

# 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-M1



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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	$\pm 15\%$
Automated Differential	$\pm 3$ SD
CK-MB (U/L)	$\pm 3$ SD
Cytomegalovirus	$\pm 2$ SD
Fibrinogen	$\pm 20\%$
Glycohemoglobin	$\pm 6\%$
Hematocrit	$\pm 6\%$
Hemoglobin	$\pm 7\%$
International Normalized Ratio (INR)	$\pm 20\%$
Platelet Count	$\pm 25\%$
Prothrombin Time	$\pm 15\%$
Red Blood Cell Count	$\pm 6\%$
Rubella	$\pm 3$ SD
Specific Gravity	$\pm 0.010$
Toxoplasma	$\pm 2$ SD
White Blood Cell Count	$\pm 15\%$

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

<b>Instrument</b>	<b>Specimen CL-1</b>						<b>Specimen CL-2</b>					
	<b>Labs</b>	<b>Mean</b>	<b>SD</b>	<b>CV</b>	<b>Median</b>	<b>Range</b>	<b>Labs</b>	<b>Mean</b>	<b>SD</b>	<b>CV</b>	<b>Median</b>	<b>Range</b>
All Method	40	2.44	0.35	14.4	2.3	2.0 - 2.9	40	17.79	1.44	8.1	17.6	15.1 - 20.5
All Abbott Cell-Dyn Instruments	13	2.83	0.13	4.4	2.9	2.4 - 3.3	13	19.27	0.48	2.5	19.3	16.3 - 22.2
Abbott Cell-Dyn Ruby	11	2.84	0.13	4.5	2.9	2.4 - 3.3	11	19.19	0.47	2.4	19.1	16.3 - 22.1
Orpheo Mythic 22	23	2.18	0.12	5.6	2.2	1.8 - 2.6	24	16.88	0.78	4.6	17.1	14.3 - 19.5
<b>Specimen CL-3</b>						<b>Specimen CL-4</b>						
All Method	40	6.67	0.66	9.9	6.5	5.6 - 7.7	40	17.79	1.37	7.7	17.6	15.1 - 20.5
All Abbott Cell-Dyn Instruments	13	7.47	0.19	2.5	7.5	6.3 - 8.6	13	19.16	0.42	2.2	19.0	16.2 - 22.1
Abbott Cell-Dyn Ruby	11	7.46	0.20	2.7	7.5	6.3 - 8.6	11	19.11	0.40	2.1	19.0	16.2 - 22.0
Orpheo Mythic 22	24	6.23	0.30	4.8	6.3	5.2 - 7.2	24	16.95	0.76	4.5	17.2	14.4 - 19.5
<b>Specimen CL-5</b>												
All Method	40	6.64	0.65	9.7	6.4	5.6 - 7.7						
All Abbott Cell-Dyn Instruments	13	7.42	0.27	3.7	7.4	6.3 - 8.6						
Abbott Cell-Dyn Ruby	11	7.43	0.30	4.0	7.5	6.3 - 8.6						
Orpheo Mythic 22	24	6.21	0.28	4.5	6.3	5.2 - 7.2						

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

<b><u>Instrument</u></b>	Specimen CL-1						Specimen CL-2					
	<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	40	2.109	0.076	3.6	2.12	1.98 - 2.24	40	5.183	0.158	3.1	5.18	4.87 - 5.50
All Abbott Cell-Dyn Instruments	13	2.150	0.064	3.0	2.15	2.02 - 2.28	13	5.251	0.181	3.5	5.33	4.93 - 5.57
Abbott Cell-Dyn Ruby	11	2.157	0.066	3.1	2.15	2.02 - 2.29	11	5.284	0.127	2.4	5.33	4.96 - 5.61
Orpheo Mythic 22	24	2.088	0.078	3.7	2.10	1.96 - 2.22	24	5.148	0.145	2.8	5.15	4.83 - 5.46
Specimen CL-3												
All Method	39	4.692	0.137	2.9	4.70	4.41 - 4.98	40	5.191	0.195	3.7	5.19	4.87 - 5.51
All Abbott Cell-Dyn Instruments	13	4.781	0.123	2.6	4.80	4.49 - 5.07	13	5.257	0.232	4.4	5.33	4.94 - 5.58
Abbott Cell-Dyn Ruby	11	4.805	0.098	2.0	4.80	4.51 - 5.10	11	5.288	0.228	4.3	5.34	4.97 - 5.61
Orpheo Mythic 22	23	4.643	0.129	2.8	4.62	4.36 - 4.93	24	5.160	0.180	3.5	5.15	4.85 - 5.48
Specimen CL-5												
All Method	38	4.678	0.138	3.0	4.68	4.39 - 4.96						
All Abbott Cell-Dyn Instruments	13	4.756	0.116	2.4	4.79	4.47 - 5.05						
Abbott Cell-Dyn Ruby	11	4.775	0.103	2.1	4.81	4.48 - 5.07						
Orpheo Mythic 22	23	4.616	0.168	3.6	4.64	4.33 - 4.90						

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

<u><b>Instrument</b></u>	Specimen CL-1						Specimen CL-2					
	<u><b>Labs</b></u>	<u><b>Mean</b></u>	<u><b>SD</b></u>	<u><b>CV</b></u>	<u><b>Median</b></u>	<u><b>Range</b></u>	<u><b>Labs</b></u>	<u><b>Mean</b></u>	<u><b>SD</b></u>	<u><b>CV</b></u>	<u><b>Median</b></u>	<u><b>Range</b></u>
All Method	39	5.25	0.44	8.4	5.0	4.8 - 5.7	40	15.81	0.55	3.5	15.7	14.6 - 17.0
All Abbott Cell-Dyn Instruments	13	5.75	0.22	3.8	5.7	5.3 - 6.2	13	16.42	0.36	2.2	16.4	15.2 - 17.6
Abbott Cell-Dyn Ruby	11	5.69	0.15	2.7	5.7	5.2 - 6.1	11	16.40	0.35	2.1	16.4	15.2 - 17.6
Orpheo Mythic 22	23	4.92	0.11	2.2	4.9	4.5 - 5.3	24	15.47	0.29	1.9	15.5	14.3 - 16.6
Specimen CL-3						Specimen CL-4						
All Method	40	12.69	0.69	5.4	12.4	11.7 - 13.6	40	15.81	0.55	3.5	15.7	14.7 - 17.0
All Abbott Cell-Dyn Instruments	13	13.55	0.28	2.1	13.5	12.5 - 14.5	13	16.36	0.47	2.9	16.5	15.2 - 17.6
Abbott Cell-Dyn Ruby	11	13.51	0.27	2.0	13.5	12.5 - 14.5	11	16.37	0.50	3.1	16.5	15.2 - 17.6
Orpheo Mythic 22	24	12.20	0.21	1.8	12.2	11.3 - 13.1	24	15.50	0.31	2.0	15.5	14.4 - 16.6
Specimen CL-5												
All Method	40	12.69	0.68	5.3	12.5	11.7 - 13.6						
All Abbott Cell-Dyn Instruments	13	13.54	0.23	1.7	13.6	12.5 - 14.5						
Abbott Cell-Dyn Ruby	11	13.54	0.24	1.8	13.6	12.5 - 14.5						
Orpheo Mythic 22	24	12.20	0.22	1.8	12.2	11.3 - 13.1						

## HEMATOLOGY W/ 5-PART DIFFERENTIAL—HEMATOCRIT (percent)

<u>Instrument</u>	Specimen CL-1						Specimen CL-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	38	16.21	0.86	5.3	16.3	15.2 - 17.2	38	46.12	2.10	4.6	46.5	43.3 - 48.9
All Abbott Cell-Dyn Instruments	11	15.31	0.67	4.4	15.3	14.3 - 16.3	11	43.74	1.12	2.6	44.2	41.1 - 46.4
Abbott Cell-Dyn Ruby	11	15.31	0.67	4.4	15.3	14.3 - 16.3	11	43.74	1.12	2.6	44.2	41.1 - 46.4
Orpheo Mythic 22	24	16.58	0.61	3.7	16.7	15.5 - 17.6	24	46.99	1.48	3.2	46.9	44.1 - 49.9
Specimen CL-3						Specimen CL-4						
All Method	38	39.21	1.70	4.3	39.3	36.8 - 41.6	38	46.15	2.36	5.1	46.2	43.3 - 49.0
All Abbott Cell-Dyn Instruments	11	37.99	0.90	2.4	38.0	35.7 - 40.3	11	43.73	1.48	3.4	44.0	41.1 - 46.4
Abbott Cell-Dyn Ruby	11	37.99	0.90	2.4	38.0	35.7 - 40.3	11	43.73	1.48	3.4	44.0	41.1 - 46.4
Orpheo Mythic 22	24	39.58	1.68	4.2	39.6	37.2 - 42.0	24	47.06	1.87	4.0	47.3	44.2 - 49.9
Specimen CL-5												
All Method	37	39.19	1.67	4.2	39.2	36.8 - 41.6						
All Abbott Cell-Dyn Instruments	11	37.71	1.02	2.7	38.0	35.4 - 40.0						
Abbott Cell-Dyn Ruby	11	37.71	1.02	2.7	38.0	35.4 - 40.0						
Orpheo Mythic 22	23	39.73	1.45	3.7	40.1	37.3 - 42.2						

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

<u><b>Instrument</b></u>	Specimen CL-1						Specimen CL-2					
	<u><b>Labs</b></u>	<u><b>Mean</b></u>	<u><b>SD</b></u>	<u><b>CV</b></u>	<u><b>Median</b></u>	<u><b>Range</b></u>	<u><b>Labs</b></u>	<u><b>Mean</b></u>	<u><b>SD</b></u>	<u><b>CV</b></u>	<u><b>Median</b></u>	<u><b>Range</b></u>
All Method	39	96.1	16.4	17.1	97	72 - 121	40	498.7	30.9	6.2	505	374 - 624
All Abbott Cell-Dyn Instruments	13	77.1	6.3	8.2	76	57 - 97	13	475.1	27.5	5.8	481	356 - 594
Abbott Cell-Dyn Ruby	11	75.8	6.1	8.0	74	56 - 95	11	474.3	30.0	6.3	481	355 - 593
Orpheo Mythic 22	23	107.0	9.6	8.9	107	80 - 134	24	512.8	24.5	4.8	519	384 - 642
Specimen CL-3						Specimen CL-4						
All Method	38	275.8	18.0	6.5	277	206 - 345	40	495.2	30.8	6.2	501	371 - 620
All Abbott Cell-Dyn Instruments	13	263.8	19.5	7.4	261	197 - 330	13	470.5	31.0	6.6	464	352 - 589
Abbott Cell-Dyn Ruby	11	263.0	19.6	7.5	261	197 - 329	11	469.4	33.3	7.1	464	352 - 587
Orpheo Mythic 22	22	282.8	14.1	5.0	284	212 - 354	24	509.2	22.7	4.5	506	381 - 637
Specimen CL-5												
All Method	38	278.2	20.2	7.3	281	208 - 348						
All Abbott Cell-Dyn Instruments	13	265.0	20.8	7.9	260	198 - 332						
Abbott Cell-Dyn Ruby	11	265.7	22.6	8.5	260	199 - 333						
Orpheo Mythic 22	22	286.6	15.5	5.4	289	214 - 359						

## HEMATOLOGY W/ 5-PART DIFFERENTIAL—NEUTROPHILS (percent)

<u><b>Instrument</b></u>	Specimen CL-1						Specimen CL-2					
	<u><b>Labs</b></u>	<u><b>Mean</b></u>	<u><b>SD</b></u>	<u><b>CV</b></u>	<u><b>Median</b></u>	<u><b>Range</b></u>	<u><b>Labs</b></u>	<u><b>Mean</b></u>	<u><b>SD</b></u>	<u><b>CV</b></u>	<u><b>Median</b></u>	<u><b>Range</b></u>
All Method	38	50.30	3.69	7.3	50.8	39.2 - 61.4	39	71.30	5.78	8.1	72.5	53.9 - 88.7
All Abbott Cell-Dyn Instruments	13	53.40	1.22	2.3	53.4	49.7 - 57.1	13	76.27	1.03	1.3	76.7	73.1 - 79.4
Abbott Cell-Dyn Ruby	11	53.38	1.33	2.5	53.4	49.3 - 57.4	11	76.27	1.06	1.4	76.7	73.0 - 79.5
Orpheo Mythic 22	23	48.29	3.36	7.0	49.0	38.1 - 58.4	24	68.23	5.32	7.8	71.0	52.2 - 84.2
Specimen CL-3						Specimen CL-4						
All Method	39	62.93	5.43	8.6	64.3	46.6 - 79.3	39	71.14	5.64	7.9	72.4	54.2 - 88.1
All Abbott Cell-Dyn Instruments	13	67.68	1.01	1.5	67.4	64.6 - 70.8	13	75.92	1.40	1.8	76.4	71.7 - 80.2
Abbott Cell-Dyn Ruby	11	67.82	1.03	1.5	67.9	64.7 - 71.0	11	75.99	1.52	2.0	76.5	71.4 - 80.6
Orpheo Mythic 22	24	60.01	4.95	8.3	61.5	45.1 - 74.9	24	68.19	5.23	7.7	70.1	52.4 - 83.9
Specimen CL-5												
All Method	39	62.58	5.70	9.1	63.7	45.4 - 79.7						
All Abbott Cell-Dyn Instruments	13	67.62	1.22	1.8	67.5	63.9 - 71.3						
Abbott Cell-Dyn Ruby	11	67.54	1.31	1.9	67.4	63.5 - 71.5						
Orpheo Mythic 22	24	59.57	5.23	8.8	61.3	43.8 - 75.3						

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

<b><i>Instrument</i></b>	<b>Specimen CL-1</b>						<b>Specimen CL-2</b>					
	<b><i>Labs</i></b>	<b><i>Mean</i></b>	<b><i>SD</i></b>	<b><i>CV</i></b>	<b><i>Median</i></b>	<b><i>Range</i></b>	<b><i>Labs</i></b>	<b><i>Mean</i></b>	<b><i>SD</i></b>	<b><i>CV</i></b>	<b><i>Median</i></b>	<b><i>Range</i></b>
All Method	38	32.66	4.48	13.7	33.7	19.2 - 46.2	37	16.09	3.75	23.3	16.4	4.8 - 27.4
All Abbott Cell-Dyn Instruments	13	34.95	3.36	9.6	36.1	24.8 - 45.1	12	16.84	1.55	9.2	16.4	12.1 - 21.5
Abbott Cell-Dyn Ruby	11	35.88	1.63	4.5	36.2	31.0 - 40.8	10	16.89	1.69	10.0	16.4	11.8 - 22.0
Orpheo Mythic 22	23	31.44	4.59	14.6	31.9	17.6 - 45.3	23	15.82	4.61	29.1	15.9	1.9 - 29.7
<b>Specimen CL-3</b>							<b>Specimen CL-4</b>					
All Method	38	20.87	4.81	23.0	21.5	6.4 - 35.3	38	16.33	3.68	22.5	16.5	5.3 - 27.4
All Abbott Cell-Dyn Instruments	13	23.87	1.44	6.1	24.1	19.5 - 28.3	13	16.80	0.97	5.8	16.6	13.8 - 19.8
Abbott Cell-Dyn Ruby	11	23.69	1.49	6.3	23.9	19.2 - 28.2	11	16.66	1.00	6.0	16.5	13.6 - 19.7
Orpheo Mythic 22	23	19.25	5.35	27.8	20.1	3.1 - 35.4	23	16.19	4.67	28.8	16.4	2.1 - 30.2
<b>Specimen CL-5</b>												
All Method	37	20.73	4.90	23.6	21.0	6.0 - 35.5						
All Abbott Cell-Dyn Instruments	12	23.43	2.08	8.9	23.7	17.1 - 29.7						
Abbott Cell-Dyn Ruby	10	23.52	2.29	9.7	23.9	16.6 - 30.4						
Orpheo Mythic 22	23	19.34	5.53	28.6	20.3	2.7 - 36.0						

## HEMATOLOGY W/ 5-PART DIFFERENTIAL—MONOCYTES (percent)

<u><b>Instrument</b></u>	Specimen CL-1						Specimen CL-2					
	<u><b>Labs</b></u>	<u><b>Mean</b></u>	<u><b>SD</b></u>	<u><b>CV</b></u>	<u><b>Median</b></u>	<u><b>Range</b></u>	<u><b>Labs</b></u>	<u><b>Mean</b></u>	<u><b>SD</b></u>	<u><b>CV</b></u>	<u><b>Median</b></u>	<u><b>Range</b></u>
All Method	39	13.14	4.85	36.9	14.3	0.0 - 27.7	38	9.26	4.19	45.3	11.2	0.0 - 21.9
All Abbott Cell-Dyn Instruments	12	7.28	1.29	17.8	7.5	3.3 - 11.2	11	4.07	0.26	6.5	4.0	3.2 - 4.9
Abbott Cell-Dyn Ruby	11	7.16	1.30	18.1	7.4	3.2 - 11.1	10	3.79	0.84	22.1	4.0	1.2 - 6.4
Orphee Mythic 22	24	16.05	2.89	18.0	15.6	7.3 - 24.8	24	12.05	1.83	15.2	12.4	6.5 - 17.6
Specimen CL-3												
All Method	v	14.65	6.68	45.6	16.0	0.0 - 34.7	39	9.09	4.09	45.0	10.6	0.0 - 21.4
All Abbott Cell-Dyn Instruments	16	7.19	1.36	18.9	7.2	3.1 - 11.3	13	4.09	0.49	11.9	4.1	2.6 - 5.6
Abbott Cell-Dyn Ruby	13	6.88	0.92	13.4	7.1	4.1 - 9.7	11	4.10	0.53	13.0	4.2	2.5 - 5.7
Orphee Mythic 22	27	18.77	4.29	22.8	17.7	5.9 - 31.7	24	11.90	1.96	16.5	12.2	6.0 - 17.8
Specimen CL-5												
All Method	39	12.66	5.86	46.3	14.2	0.0 - 30.3						
All Abbott Cell-Dyn Instruments	13	5.79	0.73	12.5	5.8	3.6 - 8.0						
Abbott Cell-Dyn Ruby	11	5.75	0.76	13.2	5.8	3.4 - 8.1						
Orphee Mythic 22	24	16.53	3.41	20.6	16.2	6.2 - 26.8						

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

<b><i>Instrument</i></b>	<b>Specimen CL-1</b>						<b>Specimen CL-2</b>					
	<b><i>Labs</i></b>	<b><i>Mean</i></b>	<b><i>SD</i></b>	<b><i>CV</i></b>	<b><i>Median</i></b>	<b><i>Range</i></b>	<b><i>Labs</i></b>	<b><i>Mean</i></b>	<b><i>SD</i></b>	<b><i>CV</i></b>	<b><i>Median</i></b>	<b><i>Range</i></b>
All Method	38	3.04	1.13	37.2	3.2	0.0 - 6.5	38	2.64	0.86	32.4	2.7	0.0 - 5.3
All Abbott Cell-Dyn Instruments	13	2.97	0.34	11.5	2.9	1.9 - 4.0	13	2.78	0.19	6.8	2.8	2.2 - 3.4
Abbott Cell-Dyn Ruby	11	3.05	0.29	9.5	3.1	2.1 - 4.0	11	2.77	0.20	7.2	2.8	2.1 - 3.4
Orpheo Mythic 22	23	3.13	1.41	45.2	3.3	0.0 - 7.4	23	2.73	0.94	34.5	2.5	0.0 - 5.6
<b>Specimen CL-3</b>							<b>Specimen CL-4</b>					
All Method	38	3.00	1.08	36.0	2.8	0.0 - 6.3	36	2.54	0.80	31.3	2.7	0.1 - 5.0
All Abbott Cell-Dyn Instruments	13	2.87	0.18	6.1	2.8	2.3 - 3.4	13	2.78	0.14	5.0	2.8	2.3 - 3.3
Abbott Cell-Dyn Ruby	11	2.85	0.18	6.2	2.8	2.3 - 3.4	11	2.78	0.15	5.5	2.7	2.3 - 3.3
Orpheo Mythic 22	23	3.17	1.33	42.1	2.9	0.0 - 7.2	23	2.88	1.52	52.7	2.7	0.0 - 7.5
<b>Specimen CL-5</b>												
All Method	37	2.84	1.14	40.0	2.9	0.0 - 6.3						
All Abbott Cell-Dyn Instruments	13	2.92	0.23	7.8	2.9	2.2 - 3.6						
Abbott Cell-Dyn Ruby	11	2.94	0.24	8.2	3.0	2.2 - 3.7						
Orpheo Mythic 22	24	3.38	2.17	64.3	3.0	0.0 - 9.9						

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

<b><i>Instrument</i></b>	<b>Specimen CL-1</b>						<b>Specimen CL-2</b>					
	<b><i>Labs</i></b>	<b><i>Mean</i></b>	<b><i>SD</i></b>	<b><i>CV</i></b>	<b><i>Median</i></b>	<b><i>Range</i></b>	<b><i>Labs</i></b>	<b><i>Mean</i></b>	<b><i>SD</i></b>	<b><i>CV</i></b>	<b><i>Median</i></b>	<b><i>Range</i></b>
All Method	39	0.52	0.47	89.4	0.4	0.0 - 2.0	37	0.29	0.20	68.9	0.2	0.0 - 0.9
All Abbott Cell-Dyn Instruments	13	0.65	0.58	89.3	0.5	0.0 - 2.5	12	0.12	0.06	49.5	0.1	0.0 - 0.3
Abbott Cell-Dyn Ruby	11	0.55	0.51	94.3	0.4	0.0 - 2.1	10	0.12	0.06	52.7	0.1	0.0 - 0.4
Orpheo Mythic 22	23	0.37	0.24	65.5	0.3	0.0 - 1.1	24	0.39	0.24	61.1	0.4	0.0 - 1.2
<b>Specimen CL-3</b>							<b>Specimen CL-4</b>					
All Method	39	0.34	0.32	95.3	0.3	0.0 - 1.4	37	0.29	0.19	66.6	0.3	0.0 - 0.9
All Abbott Cell-Dyn Instruments	13	0.05	0.07	143.0	0.0	0.0 - 0.3	12	0.17	0.17	103.4	0.1	0.0 - 0.7
Abbott Cell-Dyn Ruby	11	0.05	0.07	126.0	0.0	0.0 - 0.3	11	0.47	0.95	201.6	0.2	0.0 - 3.4
Orpheo Mythic 22	24	0.49	0.31	63.2	0.5	0.0 - 1.5	23	0.34	0.18	53.2	0.3	0.0 - 0.9
<b>Specimen CL-5</b>												
All Method	39	0.43	0.32	75.8	0.3	0.0 - 1.4						
All Abbott Cell-Dyn Instruments	13	0.16	0.14	89.5	0.1	0.0 - 0.6						
Abbott Cell-Dyn Ruby	11	0.17	0.15	86.2	0.1	0.0 - 0.7						
Orpheo Mythic 22	24	0.55	0.29	52.5	0.5	0.0 - 1.5						

## BLOOD BANK

### ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-1	Group A	35	97.22%	Acceptable
	Group AB	1	2.78%	
BB-2	Group O	35	97.22%	Acceptable
	Group AB	1	2.78%	
BB-3	Group O	36	100%	Acceptable
BB-4	Group A	36	100%	Acceptable
BB-5	Group AB	36	100%	Acceptable

### RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-1	Rh Positive	35	97.22%	Acceptable
	Rh Negative	1	2.78%	
BB-2	Rh Negative	36	100%	Acceptable
	Rh Positive	36	100%	Acceptable
BB-4	Rh Negative	36	97.22%	Acceptable
	Rh Positive	1	2.78%	
BB-5	Rh Positive	35	97.22%	Acceptable
	Rh Negative	1	2.78%	

## BLOOD BANK

### UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	Unexpected antibody detected	24	100%	Acceptable
AB-2	No unexpected antibody detected	23	95.83%	Acceptable
	Unexpected antibody detected	1	4.17%	
AB-3	Unexpected antibody detected	22	91.67%	Acceptable
	No unexpected antibody detected	2	8.33%	
AB-4	No unexpected antibody detected	23	95.83%	Acceptable
	Unexpected antibody detected	1	4.17%	
AB-5	No unexpected antibody detected	21	95.45%	Acceptable
	Unexpected antibody detected	1	4.55%	

### ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	Anti-E	11	100%	Acceptable
AB-2	No antibody detected	11	100%	Acceptable
AB-3	Anti-M	10	90.91%	Acceptable
	No antibody	1	9.09%	
AB-4	No antibody detected	11	100%	Acceptable
AB-5	No antibody detected	10	100%	Acceptable

## BLOOD BANK

### COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	Not Compatible	22	91.67%	Acceptable
	Compatible	2	8.33%	
AB-2	Compatible	20	83.33%	Acceptable
	Not Compatible	4	16.67%	
AB-3	Compatible	24	100%	Acceptable
AB-4	Compatible	22	91.67%	Acceptable
	Not Compatible	2	8.33%	
AB-5	Compatible	21	100%	Acceptable

## Coagulation

### PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-1						Specimen CG-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	77	24.86	3.34	13.4	25.3	21.1 - 28.6	77	12.90	1.57	12.2	13.0	10.9 - 14.9
Dade Innovin												
Dade Behring BFT II	5	23.00	2.29	9.9	23.4	19.5 - 26.5	5	10.23	0.33	3.2	10.1	8.6 - 11.8
Sysmex CA-500/600 series	13	22.01	0.61	2.8	22.3	18.7 - 25.4	13	11.18	0.39	3.5	11.2	9.5 - 12.9
All Coagulation Instruments	19	22.13	1.20	5.4	22.3	18.8 - 25.5	19	10.98	0.61	5.6	11.1	9.3 - 12.7
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STA Compact	5	27.88	2.23	8.0	28.7	23.6 - 32.1	5	14.53	0.17	1.2	14.6	12.3 - 16.8
RAL Clot-SP	17	27.20	1.03	3.8	27.3	23.1 - 31.3	17	14.19	0.40	2.8	14.1	12.0 - 16.4
All Coagulation Instruments	22	27.34	1.26	4.6	27.5	23.2 - 31.5	22	14.23	0.40	2.8	14.1	12.0 - 16.4
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	27.40	1.32	4.8	26.9	23.2 - 31.6	5	14.00	0.70	5.0	14.0	11.9 - 16.1
All Coagulation Instruments	6	29.30	4.19	14.3	27.7	24.9 - 33.7	6	14.16	0.58	4.1	14.1	12.0 - 16.3
HemosIL PT-Fibrinogen												
IL ACL, all models	5	20.10	0.57	2.8	20.1	17.0 - 23.2	5	12.50	0.14	1.1	12.5	10.6 - 14.4
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	26.55	0.66	2.5	26.5	22.5 - 30.6	5	12.08	0.43	3.6	12.1	10.2 - 13.9
IL TEST PT Fibrinogen												
IL ACL, all models	5	20.15	0.90	4.5	20.4	17.1 - 23.2	5	12.78	0.33	2.6	12.8	10.8 - 14.7

**PROTHROMBIN TIME (seconds)**

<b><u>Reagent/Instrument</u></b>	Specimen CG-3						Specimen CG-4					
	<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	77	15.47	1.70	11.0	15.7	13.1 - 17.8	77	35.60	5.02	14.1	36.8	30.2 - 41.0
Dade Innovin												
Dade Behring BFT II	5	12.70	0.70	5.5	12.6	10.7 - 14.7	5	34.33	1.99	5.8	35.0	29.1 - 39.5
Sysmex CA-500/600 series	13	13.73	0.47	3.4	13.8	11.6 - 15.8	13	31.68	1.11	3.5	31.7	26.9 - 36.5
All Coagulation Instruments	19	13.47	0.64	4.8	13.4	11.4 - 15.5	19	32.25	1.64	5.1	31.8	27.4 - 37.1
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STA Compact	5	16.95	0.10	0.6	16.9	14.4 - 19.5	5	40.35	1.50	3.7	41.1	34.2 - 46.5
RAL Clot-SP	17	16.98	0.49	2.9	17.1	14.4 - 19.6	17	39.46	1.63	4.1	39.8	33.5 - 45.4
All Coagulation Instruments	22	16.96	0.44	2.6	16.9	14.4 - 19.6	22	39.74	1.67	4.2	39.9	33.7 - 45.7
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	16.70	0.50	3.0	16.7	14.1 - 19.3	5	37.97	1.12	2.9	38.4	32.2 - 43.7
All Coagulation Instruments	6	17.02	0.58	3.4	17.2	14.4 - 19.6	6	38.52	1.09	2.8	38.8	32.7 - 44.3
HemosIL PT-Fibrinogen												
IL ACL, all models	5	14.90	0.71	4.7	14.9	12.6 - 17.2	5	26.00	1.13	4.4	26.0	22.1 - 29.9
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	15.68	0.32	2.0	15.7	13.3 - 18.1	5	40.60	1.04	2.6	41.0	34.5 - 46.7
IL TEST PT Fibrinogen												
IL ACL, all models	5	15.30	0.48	3.2	15.5	13.0 - 17.6	5	25.95	1.73	6.7	26.5	22.0 - 29.9

## PROTHROMBIN TIME (seconds)

### Specimen CG-5

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	77	12.26	1.46	11.9	12.6	10.4 - 14.1
Dade Innovin						
Dade Behring BFT II	5	9.33	0.15	1.6	9.4	7.9 - 10.8
Sysmex CA-500/600 series	13	10.51	0.27	2.6	10.6	8.9 - 12.1
All Coagulation Instruments	19	10.28	0.58	5.6	10.5	8.7 - 11.9
Diag Stago STA Neoplastine Cl+						
Diagnostica Stago STA Compact	5	13.60	0.29	2.2	13.6	11.5 - 15.7
RAL Clot-SP	17	13.46	0.37	2.8	13.4	11.4 - 15.5
All Coagulation Instruments	22	13.50	0.35	2.6	13.5	11.4 - 15.6
Diagnostica Stago Neoplastine Cl Plus						
Diagnostica Stago STA Compact	5	13.40	0.46	3.4	13.3	11.3 - 15.5
All Coagulation Instruments	6	13.36	0.59	4.4	13.3	11.3 - 15.4
HemosIL PT-Fibrinogen						
IL ACL, all models	5	12.15	0.35	2.9	12.2	10.3 - 14.0
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	12.10	0.14	1.2	12.1	10.2 - 14.0
IL TEST PT Fibrinogen						
IL ACL, all models	5	12.75	0.81	6.4	12.6	10.8 - 14.7

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

<b><u>Reagent/Instrument</u></b>	<b>Specimen CG-1</b>						<b>Specimen CG-2</b>					
	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
All Method	78	2.36	0.27	11.6	2.4	1.8 - 2.9	79	1.10	0.08	7.3	1.1	0.8 - 1.4
Dade Innovin												
Dade Behring BFT II	5	2.30	0.23	10.0	2.3	1.8 - 2.8	5	1.15	0.06	5.0	1.2	0.9 - 1.4
Sysmex CA-500/600 series	13	2.20	0.08	3.7	2.2	1.7 - 2.7	13	1.09	0.06	5.9	1.1	0.8 - 1.4
All Coagulation Instruments	19	2.22	0.13	5.7	2.2	1.7 - 2.7	19	1.11	0.07	6.4	1.1	0.8 - 1.4
Diag Stago STA Neoplastine Cl+												
Diagnostica Stago STA Compact	5	2.57	0.32	12.5	2.7	2.0 - 3.1	5	1.10	0.01	0.0	1.1	0.8 - 1.4
Diagnostica Stago STArt 4/8	4	-	-	-	2.7	2.0 - 3.1	5	1.20	0.14	11.8	1.2	0.9 - 1.5
RAL Clot-SP	16	2.52	0.12	4.9	2.5	2.0 - 3.1	16	1.11	0.06	5.4	1.1	0.8 - 1.4
All Coagulation Instruments	28	2.54	0.16	6.2	2.6	2.0 - 3.1	28	1.12	0.07	5.9	1.1	0.8 - 1.4
Diagnostica Stago Neoplastine Cl Plus												
Diagnostica Stago STA Compact	5	2.60	0.17	6.7	2.5	2.0 - 3.2	5	1.10	0.10	9.1	1.1	0.8 - 1.4
All Coagulation Instruments	6	2.55	0.17	6.8	2.5	2.0 - 3.1	6	1.10	0.08	7.4	1.1	0.8 - 1.4
HemosIL PT-Fibrinogen												
IL ACL, all models	5	2.50	0.01	0.0	2.5	2.0 - 3.0	5	1.10	0.01	0.0	1.1	0.8 - 1.4
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	2.35	0.17	7.4	2.3	1.8 - 2.9	5	1.05	0.06	5.5	1.1	0.8 - 1.3
IL TEST PT Fibrinogen												
IL ACL, all models	5	2.58	0.13	4.9	2.6	2.0 - 3.1	5	1.13	0.05	4.4	1.1	0.9 - 1.4

## PROTHROMBIN TIME-INTERNATIONAL NORMALIZED RATIO (INR)

<u><b>Reagent/Instrument</b></u>	Specimen CG-3						Specimen CG-4					
	<u><b>Labs</b></u>	<u><b>Mean</b></u>	<u><b>SD</b></u>	<u><b>CV</b></u>	<u><b>Median</b></u>	<u><b>Range</b></u>	<u><b>Labs</b></u>	<u><b>Mean</b></u>	<u><b>SD</b></u>	<u><b>CV</b></u>	<u><b>Median</b></u>	<u><b>Range</b></u>
All Method	79	1.38	0.10	7.6	1.4	1.1 - 1.7	79	3.62	0.54	14.8	3.6	2.8 - 4.4
Dade Innovin												
Dade Behring BFT II	5	1.38	0.10	7.0	1.4	1.1 - 1.7	5	3.23	0.15	4.7	3.2	2.5 - 3.9
Sysmex CA-500/600 series	13	1.35	0.08	5.8	1.3	1.0 - 1.7	13	3.17	0.13	3.9	3.2	2.5 - 3.9
All Coagulation Instruments	19	1.35	0.08	5.7	1.3	1.0 - 1.7	19	3.19	0.13	4.1	3.2	2.5 - 3.9
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STA Compact	5	1.37	0.06	4.2	1.4	1.0 - 1.7	5	4.07	0.32	7.9	4.2	3.2 - 4.9
Diagnostica Stago STart 4/8	5	1.50	0.14	9.4	1.5	1.2 - 1.8	5	4.70	0.01	0.0	4.7	3.7 - 5.7
RAL Clot-SP	16	1.39	0.07	4.7	1.4	1.1 - 1.7	16	4.02	0.25	6.1	4.1	3.2 - 4.9
All Coagulation Instruments	28	1.40	0.08	5.4	1.4	1.1 - 1.7	28	4.09	0.31	7.5	4.1	3.2 - 5.0
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STA Compact	5	1.33	0.06	4.3	1.3	1.0 - 1.6	5	3.93	0.12	2.9	4.0	3.1 - 4.8
All Coagulation Instruments	6	1.33	0.05	3.8	1.3	1.0 - 1.6	6	3.98	0.13	3.2	4.0	3.1 - 4.8
HemosIL PT-Fibrinogen												
IL ACL, all models	5	1.50	0.01	0.0	1.5	1.2 - 1.8	5	4.00	0.14	3.5	4.0	3.2 - 4.8
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	1.35	0.06	4.3	1.4	1.0 - 1.7	5	3.63	0.21	5.7	3.6	2.9 - 4.4
IL TEST PT Fibrinogen												
IL ACL, all models	5	1.58	0.10	6.1	1.6	1.2 - 1.9	5	4.03	0.29	7.1	4.2	3.2 - 4.9

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

**Specimen CG-5**

<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	79	1.04	0.09	8.5	1.0	0.8 - 1.3
Dade Innovin						
Dade Behring BFT II	5	1.05	0.06	5.5	1.1	0.8 - 1.3
Sysmex CA-500/600 series	13	1.03	0.06	6.1	1.0	0.8 - 1.3
All Coagulation Instruments	19	1.04	0.06	5.8	1.0	0.8 - 1.3
Diag Stago STA Neoplastine Cl+						
Diagnostica Stago STA Compact	5	1.03	0.06	5.6	1.0	0.8 - 1.3
Diagnostica Stago STart 4/8	5	1.10	0.01	0.0	1.1	0.8 - 1.4
RAL Clot-SP	16	1.02	0.04	4.3	1.0	0.8 - 1.3
All Coagulation Instruments	28	1.03	0.05	4.6	1.0	0.8 - 1.3
Diagnostica Stago Neoplastine Cl Plus						
Diagnostica Stago STA Compact	5	1.03	0.06	5.6	1.0	0.8 - 1.3
All Coagulation Instruments	6	1.03	0.05	4.9	1.0	0.8 - 1.3
HemosIL PT-Fibrinogen						
IL ACL, all models	5	1.05	0.07	6.7	1.1	0.8 - 1.3
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	1.03	0.10	9.3	1.1	0.8 - 1.3
IL TEST PT Fibrinogen						
IL ACL, all models	5	1.15	0.10	8.7	1.1	0.9 - 1.4

**ACTIVATED PARTIAL THROMBOPLASTIN (seconds)**

<b><u>Reagent/Instrument</u></b>	Specimen CG-1						Specimen CG-2					
	<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	39	39.4	6.9	17.6	38	33 - 46	39	30.3	6.0	19.8	32	25 - 35
Dade Actin FSL												
Sysmex CA-500/600 series	9	36.9	1.4	3.7	37	31 - 43	9	25.1	0.9	3.7	25	21 - 29
All Coagulation Instruments	10	36.9	1.3	3.5	37	31 - 43	10	25.3	1.1	4.2	25	21 - 30
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	5	43.4	2.5	5.8	44	36 - 50	5	33.8	1.8	5.3	34	28 - 39
All Coagulation Instruments	6	45.5	5.6	12.3	44	38 - 53	6	34.0	1.7	4.9	35	28 - 40
Diagnostica Stago STA-PTT												
Diagnostica Stago STA Compact	5	45.5	2.1	4.7	46	38 - 53	5	34.5	3.5	10.2	35	29 - 40
Hemoliance SynthASil												
IL ACL, all models	5	38.5	0.7	1.8	39	32 - 45	5	39.0	1.4	3.6	39	33 - 45
HemosIL APTT-SP												
IL ACL, all models	5	38.5	2.1	5.5	39	32 - 45	5	35.5	4.9	13.9	36	30 - 41
IL TEST APTT-SP												
IL ACL, all models	5	35.3	3.1	8.6	36	30 - 41	5	32.0	1.7	5.4	33	27 - 37

### ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

<u><b>Reagent/Instrument</b></u>	Specimen CG-3						Specimen CG-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	39	34.2	7.0	20.4	34	29 - 40	39	47.3	5.6	11.8	46	40 - 55
Dade Actin FSL												
Sysmex CA-500/600 series	9	28.8	1.2	4.2	29	24 - 34	9	44.2	1.5	3.3	45	37 - 51
All Coagulation Instruments	10	28.8	1.1	3.9	29	24 - 34	10	44.1	1.4	3.3	45	37 - 51
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	5	42.0	2.4	5.8	42	35 - 49	5	53.2	3.1	5.9	54	45 - 62
All Coagulation Instruments	6	41.3	2.7	6.6	41	35 - 48	6	52.0	4.0	7.8	52	44 - 60
Diagnostica Stago STA-PTT												
Diagnostica Stago STA Compact	5	42.5	0.7	1.7	43	36 - 49	5	55.0	1.4	2.6	55	46 - 64
Hemoliance SynthASil												
IL ACL, all models	5	35.0	1.4	4.0	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	48.0	5.7	11.8	48	40 - 56
IL TEST APTT-SP												
IL ACL, all models	5	40.7	1.2	2.8	40	34 - 47	5	44.7	2.1	4.7	44	37 - 52
<b>Specimen CG-5</b>												
<u><b>Reagent/Instrument</b></u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	39	26.3	4.4	16.9	26	22 - 31						
Dade Actin FSL												
Sysmex CA-500/600 series	9	23.0	0.7	3.1	23	19 - 27						
All Coagulation Instruments	10	23.2	0.9	4.0	23	19 - 27						
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	5	30.6	1.8	5.9	30	26 - 36						
All Coagulation Instruments	6	30.0	2.2	7.3	30	25 - 35						
Diagnostica Stago STA-PTT												
Diagnostica Stago STA Compact	5	32.0	2.8	8.8	32	27 - 37						
Hemoliance SynthASil												
IL ACL, all models	5	27.0	0.1	0.0	27	22 - 32						
HemosIL APTT-SP												
IL ACL, all models	5	27.5	0.7	2.6	28	23 - 32						
IL TEST APTT-SP												
IL ACL, all models	5	26.7	1.2	4.3	26	22 - 31						

**FIBRINOGEN (mg/dL)**

<b><u>Reagent/Instrument</u></b>	Specimen CG-1						Specimen CG-2					
	<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	13	270.4	29.8	11.0	261	216 - 325	13	453.5	43.2	9.5	459	362 - 545
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	10	261.3	14.0	5.4	257	209 - 314	10	469.6	28.8	6.1	462	375 - 564
<b>Specimen CG-3</b>												
<b><u>Reagent/Instrument</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
	All Method	13	155.2	31.8	20.5	141	13	280.3	33.3	11.9	271	224 - 337
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	10	146.4	11.8	8.1	140	117 - 176	10	265.0	9.8	3.7	265	212 - 318
<b>Specimen CG-5</b>												
<b><u>Reagent/Instrument</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>						
	All Method	13	290.9	33.2	11.4	284	13	283.9	7.9	2.8	284	227 - 350
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	10	283.9	7.9	2.8	284	227 - 341						

**URINALYSIS DIPSTICK-SPECIFIC GRAVITY**

**Specimen UA-1**

<b><u>Method</u></b>	<b><u>Labs</u></b>	<b><u>Mean</u></b>	<b><u>SD</u></b>	<b><u>CV</u></b>	<b><u>Median</u></b>	<b><u>Range</u></b>
All Method	177	1.0212	0.0058	0.6	1.020	1.011 - 1.032
All Arkay Methods	13	1.0285	0.0029	0.3	1.030	1.018 - 1.039
All Iris Diagnostics Methods	12	1.0240	0.0010	0.1	1.024	1.014 - 1.034
All Refractive Index Methods	27	1.0265	0.0029	0.3	1.025	1.016 - 1.037
All Roche Methods	35	1.0174	0.0062	0.6	1.015	1.007 - 1.028
All Siemens Methods	23	1.0204	0.0021	0.2	1.020	1.010 - 1.031
77 Elektronika LabUMat/2	17	1.0278	0.0026	0.3	1.029	1.017 - 1.038
Arkay Auton Sticks	11	1.0295	0.0012	0.1	1.030	1.019 - 1.040
Roche Chemstrips / Combur	11	1.0132	0.0025	0.2	1.015	1.003 - 1.024
Roche cobas u 411	17	1.0156	0.0029	0.3	1.015	1.005 - 1.026
Roche UriSys	18	1.0191	0.0079	0.8	1.020	1.009 - 1.030
SD UroColor Reagent Strips	14	1.0204	0.0037	0.4	1.020	1.010 - 1.031
Siemens Clinitek Status / Status+	16	1.0206	0.0016	0.2	1.020	1.010 - 1.031
UriScan Reagent Strips	21	1.0220	0.0029	0.3	1.020	1.012 - 1.033

## URINALYSIS DIPSTICK-pH

Specimen UA-1		Participant Results											
<u>Method</u>	<u>Labs</u>	<u>≤3.5</u>	<u>4.0</u>	<u>4.5</u>	<u>5.0</u>	<u>5.5</u>	<u>6.0</u>	<u>6.5</u>	<u>7.0</u>	<u>7.5</u>	<u>8.0</u>	<u>8.5</u>	<u>≥9.0</u>
ALL METHODS	206	-	-	-	-	-	-	14	179	12	1	-	-
77 Elektronika LabUMat/2	18	-	-	-	-	-	-	7	11	-	-	-	-
Acon Laboratories	5	-	-	-	-	-	-	-	2	2	1	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	1	1	-	-	-	-
Arkray Aution Sticks	12	-	-	-	-	-	-	-	12	-	-	-	-
Combi-Screen Test Strips	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	8	-	-	-	-	-	-	2	5	1	-	-	-
Other Dipstick Method	4	-	-	-	-	-	-	-	4	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche Chemstrips / Combur	25	-	-	-	-	-	-	-	25	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche cobas u 411	18	-	-	-	-	-	-	-	18	-	-	-	-
Roche Urisys	18	-	-	-	-	-	-	-	18	-	-	-	-
SD UroColor Reagent Strips	14	-	-	-	-	-	-	-	14	-	-	-	-
Siemens Clinitek Advantus	7	-	-	-	-	-	-	-	7	-	-	-	-
Siemens Clinitek Atlas	1	-	-	-	-	-	-	-	1	-	-	-	-
Siemens Clinitek Status / Status+	16	-	-	-	-	-	-	-	16	-	-	-	-
Siemens Reagent Strips	13	-	-	-	-	-	-	-	4	9	-	-	-
Urinometer	1	-	-	-	-	-	-	1	-	-	-	-	-
UriScan Pro/II	2	-	-	-	-	-	-	1	1	-	-	-	-
UriScan Reagent Strips	21	-	-	-	-	-	-	2	19	-	-	-	-
URIT Medical UriTest Analyzers	1	-	-	-	-	-	-	-	1	-	-	-	-

**URINALYSIS DIPSTICK–PROTEIN QUALITATIVE**

Specimen UA-1

**Participant Results**

<b><u>Method</u></b>	<b><u>Labs</u></b>	<b><u>Negative</u></b>	<b><u>Trace</u></b>	<b><u>(1+)</u></b>	<b><u>(2+)</u></b>	<b><u>(3+)</u></b>	<b><u>(4+)</u></b>	<b><u>10 - 20 mg/dL</u></b>	<b><u>30 - 70 mg/dL</u></b>	<b><u>75 mg/dL</u></b>	<b><u>100 - 200 mg/dL</u></b>	<b><u>≥300 - 600 mg/dL</u></b>	<b><u>&gt;600 or ≥1000 mg/dL</u></b>
ALL METHODS	207	2	-	15	118	34	-	-	1	-	35	2	-
77 Elektronika LabUMat/2	18	-	-	1	8	-	-	-	-	-	9	-	-
Acon Laboratories	5	-	-	3	2	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	-	-	-	1	1	-	-	-	-	-	-	-
Arkray Aution Sticks	12	-	-	-	12	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	1	-	-	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	-	-	-	2	-	-	-	-	-	6	-	-
Iris Ichem VELOCITY Urine Chemistry System	4	-	-	1	2	-	-	-	-	-	1	-	-
Other Analyzer Method	9	-	-	1	7	-	-	-	1	-	-	-	-
Other Dipstick Method	3	-	-	-	3	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	-	-	-	1	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	25	-	-	-	22	2	-	-	-	-	1	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	1	-	-	-	-	-	-	-
Roche cobas u 411	18	-	-	-	3	8	-	-	-	-	7	-	-
Roche Urisys	18	1	-	-	2	8	-	-	-	-	7	-	-
SD UroColor Reagent Strips	14	-	-	5	7	1	-	-	-	-	1	-	-
Siemens Clinitek Advantus	7	-	-	-	6	-	-	-	-	-	1	-	-
Siemens Clinitek Atlas	1	-	-	-	1	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	17	-	-	-	11	5	-	-	-	-	-	1	-
Siemens Reagent Strips	13	-	-	-	10	3	-	-	-	-	-	-	-
Urinometer	1	-	-	-	1	-	-	-	-	-	-	-	-
UriScan Pro/II	2	-	-	-	1	-	-	-	-	-	1	-	-
UriScan Reagent Strips	21	1	-	1	12	5	-	-	-	-	1	1	-
URIT Medical Uriptest Analyzers	1	-	-	-	1	-	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK–GLUCOSE

### Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Negative or Normal</u>	<u>Trace</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</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>
ALL METHODS	205	203	-	-	2	-	-	-	-	-	-
77 Elektronika LabUMat/2	18	18	-	-	-	-	-	-	-	-	-
Acon Laboratories	5	4	-	-	1	-	-	-	-	-	-
Arkray Auton Jet	2	2	-	-	-	-	-	-	-	-	-
Arkray Auton Sticks	12	12	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	1	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics Auton Max AX-4280	1	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	8	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	4	4	-	-	-	-	-	-	-	-	-
Other Analyzer Method	9	9	-	-	-	-	-	-	-	-	-
Other Dipstick Method	3	3	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	24	24	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-
Roche cobas u 411	18	18	-	-	-	-	-	-	-	-	-
Roche Urisys	18	18	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	14	14	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	7	7	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	16	16	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	13	13	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-
UriScan Pro/II	2	2	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	21	20	-	-	1	-	-	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK-KETONES

### Specimen UA-1

<u><b>Method</b></u>	<u><b>Labs</b></u>	<u><b>Negative</b></u>	<u><b>Trace</b></u>	<u><b>Small</b></u>	<u><b>Moderate</b></u>	<u><b>Large</b></u>	<u><b>Participant Results</b></u>							
							<u><b>(1+)</b></u>	<u><b>(2+)</b></u>	<u><b>(3+)</b></u>	<u><b>(4+)</b></u>	<u><b>5 - 10 mg/dL</b></u>	<u><b>15 - 25 mg/dL</b></u>	<u><b>40 - 60 mg/dL</b></u>	<u><b>≥80 - 100 mg/dL</b></u>
ALL METHODS	206	205	-	-	-	-	-	-	-	-	-	-	-	1
77 Elektronika LabUMat/2	18	17	-	-	-	-	-	-	-	-	-	-	-	1
Acon Laboratories	5	5	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	12	12	-	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	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	9	9	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	24	24	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	18	18	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	18	18	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	14	14	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	7	7	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	17	17	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	13	13	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	2	2	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	21	21	-	-	-	-	-	-	-	-	-	-	-	-
URIT Medical UriTest Analyzers	1	1	-	-	-	-	-	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK–BILIRUBIN

### Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	Participant Results					<u>0.5 - 1.0 mg/dL</u>	<u>2.0 - 4.0 mg/dL</u>	<u>6.0 - 10.0 mg/dL</u>	<u>&gt;10.0 mg/dL</u>
							<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>					
ALL METHODS	181	179	-	-	-	-	-	-	-	-	2	-	-	-	-
77 Elektronika LabUMat/2	17	16	-	-	-	-	-	-	-	-	1	-	-	-	-
Acon Laboratories	5	5	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	12	12	-	-	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	7	-	-	-	-	-	-	-	-	1	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	12	12	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	18	18	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	18	18	-	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	13	13	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	7	7	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	23	23	-	-	-	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK–UROBILINOGEN

### Specimen UA-1

#### Participant Results

<u>Method</u>	<u>Labs</u>	<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	181	180	-	-	1	-
77 Elektronika LabUMat/2	18	17	-	-	1	-
Acon Laboratories	5	5	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-
Arkray Aution Sticks	11	11	-	-	-	-
Combi-Screen Test Strips	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	9	9	-	-	-	-
Other Dipstick Method	3	3	-	-	-	-
Plasmatec URI PATH	1	1	-	-	-	-
Roche Chemstrips / Combur	12	12	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-
Roche cobas u 411	18	18	-	-	-	-
Roche Uri sys	18	18	-	-	-	-
SD UroColor Reagent Strips	14	14	-	-	-	-
Siemens Clinitek Advantus	7	7	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-
Siemens Clinitek Status / Status+	16	16	-	-	-	-
Siemens Reagent Strips	2	2	-	-	-	-
Urinometer	1	1	-	-	-	-
UriScan Pro/II	2	2	-	-	-	-
UriScan Reagent Strips	21	21	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-

## URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN

Specimen UA-1

## Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>(5+)</u>	<u>5 - 25 Ery/<math>\mu</math>L</u>	<u>50 - 100 Ery/<math>\mu</math>L</u>	<u>200 - 250 Ery/<math>\mu</math>L</u>	<u><math>\pm 0.03</math> mg/dL</u>	<u>0.06 - 0.10 mg/dL</u>	<u>0.2 - 0.5 mg/dL</u>	<u><math>\geq 1.0</math> mg/dL</u>
ALL METHODS	207	3	-	-	1	5	-	12	101	51	10	-	3	19	-	-	-	2
77 Elektronika LabUMat/2	18	1	-	-	-	1	-	1	12	-	-	-	-	3	-	-	-	-
Acon Laboratories	5	-	-	-	-	-	-	-	-	5	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	-
Arkray Aution Sticks	12	-	-	-	-	-	-	-	1	11	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	-	-	-	-	-	-	-	6	-	-	-	-	-	-	-	-	2
Iris Ichem VELOCITY Urine Chemistry System	4	-	-	-	-	-	-	-	3	1	-	-	-	-	-	-	-	-
Other Analyzer Method	9	-	-	-	-	-	-	-	8	-	-	-	-	1	-	-	-	-
Other Dipstick Method	3	-	-	-	-	-	-	-	2	1	-	-	-	-	-	-	-	-
Plasmatede URIPATH	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	24	-	-	-	-	-	-	-	-	23	-	-	1	-	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Roche cobas u 411	18	1	-	-	-	1	-	-	-	2	8	-	-	6	-	-	-	-
Roche Miditron Junior/II	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Roche Urisys	18	-	-	-	-	-	-	-	1	6	2	-	1	8	-	-	-	-
SD UroColor Reagent Strips	14	-	-	-	-	-	-	1	7	6	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	7	-	-	-	-	1	-	-	6	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	17	-	-	-	1	2	-	1	13	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	13	-	-	-	-	-	-	-	13	-	-	-	-	-	-	-	-	-
Urinometer	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
UriScan Pro/II	2	-	-	-	-	-	-	-	1	-	-	-	-	1	-	-	-	-
UriScan Reagent Strips	21	1	-	-	-	-	-	-	6	11	2	-	-	1	-	-	-	-
URIT Medical Uritest Analyzers	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

### Specimen UA-1

<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	191	188	-	-	-	-	2	1	-	-	-	-	-	-
77 Elektronika LabUMat/2	17	17	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	5	5	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	11	11	-	-	-	-	-	-	-	-	-	-	-	-
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	9	9	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	23	22	-	-	-	-	1	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	19	19	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	18	18	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	14	13	-	-	-	-	-	1	-	-	-	-	-	-
Siemens Clinitek Advantus	7	7	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	16	16	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	2	2	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	21	20	-	-	-	-	-	1	-	-	-	-	-	-
URIT Medical Uritest Analyzers	1	1	-	-	-	-	-	-	-	-	-	-	-	-

## URINALYSIS DIPSTICK-NITRITE

### Specimen UA-1

#### *Participant Results*

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	193	193	-
77 Elektronika LabUMat/2	18	18	-
Acon Laboratories	5	5	-
Arkray Auton Jet	2	2	-
Arkray Auton Sticks	12	12	-
Combi-Screen Test Strips	1	1	-
Iris Diagnostics Auton Max AX-4280	1	1	-
Iris Diagnostics iChem Velocity Strips	8	8	-
Iris Ichem VELOCITY Urine Chemistry System	4	4	-
Other Analyzer Method	9	9	-
Other Dipstick Method	3	3	-
Plasmatec URIPATH	1	1	-
Roche Chemstrips / Combur	24	24	-
Roche cobas 6500 / u 601	1	1	-
Roche cobas u 411	18	18	-
Roche Urisys	18	18	-
SD UroColor Reagent Strips	14	14	-
Siemens Clinitek Advantus	7	7	-
Siemens Clinitek Atlas	1	1	-
Siemens Clinitek Status / Status+	16	16	-
Siemens Reagent Strips	2	2	-
Urinometer	1	1	-
UriScan Pro/II	2	2	-
UriScan Reagent Strips	20	20	-
URIT Medical Uritest Analyzers	1	1	-

## URINALYSIS –MICROALBUMIN (dipstick only)

### Specimen UA-1

#### 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>+ (4 - 8 mg/dL)</u>	<u>++ (&gt;8 mg/dL)</u>
ALL METHODS	9	2	1	-	-	-	-	-	2	-	4
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	1
Roche Micral - 1 minute	1	-	-	-	-	-	-	-	1	-	-
Roche Urisys	1	1	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	1	1	-	-	-	-	-	-	-	-	-

## URINALYSIS –URINE hCG

### Specimen UA-1

#### Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	96	95	1
Acon Laboratories	3	3	-
Alere Clearview hCG Cassette	4	4	-
Alere hCG Cassette	21	21	-
Biotron 1-Step	1	1	-
NDC Pro Advantage	1	1	-
Other Dipstick Method	1	1	-
SD Bioline hCG	14	14	-
SD UroColor Reagent Strips	1	1	-
Siemens Clinitek 50	1	1	-
Siemens Clinitek Status / Status+	10	10	-
Stanbio QuStick	1	1	-

## MISCELLANEOUS CULTURES

### Specimen BA-1 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Bacillus sp.	50	44.25%	Acceptable
Bacillus cereus	32	28.32%	Acceptable
Gram positive bacilli	18	15.93%	Acceptable
Growth, referred for identification	1	0.88%	Acceptable
Staphylococcus pseudintermedius	5	4.42%	

Organism(s) present: *Bacillus cereus*.

### Specimen BA-2 – Stool Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Salmonella sp.	94	86.24%	Acceptable
Salmonella Group D	10	9.17%	Acceptable
Salmonella enteritidis	5	4.59%	Acceptable

Organism(s) present: *Salmonella enteritidis*.

## MISCELLANEOUS CULTURES

### Specimen BA-3 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus pseudintermedius	65	34.39%	Acceptable
Vibrio vulnificus	53	28.04%	Acceptable
Staphylococcus sp.	23	12.17%	Acceptable
Vibrio sp.	14	7.41%	Acceptable
Gram negative bacilli	2	1.06%	Acceptable
Growth, referred for identification	1	0.53%	Acceptable
Staph – coagulase negative	11	5.82%	
Vibrio parahaemolyticus	5	2.65%	
Staphylococcus aureus	5	2.65%	

Organism(s) present: *Vibrio vulnificus* and *Staphylococcus pseudintermedius*.

## ANTIMICROBIAL SUSCEPTIBILITY TESTING

<u><b>Antimicrobial</b></u>	<u><b>Disk Diffusion</b></u>				<u><b>MIC</b></u>				<u><b>Acceptable (%)</b></u>	
	<u><b>Interpretative category data</b></u>				<u><b>Interpretative category data</b></u>					
	<u><b>Labs</b></u>	<u><b>S</b></u>	<u><b>I</b></u>	<u><b>R</b></u>	<u><b>Labs</b></u>	<u><b>S</b></u>	<u><b>I</b></u>	<u><b>R</b></u>		
Amikacin	29	28	-	1	125	125	-	-	99.38%	
Amoxicillin/Clavulanate	23	20	1	2	46	42	-	4	88.89%	
Ampicillin	15	1	-	14	52	2	-	50	95.77%	
Ampicillin/Sulbactam	12	12	-	-	43	41	-	2	96.49%	
Aztreonam	11	11	-	-	35	34	-	1	97.83%	
Cefaclor	2	2	-	-	1	1	-	-	100.00%	
Cefamandole	-	-	-	-	1	1	-	-	Ungraded <sup>1</sup>	
Cefazolin	8	8	-	-	52	44	2	6	82.81%	
Cefdinir	1	1	-	-	3	3	-	-	100.00%	
Cefepime	21	21	-	-	127	125	-	2	98.70%	
Cefixime	10	10	-	-	4	4	-	-	100.00%	
Cefoperazone	5	5	-	-	1	1	-	-	100.00%	
Cefotaxime	25	25	-	-	62	61	-	1	98.86%	
Cefoxitin	10	10	-	-	53	51	-	2	97.01%	
Cefpodoxime	4	4	-	-	2	2	-	-	100.00%	
Ceftazidime	24	24	-	-	102	101	-	1	99.24%	
Ceftizoxime	1	1	-	-	4	4	-	-	100.00%	
Ceftriaxone	22	22	-	-	89	87	-	2	98.28%	
Cefuroxime	28	27	1	-	70	68	-	2	97.03%	
Ciprofloxacin	35	35	-	-	154	153	-	1	99.49%	
Colistin	2	2	-	-	6	5	-	1	Inappropriate drug <sup>2</sup>	
Doripenem	2	2	-	-	3	3	-	-	100.00%	
Doxycycline	2	2	-	-	-	-	-	-	100.00%	
Ertapenem	13	13	-	-	109	109	-	-	100.00%	
Fosfomycin	5	5	-	-	21	21	-	-	100.00%	
Gentamicin	30	30	-	-	140	139	-	1	99.44%	
Imipenem	19	19	-	-	87	87	-	-	100.00%	
Levofloxacin	15	15	-	-	54	54	-	-	100.00%	
Lomefloxacin	-	-	-	-	1	1	-	-	Ungraded <sup>1</sup>	
Meropenem	20	20	-	-	109	109	-	-	100.00%	

<sup>1</sup> This is an ungraded challenge due to lack of comparison group.

<sup>2</sup> Inappropriate method reported for this drug.

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

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>	
	Interpretative category data				Interpretative category data					
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>		
Minocycline	1	1	-	-	2	2	-	-	100.00%	
Moxifloxacin	2	2	-	-	-	-	-	-	Inappropriate drug <sup>2</sup>	
Nalidixic Acid	5	5	-	-	14	13	-	1	94.74%	
Netilmicin	5	5	-	-	1	1	-	-	100.00%	
Nitrofurantoin	29	27	2	-	109	105	3	1	95.10%	
Norfloxacin	16	16	-	-	50	49	-	1	Inappropriate drug <sup>2</sup>	
Ofloxacin	8	8	-	-	-	-	-	-	100.00%	
Oxacillin	-	-	-	-	1	-	-	1	Inappropriate drug <sup>2</sup>	
Penicillin	-	-	-	-	1	-	-	1	Inappropriate drug <sup>2</sup>	
Piperacillin	-	-	-	-	5	4	-	1	80.00%	
Piperacillin/Tazobactam	18	18	-	-	83	83	-	-	100.00%	
Polymyxin B	-	-	-	-	1	1	-	-	Inappropriate drug <sup>2</sup>	
Tetracycline	2	2	-	-	7	7	-	-	100.00%	
Ticarcillin/Clavulanate	1	1	-	-	4	4	-	-	100.00%	
Tigecycline	-	-	-	-	4	4	-	-	Inappropriate drug <sup>2</sup>	
Tobramycin	2	2	-	-	21	21	-	-	100.00%	
Trimethoprim	-	-	-	-	3	3	-	-	100.00%	
Trimethoprim/Sulfamethoxazole	29	28	-	1	142	142	-	-	99.44%	
Vancomycin	-	-	-	-	1	-	-	1	Inappropriate drug <sup>2</sup>	

Organism(s) present: *Citrobacter koseri*.

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

## **PARASITOLOGY (PA Specimens)**

### **Specimen PA-1**

<b><u>Identification</u></b>	<b><u>Labs</u></b>	<b><u>Percent</u></b>	<b><u>Performance</u></b>
Giardia lamblia	2	66.67%	Acceptable
Endolimax nana	1	33.33%	

Parasite(s) present: *Giardia lamblia*. This specimen is graded to US statistics.

### **Specimen PA-2**

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

Parasite(s) present: *Dientamoeba fragilis*. This specimen is graded to US statistics.

### **Specimen PA-3**

<b><u>Identification</u></b>	<b><u>Labs</u></b>	<b><u>Percent</u></b>	<b><u>Performance</u></b>
Pollen artifacts	12	38.71%	Acceptable
No parasite seen	3	9.68%	Acceptable
Ascaris lumbricoides eggs	14	45.16%	
Balantidium coli	1	3.23%	
Isospora belli oocysts	1	3.23%	

Parasite(s) present: No parasite seen but Pollen artifact seen. This specimen is graded to US statistics

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

### **Specimen PA-4**

<b><u>Identification</u></b>	<b><u>Labs</u></b>	<b><u>Percent</u></b>	<b><u>Performance</u></b>
Taenia sp. Eggs	21	84.00%	Acceptable
Blastocystis hominis	2	8.00%	
Balantidium coli	1	4.00%	
No parasite seen	1	4.00%	

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

### **Specimen PA-5**

<b><u>Identification</u></b>	<b><u>Labs</u></b>	<b><u>Percent</u></b>	<b><u>Performance</u></b>
Plasmodium falciparum	19	82.61%	Acceptable
Plasmodium sp.	4	17.39%	Acceptable

Parasite(s) present: *Plasmodium falciparum*.

## PARASITOLOGY (FP Specimens)

### Specimen FP-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis larvae	178	83.57%	Acceptable
Parasite egg or larvae seen – no	1	0.47%	Acceptable
No parasite seen	20	9.39%	
Blastocystis hominis	4	1.88%	
Giardia lamblia	2	0.94%	
Hookworm	2	0.94%	
Chilomastix mesnili	1	0.47%	
Enterobius vermicularis eggs	1	0.47%	
Ascaris lumbricoides eggs	1	0.47%	
Nematode like artifact	1	0.47%	
Root hair artifact	1	0.47%	
Trichinella spiralis	1	0.47%	

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

## PARASITOLOGY (FP Specimens)

### Specimen FP-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Clonorchis sinensis	86	39.81%	Acceptable
No parasite seen	96	44.44%	
Hymenolepis nana eggs	5	2.31%	
Giardia lamblia	5	2.31%	
Taenia sp. Eggs	4	1.85%	
Trichuris trichiura eggs	3	1.39%	
Enterobius vermicularis eggs	3	1.39%	
Chilomastix mesnili	3	1.39%	
Diphyllobothrium latum	2	0.93%	
Ascaris lumbricoides eggs	2	0.93%	
Strongyloides stercoralis larvae	2	0.93%	
Endolimax nana	1	0.46%	
Entamoeba histolytica	1	0.46%	
Fasciola hepatica eggs	1	0.46%	
Isospora belli oocysts	1	0.46%	
Hookworm	1	0.46%	

Parasite(s) present: *Clonorchis sinensis*. This challenge is graded by referee consensus.

## PARASITOLOGY (FP Specimens) cont'd

### Specimen FP-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	192	50.39%	Acceptable
Trichuris trichiura eggs	165	43.31%	Acceptable
Parasite egg or larvae seen – no	1	0.26%	Acceptable
No parasite seen	8	2.10%	
Taenia sp. Eggs	3	0.79%	
Entamoeba coli	3	0.79%	
Hookworm	3	0.79%	
Hymenolepis diminuta eggs	2	0.52%	
Hymenolepis nana eggs	1	0.26%	
Schistosoma sp. Eggs	1	0.26%	
Strongyloides stercoralis larvae	1	0.26%	
Trichinella spiralis	1	0.26%	

Parasite(s) present: *Entamoeba coli*.

## PARASITOLOGY (FP Specimens) cont'd

### Specimen FP-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Paragonimus westermani eggs	135	63.08%	Acceptable
Parasite egg or larvae seen – no	1	0.47%	Acceptable
Diphyllobothrium latum	31	14.49%	
Fasciola hepatica eggs	25	11.66%	
No parasite seen	8	3.74%	
Clonorchis sinensis	4	1.87%	
Hookworm	2	0.93%	
Ascaris lumbricoides eggs	2	0.93%	
Root hair artifact	1	0.47%	
Schistosoma sp. Eggs	1	0.47%	
Schistosoma haematobium eggs	1	0.47%	
Strongyloides stercoralis larvae	1	0.47%	
Trichostrongylus sp. Eggs	1	0.47%	
Trichuris trichiura eggs	1	0.47%	

Parasite(s) present: *Paragonimus westermani* eggs.

## PARASITOLOGY (FP Specimens) cont'd

### Specimen FP-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	187	93.97%	Acceptable
Plasmodium sp.	8	4.02%	
Plasmodium vivax	2	1.01%	
Babesia sp.	1	0.50%	
Mansonella ozzardi	1	0.50%	

Parasite(s) present: No parasite present.

### Antinuclear Antibody (ANA) - Qualitative

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	20	-	20	-	-	20
Bio-Rad	3	-	3	-	-	3
BioSystems	1	-	1	-	-	1
Immuno Concepts	3	-	3	-	-	3
INOVA Diagnostics	6	-	6	-	-	6
Kallestad	1	-	1	-	-	1
<u>Method</u>	Specimen AE-4		Specimen AE-5			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	-	20	-	20		
Bio-Rad	-	3	-	3		
BioSystems	-	1	-	1		
Immuno Concepts	-	3	-	3		
INOVA Diagnostics	-	6	-	6		
Kallestad	-	1	-	1		

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

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>8/ 10</u>	<u>16/ 20</u>	<u>32/ 40</u>	<u>64/ 80</u>	<u>128/ 160</u>	<u>256/ 320</u>	<u>512/ 640</u>	<u>&gt;640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>&gt;2560</u>
<b>Specimen AE-1</b>												
ALL METHODS	-	-	-	-	1	2	2	4	-	3	-	-
Bio-Rad	-	-	-	-	-	-	1	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	1	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	1	1	-	1	-	2	-	-

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

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>8/ 10</u>	<u>16/ 20</u>	<u>32/ 40</u>	<u>64/ 80</u>	<u>128/ 160</u>	<u>256/ 320</u>	<u>512/ 640</u>	<u>&gt;640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
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**Specimen AE-2**

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

**Specimen AE-3**

ALL METHODS	12	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	5	-	-	-	-	-	-	-	-	-	-	-

**Specimen AE-4**

ALL METHODS	12	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	5	-	-	-	-	-	-	-	-	-	-	-

**Specimen AE-5**

ALL METHODS	12	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	5	-	-	-	-	-	-	-	-	-	-	-

## Anti-dsDNA

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	20	20	-	-	20
BioSystems	-	1	1	-	-	1
Immuno Concepts	-	1	1	-	-	1
INOVA Diagnostics	-	10	10	-	-	10
Kallestad	-	1	1	-	-	1

  

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	20	-	20
BioSystems	-	1	-	1
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	10	-	10
Kallestad	-	1	-	1

## Anti-RNP

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	1	11	4	-	15
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	11	-	10	1	-	11

  

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	15	-	15
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	11	-	11

### Anti-RNP/Sm

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	3	4	-	7
Immuno Concepts	1	-	-	1	-	1

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7
Immuno Concepts	-	1	-	1

### Anti-SSA

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

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	-	21
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	11	-	11

## Anti-SSB

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	8	-	20	-	20
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	9	2	-	11	-	11

  

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	20	-	20
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	11	-	11

## Anti-SSA/SSB

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

  

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	1	-	1
	-	1	-	1

## Anti-Sm

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	2	19	-	21
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	11	1	10	-	11

  

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	21	-	21
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	11	-	11

Rubella—Qualitative

<u>Method</u>	Specimen RU-1		Specimen RU-2		Specimen RU-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	1	-	17	-	17
Abbott Architect	12	1	-	13	-	13
Roche cobas 6000 / e 601	1	-	-	1	-	1
Roche cobas e 411	2	-	-	2	-	2
Siemens ADVIA Centaur	1	-	-	1	-	1

  

<u>Method</u>	Specimen RU-4		Specimen RU-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	17	16	1
Abbott Architect	-	13	12	1
Roche cobas 6000 / e 601	-	1	1	-
Roche cobas e 411	-	2	2	-
Siemens ADVIA Centaur	-	1	1	-

## Rubella—Quantitative (IU/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
<b>Specimen RU-1</b>						
All Method	22	39.98	19.77	49.4	27.1	0.0 - 99.3
Abbott Architect	13	26.19	1.36	5.2	26.7	22.1 - 30.3
<b>Specimen RU-2</b>						
All Method	23	0.08	0.13	157.6	0.0	0.0 - 0.5
Abbott Architect	12	0.00	0.01	0.0	0.0	0.0 - 0.1
<b>Specimen RU-3</b>						
All Method	23	0.09	0.14	160.0	0.0	0.0 - 0.6
Abbott Architect	12	0.00	0.01	0.0	0.0	0.0 - 0.1
<b>Specimen RU-4</b>						
All Method	23	0.09	0.14	160.0	0.0	0.0 - 0.6
Abbott Architect	12	0.00	0.01	0.0	0.0	0.0 - 0.1
<b>Specimen RU-5</b>						
All Method	22	39.88	19.77	49.6	28.3	0.0 - 99.2
Abbott Architect	13	26.32	1.75	6.7	25.8	21.0 - 31.6

Syphilis Serology—Qualitative: VDRL Slide

<u>Method</u>	Specimen SY-1			Specimen SY-2			Specimen SY-3		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	-	44	45	-	-	1	-	44
Abbott Architect	1	-	-	1	-	-	-	-	1
Acon Laboratories	-	-	2	2	-	-	-	-	2
Omega Diagnostics	-	-	1	1	-	-	-	-	1
Plasmatec	-	-	1	1	-	-	-	-	1
SPINREACT	-	-	1	1	-	-	-	-	1
Standard Diagnostics	-	-	1	1	-	-	-	-	1
Wiener Lab	-	-	33	33	-	-	1	-	32
<u>Method</u>	Specimen SY-4			Specimen SY-5					
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>			
ALL METHODS	45	-	-	43	-	1			
Abbott Architect	1	-	-	-	-	1			
Acon Laboratories	2	-	-	2	-	-			
Omega Diagnostics	1	-	-	1	-	-			
Plasmatec	1	-	-	1	-	-			
SPINREACT	1	-	-	1	-	-			
Standard Diagnostics	1	-	-	1	-	-			
Wiener Lab	33	-	-	32	-	-			

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

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>0 dil</u>	<u>1 dil</u>	<u>2 dil</u>	<u>4 dil</u>	<u>8 dil</u>	<u>16 dil</u>	<u>32 dil</u>	<u>&gt;32 dil</u>
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**Specimen SY-1**

ALL METHODS	42	-	-	-	-	-	-	-	-
Plasmatec	1	-	-	-	-	-	-	-	-
Wiener Lab	36	-	-	-	-	-	-	-	-

**Specimen SY-2**

ALL METHODS	-	-	1	12	13	11	4	-	1
Plasmatec	-	-	-	1	-	-	-	-	-
Wiener Lab	-	-	1	9	12	10	3	-	1

**Specimen SY-3**

ALL METHODS	40	1	-	1	-	-	-	-	-
Plasmatec	1	-	-	-	-	-	-	-	-
Wiener Lab	35	-	-	1	-	-	-	-	-

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

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>0 dil</u>	<u>1 dil</u>	<u>2 dil</u>	<u>4 dil</u>	<u>8 dil</u>	<u>16 dil</u>	<u>32 dil</u>	<u>&gt;32 dil</u>
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**Specimen SY-4**

ALL METHODS	-	-	1	8	16	13	2	2	-
Plasmatec	-	-	-	-	1	-	-	-	-
Wiener Lab	-	-	1	5	15	13	1	1	-

**Specimen SY-5**

ALL METHODS	1	-	3	14	17	5	-	-	1
Plasmatec	-	-	-	-	1	-	-	-	-
Wiener Lab	-	-	1	13	16	4	-	-	1

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

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3		
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	
ALL METHODS	-	19	19	-	-	19	
Abbott Architect	-	3	3	-	-	3	
Biokit	-	1	1	-	-	1	
Human	-	1	1	-	-	1	
Plasmatec	-	4	4	-	-	4	
Serodia	-	2	2	-	-	2	
Standard Diagnostics	-	1	1	-	-	1	
Wiener Lab	-	1	1	-	-	1	
Specimen SY-4		Specimen SY-5					
<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>				
ALL METHODS	19	-	19	-			
Abbott Architect	3	-	3	-			
Biokit	1	-	1	-			
Human	1	-	1	-			
Plasmatec	4	-	4	-			
Serodia	2	-	2	-			
Standard Diagnostics	1	-	1	-			
Wiener Lab	1	-	1	-			

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

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	47	47	1	1	47
Abbott Architect	-	9	9	-	-	9
bioMerieux	-	1	1	-	-	1
DiaSorin	-	1	1	-	-	1
Human	-	2	2	-	-	2
Plasmatec	1	3	3	1	1	3
Roche cobas 6000 / c 501	-	2	2	-	-	2
Roche cobas e 411	-	2	2	-	-	2
Serodia	-	6	6	-	-	6
Standard Diagnostics	-	5	5	-	-	5
Specimen SY-4		Specimen SY-5				
<u>Reactive</u>		<u>Reactive</u>		<u>Non-Reactive</u>		
ALL METHODS	47	1	47	1		
Abbott Architect	9	-	9	-		
bioMerieux	1	-	1	-		
DiaSorin	1	-	1	-		
Human	2	-	2	-		
Plasmatec	3	1	3	1		
Roche cobas 6000 / c 501	2	-	2	-		
Roche cobas e 411	2	-	2	-		
Serodia	6	-	6	-		
Standard Diagnostics	5	-	5	-		

**Syphilis Serology—Qualitative: RPR**

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	65	66	-	-	66
Becton Dickinson	-	1	1	-	-	1
bioMerieux	-	5	5	-	-	5
BioSystems	-	13	13	-	-	13
Human	-	6	6	-	-	6
Omega Diagnostics	-	6	6	-	-	6
Plasmatec	-	8	8	-	-	8
Pulse Scientific	-	1	1	-	-	1
SPINREACT	1	16	17	-	-	17
Specimen SY-4		Specimen SY-5				
<u>Reactive</u>		<u>Reactive</u>		<u>Non-Reactive</u>		
ALL METHODS	65	1	66	-		
Becton Dickinson	1	-	1	-		
bioMerieux	5	-	5	-		
BioSystems	13	-	13	-		
Human	5	1	6	-		
Omega Diagnostics	6	-	6	-		
Plasmatec	8	-	8	-		
Pulse Scientific	1	-	1	-		
SPINREACT	17	-	17	-		

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

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

ALL METHODS	56	-	1	-	-	-	-	-	-
Becton Dickinson	1	-	-	-	-	-	-	-	-
bioMerieux	3	-	-	-	-	-	-	-	-
BioSystems	13	-	-	-	-	-	-	-	-
Human	4	-	-	-	-	-	-	-	-
Omega Diagnostics	5	-	-	-	-	-	-	-	-
Plasmatec	5	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	16	-	1	-	-	-	-	-	-
Wiener Lab	1	-	-	-	-	-	-	-	-

### Specimen SY-2

ALL METHODS	1	2	12	18	19	4	1	-	-
Becton Dickinson	-	-	-	-	1	-	-	-	-
bioMerieux	-	-	2	1	-	-	-	-	-
BioSystems	-	-	3	6	4	-	-	-	-
Human	-	-	-	2	2	-	-	-	-
Omega Diagnostics	1	-	-	1	2	1	-	-	-
Plasmatec	-	1	4	-	-	-	-	-	-
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	-	2	3	8	3	1	-	-
Wiener Lab	-	-	-	1	-	-	-	-	-

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

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>&gt;64</u>
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**Specimen SY-3**

ALL METHODS	57	-	-	-	-	-	-	-	-
Becton Dickinson	1	-	-	-	-	-	-	-	-
bioMerieux	3	-	-	-	-	-	-	-	-
BioSystems	13	-	-	-	-	-	-	-	-
Human	4	-	-	-	-	-	-	-	-
Omega Diagnostics	5	-	-	-	-	-	-	-	-
Plasmatec	5	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	17	-	-	-	-	-	-	-	-
Wiener Lab									

**Specimen SY-4**

ALL METHODS	1	2	12	17	18	6	1	-	-
Becton Dickinson	-	-	-	-	1	-	-	-	-
bioMerieux	-	-	2	1	-	-	-	-	-
BioSystems	-	-	5	4	4	-	-	-	-
Human	-	-	-	2	2	-	-	-	-
Omega Diagnostics	1	-	-	-	3	1	-	-	-
Plasmatec	-	1	2	2	-	-	-	-	-
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	-	1	4	7	4	1	-	-
Wiener Lab	-	-	-	1	-	-	-	-	-

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

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>&gt;64</u>
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**Specimen SY-5**

ALL METHODS	1	6	20	20	9	-	1	-	-
Becton Dickinson	-	-	-	1	-	-	-	-	-
bioMerieux	-	-	3	-	-	-	-	-	-
BioSystems	-	2	5	5	1	-	-	-	-
Human	-	-	1	3	-	-	-	-	-
Omega Diagnostics	1	-	1	-	2	-	1	-	-
Plasmatec	-	2	2	1	-	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	-	3	9	5	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-	-

**Viral Markers – Anti-HBc (IgM)**

<b><u>Method</u></b>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	-	51	-	2	49	-	3	48	-
Abbott Architect	-	24	-	1	23	-	2	22	-
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	-	11	-	1	10	-	-	11	-
Roche cobas 8000/e801	-	1	-	-	1	-	-	1	-
Roche cobas e 411	-	2	-	-	2	-	-	2	-
Roche Modular Analytics	-	2	-	-	2	-	-	2	-
Siemens ADVIA Centaur	-	4	-	-	4	-	-	4	-
VITROS 3600/4600/5600	-	3	-	-	3	-	-	3	-
VITROS ECI	-	1	-	-	1	-	-	1	-
Specimen VM-4			Specimen VM-5						
<b><u>Method</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>			
	1	50	-	-	51	-			
ALL METHODS	1	50	-	-	51	-			
Abbott Architect	1	23	-	-	24	-			
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-			
Bio-Rad Evolis	-	1	-	-	1	-			
bioMerieux Vidas, Mini									
Vidas	-	1	-	-	1	-			
Roche cobas 6000 / e 601	-	11	-	-	11	-			
Roche cobas 8000/e801	-	1	-	-	1	-			
Roche cobas e 411	-	2	-	-	2	-			
Roche Modular Analytics	-	2	-	-	2	-			
Siemens ADVIA Centaur	-	4	-	-	4	-			
VITROS 3600/4600/5600	-	3	-	-	3	-			
VITROS ECI	-	1	-	-	1	-			

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

<b><u>Method</u></b>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<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	-	70	-	52	17	1	69	1	-
Abbott Architect	-	39	-	27	11	1	39	-	-
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	-	2	-	-
Bio-Rad Evolis	-	1	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	13	-	12	1	-	12	1	-
Roche cobas 8000/e801	-	1	-	1	-	-	1	-	-
Roche cobas e 411	-	5	-	4	1	-	5	-	-
Roche Modular Analytics	-	1	-	1	-	-	1	-	-
Siemens ADVIA Centaur	-	4	-	1	3	-	4	-	-
VITROS 3600/4600/5600	-	3	-	3	-	-	3	-	-
VITROS ECI	-	1	-	1	-	-	1	-	-
Specimen VM-4					Specimen VM-5				
<b><u>Method</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>	<b><u>Positive</u></b>	<b><u>Negative</u></b>	<b><u>Equivocal</u></b>
ALL METHODS	69	1	-	1	68	-			
Abbott Architect	39	-	-	1	38	-			
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-			
Bio-Rad Evolis	1	-	-	-	1	-			
Roche cobas 6000 / e 601	12	1	-	-	12	-			
Roche cobas 8000/e801	1	-	-	-	1	-			
Roche cobas e 411	5	-	-	-	5	-			
Roche Modular Analytics	1	-	-	-	1	-			
Siemens ADVIA Centaur	4	-	-	-	4	-			
VITROS 3600/4600/5600	3	-	-	-	3	-			
VITROS ECI	1	-	-	-	1	-			

**Viral Markers – Anti-HIV**

<b><u>Method</u></b>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<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	144	-	-	3	139	1	127	16	1
Abbott Architect	63	-	-	-	63	-	63	-	-
Acon Laboratories	1	-	-	-	1	-	-	1	-
Alere Clearview HIV1/2									
STAT-PAK	1	-	-	-	1	-	-	1	-
Alere Determine HIV - moderate	2	-	-	-	2	-	-	2	-
Alere Determine HIV - waived	2	-	-	-	2	-	-	2	-
Beckman ACCESS / 2 / Dxl	3	-	-	-	3	-	2	1	-
Bio-Rad Evolis	1	-	-	-	1	-	1	-	-
bioMerieux Vidas, Mini Vidas	4	-	-	-	4	-	4	-	-
DiSorin	1	-	-	-	1	-	1	-	-
Human	3	-	-	-	3	-	-	3	-
Roche cobas 6000 / e 601	25	-	-	2	22	1	24	1	-
Roche cobas 8000/e801	1	-	-	-	1	-	1	-	-
Roche cobas e 411	11	-	-	1	10	-	11	-	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-	1	-	-
Roche Modular Analytics	3	-	-	-	3	-	2	-	1
Siemens ADVIA Centaur	6	-	-	-	6	-	6	-	-
Standard Diagnostics	2	-	-	-	2	-	-	2	-
VITROS 3600/4600/5600	5	-	-	-	5	-	5	-	-
VITROS ECI	2	-	-	-	2	-	2	-	-

**Viral Markers – Anti-HIV- cont'd**

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	143	1	127	15	1
Abbott Architect	-	63	-	63	-	-
Acon Laboratories	-	1	-	-	1	-
Alere Clearview HIV1/2						
STAT-PAK	-	1	-	-	1	-
Alere Determine HIV - moderate	-	2	-	-	2	-
Alere Determine HIV - waived	-	2	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	3	-	2	1	-
Bio-Rad Evolis	-	1	-	1	-	-
bioMerieux Vidas, Mini Vidas	-	4	-	4	-	-
DiaSorin	-	1	-	1	-	-
Human	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	24	1	24	1	-
Roche cobas 8000/e801	-	1	-	1	-	-
Roche cobas e 411	-	11	-	11	-	-
Roche Elecsys 1010 / 2010	-	1	-	1	-	-
Roche Modular Analytics	-	3	-	2	-	1
Siemens ADVIA Centaur	-	6	-	6	-	-
Standard Diagnostics	-	2	-	-	2	-
VITROS 3600/4600/5600	-	5	-	5	-	-
VITROS ECI	-	2	-	2	-	-

### Viral Markers – Anti-HAV (IgM)

<u><b>Method</b></u>	Specimen VM-1			Specimen VM-2			Specimen VM-3			
	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>	
ALL METHODS	-	57	-	-	56	-	-	57	-	
Abbott Architect	-	27	-	-	27	-	-	27	-	
Bio-Rad Evolis	-	1	-	-	1	-	-	1	-	
bioMerieux Vidas, Mini										
Vidas	-	2	-	-	2	-	-	2	-	
Roche cobas 6000 / e 601	-	14	-	-	13	-	-	14	-	
Roche cobas 8000/e801	-	1	-	-	1	-	-	1	-	
Roche cobas e 411	-	2	-	-	2	-	-	2	-	
Roche Modular Analytics	-	1	-	-	1	-	-	1	-	
Siemens ADVIA Centaur	-	5	-	-	5	-	-	5	-	
Standard Diagnostics	-	2	-	-	2	-	-	2	-	
VITROS 3600/4600/5600	-	1	-	-	1	-	-	1	-	
VITROS ECI	-	1	-	-	1	-	-	1	-	
Specimen VM-4					Specimen VM-5					
<u><b>Method</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>			<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>		
	-	57	-			-	57	-		
ALL METHODS	-	57	-			-	57	-		
Abbott Architect	-	27	-			-	27	-		
Bio-Rad Evolis	-	1	-			-	1	-		
bioMerieux Vidas, Mini										
Vidas	-	2	-			-	2	-		
Roche cobas 6000 / e 601	-	14	-			-	14	-		
Roche cobas 8000/e801	-	1	-			-	1	-		
Roche cobas e 411	-	2	-			-	2	-		
Roche Modular Analytics	-	1	-			-	1	-		
Siemens ADVIA Centaur	-	5	-			-	5	-		
Standard Diagnostics	-	2	-			-	2	-		
VITROS 3600/4600/5600	-	1	-			-	1	-		
VITROS ECI	-	1	-			-	1	-		

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

<u><b>Method</b></u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>
ALL METHODS	41	2	-	42	1	-	5	38	-
Abbott Architect	23	-	-	23	-	-	3	20	-
Bio-Rad Evolis	1	-	-	1	-	-	-	1	-
bioMerieux Vidas, Mini									
Vidas	3	-	-	3	-	-	1	2	-
Roche cobas 6000 / e 601	7	1	-	8	-	-	1	7	-
Roche cobas e 411	1	-	-	1	-	-	-	1	-
Roche Elecsys 1010 / 2010	1	-	-	1	-	-	-	1	-
Roche Modular Analytics	2	-	-	2	-	-	-	2	-
Siemens ADVIA Centaur	3	-	-	3	-	-	-	3	-
Standard Diagnostics	-	1	-	-	1	-	-	1	-
Specimen VM-4					Specimen VM-5				
<u><b>Method</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>
ALL METHODS	42	1	-	40	3	-			
Abbott Architect	23	-	-	23	-	-			
Bio-Rad Evolis	1	-	-	1	-	-			
bioMerieux Vidas, Mini									
Vidas	3	-	-	3	-	-			
Roche cobas 6000 / e 601	8	-	-	7	1	-			
Roche cobas e 411	1	-	-	1	-	-			
Roche Elecsys 1010 / 2010	1	-	-	1	-	-			
Roche Modular Analytics	2	-	-	2	-	-			
Siemens ADVIA Centaur	3	-	-	2	1	-			
Standard Diagnostics	-	1	-	-	1	-			

## Viral Markers – HBeAg

<u><b>Method</b></u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>
ALL METHODS	-	35	-	-	35	-	35	-	-
Abbott Architect	-	13	-	-	13	-	13	-	-
Bio-Rad Evolis	-	1	-	-	1	-	1	-	-
bioMerieux Vidas, Mini									
Vidas	-	1	-	-	1	-	1	-	-
DiASorin	-	1	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	14	-	-	14	-	14	-	-
Roche cobas e 411	-	1	-	-	1	-	1	-	-
Roche Modular Analytics	-	2	-	-	2	-	2	-	-
Siemens ADVIA Centaur	-	1	-	-	1	-	1	-	-
VITROS ECi	-	1	-	-	1	-	1	-	-
Specimen VM-4					Specimen VM-5				
<u><b>Method</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>				<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>
	2	33	-	-	35	-			
ALL METHODS	2	11	-	-	13	-			
Abbott Architect	-	1	-	-	1	-			
Bio-Rad Evolis									
bioMerieux Vidas, Mini									
Vidas	-	1	-	-	1	-			
DiASorin	-	1	-	-	1	-			
Roche cobas 6000 / e 601	-	14	-	-	14	-			
Roche cobas e 411	-	1	-	-	1	-			
Roche Modular Analytics	-	2	-	-	2	-			
Siemens ADVIA Centaur	-	1	-	-	1	-			
VITROS ECi	-	1	-	-	1	-			

Viral Markers – Anti-HBs

<u><b>Method</b></u>	Specimen VM-1			Specimen VM-2			Specimen VM-3			
	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>	
ALL METHODS	94	2	-	9	86	1	22	73	1	
Abbott Architect	45	-	-	6	39	-	1	44	-	
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-	-	2	-	
Bio-Rad Evolis	1	-	-	-	1	-	-	1	-	
DiaSorin	-	1	-	-	1	-	1	-	-	
Roche cobas 6000 / e 601	19	1	-	2	17	1	11	9	-	
Roche cobas 8000/e801	1	-	-	-	1	-	1	-	-	
Roche cobas e 411	8	-	-	1	7	-	6	2	-	
Roche Elecsys 1010 / 2010	2	-	-	-	2	-	1	-	1	
Roche Modular Analytics	2	-	-	-	2	-	1	1	-	
Siemens ADVIA Centaur	6	-	-	-	6	-	-	6	-	
VITROS 3600/4600/5600	5	-	-	-	5	-	-	5	-	
VITROS ECI	2	-	-	-	2	-	-	2	-	
Specimen VM-4			Specimen VM-5							
<u><b>Method</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>				
ALL METHODS	3	93	-	96	-	-				
Abbott Architect	-	45	-	45	-	-				
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	-				
Bio-Rad Evolis	-	1	-	1	-	-				
DiaSorin	1	-	-	1	-	-				
Roche cobas 6000 / e 601	1	19	-	20	-	-				
Roche cobas 8000/e801	-	1	-	1	-	-				
Roche cobas e 411	1	7	-	8	-	-				
Roche Elecsys 1010 / 2010	-	2	-	2	-	-				
Roche Modular Analytics	-	2	-	2	-	-				
Siemens ADVIA Centaur	-	6	-	6	-	-				
VITROS 3600/4600/5600	-	5	-	5	-	-				
VITROS ECI	-	2	-	2	-	-				

## Viral Markers – HBsAg

<u><b>Method</b></u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>
ALL METHODS	-	145	-	4	142	-	144	1	-
Abbott Architect	-	61	-	-	61	-	61	-	-
Beckman ACCESS / 2 / Dxl	-	3	-	-	3	-	3	-	-
Bio-Rad Evolis	-	1	-	-	1	-	1	-	-
bioMerieux Vidas, Mini									
Vidas	-	2	-	-	2	-	1	1	-
DiaSorin	-	1	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	26	-	2	24	-	25	-	-
Roche cobas 8000/e801	-	1	-	-	1	-	1	-	-
Roche cobas e 411	-	14	-	1	13	-	14	-	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	1	-	-
Roche Modular Analytics	-	3	-	-	3	-	3	-	-
Siemens ADVIA Centaur	-	7	-	-	7	-	7	-	-
Standard Diagnostics	-	8	-	-	8	-	8	-	-
VITROS 3600/4600/5600	-	5	-	-	5	-	5	-	-
VITROS ECI	-	1	-	-	2	-	2	-	-
Specimen VM-4					Specimen VM-5				
<u><b>Method</b></u>	<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>		<u><b>Positive</b></u>	<u><b>Negative</b></u>	<u><b>Equivocal</b></u>		
ALL METHODS	144	1	-		6	139	-		
Abbott Architect	61	-	-		4	57	-		
Beckman ACCESS / 2 / Dxl	3	-	-		-	3	-		
Bio-Rad Evolis	1	-	-		-	1	-		
bioMerieux Vidas, Mini									
Vidas	2	-	-		-	2	-		
DiaSorin	1	-	-		1	-	-		
Roche cobas 6000 / e 601	25	-	-		-	26	-		
Roche cobas 8000/e801	1	-	-		-	1	-		
Roche cobas e 411	13	1	-		-	13	-		
Roche Elecsys 1010 / 2010	1	-	-		-	1	-		
Roche Modular Analytics	3	-	-		-	3	-		
Siemens ADVIA Centaur	7	-	-		1	6	-		
Standard Diagnostics	8	-	-		-	8	-		
VITROS 3600/4600/5600	5	-	-		-	5	-		
VITROS ECI	2	-	-		-	2	-		

## Viral Markers – Anti-HCV

	Specimen VM-1			Specimen VM-2			Specimen VM-3		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	130	-	130	1	-	2	129	-
Abbott Architect	-	62	-	62	-	-	1	61	-
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	-	-	2	-
Bio-Rad Evolis	-	1	-	1	-	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	3	-	3	-	-	-	3	-
Human	1	-	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	21	-	21	-	-	1	20	-
Roche cobas e 411	-	12	-	12	-	-	-	12	-
Roche Elecsys 1010 / 2010	-	1	-	1	-	-	-	1	-
Roche Modular Analytics	-	3	-	3	-	-	-	3	-
Siemens ADVIA Centaur	-	5	-	5	-	-	-	5	-
Standard Diagnostics	-	5	-	5	-	-	-	5	-
VITROS 3600/4600/5600	-	5	-	5	-	-	-	5	-
VITROS ECI	-	3	-	3	-	-	-	3	-
	Specimen VM-4			Specimen VM-5					
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>			
ALL METHODS	130	1	-	-	131	-			
Abbott Architect	62	-	-	-	62	-			
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-			
Bio-Rad Evolis	1	-	-	-	1	-			
bioMerieux Vidas, Mini Vidas	3	-	-	-	3	-			
Human	-	1	-	-	1	-			
Roche cobas 6000 / e 601	21	-	-	-	21	-			
Roche cobas e 411	12	-	-	-	12	-			
Roche Elecsys 1010 / 2010	1	-	-	-	1	-			
Roche Modular Analytics	3	-	-	-	3	-			
Siemens ADVIA Centaur	5	-	-	-	5	-			
Standard Diagnostics	5	-	-	-	5	-			
VITROS 3600/4600/5600	5	-	-	-	5	-			
VITROS ECI	3	-	-	-	3	-			

### Toxoplasma gondii Antibody (IgG) - Qualitative

<u>Method</u>	Specimen TOX-1			Specimen TOX-2		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	18	-	19	-	-
Abbott Architect	1	11	-	12	-	-
bioMerieux Vidas, Mini						
Vidas	-	1	-	1	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
Roche cobas e 411	-	2	-	2	-	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
<b>Specimen TOX-1</b>						
All Method	20	0.351	0.224	63.8	0.30	0.00 - 0.80
Abbott Architect	14	0.464	0.160	34.4	0.50	0.14 - 0.79
<b>Specimen TOX-2</b>						
All Method	21	430.748	233.433	54.2	464.00	0.00 - 897.62
Abbott Architect	15	422.780	257.307	60.9	200.00	0.00 - 937.40

### Toxoplasma gondii Antibody (IgM) - Qualitative

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

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
<b>Specimen TOX-1</b>						
ALL METHODS	17	0.148	0.058	39.1	0.14	0.03 - 0.27
Abbott Architect	11	0.114	0.027	23.7	0.11	0.05 - 0.17
<b>Specimen TOX-2</b>						
ALL METHODS	18	11.243	6.776	60.3	8.36	0.00 - 24.80
Abbott Architect	12	7.841	1.517	19.3	7.55	4.80 - 10.88

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

<u>Method</u>	Specimen CMV-1			Specimen CMV-2		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	13	1	-	14	-	-
Abbott Architect	12	1	-	13	-	-
Roche cobas 6000 / e 601	1	-	-	1	-	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
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#### Specimen CMV-1

All Method	15	46.961	8.736	18.6	46.40	29.48 - 64.44
Abbott Architect	13	48.764	7.816	16.0	47.00	33.13 - 64.40

#### Specimen CMV-2

All Method	15	20.197	8.517	42.2	21.30	3.16 - 37.24
Abbott Architect	13	22.731	5.696	25.1	22.20	11.33 - 34.13

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

<u>Method</u>	Specimen CMV-1			Specimen CMV-2		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	16	-	16	-	-
Abbott Architect	-	13	-	13	-	-
Roche cobas 6000 / e 601	-	3	-	3	-	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
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#### Specimen CMV-1

All Method	13	0.159	0.049	31.0	0.15	0.06 - 0.26
Abbott Architect	11	0.159	0.053	33.6	0.15	0.05 - 0.27

#### Specimen CMV-2

All Method	13	10.403	1.733	16.7	10.80	6.93 - 13.87
Abbott Architect	11	10.895	1.350	12.4	11.22	8.19 - 13.60

### Glycohemoglobin (percent)

<u>Method</u>	Specimen GH-1						Specimen GH-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	184	8.50	0.36	4.2	8.5	7.9 - 9.1	181	5.69	0.27	4.8	5.7	5.3 - 6.1
All Hemoglobin A1c Methods	182	8.49	0.36	4.2	8.5	7.9 - 9.1	179	5.69	0.27	4.8	5.7	5.3 - 6.1
All TOSOH Methods	22	8.41	0.19	2.2	8.5	7.9 - 9.0	22	5.75	0.12	2.1	5.8	5.4 - 6.1
Beckman AU A1c	10	8.04	0.37	4.6	8.0	7.5 - 8.6	10	5.59	0.31	5.5	5.6	5.2 - 6.0
Bio-Rad D-100	14	9.05	0.19	2.1	9.2	8.5 - 9.6	14	6.31	0.09	1.5	6.3	5.9 - 6.7
Roche cobas c 501 HbA1c	12	8.15	0.30	3.7	8.2	7.6 - 8.7	12	5.41	0.24	4.4	5.4	5.0 - 5.8
Siemens DCA Vantage	71	8.55	0.24	2.8	8.6	8.0 - 9.1	69	5.63	0.14	2.5	5.6	5.2 - 6.0
Siemens Dimension HB1C	17	8.12	0.23	2.8	8.2	7.6 - 8.7	17	5.66	0.16	2.9	5.7	5.3 - 6.1
TOSOH G8	22	8.41	0.19	2.2	8.5	7.9 - 9.0	22	5.75	0.12	2.1	5.8	5.4 - 6.1

**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-1</b>						
All Method	5	22.60	3.14	13.9	24.0	13.1 - 32.1
<b>Specimen CK-2</b>						
All Method	5	3.83	0.76	19.9	4.0	1.5 - 6.2
<b>Specimen CK-3</b>						
All Method	5	40.30	5.65	14.0	42.0	23.3 - 57.3
<b>Specimen CK-4</b>						
All Method	5	77.00	10.54	13.7	78.0	45.3 - 108.7
<b>Specimen CK-5</b>						
All Method	5	13.10	1.82	13.9	14.0	7.6 - 18.6

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