

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

International Data Supplement
2021 MLE-M1



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Folate	83
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EVALUATION CRITERIA

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

Qualitative/Semi-Quantitative

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

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

Quantitative

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

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

*Whichever is greater

SEDIMENTATION RATE (MM/HR)

<u>Instrument</u>	Specimen ES-1						Specimen ES-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	152	8.5	3.1	36.1	8	0 - 18	144	52.2	11.9	22.7	50	16 - 88
All Automated Methods	33	10.0	3.5	34.8	9	0 - 21	31	65.5	10.4	15.8	67	34 - 97
All Diesse Methods	11	11.5	5.3	46.4	8	0 - 28	10	75.3	13.9	18.4	75	33 - 117
All Manual Methods	114	8.3	2.9	35.5	8	0 - 18	106	47.6	7.6	16.0	47	24 - 71
All Vital Diagnostics Methods	16	8.7	2.0	23.3	8	2 - 15	16	61.2	8.1	13.3	61	36 - 86
Vital Diagnostics Excyte M/10	9	8.0	1.4	17.7	8	3 - 13	9	59.2	8.8	14.9	60	32 - 86
Westergren - diluted	88	7.7	2.5	33.0	8	0 - 16	81	48.1	7.8	16.3	47	24 - 72
Westergren - undiluted	22	10.4	3.1	30.0	10	1 - 20	21	46.6	7.2	15.4	48	25 - 69

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

<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	31	18.18	1.39	7.7	17.8	15.4 - 21.0	31	2.27	0.31	13.5	2.2	1.9 - 2.7
All Abbott Cell-Dyn Instruments	18	19.82	1.38	6.9	20.2	16.8 - 22.8	18	3.06	0.53	17.4	2.9	2.6 - 3.6
Abbott Cell-Dyn Emerald 22	10	18.05	0.65	3.6	18.1	15.3 - 20.8	10	2.15	0.06	2.7	2.2	1.8 - 2.5
Abbott Cell-Dyn Ruby	8	19.82	1.38	6.9	20.2	16.8 - 22.8	8	3.06	0.53	17.4	2.9	2.6 - 3.6
Orpheo Mythic 22	13	17.59	1.08	6.1	17.6	14.9 - 20.3	13	2.13	0.15	7.3	2.1	1.8 - 2.5
Specimen CL-3							Specimen CL-4					
All Method	31	6.51	0.60	9.2	6.4	5.5 - 7.5	31	2.25	0.28	12.5	2.1	1.9 - 2.6
All Abbott Cell-Dyn Instruments	18	6.74	1.61	23.8	7.4	5.7 - 7.8	18	2.75	0.13	4.7	2.8	2.3 - 3.2
Abbott Cell-Dyn Emerald 22	10	6.40	0.18	2.9	6.4	5.4 - 7.4	10	2.10	0.08	3.9	2.1	1.7 - 2.5
Abbott Cell-Dyn Ruby	8	6.74	1.61	23.8	7.4	5.7 - 7.8	8	2.75	0.13	4.7	2.8	2.3 - 3.2
Orpheo Mythic 22	13	6.26	0.44	7.1	6.1	5.3 - 7.3	13	2.15	0.16	7.3	2.1	1.8 - 2.5
Specimen CL-5												
All Method	31	17.91	1.26	7.0	17.7	15.2 - 20.7						
All Abbott Cell-Dyn Instruments	18	20.30	2.18	10.7	20.0	17.2 - 23.4						
Abbott Cell-Dyn Emerald 22	10	17.93	0.43	2.4	17.9	15.2 - 20.7						
Abbott Cell-Dyn Ruby	8	20.30	2.18	10.7	20.0	17.2 - 23.4						
Orpheo Mythic 22	13	17.44	1.09	6.3	17.3	14.8 - 20.1						

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

<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	31	5.150	0.160	3.1	5.18	4.84 - 5.46	31	2.320	0.071	3.1	2.31	2.18 - 2.46
All Abbott Cell-Dyn Instruments	18	5.360	0.347	6.5	5.24	5.03 - 5.69	18	2.390	0.081	3.4	2.37	2.24 - 2.54
Abbott Cell-Dyn Emerald 22	10	4.973	0.240	4.8	5.04	4.67 - 5.28	10	2.265	0.042	1.9	2.27	2.12 - 2.41
Abbott Cell-Dyn Ruby	8	5.360	0.347	6.5	5.24	5.03 - 5.69	8	2.390	0.081	3.4	2.37	2.24 - 2.54
Orpheo Mythic 22	13	5.188	0.105	2.0	5.20	4.87 - 5.50	13	2.308	0.053	2.3	2.30	2.16 - 2.45
Specimen CL-3							Specimen CL-4					
All Method	31	4.353	0.105	2.4	4.37	4.09 - 4.62	31	2.325	0.063	2.7	2.34	2.18 - 2.47
All Abbott Cell-Dyn Instruments	18	4.438	0.099	2.2	4.41	4.17 - 4.71	18	2.375	0.030	1.3	2.38	2.23 - 2.52
Abbott Cell-Dyn Emerald 22	10	4.173	0.314	7.5	4.31	3.92 - 4.43	10	2.258	0.057	2.5	2.24	2.12 - 2.40
Abbott Cell-Dyn Ruby	8	4.438	0.099	2.2	4.41	4.17 - 4.71	8	2.375	0.030	1.3	2.38	2.23 - 2.52
Orpheo Mythic 22	13	4.332	0.105	2.4	4.37	4.07 - 4.60	13	2.330	0.057	2.4	2.33	2.19 - 2.47
Specimen CL-5												
All Method	31	5.161	0.195	3.8	5.17	4.85 - 5.48						
All Abbott Cell-Dyn Instruments	18	5.302	0.249	4.7	5.25	4.98 - 5.63						
Abbott Cell-Dyn Emerald 22	10	4.983	0.235	4.7	5.05	4.68 - 5.29						
Abbott Cell-Dyn Ruby	8	5.302	0.249	4.7	5.25	4.98 - 5.63						
Orpheo Mythic 22	13	5.163	0.103	2.0	5.18	4.85 - 5.48						

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

Instrument	Specimen CL-1						Specimen CL-2					
	Labs	Mean	SD	CV	Median	Range	Labs	Mean	SD	CV	Median	Range
All Method	31	15.32	1.12	7.3	15.1	14.2 - 16.4	31	5.02	0.47	9.4	4.9	4.6 - 5.4
All Abbott Cell-Dyn Instruments	18	17.04	0.26	1.5	17.0	15.8 - 18.3	18	5.72	0.19	3.4	5.7	5.3 - 6.2
Abbott Cell-Dyn Emerald 22	10	15.43	0.36	2.3	15.6	14.3 - 16.6	10	5.13	0.13	2.5	5.1	4.7 - 5.5
Abbott Cell-Dyn Ruby	8	17.04	0.26	1.5	17.0	15.8 - 18.3	8	5.72	0.19	3.4	5.7	5.3 - 6.2
Orphee Mythic 22	13	14.63	0.61	4.2	14.8	13.6 - 15.7	13	4.72	0.26	5.5	4.8	4.3 - 5.1
Specimen CL-3						Specimen CL-4						
All Method	31	12.23	0.91	7.5	12.0	11.3 - 13.1	31	4.94	0.43	8.7	4.9	4.5 - 5.3
All Abbott Cell-Dyn Instruments	18	13.65	0.17	1.3	13.6	12.6 - 14.7	18	5.63	0.17	3.0	5.7	5.2 - 6.1
Abbott Cell-Dyn Emerald 22	10	12.43	0.29	2.3	12.6	11.5 - 13.3	10	5.05	0.06	1.1	5.1	4.6 - 5.5
Abbott Cell-Dyn Ruby	8	13.65	0.17	1.3	13.6	12.6 - 14.7	8	5.63	0.17	3.0	5.7	5.2 - 6.1
Orphee Mythic 22	13	11.73	0.64	5.4	11.9	10.9 - 12.6	13	4.70	0.27	5.8	4.8	4.3 - 5.1
Specimen CL-5												
All Method	31	15.24	1.02	6.7	15.1	14.1 - 16.4						
All Abbott Cell-Dyn Instruments	18	16.74	0.37	2.2	16.8	15.5 - 18.0						
Abbott Cell-Dyn Emerald 22	10	15.30	0.36	2.3	15.4	14.2 - 16.4						
Abbott Cell-Dyn Ruby	8	16.74	0.37	2.2	16.8	15.5 - 18.0						
Orphee Mythic 22	13	14.65	0.66	4.5	14.9	13.6 - 15.7						

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	31	47.56	1.49	3.1	47.6	44.7 - 50.5	31	16.89	0.72	4.2	16.7	15.8 - 17.9
All Abbott Cell-Dyn Instruments	18	45.88	1.24	2.7	45.6	43.1 - 48.7	18	16.24	0.28	1.7	16.3	15.2 - 17.3
Abbott Cell-Dyn Emerald 22	10	47.40	1.31	2.8	46.8	44.5 - 50.3	10	16.40	0.48	2.9	16.4	15.4 - 17.4
Abbott Cell-Dyn Ruby	8	45.88	1.24	2.7	45.6	43.1 - 48.7	8	16.24	0.28	1.7	16.3	15.2 - 17.3
Orphee Mythic 22	13	48.17	1.22	2.5	48.6	45.2 - 51.1	13	17.32	0.60	3.5	17.3	16.2 - 18.4
Specimen CL-3												
All Method	31	39.95	1.29	3.2	40.0	37.5 - 42.4	31	16.94	0.77	4.6	16.9	15.9 - 18.0
All Abbott Cell-Dyn Instruments	18	38.37	1.50	3.9	38.3	36.0 - 40.7	18	16.25	0.26	1.6	16.2	15.2 - 17.3
Abbott Cell-Dyn Emerald 22	10	39.87	0.81	2.0	40.0	37.4 - 42.3	10	16.25	0.54	3.4	16.1	15.2 - 17.3
Abbott Cell-Dyn Ruby	8	38.37	1.50	3.9	38.3	36.0 - 40.7	8	16.25	0.26	1.6	16.2	15.2 - 17.3
Orphee Mythic 22	13	40.40	1.05	2.6	40.3	37.9 - 42.9	13	17.40	0.59	3.4	17.4	16.3 - 18.5
Specimen CL-4												
Specimen CL-5												
All Method	31	47.51	1.43	3.0	47.9	44.6 - 50.4						
All Abbott Cell-Dyn Instruments	18	45.68	1.06	2.3	45.8	42.9 - 48.5						
Abbott Cell-Dyn Emerald 22	10	47.13	1.27	2.7	46.9	44.3 - 50.0						
Abbott Cell-Dyn Ruby	8	45.68	1.06	2.3	45.8	42.9 - 48.5						
Orphee Mythic 22	13	48.28	0.87	1.8	48.4	45.3 - 51.2						

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

<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	31	498.9	47.5	9.5	485	374 - 624	31	101.9	15.3	15.0	106	76 - 128
All Abbott Cell-Dyn Instruments	18	455.3	36.1	7.9	470	341 - 570	18	81.0	13.4	16.6	78	60 - 102
Abbott Cell-Dyn Emerald 22	10	533.5	116.9	21.9	484	400 - 667	10	107.8	5.3	4.9	108	80 - 135
Abbott Cell-Dyn Ruby	8	455.3	36.1	7.9	470	341 - 570	8	81.0	13.4	16.6	78	60 - 102
Orphee Mythic 22	13	519.4	44.7	8.6	529	389 - 650	13	109.2	8.7	7.9	111	81 - 137
Specimen CL-3							Specimen CL-4					
All Method	31	287.5	20.0	7.0	288	215 - 360	31	99.8	14.4	14.5	104	74 - 125
All Abbott Cell-Dyn Instruments	18	267.7	7.6	2.8	271	200 - 335	18	76.3	5.6	7.3	79	57 - 96
Abbott Cell-Dyn Emerald 22	10	284.7	9.7	3.4	287	213 - 356	10	102.8	3.0	2.9	103	77 - 129
Abbott Cell-Dyn Ruby	8	267.7	7.6	2.8	271	200 - 335	8	76.3	5.6	7.3	79	57 - 96
Orphee Mythic 22	13	293.6	21.1	7.2	294	220 - 368	13	107.4	8.7	8.1	109	80 - 135
Specimen CL-5												
All Method	31	511.6	84.7	16.6	498	383 - 640						
All Abbott Cell-Dyn Instruments	18	447.0	58.7	13.1	458	335 - 559						
Abbott Cell-Dyn Emerald 22	10	556.5	137.1	24.6	498	417 - 696						
Abbott Cell-Dyn Ruby	8	447.0	58.7	13.1	458	335 - 559						
Orphee Mythic 22	13	518.2	63.5	12.2	500	388 - 648						

HEMATOLOGY W/ 5-PART DIFFERENTIAL—NEUTROPHILS (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	31	71.07	3.09	4.3	70.8	61.7 - 80.4	31	50.78	3.36	6.6	51.8	40.7 - 60.9
All Abbott Cell-Dyn Instruments	18	74.78	1.53	2.0	75.4	70.1 - 79.4	18	54.05	0.86	1.6	53.9	51.4 - 56.7
Abbott Cell-Dyn Emerald 22	10	64.28	6.28	9.8	66.0	45.4 - 83.2	10	50.03	2.90	5.8	50.7	41.3 - 58.8
Abbott Cell-Dyn Ruby	8	74.78	1.53	2.0	75.4	70.1 - 79.4	8	54.05	0.86	1.6	53.9	51.4 - 56.7
Orphee Mythic 22	13	70.73	1.98	2.8	70.8	64.7 - 76.7	13	49.77	3.48	7.0	51.1	39.3 - 60.3
Specimen CL-3												
All Method	31	60.09	3.54	5.9	61.1	49.4 - 70.8	31	51.21	2.44	4.8	51.8	43.8 - 58.6
All Abbott Cell-Dyn Instruments	18	62.73	0.80	1.3	62.9	60.3 - 65.2	18	53.45	0.47	0.9	53.6	52.0 - 54.9
Abbott Cell-Dyn Emerald 22	10	55.53	4.82	8.7	55.9	41.0 - 70.0	10	50.93	3.58	7.0	52.2	40.1 - 61.7
Abbott Cell-Dyn Ruby	8	62.73	0.80	1.3	62.9	60.3 - 65.2	8	53.45	0.47	0.9	53.6	52.0 - 54.9
Orphee Mythic 22	13	60.86	1.63	2.7	61.1	55.9 - 65.8	13	50.43	2.00	4.0	50.2	44.4 - 56.5
Specimen CL-4												
Specimen CL-5												
All Method	31	70.52	4.83	6.8	71.7	56.0 - 85.1						
All Abbott Cell-Dyn Instruments	18	75.38	1.47	1.9	76.0	70.9 - 79.8						
Abbott Cell-Dyn Emerald 22	10	63.98	5.42	8.5	64.7	47.7 - 80.3						
Abbott Cell-Dyn Ruby	8	75.38	1.47	1.9	76.0	70.9 - 79.8						
Orphee Mythic 22	13	71.20	1.87	2.6	71.7	65.5 - 76.9						

HEMATOLOGY W/ 5-PART DIFFERENTIAL—LYMPHOCYTES (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	31	15.34	3.32	21.6	15.8	5.3 - 25.3	31	29.31	5.88	20.1	31.6	11.6 - 47.0
All Abbott Cell-Dyn Instruments	18	16.83	1.74	10.3	16.2	11.6 - 22.1	18	32.93	0.87	2.6	33.0	30.3 - 35.6
Abbott Cell-Dyn Emerald 22	10	18.40	2.57	13.9	18.2	10.7 - 26.1	10	35.40	2.81	7.9	34.7	26.9 - 43.9
Abbott Cell-Dyn Ruby	8	16.83	1.74	10.3	16.2	11.6 - 22.1	8	32.93	0.87	2.6	33.0	30.3 - 35.6
Orpheo Mythic 22	13	13.52	2.96	21.9	14.2	4.6 - 22.5	13	24.99	4.44	17.8	27.3	11.6 - 38.4
Specimen CL-3						Specimen CL-4						
All Method	31	18.99	6.46	34.0	20.1	0.0 - 38.4	31	29.17	5.87	20.1	30.7	11.5 - 46.8
All Abbott Cell-Dyn Instruments	18	25.33	0.71	2.8	25.2	23.1 - 27.5	18	33.15	0.65	1.9	33.0	31.2 - 35.1
Abbott Cell-Dyn Emerald 22	10	24.50	0.93	3.8	24.5	21.6 - 27.4	10	35.48	3.85	10.8	34.8	23.9 - 47.1
Abbott Cell-Dyn Ruby	8	25.33	0.71	2.8	25.2	23.1 - 27.5	8	33.15	0.65	1.9	33.0	31.2 - 35.1
Orpheo Mythic 22	13	13.08	2.90	22.2	13.4	4.3 - 21.8	13	25.05	4.05	16.1	25.8	12.9 - 37.2
Specimen CL-5												
All Method	31	15.16	3.43	22.6	15.7	4.8 - 25.5						
All Abbott Cell-Dyn Instruments	18	16.58	1.69	10.2	15.8	11.5 - 21.7						
Abbott Cell-Dyn Emerald 22	10	18.88	2.99	15.8	18.5	9.9 - 27.9						
Abbott Cell-Dyn Ruby	8	16.58	1.69	10.2	15.8	11.5 - 21.7						
Orpheo Mythic 22	13	13.11	2.56	19.5	13.7	5.4 - 20.8						

HEMATOLOGY W/ 5-PART DIFFERENTIAL-MONOCYTES (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	31	10.99	3.78	34.4	12.4	0.0 - 22.4	31	13.09	5.74	43.9	12.6	0.0 - 30.4
All Abbott Cell-Dyn Instruments	18	4.58	0.15	3.3	4.6	4.1 - 5.1	18	5.90	0.80	13.6	6.1	3.4 - 8.4
Abbott Cell-Dyn Emerald 22	10	11.70	1.40	11.9	11.7	7.5 - 15.9	10	9.43	0.97	10.3	9.4	6.5 - 12.4
Abbott Cell-Dyn Ruby	8	4.58	0.15	3.3	4.6	4.1 - 5.1	8	5.90	0.80	13.6	6.1	3.4 - 8.4
Orphee Mythic 22	13	13.28	1.41	10.6	13.6	9.0 - 17.6	13	17.44	3.44	19.7	18.1	7.1 - 27.8
Specimen CL-3							Specimen CL-4					
All Method	31	13.34	5.76	43.2	13.7	0.0 - 30.7	31	13.14	5.60	42.6	13.4	0.0 - 30.0
All Abbott Cell-Dyn Instruments	18	4.50	0.61	13.5	4.5	2.6 - 6.4	18	6.35	0.68	10.7	6.5	4.3 - 8.4
Abbott Cell-Dyn Emerald 22	10	12.43	0.61	4.9	12.5	10.6 - 14.3	10	9.65	0.53	5.5	9.7	8.0 - 11.3
Abbott Cell-Dyn Ruby	8	4.50	0.61	13.5	4.5	2.6 - 6.4	8	6.35	0.68	10.7	6.5	4.3 - 8.4
Orphee Mythic 22	13	17.25	3.21	18.6	16.9	7.6 - 26.9	13	17.26	3.76	21.8	15.5	5.9 - 28.6
Specimen CL-5												
All Method	31	11.03	3.73	33.8	12.2	0.0 - 22.3						
All Abbott Cell-Dyn Instruments	18	4.68	0.30	6.4	4.7	3.7 - 5.6						
Abbott Cell-Dyn Emerald 22	10	11.63	1.24	10.7	11.5	7.8 - 15.4						
Abbott Cell-Dyn Ruby	8	4.68	0.30	6.4	4.7	3.7 - 5.6						
Orphee Mythic 22	13	13.34	1.31	9.8	13.6	9.4 - 17.3						

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

Instrument	Specimen CL-1							Specimen CL-2						
	Labs	Mean	SD	CV	Median	Range	Labs	Mean	SD	CV	Median	Range		
All Method	31	2.67	1.24	46.6	2.5	0.0 - 6.4	31	5.74	1.64	28.6	5.6	0.8 - 10.7		
All Abbott Cell-Dyn Instruments	18	3.45	0.21	6.0	3.5	2.8 - 4.1	18	6.20	0.71	11.5	6.1	4.0 - 8.4		
Abbott Cell-Dyn Emerald 22	10	3.30	1.78	54.0	3.7	0.0 - 8.7	10	4.60	1.04	22.7	4.7	1.4 - 7.8		
Abbott Cell-Dyn Ruby	8	3.45	0.21	6.0	3.5	2.8 - 4.1	8	6.20	0.71	11.5	6.1	4.0 - 8.4		
Orphee Mythic 22	13	2.10	1.02	48.5	2.0	0.0 - 5.2	13	6.04	1.98	32.8	5.0	0.0 - 12.0		
Specimen CL-3							Specimen CL-4							
All Method	31	6.47	1.43	22.1	6.6	2.1 - 10.8	31	6.13	1.38	22.6	6.0	1.9 - 10.3		
All Abbott Cell-Dyn Instruments	18	7.03	0.35	5.0	7.1	5.9 - 8.1	18	6.30	0.63	10.0	6.4	4.4 - 8.2		
Abbott Cell-Dyn Emerald 22	10	6.70	1.48	22.0	6.7	2.2 - 11.2	10	4.60	0.71	15.4	4.9	2.4 - 6.8		
Abbott Cell-Dyn Ruby	8	7.03	0.35	5.0	7.1	5.9 - 8.1	8	6.30	0.63	10.0	6.4	4.4 - 8.2		
Orphee Mythic 22	13	6.19	1.67	26.9	6.2	1.1 - 11.2	13	6.67	1.39	20.9	6.2	2.4 - 10.9		
Specimen CL-5														
All Method	31	2.55	1.33	52.3	2.6	0.0 - 6.6								
All Abbott Cell-Dyn Instruments	18	3.18	0.21	6.5	3.2	2.5 - 3.8								
Abbott Cell-Dyn Emerald 22	10	3.40	1.78	52.3	3.7	0.0 - 8.8								
Abbott Cell-Dyn Ruby	8	3.18	0.21	6.5	3.2	2.5 - 3.8								
Orphee Mythic 22	13	1.96	1.19	60.5	2.0	0.0 - 5.6								

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

Instrument	Specimen CL-1						Specimen CL-2					
	Labs	Mean	SD	CV	Median	Range	Labs	Mean	SD	CV	Median	Range
All Method	31	0.40	0.18	44.2	0.4	0.0 - 1.0	31	0.66	0.49	74.1	0.5	0.0 - 2.2
All Abbott Cell-Dyn Instruments	18	0.28	0.19	68.8	0.4	0.0 - 0.9	18	0.85	0.45	53.0	0.7	0.0 - 2.3
Abbott Cell-Dyn Emerald 22	10	0.83	0.67	81.2	0.6	0.0 - 2.9	10	0.55	0.13	23.5	0.6	0.1 - 1.0
Abbott Cell-Dyn Ruby	8	0.28	0.19	68.8	0.4	0.0 - 0.9	8	0.85	0.45	53.0	0.7	0.0 - 2.3
Orphee Mythic 22	13	0.42	0.15	36.9	0.5	0.0 - 0.9	13	0.63	0.60	95.0	0.5	0.0 - 2.5
Specimen CL-3							Specimen CL-4					
All Method	31	0.61	0.38	63.5	0.6	0.0 - 1.8	31	0.46	0.24	52.1	0.4	0.0 - 1.2
All Abbott Cell-Dyn Instruments	18	0.35	0.50	142.9	0.1	0.0 - 1.9	18	0.68	0.34	50.4	0.8	0.0 - 1.7
Abbott Cell-Dyn Emerald 22	10	1.35	1.44	106.4	0.7	0.0 - 5.7	10	0.35	0.06	16.5	0.4	0.1 - 0.6
Abbott Cell-Dyn Ruby	8	0.35	0.50	142.9	0.1	0.0 - 1.9	8	0.68	0.34	50.4	0.8	0.0 - 1.7
Orphee Mythic 22	13	0.70	0.37	53.0	0.7	0.0 - 1.9	13	0.59	0.56	95.7	0.4	0.0 - 2.3
Specimen CL-5												
All Method	31	0.36	0.21	56.5	0.3	0.0 - 1.0						
All Abbott Cell-Dyn Instruments	18	0.15	0.10	66.7	0.2	0.0 - 0.5						
Abbott Cell-Dyn Emerald 22	10	0.88	0.67	76.6	0.8	0.0 - 2.9						
Abbott Cell-Dyn Ruby	8	0.15	0.10	66.7	0.2	0.0 - 0.5						
Orphee Mythic 22	13	0.39	0.12	30.7	0.4	0.0 - 0.8						

BLOOD BANK

ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-1	Group O	16	100%	Acceptable
BB-2	Group A	17	100%	Acceptable
BB-3	Group B	18	100%	Acceptable
BB-4	Group B	18	100%	Acceptable
BB-5	Group O	16	100%	Acceptable

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-1	Rh Negative	16	100%	Acceptable
BB-2	Rh Negative	17	100%	Acceptable
BB-3	Rh Positive	18	100%	Acceptable
BB-4	Rh Positive	18	100%	Acceptable
BB-5	Rh Positive	16	100%	Acceptable

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	15	100%	Acceptable
AB-2	No unexpected antibody detected	15	100%	Acceptable
AB-3	No unexpected antibody detected	15	100%	Acceptable
AB-4	Unexpected antibody detected	14	93.33%	Acceptable
	No unexpected antibody detected	1	6.67%	
AB-5	No unexpected antibody detected	14	93.33%	Acceptable
	Unexpected antibody detected	1	6.67%	

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	Anti-D	7	100%	Acceptable
AB-2	No antibody detected	7	100%	Acceptable
AB-3	No antibody detected	7	100%	Acceptable
AB-4	Anti-E	7	100%	Acceptable
AB-5	No antibody detected	7	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	11	100%	Acceptable
AB-2	Compatible	11	100%	Acceptable
AB-3	Compatible	11	100%	Acceptable
AB-4	Compatible	9	81.82%	Acceptable
	Not Compatible	2	18.18%	
AB-5	Compatible	11	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	43	12.02	1.40	11.7	11.8	10.2 - 13.9	43	20.90	2.64	12.6	21.4	17.7 - 24.1
Dade Innovin												
Dade Behring BFT II	5	9.75	0.07	0.7	9.8	8.2 - 11.3	5	18.15	0.92	5.1	18.2	15.4 - 20.9
Sysmex CA-500/600 series	12	10.74	0.49	4.6	10.7	9.1 - 12.4	12	18.21	0.40	2.2	18.2	15.4 - 21.0
All Coagulation Instruments	18	10.61	0.55	5.1	10.7	9.0 - 12.3	18	18.14	0.44	2.4	18.1	15.4 - 20.9
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	8	13.53	0.35	2.6	13.4	11.4 - 15.6	8	23.25	0.97	4.2	23.4	19.7 - 26.8
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	6	13.63	0.51	3.7	13.7	11.5 - 15.7	6	23.22	0.57	2.5	23.5	19.7 - 26.7
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	13.33	0.06	0.4	13.3	11.3 - 15.4	5	24.87	0.38	1.5	24.7	21.1 - 28.6
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	11.34	0.22	1.9	11.3	9.6 - 13.1	5	21.44	0.27	1.3	21.4	18.2 - 24.7

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</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	43	15.03	1.84	12.2	15.0	12.7 - 17.3	43	34.26	4.66	13.6	35.0	29.1 - 39.4
Dade Innovin												
Dade Behring BFT II	5	13.35	1.34	10.1	13.4	11.3 - 15.4	5	32.60	4.53	13.9	32.6	27.7 - 37.5
Sysmex CA-500/600 series	12	13.03	0.30	2.3	13.0	11.0 - 15.0	12	28.98	0.90	3.1	28.8	24.6 - 33.4
All Coagulation Instruments	18	13.04	0.46	3.5	13.0	11.0 - 15.0	18	29.01	0.90	3.1	29.0	24.6 - 33.4
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STArt Max	8	16.86	0.40	2.4	16.8	14.3 - 19.4	8	37.09	1.97	5.3	37.2	31.5 - 42.7
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STArt Max	6	17.17	0.62	3.6	17.1	14.5 - 19.8	6	37.75	1.68	4.5	37.8	32.0 - 43.5
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	17.10	0.26	1.5	17.0	14.5 - 19.7	5	42.47	1.20	2.8	42.4	36.0 - 48.9
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	14.90	0.52	3.5	15.0	12.6 - 17.2	5	35.32	0.86	2.4	35.0	30.0 - 40.7

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	43	11.73	1.35	11.5	11.7	9.9 - 13.5
Dade Innovin						
Dade Behring BFT II	5	9.80	0.01	0.0	9.8	8.3 - 11.3
Sysmex CA-500/600 series	12	10.30	0.31	3.0	10.4	8.7 - 11.9
All Coagulation Instruments	18	10.24	0.32	3.2	10.3	8.7 - 11.8
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STArt Max	8	13.13	0.25	1.9	13.1	11.1 - 15.1
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STArt Max	6	13.23	0.45	3.4	13.3	11.2 - 15.3
Diagnostica Stago STA NeoPTimal						
Diagnostica Stago STA Compact / Max	5	12.77	0.29	2.3	12.6	10.8 - 14.7
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	11.76	0.71	6.0	11.7	9.9 - 13.6

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-1						Specimen CG-2					
	Labs	Mean	SD	CV	Median	Range	Labs	Mean	SD	CV	Median	Range
All Method	43	1.02	0.07	6.7	1.0	0.8 - 1.2	43	1.89	0.14	7.3	1.9	1.6 - 2.2
Dade Innovin												
Dade Behring BFT II	5	1.05	0.07	6.7	1.1	0.8 - 1.3	5	1.80	0.14	7.9	1.8	1.5 - 2.1
Sysmex CA-500/600 series	12	1.08	0.06	5.8	1.1	0.9 - 1.3	12	1.80	0.07	4.1	1.8	1.5 - 2.1
All Coagulation Instruments	18	1.06	0.06	5.8	1.1	0.9 - 1.3	18	1.79	0.08	4.3	1.8	1.5 - 2.1
Diag Stago STA Neoplastine Cl+												
Diagnostica Stago STArt Max	8	1.03	0.05	4.5	1.0	0.8 - 1.2	8	2.01	0.06	3.2	2.0	1.7 - 2.4
Diagnostica Stago Neoplastine Cl Plus												
Diagnostica Stago STArt Max	6	1.02	0.04	4.0	1.0	0.8 - 1.2	6	1.98	0.08	3.8	2.0	1.6 - 2.3
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	1.00	0.01	0.0	1.0	0.8 - 1.2	5	2.00	0.01	0.0	2.0	1.7 - 2.3
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	0.93	0.05	5.4	0.9	0.7 - 1.1	5	1.90	0.14	7.4	1.9	1.6 - 2.2

<u>Reagent/Instrument</u>	Specimen CG-3						Specimen CG-4					
	Labs	Mean	SD	CV	Median	Range	Labs	Mean	SD	CV	Median	Range
All Method	43	1.32	0.08	6.0	1.3	1.1 - 1.6	43	3.25	0.38	11.8	3.3	2.7 - 3.8
Dade Innovin												
Dade Behring BFT II	5	1.40	0.14	10.1	1.4	1.1 - 1.7	5	3.00	0.42	14.1	3.0	2.5 - 3.5
Sysmex CA-500/600 series	12	1.30	0.04	3.3	1.3	1.1 - 1.5	12	2.93	0.14	4.9	3.0	2.4 - 3.4
All Coagulation Instruments	18	1.31	0.07	5.2	1.3	1.1 - 1.6	18	2.93	0.18	6.1	3.0	2.4 - 3.4
Diag Stago STA Neoplastine Cl+												
Diagnostica Stago STArt Max	8	1.34	0.05	3.9	1.3	1.1 - 1.6	8	3.63	0.14	3.8	3.6	3.0 - 4.2
Diagnostica Stago Neoplastine Cl Plus												
Diagnostica Stago STArt Max	6	1.37	0.08	6.0	1.4	1.1 - 1.6	6	3.65	0.27	7.5	3.6	3.1 - 4.2
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	1.30	0.01	0.0	1.3	1.1 - 1.5	5	3.47	0.06	1.7	3.5	2.9 - 4.0
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	1.33	0.13	9.5	1.3	1.1 - 1.6	5	3.28	0.31	9.5	3.2	2.7 - 3.8

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

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	43	1.00	0.06	5.8	1.0	0.8 - 1.2
Dade Innovin						
Dade Behring BFT II	5	1.05	0.07	6.7	1.1	0.8 - 1.3
Sysmex CA-500/600 series	12	1.00	0.04	4.3	1.0	0.8 - 1.2
All Coagulation Instruments	18	1.00	0.05	5.2	1.0	0.8 - 1.2
Diag Stago STA Neoplastine Cl+						
Diagnostica Stago STArt Max	8	0.99	0.04	3.6	1.0	0.8 - 1.2
Diagnostica Stago Neoplastine Cl Plus						
Diagnostica Stago STArt Max	6	1.00	0.06	6.3	1.0	0.8 - 1.2
Diagnostica Stago STA NeoPTimal						
Diagnostica Stago STA Compact / Max	5	1.00	0.01	0.0	1.0	0.8 - 1.2
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	1.00	0.12	11.5	1.0	0.8 - 1.2

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

Specimen CG-1

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	Specimen CG-2					
							<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	22	29.4	6.8	23.1	26	25 - 34	22	38.2	7.0	18.3	40	32 - 44
Dade Actin FSL												
Sysmex CA-500/600 series	7	25.1	1.1	4.3	25	21 - 29	7	31.1	0.9	2.9	31	26 - 36
All Coagulation Instruments	8	25.3	1.0	4.1	25	21 - 30	8	31.4	1.1	3.4	31	26 - 37
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	5	31.0	0.1	0.0	31	26 - 36	5	43.7	1.2	2.6	43	37 - 51
HemosIL APTT-SP												
IL ACL, all models	5	45.0	2.8	6.3	45	38 - 52	5	43.3	2.1	4.8	44	36 - 50

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

<u>Reagent/Instrument</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	22	31.2	4.0	12.8	30	26 - 36	22	60.7	10.8	17.8	64	51 - 70
Dade Actin FSL												
Sysmex CA-500/600 series	7	27.3	1.3	4.6	27	23 - 32	7	48.9	2.9	5.8	50	41 - 57
All Coagulation Instruments	8	27.5	1.3	4.8	27	23 - 32	8	49.5	3.2	6.5	50	42 - 57
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	5	36.3	0.6	1.6	36	30 - 42	5	68.3	1.2	1.7	69	58 - 79
HemosIL APTT-SP												
IL ACL, all models	5	32.3	2.1	6.4	33	27 - 38	5	70.7	7.6	10.8	69	60 - 82
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	22	27.1	3.6	13.5	26	23 - 32						
Dade Actin FSL												
Sysmex CA-500/600 series	7	24.4	1.1	4.6	24	20 - 29						
All Coagulation Instruments	8	24.6	1.2	4.8	24	20 - 29						
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	5	29.3	0.6	2.0	29	24 - 34						
HemosIL APTT-SP												
IL ACL, all models	5	29.3	5.1	17.5	28	24 - 34						

FIBRINOGEN (mg/dL)

<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	13	433.7	60.2	13.9	440	346 - 521	13	246.4	20.8	8.4	240	197 - 296
Specimen CG-3												
<u>Reagent/Instrument</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	13	169.7	13.1	7.7	169	135 - 204	13	260.9	24.0	9.2	256	208 - 314
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	13	270.0	19.4	7.2	279						

PROTHROMBIN TIME (seconds) – XS Samples

<u>Reagent/Instrument</u>	Specimen XS-1						Specimen XS-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	27	34.39	0.94	2.7	34.3	29.2 - 39.6	27	13.87	0.30	2.2	13.9	11.7 - 16.0
All Roche CoaguChek XS Plus												
Instruments	15	33.79	0.75	2.2	33.9	28.7 - 38.9	15	13.96	0.19	1.3	13.9	11.8 - 16.1
Roche CoaguChek Pro II	12	34.99	0.70	2.0	35.3	29.7 - 40.3	12	13.78	0.38	2.7	13.6	11.7 - 15.9
Roche CoaguChek XS Plus - Waived	10	33.55	0.73	2.2	33.8	28.5 - 38.6	10	13.98	0.16	1.1	14.0	11.8 - 16.1
Roche CoaguChek XS Plus	5	34.28	0.61	1.8	34.4	29.1 - 39.5	5	13.93	0.26	1.9	13.9	11.8 - 16.1
Specimen XS-3							Specimen XS-4					
<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	23.32	0.37	1.6	23.3	19.8 - 26.9	8	15.14	0.17	1.1	15.1
All Roche CoaguChek XS Plus												
Instruments	7	23.20	0.29	1.3	23.3	19.7 - 26.7	7	15.08	0.10	0.6	15.1	12.8 - 17.4
Roche CoaguChek Pro II	1	-	-	-	23.8	19.8 - 26.9	1	-	-	-	15.4	12.8 - 17.5
Roche CoaguChek XS Plus - Waived	4	-	-	-	23.2	19.6 - 26.7	4	-	-	-	15.1	12.8 - 17.4
Roche CoaguChek XS Plus	3	-	-	-	23.3	19.7 - 26.8	3	-	-	-	15.1	12.7 - 17.4
Specimen XS-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	8	34.28	1.14	3.3	34.1						
All Roche CoaguChek XS Plus												
Instruments	7	33.85	0.71	2.1	34.1	28.7 - 39.0						
Roche CoaguChek Pro II	1	-	-	-	36.0	29.1 - 39.5						
Roche CoaguChek XS Plus - Waived	4	-	-	-	33.5	28.4 - 38.5						
Roche CoaguChek XS Plus	3	-	-	-	34.3	29.1 - 39.4						

INTERNATIONAL NORMALIZED RATIO (INR)– XS Samples

<u>Reagent/Instrument</u>	Specimen XS-1						Specimen XS-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	50	2.86	0.08	2.8	2.9	2.4 - 3.3	52	1.16	0.05	4.2	1.2	0.9 - 1.4
All Roche CoaguChek XS Plus Instruments	26	2.82	0.07	2.5	2.8	2.3 - 3.3	28	1.16	0.05	4.2	1.2	0.9 - 1.4
Roche CoaguChek Pro II	24	2.90	0.07	2.5	2.9	2.4 - 3.4	24	1.16	0.05	4.3	1.2	0.9 - 1.4
Roche CoaguChek XS Plus - Waived	20	2.82	0.07	2.6	2.8	2.3 - 3.3	22	1.16	0.05	4.2	1.2	0.9 - 1.4
Roche CoaguChek XS Plus	6	2.83	0.05	1.8	2.8	2.4 - 3.3	6	1.17	0.05	4.4	1.2	0.9 - 1.4
Specimen XS-3							Specimen XS-4					
<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	18	1.94	0.05	2.6	1.9	1.6 - 2.3	18	1.26	0.05	3.9	1.3	1.0 - 1.5
All Roche CoaguChek XS Plus Instruments	7	1.93	0.05	2.7	1.9	1.6 - 2.3	7	1.27	0.05	4.1	1.3	1.0 - 1.5
Roche CoaguChek Pro II	11	1.95	0.05	2.7	1.9	1.6 - 2.3	11	1.26	0.05	4.0	1.3	1.0 - 1.5
Roche CoaguChek XS Plus - Waived	5	1.95	0.06	3.0	2.0	1.6 - 2.3	5	1.28	0.05	3.9	1.3	1.0 - 1.5
Roche CoaguChek XS Plus	2	-	-	-	1.9	1.6 - 2.2	2	-	-	-	1.3	1.0 - 1.5
Specimen XS-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	18	2.84	0.08	2.8	2.8	2.4 - 3.3						
All Roche CoaguChek XS Plus Instruments	7	2.82	0.08	2.7	2.8	2.3 - 3.3						
Roche CoaguChek Pro II	11	2.85	0.08	2.9	2.9	2.4 - 3.3						
Roche CoaguChek XS Plus - Waived	5	2.80	0.08	2.9	2.8	2.3 - 3.3						
Roche CoaguChek XS Plus	2	-	-	-	2.9	2.4 - 3.3						

URINALYSIS DIPSTICK-SPECIFIC GRAVITY

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	116	1.0232	0.0058	0.6	1.025	1.013 - 1.034
All Iris Diagnostics Methods	5	1.0256	0.0026	0.3	1.024	1.015 - 1.036
All Refractive Index Methods	10	1.0262	0.0044	0.4	1.027	1.016 - 1.037
All Roche Methods	35	1.0191	0.0069	0.7	1.015	1.009 - 1.030
All Siemens Methods	33	1.0256	0.0020	0.2	1.025	1.015 - 1.036
77 Elektronika LabUMat/2	11	1.0296	0.0017	0.2	1.030	1.019 - 1.040
Acon Laboratories	5	1.0240	0.0042	0.4	1.025	1.014 - 1.034
Roche Chemstrips / Combur	8	1.0175	0.0026	0.3	1.018	1.007 - 1.028
Roche cobas u 411	14	1.0164	0.0024	0.2	1.015	1.006 - 1.027
Roche cobas u 601 / 701	5	1.0310	0.0010	0.1	1.031	1.021 - 1.041
Roche UriSys	16	1.0178	0.0069	0.7	1.015	1.007 - 1.028
Siemens Clinitek Advantus	13	1.0250	0.0001	0.0	1.025	1.015 - 1.035
Siemens Clinitek Status / Status+	19	1.0263	0.0023	0.2	1.025	1.016 - 1.037

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	143	-	-	-	-	-	25	78	40	-	-	-	-
77 Elektronika LabUMat/2	12	-	-	-	-	-	1	11	-	-	-	-	-
Acon Laboratories	5	-	-	-	-	-	1	2	2	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	2	-	-	-	-	-
Arkray Aution Sticks	2	-	-	-	-	-	-	2	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	-	-	-	4	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	-	-	1	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	-	-	-	-	-	-	1	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	1	-	-	-	-	-
Other Dipstick Method	4	-	-	-	-	-	-	1	3	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	1	-	-	-	-	-
Roche Chemstrips / Combur	22	-	-	-	-	-	16	6	-	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	1	-	-	-	-	-
Roche cobas u 411	14	-	-	-	-	-	1	13	-	-	-	-	-
Roche cobas u 601 / 701	5	-	-	-	-	-	1	3	1	-	-	-	-
Roche Urisys	16	-	-	-	-	-	3	13	-	-	-	-	-
SD UroColor Reagent Strips	4	-	-	-	-	-	1	1	2	-	-	-	-
Siemens Clinitek Advantus	15	-	-	-	-	-	-	1	14	-	-	-	-
Siemens Clinitek Atlas	1	-	-	-	-	-	-	1	-	-	-	-	-
Siemens Clinitek Status / Status+	18	-	-	-	-	-	-	-	18	-	-	-	-
Siemens Reagent Strips	11	-	-	-	-	-	-	11	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	1	-	-	-	-	-
UriScan Reagent Strips	1	-	-	-	-	-	1	-	-	-	-	-	-

URINALYSIS DIPSTICK–PROTEIN QUALITATIVE

Specimen UA-1

<u>Method</u>	<i>Participant Results</i>												
	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>10 - 20 mg/dL</u>	<u>30 - 70 mg/dL</u>	<u>75 mg/dL</u>	<u>100 - 200 mg/dL</u>	<u>≥300 - 600 mg/dL</u>	<u>>600 or ≥1000 mg/dL</u>
ALL METHODS	143	2	1	9	75	25	-	-	5	3	22	-	1
77 Elektronika LabUMat/2	11	-	-	1	4	-	-	-	4	-	2	-	-
Acon Laboratories	5	1	-	1	3	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	-	-	-	2	-	-	-	-	-	-	-	-
Arkray Aution Sticks	2	-	-	-	2	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	3	-	-	-	-	-	1	-	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	1	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	-	-	-	1	-	-	-	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	1	-	-
Other Dipstick Method	4	-	-	1	2	-	-	-	1	-	-	-	-
Plasmatec URI PATH	1	-	-	-	1	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	-	1	2	18	1	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	1	-	-	-	-	-	-	-
Roche cobas u 411	14	-	-	-	1	7	-	-	-	1	5	-	-
Roche cobas u 601 / 701	5	1	-	-	-	-	-	-	-	-	4	-	-
Roche Urisys	16	-	-	-	2	5	-	-	-	2	6	-	1
SD UroColor Reagent Strips	4	-	-	2	2	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	15	-	-	-	14	-	-	-	-	-	1	-	-
Siemens Clinitek Atlas	1	-	-	-	1	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	-	-	-	6	11	-	-	-	-	1	-	-
Siemens Reagent Strips	11	-	-	-	11	-	-	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	-	-	1	-	-
UriScan Reagent Strips	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>>500 or ≥1000 or ≥2000 mg/dL</u>
ALL METHODS	143	-	-	-	10	36	64	2	-	2	29
77 Elektronika LabUMat/2	12	-	-	-	-	-	6	-	-	-	6
Acon Laboratories	5	-	-	-	-	1	4	-	-	-	-
Arkray Auton Jet	2	-	-	-	-	-	2	-	-	-	-
Arkray Auton Sticks	2	-	-	-	-	-	2	-	-	-	-
Iris Diagnostics Auton Max AX-4280	1	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	-	-	3	1	-	-	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	-	1	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	-	-	-	-	-	1	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	1	-
Other Dipstick Method	4	-	-	-	-	-	3	-	-	-	1
Plasmatec URIPATH	1	-	-	-	-	1	-	-	-	-	-
Roche Chemstrips / Combur	22	-	-	-	-	-	21	1	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	1	-	-	-	-
Roche cobas u 411	14	-	-	-	-	-	8	-	-	-	6
Roche cobas u 601 / 701	5	-	-	-	-	-	-	-	-	-	5
Roche Urisys	16	-	-	-	-	-	7	-	-	-	9
SD UroColor Reagent Strips	4	-	-	-	-	3	1	-	-	-	-
Siemens Clinitek Advantus	15	-	-	-	-	14	-	-	-	-	1
Siemens Clinitek Atlas	1	-	-	-	-	1	-	-	-	-	-
Siemens Clinitek Status / Status+	18	-	-	-	10	7	-	-	-	1	-
Siemens Reagent Strips	11	-	-	-	-	9	2	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	-	-	1
UriScan Reagent Strips	1	-	-	-	-	-	1	-	-	-	-

URINALYSIS DIPSTICK-KETONES

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>Participant Results</u>								
							<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>5 - 10 mg/dL</u>	<u>15 - 25 mg/dL</u>	<u>40 - 60 mg/dL</u>	<u>≥80 - 100 mg/dL</u>	<u>≥150 mg/dL</u>
ALL METHODS	143	143	-	-	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	12	12	-	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	5	5	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	22	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	15	15	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche UriSys	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	15	15	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	18	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	11	11	-	-	-	-	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Positive (Ictotest ONLY)</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>0.5 - 1.0 mg/dL</u>	<u>2.0 - 4.0 mg/dL</u>	<u>6.0 - 10.0 mg/dL</u>	<u>>10.0 mg/dL</u>
	<u>Participant Results</u>														
ALL METHODS	120	120	-	-	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	12	12	-	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	5	5	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	14	14	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	5	5	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	15	15	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	18	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	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 <3.2 µmol/L</u>	<u>1.0 or <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	120	119	1	-	-	-
77 Elektronika LabUMat/2	12	12	-	-	-	-
Acon Laboratories	5	5	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-
Arkray Aution Sticks	2	2	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	-	1	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-
Other Dipstick Method	4	4	-	-	-	-
Plasmatec URI PATH	1	1	-	-	-	-
Roche Chemstrips / Combur	9	9	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-
Roche cobas u 411	14	14	-	-	-	-
Roche cobas u 601 / 701	5	5	-	-	-	-
Roche Uri sys	16	16	-	-	-	-
SD UroColor Reagent Strips	4	4	-	-	-	-
Siemens Clinitek Advantus	15	15	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-
Siemens Clinitek Status / Status+	18	18	-	-	-	-
Siemens Reagent Strips	1	1	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-
UriScan Reagent Strips	1	1	-	-	-	-

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN

Specimen UA-1

<u>Method</u>	<u>Participant Results</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/µL</u>	<u>50 - 100 Ery/µL</u>	<u>200 - 300 Ery/µL</u>	<u>±0.03 mg/dL</u>	<u>0.06 - 0.10 mg/dL</u>	<u>0.2 - 0.5 mg/dL</u>
ALL METHODS	143	-	-	-	-	2	-	3	65	33	10	-	-	30	-	-	-
77 Elektronika LabUMat/2	12	-	-	-	-	-	-	-	6	-	-	-	-	6	-	-	-
Acon Laboratories	5	-	-	-	-	-	-	-	1	4	-	-	-	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-
Arkray Aution Sticks	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	3	-	-	-	-	-	-	-	3	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	2	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Other Dipstick Method	4	-	-	-	-	-	-	-	1	3	-	-	-	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	21	-	-	-	-	-	-	-	1	19	-	-	-	1	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Roche cobas u 411	15	-	-	-	-	-	-	-	-	-	7	-	-	8	-	-	-
Roche cobas u 601 / 701	4	-	-	-	-	-	-	-	-	-	-	-	-	4	-	-	-
Roche Miditron Junior/II	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Roche Urisys	16	-	-	-	-	-	-	-	1	4	2	-	-	9	-	-	-
SD UroColor Reagent Strips	4	-	-	-	-	-	-	-	2	2	-	-	-	-	-	-	-
Siemens Clinitek Advantus	15	-	-	-	-	-	-	-	14	-	-	-	-	1	-	-	-
Siemens Clinitek Atlas	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	-	-	-	-	2	-	1	15	-	-	-	-	-	-	-	-
Siemens Reagent Strips	11	-	-	-	-	-	-	-	11	-	-	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
UriScan Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK—LEUKOCYTE ESTERASE

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>15 or 25 µL</u>	<u>75 or 100 µL</u>	<u>250 or 500 µL</u>
ALL METHODS	133	132	1	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	12	12	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	5	5	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	2	2	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	4	3	1	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	22	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	15	15	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	4	4	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	16	16	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	4	4	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	15	15	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	1	1	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	18	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–NITRITE

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	133	133	-
77 Elektronika LabUMat/2	12	12	-
Acon Laboratories	5	5	-
Arkray Aution Jet	2	2	-
Arkray Aution Sticks	2	2	-
Iris Diagnostics Aution Max AX-4280	1	1	-
Iris Diagnostics iChem Velocity Strips	4	4	-
Iris Diagnostics vChem Urine Strips	1	1	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-
Other Analyzer Method	1	1	-
Other Dipstick Method	4	4	-
Plasmatec URIPATH	1	1	-
Roche Chemstrips / Combur	21	21	-
Roche cobas 6500 / u 601	1	1	-
Roche cobas u 411	15	15	-
Roche cobas u 601 / 701	4	4	-
Roche SuperUA/ChemstripUA	1	1	-
Roche Urisys	16	16	-
SD UroColor Reagent Strips	4	4	-
Siemens Clinitek Advantus	15	15	-
Siemens Clinitek Atlas	1	1	-
Siemens Clinitek Status / Status+	18	18	-
Siemens Reagent Strips	1	1	-
Sysmex UN Series	1	1	-
UriScan Reagent Strips	1	1	-

URINALYSIS –MICROALBUMIN (dipstick only)

Specimen UA-1

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

URINALYSIS –URINE hCG

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>	
		<u>Positive</u>	<u>Negative</u>
ALL METHODS	86	-	86
77 Elektronika LabUMat/2	1	-	1
Abon (Alere) Biopharm	2	-	2
Acon Laboratories	5	-	5
Alere Clearview hCG Cassette	3	-	3
Alere hCG Combo Cassette	20	-	20
bioMerieux VIKIA hCG-D	1	-	1
Biosynex	1	-	1
CTK Biotech	3	-	3
JusChek	2	-	2
Other Dipstick Method	1	-	1
SD Bioline hCG	9	-	9
Siemens Clinitek Status / Status+	11	-	11
Stanbio QuStick	1	-	1

MISCELLANEOUS CULTURES

Specimen BA-1 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pseudomonas luteola	88	86.27%	Acceptable
Pseudomonas sp.	8	7.84%	Acceptable
Pseudomonas fluorescens	4	3.92%	

Organism(s) present: *Pseudomonas luteola*

Specimen BA-2 – Stool Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Bacillus cereus	30	17.14%	Acceptable
Bacillus sp.	28	16.00%	Acceptable
Gram positive bacilli	10	5.71%	Acceptable
Enterococcus faecium	70	40.00%	Acceptable
Enterococcus sp.	15	8.57%	Acceptable
Streptococcus non-hemolytic	1	0.57%	Acceptable
No enteric pathogens isolated	6	3.43%	Acceptable
No Salmonella or Shigella isolated	2	1.14%	Acceptable

Organism(s) present: *Bacillus cereus* and *Enterococcus faecium*

MISCELLANEOUS CULTURES

Specimen BA-3 – Wound Culture (Aerobic and Anaerobic)

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Corynebacterium striatum	25	15.06%	Acceptable
Corynebacterium sp.	39	23.49%	Acceptable
Gram positive bacilli	14	8.43%	Acceptable
Prevotella bivia	26	15.66%	Acceptable
Prevotella sp.	2	1.20%	Acceptable
Gram negative coccobacilli	2	1.20%	Acceptable
Gram negative bacilli	1	0.60%	Acceptable
Anaerobe present – no ID	9	5.42%	Acceptable
Anaerobe present – would refer	9	5.42%	Acceptable
Anaerobic cultures not performed	6	3.61%	Acceptable
Gram positive cocci	10	6.02%	

Organism(s) present: *Corynebacterium striatum* and *Prevotella bivia*

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Specimen UC-1, CC-1 (SUS-1) Organism(s) present: *Salmonella enteritidis*

<u>Antimicrobial</u>	<u>Disk Diffusion</u>				<u>MIC</u>				<u>Acceptable (%)</u>	
	<u>Interpretative category data</u>				<u>Interpretative category data</u>					
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>		
Amikacin	5	4	-	1	57	14	1	42	Inappropriate drug ¹	
Amoxicillin/Clavulanate	11	11	-	-	19	17	1	1	93.33%	
Ampicillin	22	22	-	-	122	120	-	2	98.61%	
Ampicillin/Sulbactam	5	5	-	-	57	55	1	1	96.77%	
Aztreonam	2	2	-	-	13	12	-	1	93.33%	
Cefaclor	1	1	-	-	-	-	-	-	Inappropriate drug ¹	
Cefamandole	-	-	-	-	1	1	-	-	Inappropriate drug ¹	
Cefazolin	1	1	-	-	21	4	-	17	Inappropriate drug ¹	
Cefdinir	2	2	-	-	-	-	-	-	100.00%	
Cefepime	9	9	-	-	81	79	-	2	97.78%	
Cefixime	10	10	-	-	1	1	-	-	100.00%	
Cefoperazone	2	2	-	-	-	-	-	-	100.00%	
Cefotaxime	10	10	-	-	51	48	-	3	95.08%	
Cefoxitin	2	2	-	-	17	7	-	10	Inappropriate drug ¹	
Cefpodoxime	4	4	-	-	3	3	-	-	100.00%	
Ceftazidime	9	9	-	-	117	114	1	2	97.62%	
Ceftolozane/Tazobactam	1	1	-	-	2	2	-	-	100.00%	
Ceftriaxone	25	25	-	-	98	98	-	-	100.00%	
Cefuroxime	5	5	-	-	23	5	-	18	Inappropriate drug ¹	
Ciprofloxacin	29	28	1	-	139	135	2	2	97.02%	
Colistin	-	-	-	-	1	1	-	-	100.00%	
Doripenem	-	-	-	-	2	2	-	-	100.00%	
Doxycycline	1	1	-	-	-	-	-	-	100.00%	
Ertapenem	1	1	-	-	61	61	-	-	100.00%	
Fosfomycin	4	3	-	1	3	2	-	1	Inappropriate drug ¹	
Gentamicin	6	5	-	1	58	10	2	46	Inappropriate drug ¹	
Imipenem	6	6	-	-	47	44	3	-	94.34%	
Levofloxacin	12	12	-	-	36	36	-	-	100.00%	
Meropenem	6	6	-	-	68	67	1	-	98.65%	
Minocycline	1	1	-	-	-	-	-	-	100.00%	

¹ This is an inappropriate drug for organism and/or source.

ANTIMICROBIAL SUSCEPTIBILITY TESTING (continued)

Specimen UC-1, CC-1 (SUS-1) Organism(s) present: *Salmonella enteritidis*

<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>		
Moxifloxacin	-	-	-	-	1	1	-	-	Inappropriate drug ¹	
Nalidixic Acid	6	6	-	-	8	8	-	-	Inappropriate drug ¹	
Nitrofurantoin	11	11	-	-	56	56	-	-	100.00%	
Norfloxacin	3	3	-	-	26	25	1	-	Inappropriate drug ¹	
Ofloxacin	5	5	-	-	-	-	-	-	Inappropriate drug ¹	
Oxacillin	-	-	-	-	1	1	-	-	Inappropriate drug ¹	
Piperacillin	-	-	-	-	1	1	-	-	100.00%	
Piperacillin/Tazobactam	7	6	-	1	53	50	-	3	93.33%	
Quinupristin/Dalfopristin	-	-	-	-	1	1	-	-	Inappropriate drug ¹	
Rifampin	-	-	-	-	1	1	-	-	Inappropriate drug ¹	
Streptomycin	1	1	-	-	-	-	-	-	Inappropriate drug ¹	
Sulfonamides	-	-	-	-	1	1	-	-	100.00%	
Tetracycline	5	5	-	-	4	4	-	-	100.00%	
Ticarcillin/Clavulanate	1	1	-	-	-	-	-	-	100.00%	
Tigecycline	-	-	-	-	2	2	-	-	Inappropriate drug ¹	
Tobramycin	1	1	-	-	4	2	-	2	Inappropriate drug ¹	
Trimethoprim	1	1	-	-	1	1	-	-	100.00%	
Trimethoprim/Sulfamethoxazole	23	22	-	1	138	138	-	-	99.38%	
Vancomycin	-	-	-	-	1	1	-	-	Inappropriate drug ¹	

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

Specimen FP-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Fasciola hepatica eggs	54	13.30%	Not graded
Diphyllobothrium latum	56	13.79%	
Balantidium coli	88	21.67%	
No parasite seen	49	12.07%	
Paragonimus westermani eggs	40	9.85%	
Entamoeba coli	39	9.61%	
Endolimax nana	20	4.93%	
Chilomastix mesnili	15	3.69%	
Entamoeba histolytica	8	1.97%	
Ascaris lumbricoides eggs	7	1.72%	
Hookworm	7	1.72%	
Blastocystis hominis	5	1.23%	

Parasite(s) present: *Fasciola hepatica* eggs. This is an ungraded challenge due to less than 80% referee consensus.

Specimen FP-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	272	73.32%	Acceptable
Blastocystis hominis	69	18.60%	Acceptable
Endolimax nana	13	3.50%	
Entamoeba histolytica	5	1.35%	

Parasite(s) present: *Giardia lamblia* and *Blastocystis hominis*

PARASITOLOGY (continued)

Specimen FP-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	264	94.29%	Acceptable
Ascaris lumbricoides eggs	3	1.07%	

Parasite(s) present: Negative (sterile)

Specimen FP-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba coli	207	33.93%	Acceptable
Taenia sp. eggs	196	32.13%	Acceptable
Entamoeba histolytica	128	20.98%	Acceptable
Protozoan cyst or trophozoite seen	2	0.33%	Acceptable
Parasite egg or larva seen – no ID	1	0.16%	Acceptable
Nonpathogenic protozoan present	1	0.16%	Acceptable
Blastocystis hominis	25	4.10%	
Endolimax nana	15	2.46%	
Ascaris lumbricoides eggs	12	1.97%	
Iodamoeba buetschlii	12	1.97%	
Hymenolepis diminuta eggs	2	0.33%	

Parasite(s) present: *Taenia* sp. eggs, *Entamoeba coli*, and *Entamoeba histolytica*

PARASITOLOGY (continued)

Specimen FP-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium ovale	22	8.00%	Acceptable
Plasmodium sp.	79	28.73%	Acceptable
Plasmodium vivax	145	52.73%	
Plasmodium falciparum	10	3.64%	
No parasite seen	6	2.18%	
Plasmodium malariae	5	1.82%	
Plasmodium knowlesi	3	1.09%	

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

PVA SLIDES (ADD-ON)

Specimen PA-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba hartmanni	1	100%	Acceptable

Parasite(s) present: *Entamoeba hartmanni*

Specimen PA-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative (sterile)	1	100%	Acceptable

Parasite(s) present: Negative (sterile)

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	1	-	21	-	21
Bio-Rad	1	-	-	1	-	1
BioSystems	2	-	-	2	-	2
Human	-	1	-	1	-	1
Immuno Concepts	2	-	-	2	-	2
INOVA Diagnostics	8	-	-	8	-	8
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	21	-	-	21		
Bio-Rad	1	-	-	1		
BioSystems	2	-	-	2		
Human	1	-	-	1		
Immuno Concepts	2	-	-	2		
INOVA Diagnostics	8	-	-	8		
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>>640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
Specimen AE-1												
ALL METHODS	-	-	-	1	-	-	1	6	1	4	3	-
Bio-Rad	-	-	-	-	-	-	-	-	-	1	-	-
Immuno Concepts	-	-	-	1	-	-	-	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	1	2	-	2	2	-
Kallestad	-	-	-	-	-	-	-	-	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>>640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
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Specimen AE-2

ALL METHODS	15	-	-	1	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	1	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	7	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

Specimen AE-3

ALL METHODS	15	-	-	1	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	1	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	7	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

Specimen AE-4

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

Specimen AE-5

ALL METHODS	15	-	-	1	-	-	-	-	-	-	-	-
Bio-Rad	1	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	1	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	7	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

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	-	18	-	18	-	18
BioSystems	-	2	-	2	-	2
Human	-	1	-	1	-	1
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	-	7	-	7	-	7
Kallestad	-	1	-	1	-	1
	Specimen AE-4		Specimen AE-5			
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	2	16	-	18		
BioSystems	-	2	-	2		
Human	-	1	-	1		
Immuno Concepts	-	1	-	1		
INOVA Diagnostics	2	5	-	7		
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	13	-	-	13	-	13
INOVA Diagnostics	8	-	-	8	-	8
	Specimen AE-4		Specimen AE-5			
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	1	12	-	13		
INOVA Diagnostics	-	8	-	8		

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	5	-	-	5	-	5
INOVA Diagnostics	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	-	5	-	5
INOVA Diagnostics	-	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	-	18	-	18	-	18
INOVA Diagnostics	-	10	-	10	-	10

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	-	-	18
INOVA Diagnostics	10	-	-	10

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	-	19	-	19	-	19
INOVA Diagnostics	-	10	-	10	-	10
<u>Method</u>	Specimen AE-4		Specimen AE-5			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	19	-	-	19		
INOVA Diagnostics	10	-	-	10		

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

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	5	13	-	18	-	18
INOVA Diagnostics	4	6	-	10	-	10
<u>Method</u>	Specimen AE-4		Specimen AE-5			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	-	18	-	18		
INOVA Diagnostics	-	10	-	10		

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	-	17	-	17	16	1
Abbott Architect	-	13	-	13	12	1
Roche cobas 6000 / e 601	-	1	-	1	1	-
Roche cobas e 411	-	1	-	1	1	-
Siemens Atellica	-	1	-	1	1	-

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

Rubella—Quantitative (IU/mL)

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

All Method	20	0.12	0.19	165.2	0.0	0.0 - 0.7
Abbott Architect	12	0.00	0.01	0.0	0.0	0.0 - 0.1

Specimen RU-2

All Method	21	0.13	0.22	163.2	0.0	0.0 - 0.8
Abbott Architect	12	0.00	0.01	0.0	0.0	0.0 - 0.1

Specimen RU-3

All Method	20	42.04	23.65	56.3	29.5	0.0 - 113.0
Abbott Architect	13	28.02	2.22	7.9	27.7	21.3 - 34.7

Specimen RU-4

All Method	20	24.40	15.35	62.9	16.3	0.0 - 70.5
Abbott Architect	13	15.47	1.53	9.9	15.6	10.8 - 20.1

Specimen RU-5

All Method	21	0.11	0.19	173.0	0.0	0.0 - 0.7
Abbott Architect	13	0.00	0.01	0.0	0.0	0.0 - 0.1

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	52	-	-	-	1	51	51	-	1
Acon Laboratories	2	-	-	-	-	2	2	-	-
CTK Biotech	1	-	-	-	-	1	1	-	-
Omega Diagnostics	1	-	-	-	-	1	1	-	-
Other Total Method	1	-	-	-	-	1	1	-	-
Roche cobas 6000 / e									
601	1	-	-	-	-	1	1	-	-
SPINREACT	1	-	-	-	-	1	1	-	-
Wiener Lab	38	-	-	-	1	37	37	-	1
<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	50	1	1	3	-	49			
Acon Laboratories	2	-	-	-	-	2			
CTK Biotech	1	-	-	-	-	1			
Omega Diagnostics	1	-	-	-	-	1			
Other Total Method	1	-	-	-	-	1			
Roche cobas 6000 / e									
601	1	-	-	-	-	1			
SPINREACT	1	-	-	-	-	1			
Wiener Lab	36	1	1	2	-	36			

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>>32 dil</u>
Specimen SY-1									
ALL METHODS	-	-	1	18	19	10	3	-	-
Omega Diagnostics	-	-	-	-	-	-	1	-	-
Wiener Lab	-	-	1	17	15	7	2	-	-
Specimen SY-2									
ALL METHODS	50	-	1	-	-	-	-	-	-
Omega Diagnostics	1	-	-	-	-	-	-	-	-
Wiener Lab	41	-	1	-	-	-	-	-	-
Specimen SY-3									
ALL METHODS	1	6	8	19	14	1	2	-	-
Omega Diagnostics	-	-	-	-	-	-	1	-	-
Wiener Lab	1	5	7	17	10	1	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>>32 dil</u>
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Specimen SY-4

ALL METHODS	1	4	4	26	10	3	2	1	-
Omega Diagnostics	-	-	-	-	-	-	-	1	-
Wiener Lab	1	3	4	22	7	3	2	-	-

Specimen SY-5

ALL METHODS	48	1	1	-	-	-	1	-	-
Omega Diagnostics	1	-	-	-	-	-	-	-	-
Wiener Lab	40	-	1	-	-	-	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	11	-	-	11	11	-
Abbott Architect	3	-	-	3	3	-
Atlas Medical	1	-	-	1	1	-
Biokit	1	-	-	1	1	-
Plasmatec	1	-	-	1	1	-
Serodia	3	-	-	3	3	-
Standard Diagnostics	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	11	-	1	10		
Abbott Architect	3	-	-	3		
Atlas Medical	1	-	-	1		
Biokit	1	-	-	1		
Plasmatec	1	-	-	1		
Serodia	3	-	-	3		
Standard Diagnostics	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	50	-	1	49	50	-
Abbott Architect	13	-	-	13	13	-
Bio-Rad Evolis	1	-	-	1	1	-
bioMerieux	1	-	-	1	1	-
DiaSorin	2	-	-	2	2	-
Human	1	-	-	1	1	-
Plasmatec	1	-	-	1	1	-
Roche cobas 6000 / c 501	1	-	-	1	1	-
Roche cobas 8000/e801	1	-	-	1	1	-
Roche cobas e 411	1	-	-	1	1	-
SD Bioline	2	-	-	2	2	-
Serodia	8	-	1	7	8	-
Siemens Immulite 2000	1	-	-	1	1	-
Standard Diagnostics	6	-	-	6	6	-
Zeus	2	-	-	2	2	-

Syphilis Serology—Qualitative: *Treponema pallidum* Antibodies

	Specimen SY-4		Specimen SY-5	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	50	-	1	49
Abbott Architect	13	-	-	13
Bio-Rad Evolis	1	-	-	1
bioMerieux	1	-	-	1
DiaSorin	2	-	-	2
Human	1	-	-	1
Plasmatec	1	-	-	1
Roche cobas 6000 / c 501	1	-	-	1
Roche cobas 8000/e801	1	-	-	1
Roche cobas e 411	1	-	-	1
SD Bioline	2	-	-	2
Serodia	8	-	-	8
Siemens Immulite 2000	1	-	-	1
Standard Diagnostics	6	-	-	6
Zeus	2	-	-	2

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	64	-	1	63	63	1
Acon Laboratories	1	-	-	1	1	-
Atlas Medical	2	-	-	2	2	-
Becton Dickinson	3	-	-	3	3	-
bioMerieux	3	-	-	3	3	-
BioSystems	13	-	-	13	13	-
Human	5	-	-	5	5	-
Lorne Laboratories	2	-	-	2	2	-
Omega Diagnostics	3	-	-	3	3	-
Plasmatec	4	-	-	4	3	1
Pulse Scientific	1	-	-	1	1	-
SPINREACT	20	-	1	19	20	-
Wiener Lab	1	-	-	1	1	-

Syphilis Serology—Qualitative: RPR (continued)

	Specimen SY-4		Specimen SY-5	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	62	2	3	61
Acon Laboratories	1	-	-	1
Atlas Medical	2	-	-	2
Becton Dickinson	3	-	-	3
bioMerieux	3	-	-	3
BioSystems	13	-	-	13
Human	5	-	-	5
Lorne Laboratories	2	-	-	2
Omega Diagnostics	3	-	-	3
Plasmatec	3	1	1	3
Pulse Scientific	1	-	-	1
SPINREACT	19	1	2	18
Wiener Lab	1	-	-	1

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>>64</u>
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Specimen SY-1

ALL METHODS	-	-	10	26	12	9	1	1	-
Atlas Medical	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	2	1	-	-	-	-
bioMerieux	-	-	1	1	-	-	-	-	-
BioSystems	-	-	2	7	1	2	1	-	-
Human	-	-	-	-	2	2	-	1	-
Lorne Laboratories	-	-	1	-	1	-	-	-	-
Omega Diagnostics	-	-	-	-	1	1	-	-	-
Plasmatec	-	-	-	1	-	1	-	-	-
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	-	3	12	6	2	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-	-

Specimen SY-2

ALL METHODS	58	1	-	-	-	-	-	-	-
Atlas Medical	1	-	-	-	-	-	-	-	-
Becton Dickinson	3	-	-	-	-	-	-	-	-
bioMerieux	2	-	-	-	-	-	-	-	-
BioSystems	13	-	-	-	-	-	-	-	-
Human	5	-	-	-	-	-	-	-	-
Lorne Laboratories	2	-	-	-	-	-	-	-	-
Omega Diagnostics	2	-	-	-	-	-	-	-	-
Plasmatec	2	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	22	1	-	-	-	-	-	-	-
Wiener Lab	1	-	-	-	-	-	-	-	-

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

<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>>64</u>
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Specimen SY-3

ALL METHODS	-	8	21	17	6	3	1	2	1
Atlas Medical	-	1	-	-	-	-	-	-	-
Becton Dickinson	-	-	1	2	-	-	-	-	-
bioMerieux	-	1	1	-	-	-	-	-	-
BioSystems	-	-	5	4	1	1	-	1	1
Human	-	1	1	-	2	-	1	-	-
Lorne Laboratories	-	1	-	1	-	-	-	-	-
Omega Diagnostics	-	-	-	1	-	1	-	-	-
Plasmatec	-	-	1	-	-	-	-	1	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	2	9	9	2	1	-	-	-
Wiener Lab	-	1	-	-	-	-	-	-	-

Specimen SY-4

ALL METHODS	1	5	20	22	6	2	1	2	-
Atlas Medical	-	1	-	-	-	-	-	-	-
Becton Dickinson	-	-	1	2	-	-	-	-	-
bioMerieux	-	1	1	-	-	-	-	-	-
BioSystems	-	-	4	5	2	1	-	1	-
Human	-	-	1	2	1	-	-	1	-
Lorne Laboratories	-	-	1	1	-	-	-	-	-
Omega Diagnostics	-	-	-	1	-	-	1	-	-
Plasmatec	-	-	-	1	-	1	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	1	3	7	10	2	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-	-

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

<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>>64</u>
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Specimen SY-5

ALL METHODS	56	1	1	-	-	1	-	-	-
Atlas Medical	1	-	-	-	-	-	-	-	-
Becton Dickinson	3	-	-	-	-	-	-	-	-
bioMerieux	2	-	-	-	-	-	-	-	-
BioSystems	13	-	-	-	-	-	-	-	-
Human	5	-	-	-	-	-	-	-	-
Lorne Laboratories	2	-	-	-	-	-	-	-	-
Omega Diagnostics	2	-	-	-	-	-	-	-	-
Plasmatec	1	1	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	21	-	1	-	-	1	-	-	-
Wiener Lab	1	-	-	-	-	-	-	-	-

Viral Markers – Anti-HBc (IgM)

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3			
	<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	-	46	-	6	40	-	1	45	-	
Abbott Alinity	-	2	-	-	2	-	-	2	-	
Abbott Architect	-	24	-	3	21	-	1	23	-	
Beckman ACCESS / 2 / Dxl	-	1	-	1	-	-	-	1	-	
Roche cobas 6000 / e 601	-	8	-	-	8	-	-	8	-	
Roche cobas 8000/e801	-	5	-	-	5	-	-	5	-	
Siemens ADVIA	-	2	-	2	-	-	-	2	-	
VITROS										
3600/4600/5600/7600	-	4	-	-	4	-	-	4	-	
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	-	46	-	6	39	1				
Abbott Alinity	-	2	-	-	2	-				
Abbott Architect	-	24	-	4	20	-				
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-				
Roche cobas 6000 / e 601	-	8	-	-	8	-				
Roche cobas 8000/e801	-	5	-	-	5	-				
Siemens ADVIA Centaur	-	2	-	2	-	-				
VITROS										
3600/4600/5600/7600	-	4	-	-	3	1				

Viral Markers – Anti-HBc (Total / IgG)

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<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	67	-	67	-	-	67	1	-
Abbott Alinity	-	6	-	6	-	-	6	-	-
Abbott Architect	1	35	-	36	-	-	35	1	-
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	-	2	-	-
DiSorin	-	1	-	8	-	-	1	-	-
Roche cobas 6000 / e 601	-	8	-	5	-	-	8	-	-
Roche cobas 8000/e801	-	5	-	2	-	-	5	-	-
Roche cobas e 411	-	2	-	3	-	-	2	-	-
Siemens ADVIA	-	3	-	1	-	-	3	-	-
Siemens Atellica	-	1	-	3	-	-	1	-	-
VITROS									
3600/4600/5600/7600	-	3	-	67	-	-	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>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	66	-	68	-	-			
Abbott Alinity	-	6	-	6	-	-			
Abbott Architect	2	34	-	36	-	-			
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	-			
DiSorin	-	1	-	1	-	-			
Roche cobas 6000 / e 601	-	8	-	8	-	-			
Roche cobas 8000/e801	-	5	-	5	-	-			
Roche cobas e 411	-	2	-	2	-	-			
Siemens ADVIA	-	3	-	3	-	-			
Siemens Atellica	-	1	-	1	-	-			
VITROS									
3600/4600/5600/7600	-	3	-	3	-	-			

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<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	140	-	1	138	-	1	139	-
Abbott Alinity	-	9	-	-	9	-	-	9	-
Abbott Architect	-	59	-	-	59	-	-	59	-
Acon Laboratories	-	1	-	-	1	-	-	1	-
Alere Clearview HIV1/2							-		
STAT-PAK	-	2	-	-	2	-	-	2	-
Alere Determine HIV - moderate	-	2	-	-	2	-	-	2	-
Alere Determine HIV - waived	-	2	-	-	2	-	-	2	-
Beckman ACCESS / 2 / Dxl	-	4	-	-	4	-	-	4	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-	-	3	-
CTK Biotech	-	1	-	-	1	-	-	1	-
DiaSorin	-	1	-	-	3	-	-	1	-
Human	-	3	-	1	16	-	-	3	-
Roche cobas 6000 / e 601	1	16	-	-	4	-	1	16	-
Roche cobas 8000/e801	-	4	-	-	8	-	-	4	-
Roche cobas e 411	-	8	-	-	1	-	-	8	-
Roche Elecsys	-	1	-	-	2	-	-	1	-
Roche Modular Analytics	-	2	-	-	5	-	-	2	-
Siemens ADVIA	-	5	-	-	1	-	-	5	-
Siemens Atellica	-	1	-	-	-	-	-	1	-
Standard Diagnostics	-	4	-	-	4	-	-	4	-
VITROS 3600/4600/5600/7600	-	5	-	-	4	-	-	4	-
VITROS ECI	-	1	-	1	1	-	-	1	-

Viral Markers – Anti-HIV- (continued)

<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	139	1	-	4	136	-
Abbott Alinity	9	-	-	-	9	-
Abbott Architect	59	-	-	-	59	-
Acon Laboratories	1	-	-	-	1	-
Alere Clearview HIV1/2						
STAT-PAK	2	-	-	-	2	-
Alere Determine HIV - moderate	2	-	-	-	2	-
Alere Determine HIV - waived	2	-	-	-	2	-
Beckman ACCESS / 2 / Dxl	4	-	-	1	3	-
bioMerieux Vidas, Mini Vidas	3	-	-	-	3	-
CTK Biotech	1	-	-	-	1	-
DiaSorin	1	-	-	-	1	-
Human	3	-	-	-	3	-
Roche cobas 6000 / e 601	16	1	-	1	16	-
Roche cobas 8000/e801	4	-	-	-	4	-
Roche cobas e 411	8	-	-	-	8	-
Roche Elecsys	1	-	-	1	-	-
Roche Modular Analytics	2	-	-	-	2	-
Siemens ADVIA	5	-	-	1	4	-
Siemens Atellica	1	-	-	-	1	-
Standard Diagnostics	4	-	-	-	4	-
VITROS 3600/4600/5600/7600	4	-	-	-	4	-
VITROS ECI	1	-	-	-	1	-

Viral Markers – Anti-HAV (IgM)

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<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	-	60	-	-	59	-	-	59	-
Abbott Architect	-	32	-	-	32	-	-	32	-
bioMerieux Vidas, Mini									
Vidas	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	11	-	-	11	-	-	11	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
Siemens ADVIA	-	2	-	-	2	-	-	2	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
Standard Diagnostics	-	4	-	-	4	-	-	4	-
VITROS									
3600/4600/5600/7600	-	3	-	-	2	-	-	2	-
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>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
	-	59	-		59	-			
ALL METHODS	-	59	-	-	59	-	-		
Abbott Architect	-	32	-	-	32	-	-		
bioMerieux Vidas, Mini									
Vidas	-	2	-	-	2	-	-		
Roche cobas 6000 / e 601	-	11	-	-	11	-	-		
Roche cobas 8000/e801	-	4	-	-	4	-	-		
Siemens ADVIA Centaur	-	2	-	-	2	-	-		
Siemens Atellica	-	1	-	-	1	-	-		
Standard Diagnostics	-	4	-	-	4	-	-		
VITROS									
3600/4600/5600/7600	-	2	-	-	2	-	-		

Viral Markers – Anti-HAV (Total/IgG)

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3			
	<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	-	42	-	35	6	-	-	41	-	
Abbott Architect	-	25	-	25	-	-	-	25	-	
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-	-	1	-	
bioMerieux Vidas, Mini										
Vidas	-	1	-	-	1	-	-	1	-	
Roche cobas 6000 / e 601	-	3	-	3	-	-	-	3	-	
Roche cobas 8000/e801	-	3	-	3	-	-	-	3	-	
Roche cobas e 411	-	2	-	1	1	-	-	2	-	
Roche Elecsys	-	1	-	-	1	-	-	1	-	
Siemens ADVIA	-	2	-	2	-	-	-	2	-	
Siemens Atellica	-	1	-	1	-	-	-	1	-	
Standard Diagnostics	-	1	-	-	1	-	-	1	-	
VITROS										
3600/4600/5600/7600	-	2	-	-	1	-	-	1	-	
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>		
	39	2	-			37	4	-		
ALL METHODS	39	2	-			37	4	-		
Abbott Architect	25	-	-			25	-	-		
Beckman ACCESS / 2 / Dxl	1	-	-			-	1	-		
bioMerieux Vidas, Mini										
Vidas	1	-	-			1	-	-		
Roche cobas 6000 / e 601	3	-	-			3	-	-		
Roche cobas 8000/e801	3	-	-			3	-	-		
Roche cobas e 411	2	-	-			2	-	-		
Roche Elecsys	1	-	-			-	1	-		
Siemens ADVIA	2	-	-			2	-	-		
Siemens Atellica	1	-	-			1	-	-		
Standard Diagnostics	-	1	-			-	1	-		
VITROS										
3600/4600/5600/7600	-	1	-			-	1	-		

Viral Markers – HBeAg

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<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	32	-	32	1	-	31	2	-
Abbott Architect	-	16	-	16	-	-	16	-	-
bioMerieux Vidas, Mini									
Vidas	-	1	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	-	8	-	8	-	-	7	1	-
Roche cobas 8000/e801	-	5	-	4	1	-	4	1	-
Siemens ADVIA	1	-	-	1	-	-	1	-	-
Siemens Atellica	-	1	-	1	-	-	1	-	-
VITROS									
3600/4600/5600/7600	-	1	-	1	-	-	1	-	-
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>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	32	-	32	1	-			
Abbott Architect	-	16	-	16	-	-			
bioMerieux Vidas, Mini									
Vidas	-	1	-	1	-	-			
Roche cobas 6000 / e 601	-	8	-	8	-	-			
Roche cobas 8000/e801	-	5	-	4	1	-			
Siemens ADVIA	1	-	-	1	-	-			
Siemens Atellica	-	1	-	1	-	-			
VITROS									
3600/4600/5600/7600	-	1	-	1	-	-			

Viral Markers – Anti-HBs

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<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	86	4	-	2	88	-	82	8	-
Abbott Alinity	6	-	-	-	6	-	5	1	-
Abbott Architect	42	-	-	-	42	-	41	1	-
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-	2	-	-
Roche cobas 6000 / e 601	11	-	-	-	11	-	11	-	-
Roche cobas 8000/e801	5	-	-	-	5	-	5	-	-
Roche cobas e 411	6	-	-	-	6	-	6	-	-
Roche Elecsys	2	-	-	-	2	-	2	-	-
Roche Modular Analytics	1	-	-	-	1	-	1	-	-
SD Bioline	-	1	-	-	1	-	-	1	-
Siemens ADVIA	4	-	-	-	4	-	2	2	-
Siemens Atellica	1	-	-	-	1	-	1	-	-
Standard Diagnostics	-	2	-	1	1	-	-	2	-
VITROS									
3600/4600/5600/7600	4	-	-	-	4	-	4	-	-
VITROS ECi	2	-	-	-	2	-	2	-	-

Viral Markers – Anti-HBs

<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	88	2	-	3	87	-
Abbott Alinity	6	-	-	-	6	-
Abbott Architect	42	-	-	-	42	-
Beckman ACCESS / 2 / Dxl	2	-	-	-	2	-
Roche cobas 6000 / e 601	11	-	-	-	11	-
Roche cobas 8000/e801	5	-	-	1	4	-
Roche cobas e 411	6	-	-	-	6	-
Roche Elecsys	2	-	-	-	2	-
Roche Modular Analytics	1	-	-	-	1	-
SD Bioline	1	-	-	-	1	-
Siemens ADVIA	4	-	-	-	4	-
Siemens Atellica	1	-	-	-	1	-
Standard Diagnostics	1	1	-	1	1	-
VITROS						
3600/4600/5600/7600	4	-	-	-	4	-
VITROS ECI	2	-	-	-	2	-

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<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	4	137	-	138	1	-	115	24	1
Abbott Alinity	-	9	-	9	-	-	9	-	-
Abbott Architect	2	57	-	59	-	-	59	-	-
Advanced Biotech	-	2	-	2	-	-	-	2	-
Beckman ACCESS / 2 / Dxl	-	4	-	4	-	-	3	-	1
bioMerieux Vidas, Mini Vidas	-	1	-	1	-	-	-	1	-
CTK Biotech	-	1	-	1	-	-	-	1	-
DiaSorin	-	1	-	-	-	-	1	-	-
Human	-	1	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	16	-	16	-	-	16	-	-
Roche cobas 8000/e801	-	5	-	5	-	-	5	-	-
Roche cobas e 411	2	6	-	7	1	-	6	2	-
Roche Elecsys	-	1	-	1	-	-	1	-	-
Roche Modular Analytics	-	2	-	2	-	-	2	-	-
SD Bioline	-	3	-	3	-	-	-	3	-
Siemens ADVIA	-	6	-	6	-	-	6	-	-
Siemens Atellica	-	1	-	1	-	-	1	-	-
Standard Diagnostics	-	9	-	9	-	-	-	9	-
VITROS 3600/4600/5600/7600	-	5	-	4	-	-	4	-	-
VITROS ECI	-	1	-	1	-	-	1	-	-

Viral Markers – HBsAg (continued)

<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	2	138	-	139	1	-
Abbott Alinity	-	9	-	9	-	-
Abbott Architect	1	58	-	59	-	-
Advanced Biotech	-	2	-	2	-	-
Beckman ACCESS / 2 / Dxl	-	4	-	4	-	-
bioMerieux Vidas, Mini						
Vidas	-	1	-	1	-	-
CTK Biotech	-	1	-	1	-	-
DiaSorin	-	1	-	1	-	-
Human	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	16	-	16	-	-
Roche cobas 8000/e801	-	5	-	5	-	-
Roche cobas e 411	1	7	-	7	1	-
Roche Elecsys	-	1	-	1	-	-
Roche Modular Analytics	-	2	-	2	-	-
SD Bioline	-	3	-	3	-	-
Siemens ADVIA	-	6	-	6	-	-
Siemens Atellica	-	1	-	1	-	-
Standard Diagnostics	-	9	-	9	-	-
VITROS						
3600/4600/5600/7600	-	4	-	4	-	-
VITROS ECI	-	1	-	1	-	-

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<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	121	1	-	24	96	-	1	120	-
Abbott Alinity	9	-	-	-	9	-	-	9	-
Abbott Architect	58	-	-	-	58	-	-	58	-
Beckman ACCESS / 2 / Dxl	3	-	-	-	3	-	-	3	-
DiaSorin	1	-	-	11	1	-	-	1	-
Roche cobas 6000 / e 601	12	-	-	4	-	-	1	11	-
Roche cobas 8000/e801	4	-	-	7	1	-	-	4	-
Roche cobas e 411	8	-	-	1	-	-	-	8	-
Roche Modular Analytics	1	-	-	-	2	-	-	1	-
SD Bioline	2	-	-	-	4	-	-	2	-
Siemens ADVIA	4	-	-	-	1	-	-	4	-
Siemens Atellica	1	-	-	-	8	-	-	1	-
Standard Diagnostics	8	-	-	-	4	-	-	8	-
VITROS									
3600/4600/5600/7600	4	1	-	-	1	-	-	4	-
VITROS ECI	1	-	-	1	-	-	-	1	-
Wantai BioPharm	1	-	-	24	96	-	-	1	-

Viral Markers – Anti-HCV

<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	-	121	-	24	96	-
Abbott Alinity	-	9	-	-	9	-
Abbott Architect	-	58	-	-	58	-
Beckman ACCESS / 2 / Dxl	-	3	-	-	3	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-
DiaSorin	-	12	-	12	-	-
Roche cobas 6000 / e 601	-	4	-	4	-	-
Roche cobas 8000/e801	-	8	-	6	1	-
Roche cobas e 411	-	1	-	1	-	-
Roche Modular Analytics	-	2	-	-	2	-
Siemens ADVIA Centaur	-	4	-	-	4	-
Siemens Atellica	-	1	-	-	1	-
Standard Diagnostics	-	8	-	-	8	-
VITROS						
3600/4600/5600/7600	-	4	-	-	4	-
VITROS ECI	-	1	-	-	1	-
Wantai BioPharm	-	1	-	1	-	-

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	-	21	-	21	-	-
Abbott Architect	-	13	-	13	-	-
bioMerieux Vidas, Mini						
Vidas	-	3	-	3	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
Roche cobas e 411	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	-	2	-	2	-	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen TOX-1						
All Method	23	0.113	0.079	70.6	0.10	0.00 - 0.36
All Roche Instruments	5	0.130	0.001	0.0	0.13	0.12 - 0.14
Abbott Architect	15	0.147	0.064	43.6	0.10	0.00 - 0.34
bioMerieux Vidas, Mini Vidas	5	0.000	0.001	0.0	0.00	0.00 - 0.01
Specimen TOX-2						
All Method	22	78.155	30.283	38.7	63.55	0.00 - 169.01
All Roche Instruments	5	143.633	10.707	7.5	148.20	111.51 - 175.76
Abbott Architect	14	62.957	4.875	7.7	61.30	48.33 - 77.59
bioMerieux Vidas, Mini Vidas	4	-	-	-	62.00	0.00 - 169.01

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	-	24	-	24	-	-
Abbott Architect	-	15	-	15	-	-
bioMerieux Vidas, Mini						
Vidas	-	3	-	3	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	2	-	2	-	-
Roche cobas e 411	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	-	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>
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Specimen TOX-1

All Method	20	0.143	0.070	49.4	0.13	0.00 - 0.36
All Roche Instruments	5	0.237	0.064	27.2	0.21	0.04 - 0.43
Abbott Architect	13	0.120	0.037	30.8	0.12	0.00 - 0.24

Specimen TOX-2

All Method	20	15.604	6.999	44.9	14.03	0.00 - 36.61
All Roche Instruments	5	30.823	3.098	10.1	31.57	21.52 - 40.12
Abbott Architect	13	13.888	1.296	9.3	14.04	9.99 - 17.78

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	16	1	-	1	16	-
Abbott Architect	13	1	-	1	13	-
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	1	-	-	-	1	-
VITROS 3600/4600/5600/7600	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	16	353.256	183.865	52.0	250.00	0.00 - 904.86
Abbott Architect	13	322.431	188.738	58.5	250.00	0.00 - 888.65

Specimen CMV-2

All Method	16	0.629	0.363	57.7	0.65	0.00 - 1.72
Abbott Architect	13	0.762	0.250	32.8	0.70	0.01 - 1.52

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	1	18	-	16	3	-
Abbott Architect	1	15	-	16	-	-
Roche cobas 6000 / e 601	-	2	-	-	2	-
VITROS 3600/4600/5600/7600	-	1	-	-	1	-

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	14	0.580	0.273	47.1	0.58	0.00 - 1.40
Abbott Architect	12	0.633	0.255	40.3	0.66	0.00 - 1.40

Specimen CMV-2

All Method	14	2.016	0.710	35.2	2.15	0.00 - 4.15
Abbott Architect	12	2.260	0.346	15.3	2.18	1.22 - 3.30

Neonatal Bilirubin, Total (mg/dL)

<u>Method</u>	Specimen NB-1							Specimen NB-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	49	7.05	0.34	4.9	7.1	5.6 - 8.5	48	19.66	0.80	4.1	19.8	15.7 - 23.6		
No Reagent Required														
Bilirubinometer / Unistat	39	7.06	0.34	4.8	7.1	5.6 - 8.5	39	19.81	0.66	3.3	20.0	15.8 - 23.8		
All Chemistry Instruments	43	7.05	0.35	4.9	7.1	5.6 - 8.5	41	19.78	0.68	3.4	20.0	15.8 - 23.8		
Specimen NB-3							Specimen NB-4							
All Method	47	0.03	0.06	237.7	0.0	0.0 - 0.5	49	12.98	0.72	5.5	13.2	10.3 - 15.6		
No Reagent Required														
Bilirubinometer / Unistat	39	0.00	0.01	0.0	0.0	0.0 - 0.4	37	13.28	0.43	3.3	13.3	10.6 - 16.0		
All Chemistry Instruments	39	0.00	0.01	0.0	0.0	0.0 - 0.4	42	13.15	0.60	4.6	13.3	10.5 - 15.8		
Specimen NB-5														
All Method	49	18.39	1.07	5.8	18.8	14.7 - 22.1								
No Reagent Required														
Bilirubinometer / Unistat	38	18.75	0.81	4.3	19.0	15.0 - 22.6								
All Chemistry Instruments	43	18.54	1.04	5.6	18.8	14.8 - 22.3								

Bilirubin, Direct (mg/dL)

<u>Method</u>	Specimen NB-1							Specimen NB-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	11	1.82	0.41	22.8	1.7	0.9 - 2.7	11	4.31	0.75	17.3	4.1	2.8 - 5.9		
Specimen NB-3							Specimen NB-4							
All Method	11	0.14	0.14	105.1	0.1	0.0 - 0.5	11	5.47	0.73	13.3	5.4	4.0 - 7.0		
Specimen NB-5														
All Method	11	6.23	0.72	11.5	6.1	4.7 - 7.7								

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	119	7.07	0.23	3.3	7.1	6.7 - 7.5	120	10.98	0.45	4.1	11.0	10.4 - 11.6
All Bio-Rad Methods	5	7.22	0.27	3.7	7.1	6.8 - 7.6	5	10.72	0.33	3.1	10.7	10.1 - 11.3
All Enzymatic A1c Methods	5	6.98	0.63	9.0	6.8	6.6 - 7.4	5	10.88	0.89	8.2	10.5	10.3 - 11.5
All Hemoglobin A1c Methods	116	7.09	0.22	3.2	7.1	6.7 - 7.5	116	10.98	0.43	3.9	11.0	10.4 - 11.6
All Roche Methods	11	6.91	0.22	3.2	6.9	6.5 - 7.3	11	11.15	0.31	2.8	11.1	10.5 - 11.8
All TOSOH Methods	13	7.23	0.27	3.8	7.3	6.8 - 7.6	13	10.04	0.35	3.5	10.0	9.5 - 10.6
Beckman AU A1c	9	6.83	0.22	3.2	6.8	6.4 - 7.2	9	10.94	0.35	3.2	10.9	10.3 - 11.5
Bio-Rad D-10 HbA1C	5	7.22	0.27	3.7	7.1	6.8 - 7.6	5	10.72	0.33	3.1	10.7	10.1 - 11.3
Roche cobas c501 HbA1c	7	7.01	0.21	3.0	7.0	6.6 - 7.4	7	11.23	0.35	3.1	11.1	10.6 - 11.8
Roche Integra A1C	4	6.73	0.05	0.7	6.7	6.3 - 7.1	4	11.00	0.18	1.7	11.0	10.4 - 11.6
Siemens DCA Vantage	57	7.11	0.18	2.6	7.1	6.7 - 7.5	56	11.04	0.22	2.0	11.0	10.4 - 11.6
Siemens Dimension HA1C	7	7.03	0.16	2.3	7.0	6.6 - 7.4	6	10.97	0.30	2.7	11.0	10.4 - 11.6
Siemens Dimension HB1C	8	7.08	0.10	1.5	7.1	6.7 - 7.5	8	11.28	0.18	1.6	11.3	10.7 - 11.9
TOSOH G8	13	7.23	0.27	3.8	7.3	6.8 - 7.6	13	10.04	0.35	3.5	10.0	9.5 - 10.6

Whole Blood Glucose (mg/dL)

<u>Method</u>	Specimen WBG-1						Specimen WBG-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	813	73.9	10.1	13.6	76	59 - 89	799	336.5	23.6	7.0	342	269 - 404
All Abbott Methods	45	60.2	7.1	11.9	59	48 - 73	44	307.2	26.8	8.7	301	245 - 369
All Arkay Methods	8	83.5	10.5	12.6	86	66 - 101	6	339.8	20.4	6.0	337	271 - 408
All Bayer Methods	19	55.5	7.1	12.9	52	44 - 67	19	265.3	30.4	11.4	254	212 - 319
All Hemocue Methods	52	93.4	11.1	11.9	94	74 - 113	49	342.5	8.0	2.3	343	273 - 411
All Lifescan Methods	10	65.0	2.7	4.2	65	52 - 78	10	354.6	26.2	7.4	367	283 - 426
All Roche Methods	499	76.4	1.6	2.2	76	61 - 92	508	343.8	8.1	2.4	344	275 - 413
Abbott FreeStyle Freedom	10	62.2	8.6	13.8	62	49 - 75	10	322.3	18.0	5.6	324	257 - 387
Abbott FreeStyle Lite/Freedom Lite	7	67.7	1.1	1.6	68	54 - 82	7	332.1	11.5	3.5	333	265 - 399
Abbott FreeStyle Precision Pro	22	58.0	6.0	10.4	57	46 - 70	21	298.0	24.7	8.3	294	238 - 358
Abbott Precision XceedPro	6	56.0	5.5	9.9	56	44 - 68	6	285.2	26.8	9.4	288	228 - 343
Arkay Platinum	25	88.5	2.9	3.3	89	70 - 107	23	347.6	10.6	3.0	349	278 - 418
Bayer Contour	21	54.7	6.1	11.2	52	43 - 66	21	261.1	26.0	10.0	248	208 - 314
HemoCue Glucose 201	52	93.9	9.8	10.5	95	75 - 113	49	343.2	7.1	2.1	343	274 - 412
Home Diagnostics True Balance / TrueTrack	12	184.3	11.8	6.4	185	147 - 222	9	582.7	24.2	4.2	593	466 - 700
Lifescan One Touch Ultra	23	63.4	6.0	9.5	64	50 - 77	23	350.9	46.5	13.3	366	280 - 422
Medline EvenCare G2 / G3	19	70.4	7.2	10.2	72	56 - 85	19	322.5	40.4	12.5	325	257 - 387
NOVA Biomedical StatStrip	53	60.5	5.1	8.4	60	48 - 73	52	286.8	19.9	6.9	288	229 - 345
Quintet / AC	35	63.1	4.6	7.2	63	50 - 76	36	355.4	14.5	4.1	359	284 - 427
Roche Accu-Chek Inform	10	74.7	1.7	2.3	75	59 - 90	10	339.5	2.5	0.7	340	271 - 408
Roche Accu-Chek Inform II	340	76.4	1.7	2.2	77	61 - 92	348	345.3	7.8	2.2	346	276 - 415
Roche Accu-Chek Performa	146	76.4	1.6	2.0	76	61 - 92	146	340.7	7.9	2.3	342	272 - 409
True Metrix Pro	17	60.1	3.7	6.2	60	48 - 73	18	299.4	19.2	6.4	301	239 - 360

Whole Blood Glucose (mg/dL) (continued)

<u>Method</u>	Specimen WBG-3							Specimen WBG-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	159	107.7	9.8	9.1	112	86 - 130	161	291.4	25.6	8.8	298	233 - 350		
All Abbott Methods	10	97.9	7.6	7.8	98	78 - 118	10	281.2	23.1	8.2	279	224 - 338		
All Lifescan Methods	3	-	-	-	114	91 - 138	3	-	-	-	324	258 - 388		
All Roche Methods	92	113.5	2.1	1.8	113	90 - 137	94	303.1	6.6	2.2	303	242 - 364		
Abbott FreeStyle Freedom	10	97.9	7.6	7.8	98	78 - 118	10	281.2	23.1	8.2	279	224 - 338		
Lifescan One Touch Ultra	18	102.6	14.0	13.7	102	82 - 124	18	301.5	46.2	15.3	287	241 - 362		
NOVA Biomedical StatStrip	33	97.2	6.5	6.7	99	77 - 117	34	259.0	14.3	5.5	260	207 - 311		
Roche Accu-Chek Inform	10	113.0	1.6	1.4	113	90 - 136	10	300.3	3.0	1.0	300	240 - 361		
Roche Accu-Chek Inform II	72	113.7	2.3	2.0	113	90 - 137	73	303.7	6.9	2.3	303	242 - 365		
Roche Accu-Chek Performa	11	113.5	2.2	1.9	114	90 - 137	11	301.5	6.7	2.2	303	241 - 362		
True Metrix Pro	2	-	-	-	491	392 - 589	2	-	-	-	264	211 - 317		
Specimen WBG-5														
<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>								
All Method	161	95.2	9.9	10.4	100	76 - 115								
All Abbott Methods	10	83.6	6.3	7.6	83	66 - 101								
All Lifescan Methods	3	-	-	-	99	78 - 118								
All Roche Methods	94	101.5	2.2	2.1	101	81 - 122								
Abbott FreeStyle Freedom	10	83.6	6.3	7.6	83	66 - 101								
Lifescan One Touch Ultra	18	89.7	14.4	16.0	86	71 - 108								
NOVA Biomedical StatStrip	34	85.0	5.9	6.9	86	67 - 102								
Roche Accu-Chek Inform	10	100.6	2.3	2.3	101	80 - 121								
Roche Accu-Chek Inform II	73	101.6	2.2	2.2	101	81 - 122								
Roche Accu-Chek Performa	11	101.3	1.8	1.8	102	81 - 122								
True Metrix Pro	2	-	-	-	78	62 - 94								

Folate (ng/mL)

Method	Specimen SC-1						Specimen SC-2					
	Labs	Mean	SD	CV	Median	Range	Labs	Mean	SD	CV	Median	Range
All Method	24	9.38	3.60	38.4	10.3	6.5 - 12.2	26	0.99	0.71	71.3	0.5	0.0 - 2.0
All Roche Instruments	8	7.95	1.36	17.0	7.9	5.5 - 10.4	9	1.48	0.83	56.0	2.0	0.4 - 2.5
All Siemens Dimension Instruments	6	6.17	1.02	16.5	6.4	4.3 - 8.1	6	0.77	0.14	17.8	0.8	0.0 - 1.8
All Siemens Dimension Instruments	6	6.17	1.02	16.5	6.4	4.3 - 8.1	6	0.77	0.14	17.8	0.8	0.0 - 1.8
All Siemens Dimension Instruments	6	6.17	1.02	16.5	6.4	4.3 - 8.1	6	0.77	0.14	17.8	0.8	0.0 - 1.8
All Siemens Dimension Instruments	6	6.17	1.02	16.5	6.4	4.3 - 8.1	6	0.77	0.14	17.8	0.8	0.0 - 1.8
All TOSOH Instruments	8	5.79	0.87	15.0	5.5	4.0 - 7.6	8	1.03	0.85	83.1	0.8	0.0 - 2.1
Abbott Architect	6	13.90	3.59	25.8	15.0	9.7 - 18.1	6	0.72	0.69	96.0	0.4	0.0 - 1.8
Beckman ACCESS / 2 / Dxl	23	11.74	1.16	9.9	11.7	8.2 - 15.3	23	0.23	0.34	143.4	0.1	0.0 - 1.3
Roche cobas e 601/e 602	5	7.60	1.45	19.1	7.8	5.3 - 9.9	6	1.55	0.74	47.5	2.0	0.5 - 2.6
Siemens Dimension	5	6.20	1.13	18.3	6.8	4.3 - 8.1	5	0.80	0.12	15.3	0.8	0.0 - 1.8

CK-MB - Quantitative (U/L)

Method	Specimen CK-1						Specimen CK-2						
	Labs	Mean	SD	CV	Median	Range	Labs	Mean	SD	CV	Median	Range	
All Method	6	5.30	0.99	18.7	5.3	2.3 - 8.3	6	38.60	6.51	16.9	38.6	19.0 - 58.2	
Specimen CK-3						Specimen CK-4							
All Method	6	4.10	0.14	3.4	4.1	3.6 - 4.6	6	21.50	3.54	16.4	21.5	10.8 - 32.2	
Specimen CK-5													
All Method	6	73.00	11.31	15.5	73.0	39.0 - 107.0							

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