100%	Acceptable
BB-9	Group A	27	100%	Acceptable
BB-10	Group O	27	100%	Acceptable

### RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-6	Rh Negative	27	100%	Acceptable
BB-7	Rh Negative	27	100%	Acceptable
BB-8	Rh Positive	26	100%	Acceptable
BB-9	Rh Positive	27	100%	Acceptable
BB-10	Rh Positive	27	100%	Acceptable

## 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	18	94.74%	Acceptable
	Unexpected antibody detected	1	5.26%	
AB-7	Unexpected antibody detected	20	100%	Acceptable
AB-8	No unexpected antibody detected	20	100%	Acceptable
AB-9	No unexpected antibody detected	20	100%	Acceptable
AB-10	Unexpected antibody detected	20	100%	Acceptable

### ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	No antibody detected	11	100%	Acceptable
AB-7	Anti-D	11	100%	Acceptable
AB-8	No antibody detected	11	100%	Acceptable
AB-9	No antibody detected	11	100%	Acceptable
AB-10	Anti-K	11	100%	Acceptable

## BLOOD BANK

### COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	Compatible	17	89.47%	Acceptable
	Not Compatible	2	10.53%	
AB-7	Not Compatible	18	90.00%	Acceptable
	Compatible	2	10.00%	
AB-8	Compatible	20	100%	Acceptable
AB-9	Compatible	20	100%	Acceptable
AB-10	Compatible	18	90.00%	Acceptable
	Not Compatible	2	10.00%	

# 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	67	12.75	1.50	11.7	12.6	10.8 - 14.7	67	12.32	1.71	13.9	12.5	10.4 - 14.2
Dade Innovin												
Dade Behring BFT II	5	10.40	0.27	2.6	10.5	8.8 - 12.0	5	9.55	0.17	1.8	9.6	8.1 - 11.0
Sysmex CA-500/600 series	13	11.17	0.22	1.9	11.1	9.4 - 12.9	13	10.51	0.19	1.8	10.4	8.9 - 12.1
All Coagulation Instruments	20	11.13	0.56	5.0	11.1	9.4 - 12.8	20	10.42	0.57	5.5	10.4	8.8 - 12.0
Diag Stago STA Neoplastine CI+												
RAL Clot-SP	16	14.39	0.47	3.3	14.4	12.2 - 16.6	16	13.61	0.39	2.9	13.8	11.5 - 15.7
All Coagulation Instruments	19	14.34	0.53	3.7	14.4	12.1 - 16.5	19	13.55	0.40	2.9	13.5	11.5 - 15.6
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	13.60	0.01	0.0	13.6	11.5 - 15.7	5	13.50	0.14	1.0	13.5	11.4 - 15.6
RAL Clot-SP	5	14.35	0.21	1.5	14.4	12.1 - 16.6	5	13.50	0.28	2.1	13.5	11.4 - 15.6
All Coagulation Instruments	10	13.98	0.45	3.2	13.9	11.8 - 16.1	10	13.50	0.18	1.4	13.5	11.4 - 15.6
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	11.84	0.42	3.6	11.7	10.0 - 13.7	5	12.88	2.54	19.7	11.9	10.9 - 14.9
HUMAN HemoStat Thromboplastin - SI												
Human HumaClot Junior	5	15.65	2.90	18.5	15.7	13.3 - 18.0	5	14.80	3.11	21.0	14.8	12.5 - 17.1
IL TEST PT Fibrinogen												
IL ACL, all models	5	12.80	0.62	4.9	12.6	10.8 - 14.8	5	12.68	0.98	7.7	12.4	10.7 - 14.6

**PROTHROMBIN TIME (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	67	15.36	1.60	10.4	15.2	13.0 - 17.7	67	35.73	5.09	14.2	37.5	30.3 - 41.1
Dade Innovin												
Dade Behring BFT II	5	13.08	0.29	2.2	13.0	11.1 - 15.1	5	35.13	1.72	4.9	35.8	29.8 - 40.4
Sysmex CA-500/600 series	13	13.58	0.25	1.8	13.7	11.5 - 15.7	13	31.84	1.31	4.1	32.0	27.0 - 36.7
All Coagulation Instruments	20	13.45	0.35	2.6	13.5	11.4 - 15.5	20	33.05	2.41	7.3	32.7	28.0 - 38.1
Diag Stago STA Neoplastine CI+												
RAL Clot-SP	16	16.96	0.53	3.1	17.0	14.4 - 19.6	16	39.96	1.46	3.7	39.8	33.9 - 46.0
All Coagulation Instruments	19	16.90	0.52	3.1	16.9	14.3 - 19.5	19	40.21	1.49	3.7	40.0	34.1 - 46.3
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	16.20	0.01	0.0	16.2	13.7 - 18.7	5	38.50	0.14	0.4	38.5	32.7 - 44.3
RAL Clot-SP	5	17.15	0.35	2.1	17.2	14.5 - 19.8	5	40.35	2.05	5.1	40.4	34.2 - 46.5
All Coagulation Instruments	10	16.68	0.59	3.5	16.6	14.1 - 19.2	10	39.43	1.60	4.0	38.8	33.5 - 45.4
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	15.10	0.19	1.2	15.2	12.8 - 17.4	5	39.00	1.63	4.2	39.9	33.1 - 44.9
HUMAN HemoStat Thromboplastin - SI												
Human HumaClot Junior	5	16.55	2.33	14.1	16.6	14.0 - 19.1	5	33.50	6.22	18.6	33.5	28.4 - 38.6
IL TEST PT Fibrinogen												
IL ACL, all models	5	15.35	0.98	6.4	15.0	13.0 - 17.7	5	26.28	0.94	3.6	26.1	22.3 - 30.3

**PROTHROMBIN TIME (seconds)**

<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	66	24.94	3.01	12.1	26.0	21.2 - 28.7
Dade Innovin						
Dade Behring BFT II	5	25.28	1.76	6.9	25.3	21.4 - 29.1
Sysmex CA-500/600 series	13	22.14	1.54	7.0	22.0	18.8 - 25.5
All Coagulation Instruments	20	23.05	2.01	8.7	22.6	19.5 - 26.6
Diag Stago STA Neoplastine CI+						
RAL Clot-SP	16	27.78	1.24	4.4	27.5	23.6 - 32.0
All Coagulation Instruments	19	27.73	1.14	4.1	27.5	23.5 - 31.9
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STA Compact	5	26.75	0.35	1.3	26.8	22.7 - 30.8
RAL Clot-SP	5	27.85	1.06	3.8	27.9	23.6 - 32.1
All Coagulation Instruments	10	27.30	0.91	3.3	27.1	23.2 - 31.4
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	26.24	0.60	2.3	26.5	22.3 - 30.2
HUMAN HemoStat Thromboplastin - SI						
Human HumaClot Junior	4	-	-	-	21.5	21.2 - 28.7
IL TEST PT Fibrinogen						
IL ACL, all models	5	20.95	0.98	4.7	20.9	17.8 - 24.1



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

<b><u>Reagent/Instrument</u></b>	<b>Specimen CG-6</b>						<b>Specimen CG-7</b>					
	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
All Method	63	1.10	0.08	7.5	1.1	0.8 - 1.4	63	1.04	0.07	6.3	1.0	0.8 - 1.3
Dade Innovin												
Dade Behring BFT II	5	1.15	0.06	5.0	1.2	0.9 - 1.4	5	1.08	0.05	4.7	1.1	0.8 - 1.3
Sysmex CA-500/600 series	13	1.09	0.06	5.9	1.1	0.8 - 1.4	13	1.03	0.06	6.1	1.0	0.8 - 1.3
All Coagulation Instruments	20	1.11	0.06	5.8	1.1	0.8 - 1.4	20	1.04	0.06	5.8	1.0	0.8 - 1.3
Diag Stago STA Neoplastine CI+												
RAL Clot-SP	15	1.11	0.06	5.7	1.1	0.8 - 1.4	15	1.04	0.06	6.1	1.0	0.8 - 1.3
All Coagulation Instruments	18	1.12	0.06	5.5	1.1	0.8 - 1.4	18	1.03	0.06	5.7	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	5	1.00	0.01	0.0	1.0	0.8 - 1.2
RAL Clot-SP	5	1.10	0.01	0.0	1.1	0.8 - 1.4	5	1.00	0.01	0.0	1.0	0.8 - 1.2
All Coagulation Instruments	10	1.05	0.06	5.5	1.1	0.8 - 1.3	10	1.00	0.01	0.0	1.0	0.8 - 1.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	1.00	0.07	7.1	1.0	0.8 - 1.2	5	1.08	0.19	17.8	1.0	0.8 - 1.3
IL TEST PT Fibrinogen												
IL ACL, all models	5	1.15	0.13	11.2	1.2	0.9 - 1.4	5	1.13	0.19	16.8	1.1	0.9 - 1.4

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

<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	63	1.36	0.07	5.1	1.4	1.0 - 1.7	63	3.69	0.46	12.4	3.8	2.9 - 4.5
Dade Innovin												
Dade Behring BFT II	5	1.43	0.05	3.5	1.4	1.1 - 1.8	5	3.30	0.08	2.5	3.3	2.6 - 4.0
Sysmex CA-500/600 series	13	1.34	0.05	3.8	1.3	1.0 - 1.7	13	3.21	0.15	4.7	3.2	2.5 - 3.9
All Coagulation Instruments	20	1.35	0.06	4.5	1.3	1.0 - 1.7	20	3.25	0.18	5.7	3.2	2.6 - 3.9
Diag Stago STA Neoplastine CI+												
RAL Clot-SP	15	1.38	0.06	4.1	1.4	1.1 - 1.7	15	4.01	0.13	3.3	4.0	3.2 - 4.9
All Coagulation Instruments	18	1.38	0.05	4.0	1.4	1.1 - 1.7	18	4.07	0.20	5.0	4.1	3.2 - 4.9
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	1.30	0.01	0.0	1.3	1.0 - 1.6	5	4.00	0.01	0.0	4.0	3.2 - 4.8
RAL Clot-SP	5	1.40	0.01	0.0	1.4	1.1 - 1.7	5	4.45	0.07	1.6	4.5	3.5 - 5.4
All Coagulation Instruments	10	1.35	0.06	4.3	1.4	1.0 - 1.7	10	4.23	0.26	6.2	4.2	3.3 - 5.1
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	1.28	0.08	6.5	1.3	1.0 - 1.6	5	3.42	0.25	7.3	3.4	2.7 - 4.2
IL TEST PT Fibrinogen												
IL ACL, all models	5	1.58	0.22	14.1	1.5	1.2 - 1.9	5	4.13	0.31	7.5	4.2	3.3 - 5.0

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

**Specimen CG-10**

<b><u>Reagent/Instrument</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
All Method	63	2.43	0.23	9.3	2.5	1.9 - 3.0
Dade Innovin						
Dade Behring BFT II	5	2.53	0.10	3.8	2.6	2.0 - 3.1
Sysmex CA-500/600 series	13	2.22	0.20	9.0	2.1	1.7 - 2.7
All Coagulation Instruments	20	2.29	0.21	9.2	2.2	1.8 - 2.8
Diag Stago STA Neoplastine CI+						
RAL Clot-SP	15	2.57	0.15	6.0	2.5	2.0 - 3.1
All Coagulation Instruments	18	2.58	0.14	5.6	2.5	2.0 - 3.1
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STA Compact	5	2.50	0.01	0.0	2.5	2.0 - 3.0
RAL Clot-SP	5	2.70	0.01	0.0	2.7	2.1 - 3.3
All Coagulation Instruments	10	2.60	0.12	4.4	2.6	2.0 - 3.2
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	2.26	0.15	6.7	2.2	1.8 - 2.8
IL TEST PT Fibrinogen						
IL ACL, all models	5	2.75	0.34	12.4	2.7	2.2 - 3.3

**ACTIVATED PARTIAL THROMBOPLASTIN (seconds)**

<b><u>Reagent/Instrument</u></b>	<b>Specimen CG-6</b>						<b>Specimen CG-7</b>					
	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
All Method	35	30.2	5.8	19.1	29	25 - 35	35	26.4	2.8	10.6	26	22 - 31
Dade Actin FSL												
Sysmex CA-500/600 series	7	24.3	0.8	3.1	24	20 - 28	7	23.3	0.5	2.1	23	19 - 27
All Coagulation Instruments	10	24.7	1.1	4.5	25	20 - 29	10	23.7	1.0	4.2	23	20 - 28
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	5	34.0	1.4	4.2	34	28 - 40	5	30.0	0.1	0.0	30	25 - 35
Hemoliance SynthASil												
IL ACL, all models	5	38.0	1.4	3.7	38	32 - 44	5	26.5	0.7	2.7	27	22 - 31
HemosIL APTT-SP												
IL ACL, all models	5	35.0	4.2	12.1	35	29 - 41	5	27.5	0.7	2.6	28	23 - 32
HUMAN HemoStat aPTT - EL												
Human HumaClot Junior	4	-	-	-	29	25 - 35	5	28.0	0.1	0.0	28	23 - 33
IL TEST APTT-SP												
IL ACL, all models	5	33.0	2.8	8.6	33	28 - 38	4	-	-	-	26	22 - 31

**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	35	34.6	5.6	16.3	35	29 - 40	36	48.3	4.8	9.9	48	41 - 56
Dade Actin FSL												
Sysmex CA-500/600 series	7	28.9	1.5	5.1	28	24 - 34	7	44.0	1.4	3.2	44	37 - 51
All Coagulation Instruments	10	29.1	1.5	5.0	29	24 - 34	10	44.6	1.8	4.1	45	37 - 52
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	5	42.0	0.1	0.0	42	35 - 49	5	54.0	1.4	2.6	54	45 - 63
Hemoliance SynthASil												
IL ACL, all models	5	35.0	0.1	0.0	35	29 - 41	5	49.5	0.7	1.4	50	42 - 57
HemosIL APTT-SP												
IL ACL, all models	5	38.5	4.9	12.9	39	32 - 45	5	47.5	4.9	10.4	48	40 - 55
HUMAN HemoStat aPTT - EL												
Human HumaClot Junior	4	-	-	-	33	29 - 40	5	55.0	2.8	5.1	55	46 - 64
IL TEST APTT-SP												
IL ACL, all models	5	40.5	3.5	8.7	41	34 - 47	5	44.5	2.1	4.8	45	37 - 52
<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	36	38.9	4.3	11.0	38	33 - 45						
Dade Actin FSL												
Sysmex CA-500/600 series	7	35.9	0.9	2.5	36	30 - 42						
All Coagulation Instruments	10	36.4	1.4	3.9	36	30 - 42						
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	5	44.0	0.1	0.0	44	37 - 51						
Hemoliance SynthASil												
IL ACL, all models	5	40.5	0.7	1.7	41	34 - 47						
HemosIL APTT-SP												
IL ACL, all models	5	38.5	3.5	9.2	39	32 - 45						
HUMAN HemoStat aPTT - EL												
Human HumaClot Junior	5	38.0	8.5	22.3	38	32 - 44						
IL TEST APTT-SP												
IL ACL, all models	5	35.5	0.7	2.0	36	30 - 41						

**FIBRINOGEN (mg/dL)**

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	8	438.2	57.7	13.2	450	350 - 526	8	255.0	34.5	13.5	257	204 - 306
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	5	452.3	40.8	9.0	468	361 - 543	5	279.3	20.3	7.3	289	223 - 336

  

Specimen CG-8							Specimen CG-9					
<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	8	142.8	19.8	13.8	143	114 - 172	8	258.4	8.0	3.1	263	206 - 311
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	5	147.7	13.6	9.2	143	118 - 178	5	260.7	6.8	2.6	263	208 - 313

  

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	8	255.0	25.0	9.8	267	204 - 306
Diagnostica Stago STA Fibrinogen						
Diagnostica Stago STA Compact	5	262.0	19.0	7.3	267	209 - 315

**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	164	1.0231	0.0053	0.5	1.025	1.013 - 1.034
All Arkray Methods	15	1.0260	0.0031	0.3	1.025	1.016 - 1.036
All Iris Diagnostics Methods	11	1.0245	0.0024	0.2	1.025	1.014 - 1.035
All Refractive Index Methods	27	1.0255	0.0032	0.3	1.025	1.015 - 1.036
All Roche Methods	37	1.0192	0.0051	0.5	1.020	1.009 - 1.030
All Siemens Methods	20	1.0198	0.0026	0.3	1.020	1.009 - 1.030
77 Elektronika LabUMat/2	16	1.0315	0.0015	0.2	1.032	1.021 - 1.042
Arkray Aution Sticks	13	1.0257	0.0032	0.3	1.025	1.015 - 1.036
Roche Chemstrips / Combur	13	1.0181	0.0025	0.2	1.020	1.008 - 1.029
Roche cobas u 411	21	1.0183	0.0024	0.2	1.020	1.008 - 1.029
Roche Urisys	16	1.0204	0.0072	0.7	1.015	1.010 - 1.031
Siemens Clinitek Status / Status+	16	1.0194	0.0024	0.2	1.020	1.009 - 1.030
UriScan Reagent Strips	18	1.0249	0.0028	0.3	1.025	1.014 - 1.035

## 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	191	-	-	-	142	23	22	1	2	1	-	-	-
77 Elektronika LabUMat/2	18	-	-	-	17	1	-	-	-	-	-	-	-
Acon Laboratories	4	-	-	-	2	-	2	-	-	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	1	-	-	-	-	-	-	-
Arkray Aution Sticks	14	-	-	-	11	3	-	-	-	-	-	-	-
Arkray PocketChem UA	1	-	-	-	-	-	-	-	1	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	1	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	1	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	-	-	-	8	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	4	-	-	-	3	1	-	-	-	-	-	-	-
Other Analyzer Method	4	-	-	-	2	2	-	-	-	-	-	-	-
Other Dipstick Method	3	-	-	-	2	-	1	-	-	-	-	-	-
Plasmatec URIPATH	1	-	-	-	1	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	27	-	-	-	26	-	1	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	1	-	-	-	-	-	-	-	-
Roche cobas u 411	21	-	-	-	21	-	-	-	-	-	-	-	-
Roche Urisys	17	-	-	-	16	-	-	1	-	-	-	-	-
SD UroColor Reagent Strips	10	-	-	-	3	2	4	-	1	-	-	-	-
Siemens Clinitek Advantus	4	-	-	-	-	2	2	-	-	-	-	-	-
Siemens Clinitek Status / Status+	16	-	-	-	9	7	-	-	-	-	-	-	-
Siemens Reagent Strips	13	-	-	-	2	-	11	-	-	-	-	-	-
Urinometer	1	-	-	-	-	1	-	-	-	-	-	-	-
UriScan Pro/II	2	-	-	-	1	1	-	-	-	-	-	-	-
UriScan Reagent Strips	17	-	-	-	14	2	-	-	-	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	193	188	-	3	-	-	-	1	-	-	1	-	-
77 Elektronika LabUMat/2	18	18	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	4	4	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	14	14	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	1	-	-	-	-	-	-	-	-	-	1	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	8	8	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	4	4	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	4	4	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	3	3	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	27	26	-	1	-	-	-	-	-	-	-	-	-
Roche cobas u 411	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	21	20	-	1	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	17	17	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	10	9	-	1	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	4	4	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	17	17	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	13	13	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	2	2	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	18	17	-	-	-	-	-	1	-	-	-	-	-

## 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	193	4	21	25	14	12	76	3	6	6	26
77 Elektronika LabUMat/2	19	-	-	1	-	-	10	1	-	-	7
Acon Laboratories	4	-	-	-	-	-	4	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	1	-	-	-	-
Arkray Aution Sticks	14	-	-	-	-	-	14	-	-	-	-
Arkray PocketChem UA	1	1	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	1	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	-	-	-	-	2	-	-	2	4	-
Iris Ichem VELOCITY Urine Chemistry System	4	-	-	1	1	1	-	-	-	1	-
Other Analyzer Method	4	-	-	-	-	-	3	-	-	-	1
Other Dipstick Method	3	-	1	-	1	1	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	27	-	-	-	-	3	23	1	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	1	-	-	-	-
Roche cobas u 411	21	-	-	-	-	3	10	-	-	-	8
Roche Urisys	17	-	-	-	-	-	6	-	1	-	10
SD UroColor Reagent Strips	10	1	-	1	5	-	2	-	1	-	-
Siemens Clinitek Advantus	4	-	3	1	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	16	-	5	9	2	-	-	-	-	-	-
Siemens Reagent Strips	13	-	7	5	1	-	-	-	-	-	-
Urinometer	1	-	-	-	1	-	-	-	-	-	-
UriScan Pro/II	2	-	-	1	-	-	-	-	1	-	-
UriScan Reagent Strips	18	1	5	5	3	1	-	1	1	1	-

**URINALYSIS DIPSTICK–KETONES**

**Specimen UA-2**

<u>Method</u>	<u>Labs</u>	<u>Participant Results</u>										<u>5 - 10</u> <u>mg/dL</u>	<u>15 - 25</u> <u>mg/dL</u>	<u>40 - 60</u> <u>mg/dL</u>	<u>≥80 - 100</u> <u>mg/dL</u>	<u>≥150</u> <u>mg/dL</u>
		<u>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>						
ALL METHODS	194	11	2	-	-	-	20	84	33	5	-	5	25	1	8	
77 Elektronika LabUMat/2	19	-	-	-	-	-	7	6	-	-	-	2	4	-	-	
Acon Laboratories	4	1	-	-	-	-	1	2	-	-	-	-	-	-	-	
Arkray Aution Jet	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	
Arkray Aution Sticks	14	-	-	-	-	-	-	14	-	-	-	-	-	-	-	
Arkray PocketChem UA	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-	
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	
Iris Diagnostics iChem Velocity Strips	8	-	-	-	-	-	-	-	1	-	-	2	5	-	-	
Iris Ichem VELOCITY Urine Chemistry System	4	-	-	-	-	-	1	1	-	-	-	1	1	-	-	
Other Analyzer Method	4	-	-	-	-	-	-	4	-	-	-	-	-	-	-	
Other Dipstick Method	3	1	-	-	-	-	1	1	-	-	-	-	-	-	-	
Plasmatec URIPATH	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	
Roche Chemstrips / Combur	27	5	2	-	-	-	2	10	7	1	-	-	-	-	-	
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	
Roche cobas u 411	21	-	-	-	-	-	-	3	7	3	-	-	4	1	3	
Roche Urisys	17	-	-	-	-	-	-	2	3	1	-	-	7	-	4	
SD UroColor Reagent Strips	10	1	-	-	-	-	1	4	3	-	-	-	-	-	1	
Siemens Clinitek Advantus	4	-	-	-	-	-	1	3	-	-	-	-	-	-	-	
Siemens Clinitek Status / Status+	17	-	-	-	-	-	-	15	2	-	-	-	-	-	-	
Siemens Reagent Strips	13	-	-	-	-	-	-	6	7	-	-	-	-	-	-	
Urinometer	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	
UriScan Pro/II	2	-	-	-	-	-	1	-	-	-	-	-	1	-	-	
UriScan Reagent Strips	18	2	-	-	-	-	2	10	1	-	-	-	3	-	-	

**URINALYSIS DIPSTICK–BILIRUBIN**

**Specimen UA-2**

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Participant Results</u>					<u>0.5 - 1.0</u> <u>mg/dL</u>	<u>2.0 - 4.0</u> <u>mg/dL</u>	<u>6.0 - 10.0</u> <u>mg/dL</u>	<u>&gt;10.0</u> <u>mg/dL</u>
						<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>				
ALL METHODS	168	167	-	-	-	-	-	-	-	-	1	-	-	-
77 Elektronika LabUMat/2	17	17	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	4	4	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	14	14	-	-	-	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	1	1	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	8	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	4	3	-	-	-	-	-	-	-	-	1	-	-	-
Other Analyzer Method	4	4	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	14	14	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	21	21	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	17	17	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	10	10	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	4	4	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	16	16	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	2	2	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	19	19	-	-	-	-	-	-	-	-	-	-	-	-

## 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	167	165	2	-	-	-
77 Elektronika LabUMat/2	18	18	-	-	-	-
Acon Laboratories	4	4	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-
Arkray Aution Sticks	13	13	-	-	-	-
Arkray PocketChem UA	1	1	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	8	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	4	4	-	-	-	-
Other Analyzer Method	4	3	1	-	-	-
Other Dipstick Method	3	3	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-
Roche Chemstrips / Combur	14	14	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-
Roche cobas u 411	21	21	-	-	-	-
Roche Urisys	17	17	-	-	-	-
SD UroColor Reagent Strips	10	9	1	-	-	-
Siemens Clinitek Advantus	4	4	-	-	-	-
Siemens Clinitek Status / Status+	16	16	-	-	-	-
Siemens Reagent Strips	2	2	-	-	-	-
Urinometer	1	1	-	-	-	-
UriScan Pro/II	2	2	-	-	-	-
UriScan Reagent Strips	18	18	-	-	-	-

**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>250</u> <u>Ery/<math>\mu</math>L</u>	<u><math>\pm</math>0.03</u> <u>mg/dL</u>	<u>0.06</u> <u>-</u> <u>0.10</u> <u>mg/</u> <u>dL</u>	<u>0.2 -</u> <u>0.5</u> <u>mg/</u> <u>dL</u>	<u><math>\geq</math> 1.0</u> <u>mg/</u> <u>dL</u>
ALL METHODS	193	189	1	-	-	-	-	-	2	-	-	-	-	-	1	-	-	-
77 Elektronika LabUMat/2	18	18	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	14	14	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	4	2	1	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Other Analyzer Method	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	26	26	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	21	21	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Miditron Junior/II	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	17	17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	10	9	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	17	17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	13	13	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	18	18	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

**URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE**

**Specimen UA-2**

<u>Method</u>	<i>Participant Results</i>												
	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>15 or 25 µL</u>	<u>75 or 100 µL</u>	<u>250 or 500 µL</u>
ALL METHODS	178	6	1	2	1	-	8	35	71	2	1	2	49
77 Elektronika LabUMat/2	18	-	-	-	-	-	-	1	11	-	-	-	6
Acon Laboratories	4	-	-	-	-	-	-	3	1	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	-	-	-	-	-	-	1
Arkray Aution Sticks	13	-	-	-	-	-	-	1	-	-	-	-	12
Arkray PocketChem UA	1	1	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	-	-	-	-	-	-	-	5	-	-	1	2
Iris Ichem VELOCITY Urine Chemistry System	4	-	-	-	-	-	-	-	3	-	-	-	1
Other Analyzer Method	4	-	-	-	-	-	-	-	1	-	-	-	3
Other Dipstick Method	3	-	-	-	-	-	-	1	2	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	1	-	-	-	-	-
Roche Chemstrips / Combur	25	-	-	-	-	-	-	1	23	1	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	21	-	-	-	-	-	-	-	10	-	-	-	11
Roche Urisys	17	-	-	-	-	-	-	-	6	-	-	-	11
SD UroColor Reagent Strips	10	2	-	-	-	-	-	3	4	-	-	-	1
Siemens Clinitek Advantus	4	-	-	-	-	-	2	2	-	-	-	-	-
Siemens Clinitek Status / Status+	16	-	-	2	1	-	2	10	1	-	-	-	-
Siemens Reagent Strips	2	1	-	-	-	-	-	1	-	-	-	-	-
Urinometer	1	-	-	-	-	-	-	1	-	-	-	-	-
UriScan Pro/II	2	-	-	-	-	-	-	1	-	-	-	1	-
UriScan Reagent Strips	18	-	1	-	-	-	4	7	3	1	1	-	1

## URINALYSIS DIPSTICK–NITRITE

### Specimen UA-2

#### Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	181	8	173
77 Elektronika LabUMat/2	18	-	18
Acon Laboratories	4	-	4
Arkray Aution Jet	1	-	1
Arkray Aution Sticks	14	1	13
Arkray PocketChem UA	1	1	-
DIRUI H-800 Urine Analyzer	1	1	-
Iris Diagnostics Aution Max AX-4280	1	-	1
Iris Diagnostics iChem Velocity Strips	8	-	8
Iris Ichem VELOCITY Urine Chemistry System	4	-	4
Other Analyzer Method	4	-	4
Other Dipstick Method	3	-	3
Plasmatec URIPATH	1	-	1
Roche Chemstrips / Combur	27	1	26
Roche cobas 6500 / u 601	1	-	1
Roche cobas u 411	21	-	21
Roche Urisys	17	2	15
SD UroColor Reagent Strips	10	2	8
Siemens Clinitek Advantus	4	-	4
Siemens Clinitek Status / Status+	16	-	16
Siemens Reagent Strips	2	-	2
Urinometer	1	-	1
UriScan Pro/II	2	-	2
UriScan Reagent Strips	18	-	18



**URINALYSIS –MICROALBUMIN (dipstick only)**

**Specimen UA-2**

*Participant Results*

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>10 mg/L</u>	<u>20 mg/L</u>	<u>30 mg/L</u>	<u>50 mg/L</u>	<u>80 mg/L</u>	<u>100 mg/L</u>	<u>150 mg/L</u>	<u>+</u> (4 - 8 <u>mg/dL</u> )	<u>++</u> (>8 <u>mg/dL</u> )
ALL METHODS	7	6	1	-	-	-	-	-	-	-	-
Arkay Aution Sticks	1	1	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-	-	-	-	-	-
Roche Micral - 1 minute	1	1	-	-	-	-	-	-	-	-	-

**URINALYSIS –URINE hCG**

**Specimen UA-2**

*Participant Results*

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	103	1	102
Acon Laboratories	5	-	5
Alere Aceava hCG-Urine	2	-	2
Alere Clearview hCG Cassette	3	-	3
Alere hCG Cassette	22	-	22
Other Dipstick Method	3	-	3
SD Bioline hCG	11	-	11
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>
Aerococcus viridans	84	73.68%	Acceptable
Gram positive cocci	4	3.51%	Acceptable
Aerococcus sp.	2	1.75%	Acceptable
Streptococcus alpha-hemolytic	15	13.16%	
Streptococcus viridans group	5	4.39%	

Organism(s) present: *Aerococcus viridans*.

### Specimen BA-5 – Sputum Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Streptococcus anginosus	63	35.80%	Acceptable
Micrococcus luteus	47	26.70%	Acceptable
Micrococcus sp.	18	10.23%	Acceptable
Streptococcus viridans group	3	1.70%	Acceptable
Strep – beta hemo; not Grp A	2	1.14%	Acceptable
Streptococcus Group C	24	13.64%	
Streptococcus sanguinis	6	3.44%	

Organism(s) present: *Streptococcus anginosus* and *Micrococcus luteus*.

## MISCELLANEOUS CULTURES

### Specimen BA-6 – Stool Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Yersinia enterocolitica	100	80.00%	Acceptable
Streptococcus constellatus	8	6.40%	Acceptable
Yersinia sp.	5	4.00%	Acceptable
Gram negative bacilli	1	0.80%	Acceptable

Organism(s) present: *Yersinia enterocolitica* and *Streptococcus constellatus*.

**ANTIMICROBIAL SUSCEPTIBILITY TESTING**

<b>Specimen UC-6, CC-6 (SUS-6)</b>	<b>-----Disk Diffusion-----</b>				<b>-----MIC-----</b>				<b><u>Acceptable (%)</u></b>
	<b><i>Interpretative category data</i></b>				<b><i>Interpretative category data</i></b>				
	<b><u>Labs</u></b>	<b><u>S</u></b>	<b><u>I</u></b>	<b><u>R</u></b>	<b><u>Labs</u></b>	<b><u>S</u></b>	<b><u>I</u></b>	<b><u>R</u></b>	
<b><u>Antimicrobial</u></b>									
Amikacin	10	9	-	1	7	6	-	1	Inappropriate drug <sup>1</sup>
Amoxicillin/Clavulanate	15	14	-	1	30	28	-	2	93.62%
Ampicillin	6	1	-	5	35	6	-	29	Inappropriate drug <sup>1</sup>
Ampicillin/Sulbactam	6	6	-	-	24	24	-	-	100.00%
Aztreonam	-	-	-	-	3	3	-	-	Inappropriate drug <sup>1</sup>
Cefaclor	3	3	-	-	1	1	-	-	100.00%
Cefamandole	-	-	-	-	1	1	-	-	Ungraded <sup>2</sup>
Cefazolin	4	4	-	-	12	12	-	-	100.00%
Cefdinir	1	1	-	-	4	4	-	-	100.00%
Cefepime	5	5	-	-	7	7	-	-	100.00%
Cefixime	5	4	-	1	2	2	-	-	Inappropriate drug <sup>1</sup>
Cefoperazone	2	2	-	-	2	2	-	-	100.00%
Cefotaxime	6	6	-	-	9	9	-	-	100.00%
Cefotetan	-	-	-	-	1	1	-	-	Ungraded <sup>2</sup>
Cefoxitin	20	20	-	-	24	23	1	-	97.73%
Cefpodoxime	-	-	-	-	1	1	-	-	Ungraded <sup>2</sup>
Ceftaroline	1	1	-	-	21	21	-	-	100.00%
Ceftazidime	4	4	-	-	3	2	1	-	Inappropriate drug <sup>1</sup>
Ceftizoxime	-	-	-	-	1	1	-	-	Ungraded <sup>2</sup>
Ceftolozane/Tazobactam	-	-	-	-	2	2	-	-	Inappropriate drug <sup>1</sup>
Ceftriaxone	8	8	-	-	8	7	-	1	94.44%
Cefuroxime	7	7	-	-	5	4	-	1	91.67%
Ciprofloxacin	28	28	-	-	132	132	-	-	100.00%
Clindamycin	-	-	-	-	9	9	-	-	100.00%
Colistin	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Dalbavancin	-	-	-	-	2	2	-	-	100.00%
Daptomycin	-	-	-	-	39	38	-	1	97.50%
Doripenem	2	2	-	-	1	1	-	-	100.00%
Doxycycline	4	4	-	-	2	2	-	-	100.00%
Ertapenem	2	2	-	-	2	2	-	-	100.00%

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

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

ANTIMICROBIAL SUSCEPTIBILITY TESTING (cont'd)

<b>Specimen UC-6, CC-6 (SUS-6)</b>	<b>-----Disk Diffusion-----</b>				<b>-----MIC-----</b>				<b>Acceptable (%)</b>
	<b>Interpretative category data</b>				<b>Interpretative category data</b>				
	<b><u>Labs</u></b>	<b><u>S</u></b>	<b><u>I</u></b>	<b><u>R</u></b>	<b><u>Labs</u></b>	<b><u>S</u></b>	<b><u>I</u></b>	<b><u>R</u></b>	
<b><u>Antimicrobial</u></b>									
Fosfomycin	5	5	-	-	3	3	-	-	Inappropriate drug <sup>1</sup>
Gatifloxacin	-	-	-	-	1	1	-	-	Ungraded <sup>2</sup>
Gentamicin	31	30	-	1	122	121	-	1	98.73%
Imipenem	6	6	-	-	6	6	-	-	100.00%
Kanamycin	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Levofloxacin	12	12	-	-	61	61	-	-	100.00%
Linezolid	18	18	-	-	78	78	-	-	100.00%
Lomefloxacin	-	-	-	-	1	1	-	-	100.00%
Meropenem	6	6	-	-	3	3	-	-	100.00%
Minocycline	1	1	-	-	17	17	-	-	100.00%
Moxifloxacin	4	4	-	-	40	40	-	-	100.00%
Nalidixic Acid	1	-	-	1	1	1	-	-	Inappropriate drug <sup>1</sup>
Netilmicin	4	4	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Nitrofurantoin	32	32	-	-	138	138	-	-	100.00%
Norfloxacin	6	5	1	-	11	11	-	-	Inappropriate drug <sup>1</sup>
Ofloxacin	5	5	-	-	4	4	-	-	100.00%
Oxacillin	15	15	-	-	137	136	-	1	99.36%
Penicillin	18	2	-	16	50	4	-	46	91.43%
Piperacillin	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Piperacillin/Tazobactam	3	3	-	-	5	5	-	-	100.00%
Polymyxin B	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Quinupristin/Dalfopristin	-	-	-	-	25	25	-	-	100.00%
Rifampin	13	13	-	-	65	65	-	-	100.00%

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

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

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

<b>Specimen UC-6, CC-6 (SUS-6)</b>	<b>-----Disk Diffusion-----</b>				<b>-----MIC-----</b>				<b><u>Acceptable (%)</u></b>
	<b><i>Interpretative category data</i></b>				<b><i>Interpretative category data</i></b>				
<b><u>Antimicrobial</u></b>	<b><u>Labs</u></b>	<b><u>S</u></b>	<b><u>I</u></b>	<b><u>R</u></b>	<b><u>Labs</u></b>	<b><u>S</u></b>	<b><u>I</u></b>	<b><u>R</u></b>	
Streptomycin	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Sulfonamides	-	-	-	-	1	1	-	-	Ungraded <sup>2</sup>
Teicoplanin	3	2	1	-	37	36	-	1	95.00%
Tetracycline	11	11	-	-	66	66	-	-	100.00%
Ticarcillin/Clavulanate	-	-	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Tobramycin	1	1	-	-	1	1	-	-	Inappropriate drug <sup>1</sup>
Trimethoprim	-	-	-	-	4	4	-	-	100.00%
Trimethoprim/Sulfamethoxazole	31	31	-	-	152	152	-	-	100.00%
Vancomycin	8	8	-	-	116	116	-	-	100.00%

Organism(s) present: *Staphylococcus aureus*.

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

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

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

## PARASITOLOGY (PA Specimens)

### Specimen PA-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Protozoan cyst or trophozoite	1	33.33%	Acceptable
Trichomonas hominis	1	33.33%	
No parasite seen			

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

### Specimen PA-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	2	66.67%	Acceptable
Entamoeba coli	1	33.33%	

Parasite(s) present: *Endolimax nana*. This specimen is graded to US statistics.

### Specimen PA-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Clonorchis sinensis	16	72.73%	Acceptable
Pollen artifact	4	18.18%	
Hymenolepis diminuta eggs	1	4.55%	
Taenia sp. Eggs	1	4.55%	

Parasite(s) present: *Clonorchis sinensis*.

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

**Specimen PA-9**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	18	100%	Acceptable

Parasite(s) present: *Ascaris lumbricoides* eggs.

**Specimen PA-10**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	17	94.44%	Acceptable
Iodamoeba buetschlii	1	5.56%	

Parasite(s) present: No parasite seen.



## PARASITOLOGY (FP Specimens)

### Specimen FP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	237	48.67%	Acceptable
Entamoeba coli	108	22.18%	Acceptable
Entamoeba histolytica	84	17.25%	Acceptable
Protozoan cyst or trophozoite	1	0.21%	Acceptable
Blastocystis hominis	25	5.13%	
Endolimax nana	23	4.72%	
Iodamoeba buetschlii	2	0.41%	
Strongyloides stercoralis larvae	1	0.21%	
Trichostrongylus sp. Eggs	1	0.21%	
Parasite egg or larvae seen – no	1	0.21%	
No parasite seen	1	0.21%	
Chilomastix mesnili	1	0.21%	
Entamoeba hartmanni	1	0.21%	
Enterobius vermicularis eggs	1	0.21%	

Parasite(s) present: *Giardia lamblia*, *Entamoeba coli*, and *Entamoeba histolytica*.

## PARASITOLOGY (FP Specimens)

### Specimen FP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba coli	230	87.45%	Acceptable
Protozoan cyst or trophozoite	1	0.38%	Acceptable
Entamoeba histolytica	19	7.22%	
Endolimax nana	3	1.14%	
No parasite seen	2	0.76%	
Strongyloides stercoralis larvae	2	0.76%	
Taenia sp. Eggs	1	0.38%	
Parasite egg or larvae seen – no	1	0.38%	
Entamoeba hartmanni	1	0.38%	
Clonorchis sinensis	1	0.38%	
Balantidium coli	1	0.38%	
Blastocystis hominis	1	0.38%	

Parasite(s) present: *Entamoeba coli*.

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

**Specimen FP-8**

<b><u>Identification</u></b>	<b><u>Labs</u></b>	<b><u>Percent</u></b>	<b><u>Performance</u></b>
Taenia sp. Eggs	193	73.38%	Acceptable
Parasite egg or larvae seen – no	1	0.38%	Acceptable
No parasite seen	22	8.37%	
Blastocystis hominis	17	6.46%	
Ascaris lumbricoides eggs	13	4.94%	
Endolimax nana	6	2.28%	
Hymenolepis nana eggs	4	1.52%	
Entamoeba coli	2	0.76%	
Hymenolepis diminuta eggs	2	0.76%	
Entamoeba histolytica	1	0.38%	
Isospora belli oocysts	1	0.38%	
Pollen artifact	1	0.38%	

Parasite(s) present: *Taenia sp. eggs*.

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

**Specimen FP-9**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	221	90.95%	Acceptable
Endolimax nana	9	3.70%	
Entamoeba histolytica	4	1.65%	
Iodamoeba buetschlii	3	1.23%	
Isospora belli oocysts	1	0.41%	
Taenia sp. Eggs	1	0.41%	
Nonpathogenic protozoan present	1	0.41%	
Entamoeba coli	1	0.41%	
Blastocystis hominis	1	0.41%	
Nematode-like artifact	1	0.41%	

Parasite(s) present: No parasite seen.

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

**Specimen FP-10**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium sp.	54	22.78%	Acceptable
Plasmodium ovale	18	7.59%	Acceptable
Plasmodium vivax	132	55.70%	
Plasmodium falciparum	11	4.64%	
Plasmodium malariae	11	4.64%	
No parasite seen	8	3.38%	
Babesia sp.	1	0.42%	
Toxoplasma gondii	1	0.42%	
Trypanosoma cruzi	1	0.42%	

Parasite(s) present: *Plasmodium ovale*.

**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	22	1	-	23	21	2
Bio-Rad	2	-	-	2	2	-
BioSystems	1	-	-	1	1	-
Immuno Concepts	3	-	-	3	2	1
INOVA Diagnostics	9	-	-	9	8	1
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	23	-	2	21
Bio-Rad	2	-	-	2
BioSystems	1	-	-	1
Immuno Concepts	3	-	-	3
INOVA Diagnostics	9	-	1	8
Kallestad	1	-	-	1

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

<u>Specimen/Method</u>	<u>N/A</u> <u>(Neg)</u>	<u>8/</u> <u>10</u>	<u>16/</u> <u>20</u>	<u>32/</u> <u>40</u>	<u>64/</u> <u>80</u>	<u>128/</u> <u>160</u>	<u>256/</u> <u>320</u>	<u>512/</u> <u>640</u>	<u>&gt;640</u>	<u>1024/</u> <u>1280</u>	<u>2048/</u> <u>2560</u>	<u>≥2560</u>
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**Specimen AE-6**

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

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

<u>Specimen/Method</u>	<u>N/A</u> <u>(Neg)</u>	<u>8/</u> <u>10</u>	<u>16/</u> <u>20</u>	<u>32/</u> <u>40</u>	<u>64/</u> <u>80</u>	<u>128/</u> <u>160</u>	<u>256/</u> <u>320</u>	<u>512/</u> <u>640</u>	<u>&gt;640</u>	<u>1024/</u> <u>1280</u>	<u>2048/</u> <u>2560</u>	<u>≥2560</u>
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**Specimen AE-7**

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

**Specimen AE-8**

ALL METHODS	1	-	-	-	-	-	5	3	2	4	-	-
Bio-Rad	-	-	-	-	-	-	1	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	-	1	1	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	2	1	-	2	-	-
Kallestad	-	-	-	-	-	-	-	-	-	1	-	-

**Specimen AE-9**

ALL METHODS	-	-	-	-	1	1	4	5	2	2	-	-
Bio-Rad	-	-	-	-	1	-	-	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	-	1	1	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	3	1	-	1	-	-
Kallestad	-	-	-	-	-	-	-	-	-	1	-	-

**Specimen AE-10**

ALL METHODS	14	-	-	-	1	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	5	-	-	-	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	-	20	8	13
BioSystems	-	1	-	1	-	1
Immuno Concepts	-	2	-	2	1	1
INOVA Diagnostics	-	9	-	8	4	5
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	2	19	-	21
BioSystems	1	-	-	1
Immuno Concepts	-	2	-	2
INOVA Diagnostics	1	8	-	9
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	15	-	-	15	-	15
INOVA Diagnostics	10	-	-	10	-	10

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	15	-	15
INOVA Diagnostics	-	10	-	10



**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	7	-	-	7	1	6
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	1	6	-	7
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	-	22	-	22	-	22
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	11	-	11	-	11

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	22	-	-	22
Immuno Concepts	1	-	-	1
INOVA Diagnostics	11	-	-	11

**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	-	22	-	22	-	22
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	11	-	11	-	11

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	22	-	-	22
Immuno Concepts	1	-	-	1
INOVA Diagnostics	11	-	-	11

**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	11	11	-	22	-	22
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	10	1	-	11	-	11

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	21	-	22
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	11	-	11

**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	14	1	-	15	14	1
Abbott Architect	11	1	-	12	11	1
Roche cobas e 411	2	-	-	2	2	-
Siemens ADVIA Centaur	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	-	15	14	1
Abbott Architect	-	12	11	1
Roche cobas e 411	-	2	2	-
Siemens ADVIA Centaur	-	1	1	-

**Rubella—Quantitative (IU/mL)**

<b><u>Specimen/Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
<b>Specimen RU-6</b>						
All Method	20	46.61	25.99	55.8	30.2	0.0 - 124.6
Abbott Architect	12	29.45	1.22	4.2	29.4	25.7 - 33.2
<b>Specimen RU-7</b>						
All Method	20	0.07	0.12	162.4	0.0	0.0 - 0.5
Abbott Architect	11	0.00	0.01	0.0	0.0	0.0 - 0.1
<b>Specimen RU-8</b>						
All Method	20	60.42	31.84	52.7	39.5	0.0 - 156.0
Abbott Architect	12	38.62	2.57	6.7	38.3	30.9 - 46.4
<b>Specimen RU-9</b>						
All Method	21	0.08	0.12	144.2	0.0	0.0 - 0.5
Abbott Architect	11	0.00	0.01	0.0	0.0	0.0 - 0.1
<b>Specimen RU-10</b>						
All Method	20	59.81	32.73	54.7	39.0	0.0 - 158.0
Abbott Architect	12	37.44	2.13	5.7	37.3	31.0 - 43.9

**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	56	3	-	59	-	-	-	-	59
Abbott Architect	2	-	-	2	-	-	-	-	2
Acon Laboratories	2	-	-	2	-	-	-	-	2
BioSystems	2	-	-	2	-	-	-	-	2
Omega Diagnostics	2	1	-	3	-	-	-	-	3
Plasmatec	2	1	-	3	-	-	-	-	3
SPINREACT	2	-	-	2	-	-	-	-	2
Standard Diagnostics	1	-	-	1	-	-	-	-	1
Wiener Lab	38	1	-	39	-	-	-	-	39

<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	58	1	-	-	-	59
Abbott Architect	2	-	-	-	-	2
Acon Laboratories	2	-	-	-	-	2
BioSystems	2	-	-	-	-	2
Omega Diagnostics	2	1	-	-	-	3
Plasmatec	3	-	-	-	-	3
SPINREACT	2	-	-	-	-	2
Standard Diagnostics	1	-	-	-	-	1
Wiener Lab	39	-	-	-	-	39

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

<b><u>Specimen/Method</u></b>	<b><u>N/A (Neg)</u></b>	<b><u>0 dils</u></b>	<b><u>1 dil</u></b>	<b><u>2 dils</u></b>	<b><u>4 dils</u></b>	<b><u>8 dils</u></b>	<b><u>16 dils</u></b>	<b><u>32 dils</u></b>	<b><u>&gt;32 dils</u></b>
<b>Specimen SY-6</b>									
ALL METHODS	-	1	11	30	10	1	-	-	-
BioSystems	-	-	1	1	-	-	-	-	-
Human	-	-	1	-	-	-	-	-	-
Omega Diagnostics	-	-	1	1	-	-	-	-	-
Plasmatec	-	-	1	2	-	-	-	-	-
Wiener Lab	-	1	7	22	10	1	-	-	-
<b>Specimen SY-7</b>									
ALL METHODS	-	1	4	17	24	5	1	-	1
BioSystems	-	-	-	2	-	-	-	-	-
Human	-	-	1	-	-	-	-	-	-
Omega Diagnostics	-	-	-	1	1	-	-	-	-
Plasmatec	-	-	1	1	1	-	-	-	-
Wiener Lab	-	1	2	12	19	5	1	-	1
<b>Specimen SY-8</b>									
ALL METHODS	53	-	-	-	-	-	-	-	-
BioSystems	2	-	-	-	-	-	-	-	-
Human	1	-	-	-	-	-	-	-	-
Omega Diagnostics	2	-	-	-	-	-	-	-	-
Plasmatec	3	-	-	-	-	-	-	-	-
Wiener Lab	41	-	-	-	-	-	-	-	-

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

<b><u>Specimen/Method</u></b>	<b><u>N/A (Neg)</u></b>	<b><u>0 dils</u></b>	<b><u>1 dil</u></b>	<b><u>2 dils</u></b>	<b><u>4 dils</u></b>	<b><u>8 dils</u></b>	<b><u>16 dils</u></b>	<b><u>32 dils</u></b>	<b><u>&gt;32 dils</u></b>
<b>Specimen SY-9</b>									
ALL METHODS	1	-	13	28	8	2	1	-	-
BioSystems	-	-	1	1	-	-	-	-	-
Human	-	-	1	-	-	-	-	-	-
Omega Diagnostics	1	-	-	1	-	-	-	-	-
Plasmatec	-	-	1	1	1	-	-	-	-
Wiener Lab	-	-	9	24	6	2	-	-	-
<b>Specimen SY-10</b>									
ALL METHODS	52	-	1	-	-	-	-	-	-
BioSystems	2	-	-	-	-	-	-	-	-
Human	1	-	-	-	-	-	-	-	-
Omega Diagnostics	1	-	1	-	-	-	-	-	-
Plasmatec	3	-	-	-	-	-	-	-	-
Wiener Lab	41	-	-	-	-	-	-	-	-



**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	19	-	19	-	-	19
Abbott Architect	3	-	3	-	-	3
Biokit	1	-	1	-	-	1
Human	1	-	1	-	-	1
Plasmatec	4	-	4	-	-	4
Serodia	3	-	3	-	-	3
Standard Diagnostics	1	-	1	-	-	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	19	-	-	19
Abbott Architect	3	-	-	3
Biokit	1	-	-	1
Human	1	-	-	1
Plasmatec	4	-	-	4
Serodia	3	-	-	3
Standard Diagnostics	1	-	-	1
Wiener Lab	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	55	-	54	-	-	55
Abbott Architect	9	-	9	-	-	9
bioMerieux	1	-	1	-	-	1
BioSystems	1	-	1	-	-	1
DiaSorin	1	-	1	-	-	1
Human	2	-	2	-	-	2
Plasmatec	4	-	4	-	-	4
Roche cobas 6000 / c 501	2	-	2	-	-	2
Roche cobas 8000/e801	1	-	1	-	-	1
Roche cobas e 411	1	-	1	-	-	1
Serodia	9	-	9	-	-	9
Standard Diagnostics	6	-	6	-	-	6
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	54	-	-	54
Abbott Architect	9	-	-	9
bioMerieux	1	-	-	1
BioSystems	1	-	-	1
DiaSorin	1	-	-	1
Human	2	-	-	2
Plasmatec	4	-	-	4
Roche cobas 6000 / c 501	2	-	-	2
Roche cobas 8000/e801	1	-	-	1
Roche cobas e 411	1	-	-	1
Serodia	9	-	-	9
Standard Diagnostics	6	-	-	6
Wiener Lab	1	-	-	1

**Syphilis Serology—Qualitative: RPR**

<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	97	1	98	-	-	98
Abbott Architect	1	-	1	-	-	1
Becton Dickinson	2	-	2	-	-	2
bioMerieux	4	-	4	-	-	4
BioSystems	18	-	18	-	-	18
Human	7	-	7	-	-	7
Omega Diagnostics	16	-	16	-	-	16
Plasmatec	22	1	23	-	-	23
Pulse Scientific	1	-	1	-	-	1
SPINREACT	18	-	18	-	-	18

	<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	96	2	-	98
Abbott Architect	1	-	-	1
Becton Dickinson	2	-	-	2
bioMerieux	4	-	-	4
BioSystems	18	-	-	18
Human	7	-	-	7
Omega Diagnostics	16	-	-	16
Plasmatec	22	1	-	23
Pulse Scientific	1	-	-	1
SPINREACT	18	-	-	18

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

<b><u>Specimen/Method</u></b>	<b><u>N/A</u></b> <b><u>(Neg)</u></b>	<b><u>1</u></b>	<b><u>2</u></b>	<b><u>4</u></b>	<b><u>8</u></b>	<b><u>16</u></b>	<b><u>32</u></b>	<b><u>64</u></b>	<b><u>&gt;64</u></b>
<b>Specimen SY-6</b>									
ALL METHODS	4	16	48	10	3	-	1	1	-
Becton Dickinson	-	-	1	1	-	-	-	-	-
bioMerieux	-	1	2	-	-	-	-	-	-
BioSystems	-	2	10	4	-	-	-	-	-
Human	-	3	3	-	-	-	-	-	-
Omega Diagnostics	2	4	4	2	1	-	1	-	-
Plasmatec	2	3	10	1	-	-	-	1	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	2	13	2	1	-	-	-	-

**Specimen SY-7**

ALL METHODS	1	2	24	44	8	2	-	-	2
Becton Dickinson	-	-	-	-	2	-	-	-	-
bioMerieux	-	-	1	2	-	-	-	-	-
BioSystems	-	-	5	10	1	-	-	-	-
Human	-	-	3	3	-	-	-	-	-
Omega Diagnostics	1	1	5	4	2	1	-	-	-
Plasmatec	-	1	5	8	-	1	-	-	2
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	-	3	13	2	-	-	-	-

**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-8</b>									
ALL METHODS	83	-	-	-	-	-	-	-	-
Becton Dickinson	2	-	-	-	-	-	-	-	-
bioMerieux	3	-	-	-	-	-	-	-	-
BioSystems	16	-	-	-	-	-	-	-	-
Human	6	-	-	-	-	-	-	-	-
Omega Diagnostics	14	-	-	-	-	-	-	-	-
Plasmatec	17	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	18	-	-	-	-	-	-	-	-

**Specimen SY-9**

ALL METHODS	5	14	48	11	4	-	-	-	1
Becton Dickinson	-	-	-	2	-	-	-	-	-
bioMerieux	-	1	2	-	-	-	-	-	-
BioSystems	-	1	12	2	1	-	-	-	-
Human	-	3	3	-	-	-	-	-	-
Omega Diagnostics	2	3	8	-	-	-	-	-	1
Plasmatec	2	3	9	2	1	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	2	10	5	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	82	1	-	-	-	-	-	-	-
Becton Dickinson	2	-	-	-	-	-	-	-	-
bioMerieux	3	-	-	-	-	-	-	-	-
BioSystems	15	1	-	-	-	-	-	-	-
Human	6	-	-	-	-	-	-	-	-
Omega Diagnostics	14	-	-	-	-	-	-	-	-
Plasmatec	17	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	18	-	-	-	-	-	-	-	-

**Viral Markers – Anti-HBc (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	51	-	-	-	51	-	-	51	-
Abbott Architect	27	-	-	-	27	-	-	27	-
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-	-	1	-
Bio-Rad Evolis	1	-	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	1	-	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	7	-	-	-	7	-	-	7	-
Roche cobas 8000/e801	4	-	-	-	4	-	-	4	-
Roche cobas e 411	2	-	-	-	2	-	-	2	-
Roche Modular Analytics	1	-	-	-	1	-	-	1	-
Siemens ADVIA Centaur	3	-	-	-	3	-	-	3	-
VITROS 3600/4600/5600	3	-	-	-	3	-	-	3	-
VITROS Eci	1	-	-	-	1	-	-	1	-

<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	-	51	-	-	51	-
Abbott Architect	-	27	-	-	27	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-
Bio-Rad Evolis	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	7	-	-	7	-
Roche cobas 8000/e801	-	4	-	-	4	-
Roche cobas e 411	-	2	-	-	2	-
Roche Modular Analytics	-	1	-	-	1	-
Siemens ADVIA Centaur	-	3	-	-	3	-
VITROS 3600/4600/5600	-	3	-	-	3	-
VITROS Eci	-	1	-	-	1	-

**Viral Markers – Anti-HBc (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	74	-	-	-	74	-	74	-	-
Abbott Architect	43	-	-	-	43	-	43	-	-
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-	2	-	-
Bio-Rad Evolis	1	-	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	11	-	-	-	11	-	11	-	-
Roche cobas 8000/e801	4	-	-	-	4	-	4	-	-
Roche cobas e 411	4	-	-	-	4	-	4	-	-
Siemens ADVIA Centaur	4	-	-	-	4	-	4	-	-
VITROS 3600/4600/5600	3	-	-	-	3	-	3	-	-
VITROS ECI	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	4	70	-	1	73	-
Abbott Architect	2	41	-	-	43	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-
Bio-Rad Evolis	-	1	-	-	1	-
Roche cobas 6000 / e 601	1	10	-	-	11	-
Roche cobas 8000/e801	-	4	-	-	4	-
Roche cobas e 411	-	4	-	-	4	-
Siemens ADVIA Centaur	-	4	-	-	4	-
VITROS 3600/4600/5600	-	3	-	-	3	-
VITROS ECI	-	1	-	-	1	-



**Viral Markers – Anti-HIV**

<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	-	1	169	-	1	169	-
Abbott Architect	-	70	-	-	70	-	-	70	-
Acon Laboratories	-	1	-	-	1	-	-	1	-
Alere Determine HIV - moderate	-	4	-	-	4	-	-	4	-
Alere Determine HIV - waived	-	1	-	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	3	-	-	3	-	-	3	-
Bio-Rad Evolis	-	1	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-	-	3	-
Human	-	3	-	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	32	-	1	31	-	1	31	-
Roche cobas 8000/e801	-	3	-	-	3	-	-	3	-
Roche cobas e 411	-	15	-	-	15	-	-	15	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	-	1	-
Roche Modular Analytics	-	2	-	-	2	-	-	2	-
Siemens ADVIA Centaur	-	8	-	-	8	-	-	8	-
Standard Diagnostics	-	4	-	-	4	-	-	4	-
VITROS 3600/4600/5600	-	6	-	-	6	-	-	6	-
VITROS ECI	-	2	-	-	2	-	-	2	-

**Viral Markers – Anti-HIV- cont'd**

<b><u>Method</u></b>	<b>Specimen VM-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	165	2	170	-	-
Abbott Architect	-	70	-	70	-	-
Acon Laboratories	-	1	-	1	-	-
Alere Determine HIV - moderate	-	4	-	4	-	-
Alere Determine HIV - waived	-	1	-	1	-	-
Beckman ACCESS / 2 / Dxl	-	3	-	3	-	-
Bio-Rad Evolis	-	1	-	1	-	-
bioMerieux Vidas, Mini Vidas	-	3	-	3	-	-
Human	-	3	-	3	-	-
Roche cobas 6000 / e 601	-	31	1	32	-	-
Roche cobas 8000/e801	-	3	-	3	-	-
Roche cobas e 411	3	11	1	15	-	-
Roche Elecsys 1010 / 2010	-	1	-	1	-	-
Roche Modular Analytics	-	2	-	2	-	-
Siemens ADVIA Centaur	-	8	-	8	-	-
Standard Diagnostics	-	4	-	4	-	-
VITROS 3600/4600/5600	-	6	-	6	-	-
VITROS ECI	-	2	-	2	-	-

**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	-	57	-	-	57	-	-	57	-
Abbott Architect	-	29	-	-	29	-	-	29	-
Bio-Rad Evolis	-	1	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	10	-	-	10	-	-	10	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
Roche cobas e 411	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	4	-	-	4	-	-	4	-
Standard Diagnostics	-	3	-	-	3	-	-	3	-
VITROS 3600/4600/5600	-	1	-	-	1	-	-	1	-
VITROS ECI	-	1	-	-	1	-	-	1	-

<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	-	57	-	-	57	-
Abbott Architect	-	29	-	-	29	-
Bio-Rad Evolis	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	10	-	-	10	-
Roche cobas 8000/e801	-	4	-	-	4	-
Roche cobas e 411	-	1	-	-	1	-
Siemens ADVIA Centaur	-	4	-	-	4	-
Standard Diagnostics	-	3	-	-	3	-
VITROS 3600/4600/5600	-	1	-	-	1	-
VITROS ECI	-	1	-	-	1	-

**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	-	62	-	61	1	-	-	62	-
Abbott Architect	-	29	-	29	-	-	-	29	-
Bio-Rad Evolis	-	1	-	1	-	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	2	-	2	-	-	-	2	-
Roche cobas 6000 / e 601	-	13	-	13	-	-	-	13	-
Roche cobas 8000/e801	-	3	-	3	-	-	-	3	-
Roche cobas e 411	-	6	-	6	-	-	-	6	-
Roche Elecsys 1010 / 2010	-	1	-	1	-	-	-	1	-
Roche Modular Analytics	-	1	-	1	-	-	-	1	-
Siemens ADVIA Centaur	-	4	-	4	-	-	-	4	-
Standard Diagnostics	-	1	-	-	1	-	-	1	-
VITROS ECI	-	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	60	1	1	61	1	-
Abbott Architect	28	-	1	29	-	-
Bio-Rad Evolis	1	-	-	1	-	-
bioMerieux Vidas, Mini Vidas	2	-	-	2	-	-
Roche cobas 6000 / e 601	13	-	-	13	-	-
Roche cobas 8000/e801	3	-	-	3	-	-
Roche cobas e 411	6	-	-	6	-	-
Roche Elecsys 1010 / 2010	1	-	-	1	-	-
Roche Modular Analytics	1	-	-	1	-	-
Siemens ADVIA Centaur	4	-	-	4	-	-
Standard Diagnostics	-	1	-	-	1	-
VITROS ECI	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	1	33	-	1	33	-	-	34	-
Abbott Architect	-	14	-	1	13	-	-	14	-
Bio-Rad Evolis	-	1	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	-	1	-
DiaSorin	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	11	-	-	11	-	-	11	-
Roche cobas 8000/e801	-	3	-	-	3	-	-	3	-
Roche Modular Analytics	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	1	-	-	-	1	-	-	1	-
VITROS ECI	-	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	-	34	-	-	34	-
Abbott Architect	-	14	-	-	14	-
Bio-Rad Evolis	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-
DiaSorin	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	11	-	-	11	-
Roche cobas e 411	-	3	-	-	3	-
Roche Modular Analytics	-	1	-	-	1	-
Siemens ADVIA Centaur	-	1	-	-	1	-
VITROS ECI	-	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	1	118	-	119	-	-	119	-	-
Abbott Architect	-	49	-	49	-	-	49	-	-
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	-	2	-	-
Bio-Rad Evolis	-	1	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	1	26	-	27	-	-	27	-	-
Roche cobas 8000/e801	-	4	-	4	-	-	4	-	-
Roche cobas e 411	-	12	-	12	-	-	12	-	-
Roche Elecsys 1010 / 2010	-	2	-	2	-	-	2	-	-
Roche Modular Analytics	-	1	-	1	-	-	1	-	-
Siemens ADVIA Centaur	-	8	-	8	-	-	8	-	-
Standard Diagnostics	-	1	-	1	-	-	1	-	-
VITROS 3600/4600/5600	-	6	-	6	-	-	6	-	-
VITROS ECI	-	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	20	97	2	119	-	-
Abbott Architect	10	39	-	49	-	-
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	-
Bio-Rad Evolis	-	1	-	1	-	-
DiaSorin	6	20	1	27	-	-
Roche cobas 6000 / e 601	-	4	-	4	-	-
Roche cobas 8000/e801	2	9	1	12	-	-
Roche cobas e 411	1	1	-	2	-	-
Roche Elecsys 1010 / 2010	-	1	-	1	-	-
Roche Modular Analytics	-	8	-	8	-	-
Siemens ADVIA Centaur	-	1	-	1	-	-
VITROS 3600/4600/5600	-	6	-	6	-	-
VITROS ECI	-	3	-	3	-	-

**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	-	3	169	-	2	169	-
Abbott Architect	67	-	-	-	67	-	-	67	-
Beckman ACCESS / 2 / Dxl	3	-	-	-	3	-	-	3	-
Bio-Rad Evolis	1	-	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	2	-	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	33	-	-	2	31	-	-	33	-
Roche cobas 8000/e801	4	-	-	-	4	-	-	4	-
Roche cobas e 411	17	1	-	-	18	-	1	17	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-	-	1	-
Roche Modular Analytics	2	-	-	-	2	-	-	2	-
Siemens ADVIA Centaur	7	1	-	-	8	-	-	8	-
Standard Diagnostics	12	-	-	-	12	-	-	12	-
VITROS 3600/4600/5600	6	-	-	-	6	-	-	6	-
VITROS ECI	2	-	-	-	2	-	-	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	2	168	1	1	169	-
Abbott Architect	1	66	-	1	66	-
Beckman ACCESS / 2 / Dxl	-	3	-	-	3	-
Bio-Rad Evolis	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	32	1	-	33	-
Roche cobas 8000/e801	-	4	-	-	4	-
Roche cobas e 411	1	17	-	-	18	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-
Roche Modular Analytics	-	2	-	-	2	-
Siemens ADVIA Centaur	-	8	-	-	8	-
Standard Diagnostics	-	12	-	-	12	-
VITROS 3600/4600/5600	-	6	-	-	6	-
VITROS ECI	-	2	-	-	1	-

## Viral Markers – Anti-HCV

<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	-	151	-	-	151	-	1	150	-
Abbott Architect	-	67	-	-	67	-	-	67	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-	-	2	-
Bio-Rad Evolis	-	1	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	25	-	-	25	-	1	24	-
Roche cobas 8000/e801	-	3	-	-	3	-	-	3	-
Roche cobas e 411	-	14	-	-	14	-	-	14	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	-	1	-
Roche Modular Analytics	-	2	-	-	2	-	-	2	-
Siemens ADVIA Centaur	-	7	-	-	7	-	-	7	-
Standard Diagnostics	-	7	-	-	7	-	-	7	-
VITROS 3600/4600/5600	-	6	-	-	6	-	-	6	-
VITROS ECI	-	3	-	-	3	-	-	3	-

  

<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	151	-	-	-	151	-
Abbott Architect	67	-	-	-	67	-
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-
Bio-Rad Evolis	1	-	-	-	1	-
bioMerieux Vidas, Mini Vidas	2	-	-	-	2	-
Human	25	-	-	-	25	-
Roche cobas 6000 / e 601	3	-	-	-	3	-
Roche cobas e 411	14	-	-	-	14	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-
Roche Modular Analytics	2	-	-	-	2	-
Siemens ADVIA Centaur	7	-	-	-	7	-
Standard Diagnostics	7	-	-	-	7	-
VITROS 3600/4600/5600	6	-	-	-	6	-
VITROS ECI	3	-	-	-	3	-



**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	17	-	-	-	17	-
Abbott Architect	12	-	-	-	12	-
bioMerieux Vidas, Mini Vidas	1	-	-	-	1	-
DiaSorin	1	-	-	-	1	-
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	19	599.716	445.466	74.3	703.60	0.00 - 1490.65
Abbott Architect	15	539.107	344.544	63.9	703.60	0.00 - 1228.20
<b>Specimen TOX-4</b>						
All Method	21	0.319	0.229	71.9	0.40	0.00 - 0.78
Abbott Architect	15	0.420	0.186	44.3	0.40	0.04 - 0.80

**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	19	-	-	-	19	-
Abbott Architect	14	-	-	-	14	-
bioMerieux Vidas, Mini Vidas	1	-	-	-	1	-
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	2	-	-	-	2	-
Roche cobas e 411	1	-	-	-	1	-

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

<b><u>Specimen/Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
<b>Specimen TOX-3</b>						
ALL METHODS	18	8.426	4.499	53.4	6.88	0.00 - 17.43
Abbott Architect	13	6.465	0.952	14.7	6.34	4.56 - 8.37
<b>Specimen TOX-4</b>						
ALL METHODS	17	0.144	0.046	31.7	0.14	0.05 - 0.24
Abbott Architect	13	0.126	0.030	23.9	0.13	0.06 - 0.19

**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	12	-	13	-	-
Abbott Architect	1	11	-	12	-	-
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	2.089	1.167	55.8	2.10	0.00 - 4.43
Abbott Architect	13	2.254	0.939	41.6	2.10	0.37 - 4.14
<b>Specimen CMV-4</b>						
All Method	16	37.716	12.687	33.6	37.70	12.34 - 63.09
Abbott Architect	13	40.731	11.993	29.4	42.00	16.74 - 64.72

**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	15	2	-	-	17	-
Abbott Architect	15	-	-	-	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	3.405	1.410	41.4	3.67	0.58 - 6.23
Abbott Architect	12	3.855	0.879	22.8	3.98	2.09 - 5.62
<b>Specimen CMV-4</b>						
All Method	14	0.198	0.049	24.6	0.20	0.10 - 0.30
Abbott Architect	12	0.211	0.037	17.5	0.20	0.13 - 0.29

**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	50	7.13	0.38	5.3	7.1	5.7 - 8.6	46	0.02	0.05	303.6	0.0	0.0 - 0.5
No Reagent Required												
Bilirubinometer / Unistat	37	7.13	0.38	5.4	7.2	5.7 - 8.6	37	0.00	0.01	0.0	0.0	0.0 - 0.4
All Chemistry Instruments	42	7.14	0.39	5.5	7.2	5.7 - 8.6	39	0.01	0.03	624.4	0.0	0.0 - 0.5
<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	50	18.17	0.79	4.4	18.4	14.5 - 21.8	45	0.01	0.04	361.2	0.0	0.0 - 0.5
No Reagent Required												
Bilirubinometer / Unistat	37	18.43	0.61	3.3	18.4	14.7 - 22.2	37	0.00	0.01	0.0	0.0	0.0 - 0.4
All Chemistry Instruments	42	18.30	0.72	3.9	18.4	14.6 - 22.0	38	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	49	11.18	0.57	5.1	11.3	8.9 - 13.5						
No Reagent Required												
Bilirubinometer / Unistat	37	11.31	0.49	4.3	11.3	9.0 - 13.6						
All Chemistry Instruments	42	11.29	0.50	4.4	11.3	9.0 - 13.6						

**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	1.74	0.23	13.5	1.7	1.2 - 2.3	10	0.05	0.08	163.3	0.0	0.0 - 0.3
<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	4.34	0.64	14.8	4.2	3.0 - 5.7	10	0.04	0.07	191.1	0.0	0.0 - 0.2
<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	4.92	0.50	10.1	4.8	3.9 - 6.0						

## 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	170	5.68	0.28	4.9	5.7	5.3 - 6.1	168	10.89	0.40	3.7	10.9	10.2 - 11.6
All Hemoglobin A1c Methods	170	5.68	0.28	4.9	5.7	5.3 - 6.1	168	10.89	0.40	3.7	10.9	10.2 - 11.6
All Roche Methods	15	5.34	0.20	3.8	5.3	5.0 - 5.7	14	10.95	0.29	2.6	10.9	10.2 - 11.7
All TOSOH Methods	20	5.56	0.08	1.4	5.6	5.2 - 5.9	20	10.36	0.17	1.6	10.3	9.7 - 11.0
Beckman AU A1c	10	5.37	0.21	3.8	5.4	5.0 - 5.7	10	11.06	0.37	3.4	11.1	10.3 - 11.8
Bio-Rad D-100	13	6.09	0.13	2.2	6.1	5.7 - 6.5	14	11.06	0.16	1.5	11.1	10.4 - 11.8
Siemens DCA Vantage	70	5.76	0.16	2.8	5.8	5.4 - 6.2	69	10.92	0.31	2.8	10.8	10.2 - 11.6
Siemens Dimension HB1C	16	5.67	0.24	4.2	5.7	5.3 - 6.1	16	10.94	0.37	3.4	11.1	10.2 - 11.6
TOSOH G8	20	5.56	0.08	1.4	5.6	5.2 - 5.9	20	10.36	0.17	1.6	10.3	9.7 - 11.0

## 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	754	203.2	14.7	7.2	204	162 - 244	760	114.5	11.1	9.7	114	91 - 138
All Abbott Methods	49	195.8	12.1	6.2	197	156 - 235	49	105.1	6.6	6.3	105	84 - 127
All Arkray Methods	8	255.5	40.3	15.8	277	204 - 307	8	133.0	10.8	8.1	134	106 - 160
All Bayer Methods	29	164.8	12.4	7.5	163	131 - 198	29	86.8	7.9	9.1	87	69 - 105
All Hemocue Methods	63	218.4	7.2	3.3	219	174 - 263	63	136.9	6.2	4.5	137	109 - 165
All Lifescan Methods	16	218.3	21.6	9.9	219	174 - 262	16	116.9	8.8	7.5	116	93 - 141
All Roche Methods	462	204.1	4.3	2.1	204	163 - 245	464	114.3	2.6	2.3	114	91 - 138
Abbott FreeStyle Lite/Freedom Lite	7	187.3	11.0	5.9	187	149 - 225	7	103.7	4.8	4.6	104	82 - 125
Abbott FreeStyle Precision Pro	18	196.3	13.3	6.8	199	157 - 236	18	104.2	7.4	7.1	106	83 - 126
Abbott Precision XceedPro	23	196.6	8.8	4.5	198	157 - 236	23	105.8	6.2	5.8	105	84 - 127
Arkray Platinum	26	232.3	28.0	12.1	219	185 - 279	26	129.4	6.7	5.2	129	103 - 156
Bayer Contour	31	164.4	12.1	7.3	162	131 - 198	30	86.1	6.4	7.5	87	68 - 104
HemoCue Glucose 201	65	218.3	7.2	3.3	218	174 - 262	66	136.9	6.2	4.5	137	109 - 165
Home Diagnostics True Balance / TrueTrack	13	447.5	29.9	6.7	455	358 - 538	13	278.9	18.9	6.8	282	223 - 335
Lifescan One Touch Ultra	13	226.4	13.9	6.1	225	181 - 272	13	119.9	6.2	5.1	118	95 - 144
Medline EvenCare G2 / G3	12	210.3	12.1	5.8	209	168 - 253	12	118.8	5.2	4.4	119	95 - 143
NOVA Biomedical StatStrip	29	174.8	7.8	4.4	175	139 - 210	29	98.7	4.6	4.7	99	78 - 119
Quintet / AC	30	209.8	10.7	5.1	210	167 - 252	29	113.0	6.3	5.6	112	90 - 136
Roche Accu-Chek Aviva	5	206.2	4.3	2.1	207	164 - 248	5	116.4	2.8	2.4	117	93 - 140
Roche Accu-Chek Inform	10	200.5	2.0	1.0	200	160 - 241	10	112.0	3.2	2.9	113	89 - 135
Roche Accu-Chek Inform II	290	203.5	4.2	2.1	203	162 - 245	290	114.0	2.3	2.0	113	91 - 137
Roche Accu-Chek Performa	157	205.3	4.3	2.1	205	164 - 247	157	114.7	2.8	2.5	115	91 - 138
True Metrix Pro	16	181.4	32.5	17.9	178	145 - 218	15	99.1	5.7	5.7	99	79 - 119

**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	131	55.1	5.6	10.1	57	43 - 68	127	358.8	14.5	4.0	360	287 - 431
All Abbott Methods	18	46.2	1.7	3.7	46	34 - 59	18	362.5	20.1	5.5	361	290 - 435
All Hemocue Methods	1	-	-	-	83	66 - 100	1	-	-	-	366	292 - 440
All Lifescan Methods	4	-	-	-	45	34 - 59	4	-	-	-	409	324 - 487
All Roche Methods	91	58.0	1.6	2.8	58	45 - 70	92	360.5	7.9	2.2	361	288 - 433
Abbott FreeStyle Precision Pro	10	46.9	2.0	4.2	47	34 - 59	10	362.2	19.2	5.3	362	289 - 435
Abbott Precision XceedPro	7	45.4	0.8	1.7	45	33 - 58	7	356.1	13.0	3.6	359	284 - 428
HemoCue Glucose 201	1	-	-	-	83	66 - 100	1	-	-	-	366	292 - 440
Lifescan One Touch Ultra	4	-	-	-	45	34 - 59	4	-	-	-	409	324 - 487
Medline EvenCare G2 / G3	1	-	-	-	52	40 - 64	1	-	-	-	363	290 - 436
NOVA Biomedical StatStrip	9	46.0	1.8	3.9	46	34 - 58	9	322.4	7.7	2.4	322	257 - 387
Roche Accu-Chek Inform	10	56.7	1.1	1.9	57	44 - 69	10	359.2	6.7	1.9	360	287 - 432
Roche Accu-Chek Inform II	58	58.3	1.4	2.3	58	46 - 71	59	361.6	8.3	2.3	362	289 - 434
Roche Accu-Chek Performa	23	57.8	2.2	3.8	57	45 - 70	23	358.2	7.0	1.9	356	286 - 430
True Metrix Pro	1	-	-	-	46	34 - 58	1	-	-	-	347	277 - 417

<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	128	284.2	14.4	5.1	284	227 - 342
All Abbott Methods	18	287.2	13.8	4.8	285	229 - 345
All Hemocue Methods	1	-	-	-	298	238 - 358
All Lifescan Methods	4	-	-	-	323	256 - 385
All Roche Methods	91	284.8	5.9	2.1	285	227 - 342
Abbott FreeStyle Precision Pro	10	288.2	9.5	3.3	287	230 - 346
Abbott Precision XceedPro	7	280.1	9.9	3.5	276	224 - 337
HemoCue Glucose 201	1	-	-	-	298	238 - 358
Lifescan One Touch Ultra	4	-	-	-	323	256 - 385
Medline EvenCare G2 / G3	1	-	-	-	326	260 - 392
NOVA Biomedical StatStrip	9	252.1	4.6	1.8	251	201 - 303
Roche Accu-Chek Inform	10	282.6	6.1	2.1	281	226 - 340
Roche Accu-Chek Inform II	58	285.6	5.5	1.9	285	228 - 343
Roche Accu-Chek Performa	23	283.8	6.8	2.4	281	227 - 341
True Metrix Pro	1	-	-	-	260	208 - 312

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
<b>Specimen CK-6</b>						
All Method	17	16.26	2.03	12.5	16.7	10.1 - 22.4
Roche cobas 6000 / c 501	13	16.85	1.16	6.9	16.8	13.3 - 20.4
<b>Specimen CK-7</b>						
All Method	17	48.89	5.26	10.8	51.1	33.1 - 64.7
Roche cobas 6000 / c 501	13	50.57	2.23	4.4	51.2	43.8 - 57.3
<b>Specimen CK-8</b>						
All Method	17	92.14	9.64	10.5	95.5	63.2 - 121.1
Roche cobas 6000 / c 501	13	95.22	4.13	4.3	95.8	82.8 - 107.7
<b>Specimen CK-9</b>						
All Method	17	6.08	0.84	13.8	6.1	3.5 - 8.6
Roche cobas 6000 / c 501	13	6.26	0.63	10.1	6.3	4.3 - 8.2
<b>Specimen CK-10</b>						
All Method	17	27.54	3.10	11.2	28.2	18.2 - 36.9
Roche cobas 6000 / c 501	13	28.52	1.47	5.2	28.5	24.0 - 33.0

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