

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-M2**



Total Commitment to Education and Service
Provided by ACP, Inc.

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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-3						Specimen ES-4					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	143	46.3	11.1	24.1	43	12 - 80	150	9.9	3.5	35.5	10	0 - 21
All Automated Methods	30	60.5	9.1	15.1	61	33 - 88	31	11.7	3.9	33.4	11	0 - 24
All Diesse Methods	9	70.6	16.2	22.9	68	22 - 120	10	13.5	4.5	33.4	13	0 - 28
All Manual Methods	108	42.1	8.0	19.1	40	17 - 67	110	9.2	2.8	30.1	9	0 - 18
All Vital Diagnostics Methods	15	60.7	8.6	14.1	61	34 - 87	15	10.2	3.0	29.2	11	1 - 20
Vital Diagnostics Excyte M/10	9	58.3	6.0	10.2	61	40 - 77	9	9.7	3.2	32.7	10	0 - 20
Westergren - diluted	86	42.3	8.0	18.9	41	18 - 67	86	8.5	2.3	27.0	9	1 - 16
Westergren - undiluted	20	42.9	10.8	25.2	40	10 - 76	21	11.0	3.2	28.8	10	1 - 21

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	31	2.67	0.34	12.8	2.5	2.2 - 3.1	31	19.21	1.68	8.8	18.2	16.3 - 22.1
All Abbott Cell-Dyn Instruments	18	3.14	0.17	5.3	3.1	2.6 - 3.7	18	21.58	0.58	2.7	21.3	18.3 - 24.9
Abbott Cell-Dyn Emerald 22	10	2.40	0.08	3.4	2.4	2.0 - 2.8	10	18.30	0.98	5.4	18.1	15.5 - 21.1
Abbott Cell-Dyn Ruby	8	3.14	0.17	5.3	3.1	2.6 - 3.7	8	21.58	0.58	2.7	21.3	18.3 - 24.9
Orphee Mythic 22	13	2.51	0.15	5.8	2.5	2.1 - 2.9	13	18.19	0.42	2.3	18.1	15.4 - 21.0

<u>Instrument</u>	Specimen CL-8						Specimen CL-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	31	19.14	1.73	9.0	18.4	16.2 - 22.1	31	7.35	0.72	9.8	7.1	6.2 - 8.5
All Abbott Cell-Dyn Instruments	18	21.52	1.13	5.2	21.2	18.2 - 24.8	18	8.34	0.36	4.3	8.4	7.0 - 9.6
Abbott Cell-Dyn Emerald 22	10	17.78	0.39	2.2	17.9	15.1 - 20.5	10	6.83	0.36	5.3	7.0	5.8 - 7.9
Abbott Cell-Dyn Ruby	8	21.52	1.13	5.2	21.2	18.2 - 24.8	8	8.34	0.36	4.3	8.4	7.0 - 9.6
Orphee Mythic 22	13	18.33	0.41	2.2	18.3	15.5 - 21.1	13	6.99	0.23	3.3	7.0	5.9 - 8.1

<u>Instrument</u>	Specimen CL-10					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	31	8.73	0.88	10.1	8.4	7.4 - 10.1
All Abbott Cell-Dyn Instruments	18	9.72	0.97	10.0	10.1	8.2 - 11.2
Abbott Cell-Dyn Emerald 22	10	8.28	0.30	3.6	8.3	7.0 - 9.6
Abbott Cell-Dyn Ruby	8	9.72	0.97	10.0	10.1	8.2 - 11.2
Orphee Mythic 22	13	8.27	0.23	2.8	8.3	7.0 - 9.6

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	31	2.179	0.104	4.8	2.17	2.04 - 2.31	31	5.021	0.239	4.8	4.96	4.71 - 5.33
All Abbott Cell-Dyn Instruments	18	2.302	0.066	2.9	2.26	2.16 - 2.45	18	5.308	0.234	4.4	5.28	4.98 - 5.63
Abbott Cell-Dyn Emerald 22	10	2.090	0.029	1.4	2.10	1.96 - 2.22	10	4.838	0.068	1.4	4.86	4.54 - 5.13
Abbott Cell-Dyn Ruby	8	2.302	0.066	2.9	2.26	2.16 - 2.45	8	5.308	0.234	4.4	5.28	4.98 - 5.63
Orphee Mythic 22	13	2.146	0.074	3.4	2.16	2.01 - 2.28	13	4.934	0.101	2.0	4.95	4.63 - 5.23
	Specimen CL-8						Specimen CL-9					
All Method	31	5.006	0.258	5.2	4.98	4.70 - 5.31	31	4.669	0.277	5.9	4.66	4.38 - 4.95
All Abbott Cell-Dyn Instruments	18	5.302	0.212	4.0	5.24	4.98 - 5.63	18	4.972	0.198	4.0	5.03	4.67 - 5.28
Abbott Cell-Dyn Emerald 22	10	4.838	0.128	2.6	4.85	4.54 - 5.13	10	4.533	0.053	1.2	4.54	4.26 - 4.81
Abbott Cell-Dyn Ruby	8	5.302	0.212	4.0	5.24	4.98 - 5.63	8	4.972	0.198	4.0	5.03	4.67 - 5.28
Orphee Mythic 22	13	4.906	0.172	3.5	4.92	4.61 - 5.21	13	4.549	0.243	5.4	4.61	4.27 - 4.83
	Specimen CL-10											
All Method	31	6.194	0.311	5.0	6.11	5.82 - 6.57						
All Abbott Cell-Dyn Instruments	18	6.606	0.203	3.1	6.71	6.20 - 7.01						
Abbott Cell-Dyn Emerald 22	10	6.013	0.049	0.8	6.02	5.65 - 6.38						
Abbott Cell-Dyn Ruby	8	6.606	0.203	3.1	6.71	6.20 - 7.01						
Orphee Mythic 22	13	6.028	0.156	2.6	6.10	5.66 - 6.39						

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	31	4.93	0.43	8.7	4.8	4.5 - 5.3	31	15.74	0.74	4.7	15.4	14.6 - 16.9
All Abbott Cell-Dyn Instruments	18	5.52	0.08	1.5	5.5	5.1 - 6.0	18	16.72	0.31	1.9	16.7	15.5 - 17.9
Abbott Cell-Dyn Emerald 22	10	4.70	0.12	2.5	4.7	4.3 - 5.1	10	15.30	0.20	1.3	15.3	14.2 - 16.4
Abbott Cell-Dyn Ruby	8	5.52	0.08	1.5	5.5	5.1 - 6.0	8	16.72	0.31	1.9	16.7	15.5 - 17.9
Orphee Mythic 22	13	4.64	0.15	3.3	4.6	4.3 - 5.0	13	15.29	0.33	2.2	15.2	14.2 - 16.4
	Specimen CL-8						Specimen CL-9					
All Method	31	15.75	0.71	4.5	15.5	14.6 - 16.9	31	12.35	0.76	6.2	12.1	11.4 - 13.3
All Abbott Cell-Dyn Instruments	18	16.74	0.29	1.7	16.6	15.5 - 18.0	18	13.44	0.25	1.9	13.5	12.4 - 14.4
Abbott Cell-Dyn Emerald 22	10	15.45	0.33	2.1	15.4	14.3 - 16.6	10	12.10	0.24	2.0	12.1	11.2 - 13.0
Abbott Cell-Dyn Ruby	8	16.74	0.29	1.7	16.6	15.5 - 18.0	8	13.44	0.25	1.9	13.5	12.4 - 14.4
Orphee Mythic 22	13	15.28	0.25	1.6	15.3	14.2 - 16.4	13	11.80	0.19	1.6	11.8	10.9 - 12.7
	Specimen CL-10											
All Method	31	17.62	0.94	5.3	17.2	16.3 - 18.9						
All Abbott Cell-Dyn Instruments	18	18.94	0.32	1.7	18.9	17.6 - 20.3						
Abbott Cell-Dyn Emerald 22	10	17.13	0.29	1.7	17.1	15.9 - 18.4						
Abbott Cell-Dyn Ruby	8	18.94	0.32	1.7	18.9	17.6 - 20.3						
Orphee Mythic 22	13	17.04	0.40	2.4	16.9	15.8 - 18.3						

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	31	15.84	0.74	4.7	15.8	14.8 - 16.8	31	46.04	1.14	2.5	46.2	43.2 - 48.9
All Abbott Cell-Dyn Instruments	18	15.86	0.69	4.3	15.8	14.9 - 16.9	18	46.50	1.53	3.3	46.7	43.7 - 49.3
Abbott Cell-Dyn Emerald 22	10	15.23	0.26	1.7	15.2	14.3 - 16.2	10	45.25	0.95	2.1	45.3	42.5 - 48.0
Abbott Cell-Dyn Ruby	8	15.86	0.69	4.3	15.8	14.9 - 16.9	8	46.50	1.53	3.3	46.7	43.7 - 49.3
Orphee Mythic 22	13	16.19	0.80	5.0	16.6	15.2 - 17.2	13	46.15	0.86	1.9	46.3	43.3 - 49.0
	Specimen CL-8						Specimen CL-9					
All Method	31	46.03	1.39	3.0	46.1	43.2 - 48.8	31	38.92	1.79	4.6	39.4	36.5 - 41.3
All Abbott Cell-Dyn Instruments	18	46.35	1.78	3.8	45.9	43.5 - 49.2	18	40.16	0.92	2.3	40.1	37.7 - 42.6
Abbott Cell-Dyn Emerald 22	10	45.35	1.77	3.9	45.6	42.6 - 48.1	10	37.85	1.01	2.7	37.7	35.5 - 40.2
Abbott Cell-Dyn Ruby	8	46.35	1.78	3.8	45.9	43.5 - 49.2	8	40.16	0.92	2.3	40.1	37.7 - 42.6
Orphee Mythic 22	13	46.23	0.96	2.1	46.1	43.4 - 49.1	13	38.69	2.14	5.5	39.5	36.3 - 41.1
	Specimen CL-10											
All Method	31	53.77	1.78	3.3	53.9	50.5 - 57.0						
All Abbott Cell-Dyn Instruments	18	55.24	1.22	2.2	55.7	51.9 - 58.6						
Abbott Cell-Dyn Emerald 22	10	53.08	1.37	2.6	52.6	49.8 - 56.3						
Abbott Cell-Dyn Ruby	8	55.24	1.22	2.2	55.7	51.9 - 58.6						
Orphee Mythic 22	13	53.20	1.84	3.4	53.7	50.0 - 56.4						

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	31	99.8	16.7	16.7	102	74 - 125	31	503.8	18.7	3.7	502	377 - 630
All Abbott Cell-Dyn Instruments	18	80.4	3.6	4.5	79	60 - 101	18	508.4	21.6	4.2	497	381 - 636
Abbott Cell-Dyn Emerald 22	10	99.0	9.1	9.1	102	74 - 124	10	520.0	53.7	10.3	504	390 - 650
Abbott Cell-Dyn Ruby	8	80.4	3.6	4.5	79	60 - 101	8	508.4	21.6	4.2	497	381 - 636
Orphee Mythic 22	13	112.3	12.1	10.8	110	84 - 141	13	504.3	17.1	3.4	503	378 - 631
Specimen CL-8												
All Method	31	498.6	22.5	4.5	497	373 - 624	31	281.0	15.5	5.5	278	210 - 352
All Abbott Cell-Dyn Instruments	18	510.6	21.7	4.2	518	382 - 639	18	287.4	16.8	5.8	280	215 - 360
Abbott Cell-Dyn Emerald 22	10	484.5	15.5	3.2	488	363 - 606	10	273.3	17.3	6.3	266	204 - 342
Abbott Cell-Dyn Ruby	8	510.6	21.7	4.2	518	382 - 639	8	287.4	16.8	5.8	280	215 - 360
Orphee Mythic 22	13	522.8	73.5	14.1	501	392 - 654	13	335.8	155.8	46.4	284	251 - 420
Specimen CL-10												
All Method	31	137.7	50.0	36.3	123	103 - 173						
All Abbott Cell-Dyn Instruments	18	200.4	33.7	16.8	183	150 - 251						
Abbott Cell-Dyn Emerald 22	10	92.0	17.6	19.2	92	69 - 115						
Abbott Cell-Dyn Ruby	8	200.4	33.7	16.8	183	150 - 251						
Orphee Mythic 22	13	119.0	16.4	13.8	120	89 - 149						

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	31	45.06	3.78	8.4	45.3	33.7 - 56.4	31	68.82	2.18	3.2	68.8	62.2 - 75.4
All Abbott Cell-Dyn Instruments	18	48.98	0.46	0.9	49.0	47.5 - 50.4	18	71.52	0.78	1.1	71.3	69.1 - 73.9
Abbott Cell-Dyn Emerald 22	10	42.73	5.00	11.7	44.4	27.7 - 57.8	10	67.35	1.27	1.9	67.4	63.5 - 71.2
Abbott Cell-Dyn Ruby	8	48.98	0.46	0.9	49.0	47.5 - 50.4	8	71.52	0.78	1.1	71.3	69.1 - 73.9
Orphee Mythic 22	13	43.79	2.41	5.5	43.5	36.5 - 51.1	13	67.86	1.53	2.3	68.3	63.2 - 72.5
<u>Instrument</u>	Specimen CL-8						Specimen CL-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	31	68.26	2.72	4.0	68.2	60.1 - 76.5	31	54.42	5.03	9.2	53.4	39.3 - 69.6
All Abbott Cell-Dyn Instruments	18	71.56	0.47	0.7	71.4	70.1 - 73.0	18	60.70	1.00	1.7	60.5	57.6 - 63.8
Abbott Cell-Dyn Emerald 22	10	66.43	1.71	2.6	66.7	61.2 - 71.6	10	52.23	1.41	2.7	52.5	48.0 - 56.5
Abbott Cell-Dyn Ruby	8	71.56	0.47	0.7	71.4	70.1 - 73.0	8	60.70	1.00	1.7	60.5	57.6 - 63.8
Orphee Mythic 22	13	67.13	2.09	3.1	67.2	60.8 - 73.4	13	51.19	3.64	7.1	52.4	40.2 - 62.2
<u>Instrument</u>	Specimen CL-10											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	31	67.41	3.85	5.7	67.2	55.8 - 79.0						
All Abbott Cell-Dyn Instruments	18	71.74	1.13	1.6	71.1	68.3 - 75.2						
Abbott Cell-Dyn Emerald 22	10	67.45	1.52	2.3	67.2	62.8 - 72.1						
Abbott Cell-Dyn Ruby	8	71.74	1.13	1.6	71.1	68.3 - 75.2						
Orphee Mythic 22	13	64.30	2.86	4.5	64.1	55.7 - 72.9						

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	31	26.35	6.62	25.1	26.1	6.4 - 46.3	31	13.74	2.22	16.2	13.9	7.0 - 20.5
All Abbott Cell-Dyn Instruments	18	33.72	3.13	9.3	32.3	24.3 - 43.2	18	14.64	0.78	5.3	15.0	12.3 - 17.0
Abbott Cell-Dyn Emerald 22	10	18.60	3.75	20.2	18.7	7.3 - 29.9	10	10.20	1.57	15.4	10.5	5.4 - 15.0
Abbott Cell-Dyn Ruby	8	33.72	3.13	9.3	32.3	24.3 - 43.2	8	14.64	0.78	5.3	15.0	12.3 - 17.0
Orphee Mythic 22	13	24.40	3.36	13.8	23.6	14.3 - 34.5	13	14.50	1.71	11.8	14.2	9.3 - 19.7

<u>Instrument</u>	Specimen CL-8						Specimen CL-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	31	13.94	2.32	16.6	14.1	6.9 - 20.9	31	18.31	4.89	26.7	19.7	3.6 - 33.0
All Abbott Cell-Dyn Instruments	18	14.66	0.68	4.6	14.6	12.6 - 16.7	18	22.96	1.41	6.1	23.1	18.7 - 27.2
Abbott Cell-Dyn Emerald 22	10	10.53	1.16	11.0	10.7	7.0 - 14.1	10	11.33	3.07	27.1	11.7	2.1 - 20.6
Abbott Cell-Dyn Ruby	8	14.66	0.68	4.6	14.6	12.6 - 16.7	8	22.96	1.41	6.1	23.1	18.7 - 27.2
Orphee Mythic 22	13	14.78	2.18	14.7	14.3	8.2 - 21.4	13	18.03	3.33	18.5	17.5	8.0 - 28.1

<u>Instrument</u>	Specimen CL-10					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	31	14.68	3.29	22.4	16.0	4.8 - 24.6
All Abbott Cell-Dyn Instruments	18	18.04	0.92	5.1	18.5	15.2 - 20.9
Abbott Cell-Dyn Emerald 22	10	10.43	1.31	12.5	10.3	6.5 - 14.4
Abbott Cell-Dyn Ruby	8	18.04	0.92	5.1	18.5	15.2 - 20.9
Orphee Mythic 22	13	14.10	2.31	16.4	13.5	7.1 - 21.1

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	31	20.67	7.92	38.3	23.1	0.0 - 44.5	31	10.29	3.67	35.7	12.4	0.0 - 21.3
All Abbott Cell-Dyn Instruments	18	9.50	1.80	19.0	10.4	4.0 - 15.0	18	4.96	0.47	9.4	4.8	3.5 - 6.4
Abbott Cell-Dyn Emerald 22	10	25.98	4.15	16.0	26.5	13.5 - 38.5	10	11.88	1.75	14.8	12.3	6.6 - 17.2
Abbott Cell-Dyn Ruby	8	9.50	1.80	19.0	10.4	4.0 - 15.0	8	4.96	0.47	9.4	4.8	3.5 - 6.4
Orphee Mythic 22	13	25.00	2.76	11.0	24.9	16.7 - 33.3	13	12.83	0.52	4.1	12.9	11.2 - 14.4
Specimen CL-8												
All Method	31	10.43	3.89	37.3	12.3	0.0 - 22.1	31	17.31	7.79	45.0	20.5	0.0 - 40.7
All Abbott Cell-Dyn Instruments	18	5.06	0.32	6.3	5.1	4.0 - 6.1	18	6.52	0.55	8.4	6.3	4.8 - 8.2
Abbott Cell-Dyn Emerald 22	10	11.75	1.71	14.5	12.3	6.6 - 16.9	10	19.35	3.13	16.2	20.7	9.9 - 28.8
Abbott Cell-Dyn Ruby	8	5.06	0.32	6.3	5.1	4.0 - 6.1	8	6.52	0.55	8.4	6.3	4.8 - 8.2
Orphee Mythic 22	13	13.13	1.82	13.9	12.7	7.6 - 18.6	13	23.04	3.35	14.5	22.0	12.9 - 33.1
Specimen CL-10												
All Method	31	12.42	5.37	43.2	14.2	0.0 - 28.6						
All Abbott Cell-Dyn Instruments	18	5.02	0.44	8.8	5.1	3.6 - 6.4						
Abbott Cell-Dyn Emerald 22	10	13.93	2.17	15.6	14.3	7.4 - 20.5						
Abbott Cell-Dyn Ruby	8	5.02	0.44	8.8	5.1	3.6 - 6.4						
Orphee Mythic 22	13	16.29	2.50	15.3	16.7	8.7 - 23.8						

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

<u>Instrument</u>	Specimen CL-6						Specimen CL-7						
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	
All Method	31	6.68	1.47	21.9	6.5	2.2 - 11.1	31	6.97	2.14	30.7	8.0	0.5 - 13.4	
All Abbott Cell-Dyn Instruments	18	7.02	0.78	11.1	6.9	4.6 - 9.4	18	8.52	0.41	4.9	8.5	7.2 - 9.8	
Abbott Cell-Dyn Emerald 22	10	8.63	1.42	16.4	8.9	4.3 - 12.9	10	9.27	1.42	15.3	9.0	5.0 - 13.6	
Abbott Cell-Dyn Ruby	8	7.02	0.78	11.1	6.9	4.6 - 9.4	8	8.52	0.41	4.9	8.5	7.2 - 9.8	
Orphee Mythic 22	13	5.60	0.76	13.5	5.8	3.3 - 7.9	13	4.87	0.29	6.0	4.8	3.9 - 5.8	
	Specimen CL-8						Specimen CL-9						
All Method	31	7.13	2.38	33.3	8.1	0.0 - 14.3	31	10.04	3.20	31.9	9.4	0.4 - 19.7	
All Abbott Cell-Dyn Instruments	18	8.40	0.29	3.5	8.3	7.5 - 9.3	18	9.72	0.44	4.6	9.7	8.3 - 11.1	
Abbott Cell-Dyn Emerald 22	10	10.27	1.07	10.4	10.5	7.0 - 13.5	10	15.70	1.08	6.9	15.4	12.4 - 19.0	
Abbott Cell-Dyn Ruby	8	8.40	0.29	3.5	8.3	7.5 - 9.3	8	9.72	0.44	4.6	9.7	8.3 - 11.1	
Orphee Mythic 22	13	4.89	0.79	16.2	4.9	2.5 - 7.3	13	7.84	1.29	16.4	8.0	3.9 - 11.8	
	Specimen CL-10												
All Method	31	5.07	1.20	23.6	5.1	1.4 - 8.7							
All Abbott Cell-Dyn Instruments	18	5.08	0.24	4.7	5.1	4.3 - 5.8							
Abbott Cell-Dyn Emerald 22	10	6.53	0.65	10.0	6.5	4.5 - 8.5							
Abbott Cell-Dyn Ruby	8	5.08	0.24	4.7	5.1	4.3 - 5.8							
Orphee Mythic 22	13	4.18	1.20	28.7	3.7	0.5 - 7.8							

BLOOD BANK

ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-6	Group A	18	100%	Acceptable
BB-7	Group A	18	100%	Acceptable
BB-8	Group O	18	100%	Acceptable
BB-9	Group B	18	100%	Acceptable
BB-10	Group O	18	100%	Acceptable

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-6	Rh Negative	16	88.89%	Acceptable
	Rh Positive	2	11.11%	
BB-7	Rh Positive	18	100%	Acceptable
BB-8	Rh Negative	18	100%	Acceptable
BB-9	Rh Positive	18	100%	Acceptable
BB-10	Rh Positive	18	100%	Acceptable

UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	No unexpected antibody detected	15	100%	Acceptable
AB-7	Unexpected antibody detected	15	100%	Acceptable
AB-8	Unexpected antibody detected	15	100%	Acceptable
AB-9	No unexpected antibody detected	14	93.33%	Acceptable
	Unexpected antibody detected	1	6.67%	
AB-10	No unexpected antibody detected	14	93.33%	Acceptable
	Unexpected antibody detected	1	6.67%	

BLOOD BANK

ANTIBODY IDENTIFICATION

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

COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	Compatible	13	100%	Acceptable
AB-7	Compatible	13	100%	Acceptable
AB-8	Not Compatible	13	100%	Acceptable
AB-9	Compatible	12	92.31%	Acceptable
	Not Compatible	1	7.69%	
AB-10	Compatible	12	92.31%	Acceptable
	Not Compatible	1	7.69%	

Coagulation

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-6						Specimen CG-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	43	20.66	2.38	11.5	20.4	17.5 - 23.8	43	33.38	4.47	13.4	33.0	28.3 - 38.4
Dade Innovin												
Dade Behring BFT II	5	18.50	0.85	4.6	18.5	15.7 - 21.3	5	31.50	1.70	5.4	31.5	26.7 - 36.3
Sysmex CA-500/600 series	12	18.62	0.59	3.1	18.5	15.8 - 21.5	12	29.71	1.10	3.7	29.5	25.2 - 34.2
All Coagulation Instruments	18	18.54	0.58	3.1	18.4	15.7 - 21.4	18	29.85	1.27	4.3	29.7	25.3 - 34.4
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	8	22.37	0.48	2.1	22.5	19.0 - 25.8	8	36.22	1.44	4.0	36.6	30.7 - 41.7
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	6	22.95	1.45	6.3	23.0	19.5 - 26.4	6	36.76	3.00	8.2	37.7	31.2 - 42.3
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	25.65	0.21	0.8	25.7	21.8 - 29.5	5	43.90	0.14	0.3	43.9	37.3 - 50.5
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	20.85	1.11	5.3	20.9	17.7 - 24.0	5	34.45	2.22	6.4	34.6	29.2 - 39.7
<u>Reagent/Instrument</u>	Specimen CG-8						Specimen CG-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	43	11.48	1.25	10.9	11.0	9.7 - 13.3	43	11.86	1.33	11.2	11.4	10.0 - 13.7
Dade Innovin												
Dade Behring BFT II	5	9.60	0.01	0.0	9.6	8.1 - 11.1	5	9.85	0.21	2.2	9.9	8.3 - 11.4
Sysmex CA-500/600 series	12	10.38	0.33	3.2	10.4	8.8 - 12.0	12	10.94	0.57	5.2	10.9	9.2 - 12.6
All Coagulation Instruments	18	10.32	0.41	3.9	10.4	8.7 - 11.9	18	10.78	0.62	5.7	10.8	9.1 - 12.4
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	8	12.77	0.38	3.0	12.7	10.8 - 14.7	8	13.17	0.31	2.4	13.1	11.1 - 15.2
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	6	13.13	0.43	3.3	13.2	11.1 - 15.1	6	13.68	0.64	4.7	13.7	11.6 - 15.8
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	12.65	0.07	0.6	12.7	10.7 - 14.6	5	13.10	0.42	3.2	13.1	11.1 - 15.1
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	11.28	0.49	4.4	11.2	9.5 - 13.0	5	11.18	0.36	3.2	11.2	9.5 - 12.9

PROTHROMBIN TIME (seconds)**Specimen CG-10**

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	43	14.77	1.71	11.6	14.3	12.5 - 17.0
Dade Innovin						
Dade Behring BFT II	5	12.65	0.07	0.6	12.7	10.7 - 14.6
Sysmex CA-500/600 series	12	13.15	0.47	3.6	13.1	11.1 - 15.2
All Coagulation Instruments	18	13.08	0.45	3.4	12.9	11.1 - 15.1
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	8	16.40	0.53	3.2	16.2	13.9 - 18.9
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STart Max	6	16.80	0.77	4.6	17.1	14.2 - 19.4
Diagnostica Stago STA NeoPTimal						
Diagnostica Stago STA Compact / Max	5	17.30	0.14	0.8	17.3	14.7 - 19.9
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	14.62	0.69	4.7	14.6	12.4 - 16.9

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-6						Specimen CG-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	44	1.89	0.17	8.8	1.9	1.6 - 2.2	44	3.24	0.44	13.7	3.1	2.7 - 3.8
Dade Innovin												
Dade Behring BFT II	5	1.80	0.14	7.9	1.8	1.5 - 2.1	5	2.85	0.21	7.4	2.9	2.4 - 3.3
Sysmex CA-500/600 series	12	1.85	0.09	4.7	1.8	1.5 - 2.2	12	2.97	0.14	4.8	2.9	2.5 - 3.5
All Coagulation Instruments	18	1.83	0.10	5.7	1.8	1.5 - 2.2	18	2.94	0.17	5.6	2.9	2.4 - 3.4
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	8	2.00	0.06	2.9	2.0	1.7 - 2.3	8	3.73	0.21	5.7	3.8	3.1 - 4.3
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	6	2.01	0.19	9.3	2.0	1.7 - 2.4	6	3.66	0.33	8.9	3.8	3.1 - 4.3
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	2.03	0.12	5.7	2.1	1.7 - 2.4	5	3.67	0.23	6.3	3.8	3.1 - 4.3
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	1.84	0.26	14.2	1.8	1.5 - 2.2	5	3.18	0.44	14.0	3.0	2.7 - 3.7
<u>Reagent/Instrument</u>	Specimen CG-8						Specimen CG-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	44	0.98	0.07	7.0	1.0	0.8 - 1.2	44	1.02	0.08	7.9	1.0	0.8 - 1.2
Dade Innovin												
Dade Behring BFT II	5	1.00	0.01	0.0	1.0	0.8 - 1.2	5	1.10	0.01	0.0	1.1	0.9 - 1.3
Sysmex CA-500/600 series	12	1.03	0.06	6.1	1.0	0.8 - 1.2	12	1.06	0.05	4.8	1.1	0.9 - 1.3
All Coagulation Instruments	18	1.02	0.06	6.2	1.0	0.8 - 1.2	18	1.05	0.06	5.9	1.1	0.8 - 1.3
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	8	0.96	0.05	5.6	1.0	0.8 - 1.2	8	1.01	0.04	3.7	1.0	0.8 - 1.2
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	6	0.99	0.07	7.0	1.0	0.8 - 1.2	6	1.06	0.08	7.4	1.0	0.8 - 1.3
Diagnostica Stago STA NeoPTimal												
Diagnostica Stago STA Compact / Max	5	0.97	0.06	6.0	1.0	0.8 - 1.2	5	1.00	0.01	0.0	1.0	0.8 - 1.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	0.96	0.09	9.3	0.9	0.8 - 1.2	5	0.92	0.11	11.9	0.9	0.7 - 1.1

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

Specimen CG-10

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	44	1.31	0.09	6.5	1.3	1.1 - 1.6
Dade Innovin						
Dade Behring BFT II	5	1.30	0.01	0.0	1.3	1.1 - 1.5
Sysmex CA-500/600 series	12	1.30	0.07	5.4	1.3	1.1 - 1.5
All Coagulation Instruments	18	1.28	0.10	7.4	1.3	1.0 - 1.5
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	8	1.34	0.05	4.0	1.3	1.1 - 1.6
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STart Max	6	1.34	0.08	5.9	1.4	1.1 - 1.6
Diagnostica Stago STA NeoPTimal						
Diagnostica Stago STA Compact / Max	5	1.37	0.06	4.2	1.4	1.1 - 1.6
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	1.28	0.16	12.8	1.2	1.0 - 1.5

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

<u>Reagent/Instrument</u>	Specimen CG-6						Specimen CG-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	27	37.5	6.4	16.9	40	31 - 44	27	60.1	11.2	18.6	61	51 - 70
Dade Actin FSL												
Sysmex CA-500/600 series	7	30.6	1.2	3.9	31	26 - 36	7	48.8	1.4	2.8	49	41 - 57
All Coagulation Instruments	8	31.1	1.8	5.9	31	26 - 36	8	49.1	1.7	3.4	49	41 - 57
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	5	42.3	1.5	3.6	42	35 - 49	5	64.3	4.9	7.7	62	54 - 74
HemosIL APTT-SP												
IL ACL, all models	5	42.5	3.7	8.7	43	36 - 49	5	71.5	8.1	11.3	73	60 - 83
IL TEST APTT												
IL ACL, all models	5	42.5	2.1	5.0	43	36 - 49	5	69.5	6.4	9.2	70	59 - 80

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

<u>Reagent/Instrument</u>	Specimen CG-8						Specimen CG-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	27	27.3	2.8	10.1	27	23 - 32	27	28.6	5.5	19.2	26	24 - 33
Dade Actin FSL												
Sysmex CA-500/600 series	7	24.5	0.8	3.1	24	20 - 29	7	24.4	0.9	3.8	24	20 - 29
All Coagulation Instruments	8	24.8	1.1	4.4	24	21 - 29	8	24.6	1.0	4.1	24	20 - 29
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact / Max	5	29.7	1.2	3.9	29	25 - 35	5	31.0	1.0	3.2	31	26 - 36
HemosIL APTT-SP												
IL ACL, all models	5	28.5	1.7	6.1	28	24 - 33	5	30.0	1.4	4.7	30	25 - 35
IL TEST APTT												
IL ACL, all models	5	29.0	2.8	9.8	29	24 - 34	5	-	-	-	43	24 - 33

<u>Reagent/Instrument</u>	Specimen CG-10					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	27	32.1	4.2	13.0	34	27 - 37
Dade Actin FSL						
Sysmex CA-500/600 series	7	28.8	3.5	12.2	28	24 - 34
All Coagulation Instruments	8	28.9	3.3	11.4	28	24 - 34
Diagnostica Stago STA C.K. Prest						
Diagnostica Stago STA Compact / Max	5	36.3	1.5	4.2	36	30 - 42
HemosIL APTT-SP						
IL ACL, all models	5	33.0	3.5	10.5	34	28 - 38
IL TEST APTT						
IL ACL, all models	5	35.0	2.8	8.1	35	29 - 41

FIBRINOGEN (mg/dL)

Specimen CG-6							Specimen CG-7					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	16	245.4	23.9	9.7	254	196 - 295	17	251.5	22.2	8.8	259	201 - 302
IL Fibrinogen-C												
IL ACL, all models	4	-	-	-	269	196 - 295	5	262.0	21.4	8.2	269	209 - 315

Specimen CG-8							Specimen CG-9					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	275.8	36.7	13.3	282	220 - 331	17	443.1	66.4	15.0	451	354 - 532
IL Fibrinogen-C												
IL ACL, all models	5	308.7	14.4	4.7	317	246 - 371	5	441.0	63.2	14.3	427	352 - 530

Specimen CG-10						
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	17	165.6	18.3	11.1	167	132 - 199
IL Fibrinogen-C						
IL ACL, all models	5	177.7	18.7	10.5	170	142 - 214

PROTHROMBIN TIME (seconds) – XS Samples

<u>Reagent/Instrument</u>	Specimen XS-6						Specimen XS-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	27	22.73	0.38	1.7	22.7	19.3 - 26.2	27	33.77	0.75	2.2	33.9	28.7 - 38.9
All Roche CoaguChek XS Plus Instruments	15	22.60	0.39	1.7	22.5	19.2 - 26.0	15	33.37	0.76	2.3	33.4	28.3 - 38.4
Roche CoaguChek Pro II	12	22.85	0.34	1.5	22.9	19.4 - 26.3	12	34.14	0.54	1.6	34.1	29.0 - 39.3
Roche CoaguChek XS Plus - Waived	10	22.59	0.40	1.8	22.6	19.1 - 26.0	10	33.28	0.94	2.8	33.3	28.2 - 38.3
Roche CoaguChek XS Plus	5	22.62	0.42	1.9	22.5	19.2 - 26.1	5	33.52	0.38	1.1	33.4	28.4 - 38.6

<u>Reagent/Instrument</u>	Specimen XS-8						Specimen XS-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	8	33.32	1.10	3.3	33.3	28.3 - 38.4	8	22.30	0.32	1.4	22.2	18.9 - 25.7
All Roche CoaguChek XS Plus Instruments	7	33.13	1.33	4.0	32.9	28.1 - 38.1	7	22.23	0.13	0.6	22.2	18.8 - 25.6
Roche CoaguChek Pro II	1	-	-	-	33.7	28.3 - 38.4	1	-	-	-	22.5	18.9 - 25.7
Roche CoaguChek XS Plus - Waived	4	-	-	-	33.4	28.3 - 38.4	4	-	-	-	22.2	18.8 - 25.6
Roche CoaguChek XS Plus	3	-	-	-	32.9	27.9 - 37.9	3	-	-	-	22.3	18.9 - 25.6

<u>Reagent/Instrument</u>	Specimen XS-10					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	8	15.02	0.10	0.7	15.1	12.7 - 17.3
All Roche CoaguChek XS Plus Instruments	7	15.08	0.05	0.3	15.1	12.8 - 17.4
Roche CoaguChek Pro II	1	-	-	-	14.9	12.7 - 17.3
Roche CoaguChek XS Plus - Waived	4	-	-	-	15.1	12.7 - 17.4
Roche CoaguChek XS Plus	3	-	-	-	15.1	12.8 - 17.4

INTERNATIONAL NORMALIZED RATIO (INR)– XS Samples

<u>Reagent/Instrument</u>	Specimen XS-6						Specimen XS-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	50	1.88	0.04	2.3	1.9	1.5 - 2.2	50	2.79	0.08	2.9	2.8	2.3 - 3.3
All Roche CoaguChek XS Plus Instruments	26	1.86	0.06	3.0	1.9	1.5 - 2.2	26	2.76	0.08	3.0	2.8	2.3 - 3.2
Roche CoaguChek Pro II	24	1.90	0.04	1.9	1.9	1.6 - 2.2	24	2.83	0.06	2.2	2.8	2.4 - 3.3
Roche CoaguChek XS Plus - Waived	20	1.88	0.04	2.4	1.9	1.5 - 2.2	20	2.75	0.09	3.4	2.7	2.3 - 3.2
Roche CoaguChek XS Plus	6	1.80	0.11	5.9	1.8	1.5 - 2.1	6	2.79	0.04	1.3	2.8	2.3 - 3.3

<u>Reagent/Instrument</u>	Specimen XS-8						Specimen XS-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	18	2.79	0.06	2.2	2.8	2.3 - 3.3	18	1.87	0.05	2.5	1.9	1.5 - 2.2
All Roche CoaguChek XS Plus Instruments	7	2.77	0.08	3.0	2.8	2.3 - 3.2	7	1.87	0.05	2.8	1.9	1.5 - 2.2
Roche CoaguChek Pro II	11	2.80	0.04	1.6	2.8	2.3 - 3.3	11	1.87	0.05	2.5	1.9	1.5 - 2.2
Roche CoaguChek XS Plus - Waived	5	2.78	0.10	3.5	2.8	2.3 - 3.2	5	1.88	0.05	2.7	1.9	1.5 - 2.2
Roche CoaguChek XS Plus	2	-	-	-	2.8	2.3 - 3.2	2	-	-	-	1.9	1.5 - 2.2

<u>Reagent/Instrument</u>	Specimen XS-10					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	18	1.24	0.05	4.1	1.2	1.0 - 1.5
All Roche CoaguChek XS Plus Instruments	7	1.28	0.04	3.5	1.3	1.0 - 1.5
Roche CoaguChek Pro II	11	1.23	0.05	3.8	1.2	1.0 - 1.5
Roche CoaguChek XS Plus - Waived	5	-	-	-	1.3	1.0 - 1.5
Roche CoaguChek XS Plus	2	-	-	-	1.3	1.1 - 1.5

URINALYSIS DIPSTICK–SPECIFIC GRAVITY

Specimen UA-2

<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	124	1.0182	0.0074	0.7	1.018	1.008 - 1.029
All Iris Diagnostics Methods	6	1.0282	0.0004	0.0	1.028	1.018 - 1.039
All Refractive Index Methods	11	1.0285	0.0030	0.3	1.028	1.018 - 1.039
All Roche Methods	41	1.0140	0.0073	0.7	1.010	1.003 - 1.024
All Siemens Methods	33	1.0203	0.0021	0.2	1.020	1.010 - 1.031
77 Elektronika LabUMat/2	9	1.0272	0.0055	0.5	1.025	1.017 - 1.038
Acon Laboratories	7	1.0143	0.0020	0.2	1.015	1.004 - 1.025
Roche Chemstrips / Combur	9	1.0114	0.0022	0.2	1.010	1.001 - 1.022
Roche cobas u 411	20	1.0118	0.0030	0.3	1.010	1.001 - 1.022
Roche cobas u 601 / 701	6	1.0250	0.0120	1.2	1.032	1.015 - 1.035
Roche Urisys	15	1.0125	0.0052	0.5	1.010	1.002 - 1.023
Siemens Clinitek Advantus	13	1.0200	0.0001	0.0	1.020	1.010 - 1.030
Siemens Clinitek Status / Status+	18	1.0211	0.0021	0.2	1.020	1.011 - 1.032

URINALYSIS DIPSTICK-pH

Specimen UA-2

Participant Results

<u>Method</u>	<u>Labs</u>	<u>≤3.5</u>	<u>4.0</u>	<u>4.5</u>	<u>5.0</u>	<u>5.5</u>	<u>6.0</u>	<u>6.5</u>	<u>7.0</u>	<u>7.5</u>	<u>8.0</u>	<u>8.5</u>	<u>≥9.0</u>
ALL METHODS	149	-	-	-	1	-	-	-	33	30	82	3	-
77 Elektronika LabUMat/2	10	-	-	-	-	-	-	-	9	1	-	-	-
Acon Laboratories	7	-	-	-	-	-	-	-	-	-	7	-	-
Arkray Aution AU-4050	1	-	-	-	-	-	-	-	-	1	-	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	-	-	2	-	-
Arkray Aution Sticks	1	-	-	-	-	-	-	-	-	1	-	-	-
Combi-Screen Test Strips	1	-	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	-	1	-	-	-
Iris Diagnostics iChem Velocity Strips	5	-	-	-	-	-	-	-	-	5	-	-	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	-	-	-	-	1	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	-	-	-	-	-	-	-	-	1	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	1	-	-	-
Other Dipstick Method	3	-	-	-	-	-	-	-	-	-	3	-	-
Roche Chemstrips / Combur	22	-	-	-	-	-	-	-	3	2	17	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	-	-	1	-	-
Roche cobas u 411	21	-	-	-	-	-	-	-	14	-	7	-	-
Roche cobas u 601 / 701	6	-	-	-	1	-	-	-	-	-	4	1	-
Roche Urisys	15	-	-	-	-	-	-	-	5	-	10	-	-
SD UroColor Reagent Strips	4	-	-	-	-	-	-	-	1	-	3	-	-
Siemens Clinitek Advantus	14	-	-	-	-	-	-	-	-	5	9	-	-
Siemens Clinitek Status / Status+	18	-	-	-	-	-	-	-	-	8	8	2	-
Siemens Reagent Strips	11	-	-	-	-	-	-	-	-	2	9	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	-	1	-	-	-
Urinometer	1	-	-	-	-	-	-	-	-	-	1	-	-
UriScan Reagent Strips	1	-	-	-	-	-	-	-	-	-	1	-	-

URINALYSIS DIPSTICK–PROTEIN QUALITATIVE
Specimen UA-2

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>10 - 20</u> <u>mg/dL</u>	<u>30 - 70</u> <u>mg/dL</u>	<u>75</u> <u>mg/dL</u>	<u>100 - 200</u> <u>mg/dL</u>	<u>≥300 - 600</u> <u>mg/dL</u>	<u>>600 or ≥1000</u> <u>mg/dL</u>
ALL METHODS	150	2	-	2	72	42	-	1	2	3	24	2	-
77 Elektronika LabUMat/2	9	-	-	-	3	-	-	-	2	-	3	1	-
Acon Laboratories	7	-	-	-	6	1	-	-	-	-	-	-	-
Arkray Aution AU-4050	1	-	-	-	1	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	-	-	-	1	1	-	-	-	-	-	-	-
Arkray Aution Sticks	1	-	-	-	1	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	1	-	-	-	1	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	5	-	-	-	3	-	-	-	-	-	2	-	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	1	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	-	-	-	1	-	-	-	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	1	-	-
Other Dipstick Method	3	-	-	1	-	2	-	-	-	-	-	-	-
Plasmatec URIPATH	1	-	-	-	1	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	-	-	-	18	3	-	1	-	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	1	-	-	-	-	-	-	-
Roche cobas u 411	21	-	-	-	3	12	-	-	-	1	5	-	-
Roche cobas u 601 / 701	6	2	-	-	-	-	-	-	-	-	4	-	-
Roche Urisys	15	-	-	-	2	4	-	-	-	2	7	-	-
SD UroColor Reagent Strips	4	-	-	-	4	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	14	-	-	-	13	-	-	-	-	-	1	-	-
Siemens Clinitek Status / Status+	18	-	-	-	-	17	-	-	-	-	-	1	-
Siemens Reagent Strips	11	-	-	-	11	-	-	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	-	-	1	-	-
Urinometer	1	-	-	-	1	-	-	-	-	-	-	-	-
UriScan Reagent Strips	1	-	-	-	-	1	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-2

<u>Method</u>	<u>Labs</u>	<u>Negative or Normal</u>	<u>Trace</u>	<u>(1+)</u>	<u>Participant Results</u>			<u>30 - 100 mg/dL</u>	<u>150 - 300 mg/dL</u>	<u>500 mg/dL</u>	<u>>500 or ≥1000 or ≥2000 mg/dL</u>
					<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>				
ALL METHODS	150	149	-	-	-	-	-	1	-	-	
77 Elektronika LabUMat/2	10	10	-	-	-	-	-	-	-	-	
Acon Laboratories	7	7	-	-	-	-	-	-	-	-	
Arkray Aution AU-4050	1	1	-	-	-	-	-	-	-	-	
Arkray Aution Jet	2	2	-	-	-	-	-	-	-	-	
Arkray Aution Sticks	1	1	-	-	-	-	-	-	-	-	
Combi-Screen Test Strips	1	1	-	-	-	-	-	-	-	-	
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	
Iris Diagnostics iChem Velocity Strips	5	5	-	-	-	-	-	-	-	-	
Iris Diagnostics vChem Urine Strips	1	1	-	-	-	-	-	-	-	-	
Iris Ichem VELOCITY Urine Chemistry System	1	1	-	-	-	-	-	-	-	-	
Other Analyzer Method	1	1	-	-	-	-	-	-	-	-	
Other Dipstick Method	3	3	-	-	-	-	-	-	-	-	
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	
Roche Chemstrips / Combur	22	22	-	-	-	-	-	-	-	-	
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	
Roche cobas u 411	21	21	-	-	-	-	-	-	-	-	
Roche cobas u 601 / 701	6	5	-	-	-	-	-	1	-	-	
Roche Urisys	15	15	-	-	-	-	-	-	-	-	
SD UroColor Reagent Strips	4	4	-	-	-	-	-	-	-	-	
Siemens Clinitek Advantus	14	14	-	-	-	-	-	-	-	-	
Siemens Clinitek Status / Status+	18	18	-	-	-	-	-	-	-	-	
Siemens Reagent Strips	11	11	-	-	-	-	-	-	-	-	
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	
Urinometer	1	1	-	-	-	-	-	-	-	-	
UriScan Reagent Strips	1	1	-	-	-	-	-	-	-	-	

URINALYSIS DIPSTICK–KETONES

Specimen UA-2

<u>Method</u>	<u>Labs</u>	<u>Participant Results</u>													
		<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>5 - 10</u> <u>mg/dL</u>	<u>15 - 25</u> <u>mg/dL</u>	<u>40 - 60</u> <u>mg/dL</u>	<u>≥80 - 100</u> <u>mg/dL</u>	<u>≥150</u> <u>mg/dL</u>
ALL METHODS	150	2	-	-	-	-	-	-	65	50	-	1	-	6	26
77 Elektronika LabUMat/2	10	-	-	-	-	-	-	-	4	-	-	-	-	-	6
Acon Laboratories	7	1	-	-	-	-	-	-	6	-	-	-	-	-	-
Arkray Aution AU-4050	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	-	2	-	-	-	-	-
Arkray Aution Sticks	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Combi-Screen Test Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	5	-	-	-	-	-	-	-	-	3	-	-	-	1	1
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-
Other Dipstick Method	3	-	-	-	-	-	-	-	3	-	-	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Roche Chemstrips / Combur	22	-	-	-	-	-	-	-	19	2	-	1	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Roche cobas u 411	22	-	-	-	-	-	-	-	1	14	-	-	-	1	6
Roche cobas u 601 / 701	5	1	-	-	-	-	-	-	-	-	-	-	-	-	4
Roche Urisys	15	-	-	-	-	-	-	-	5	1	-	-	-	1	8
SD UroColor Reagent Strips	4	-	-	-	-	-	-	-	4	-	-	-	-	-	-
Siemens Clinitek Advantus	14	-	-	-	-	-	-	-	13	-	-	-	-	1	-
Siemens Clinitek Status / Status+	18	-	-	-	-	-	-	-	4	13	-	-	-	-	1
Siemens Reagent Strips	11	-	-	-	-	-	-	-	1	10	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-
Urinometer	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
UriScan Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-2

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Positive (Ictotest ONLY)</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Participant Results</u>								
							<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>0.5 - 1.0 mg/dL</u>	<u>2.0 - 4.0 mg/dL</u>	<u>6.0 - 10.0 mg/dL</u>	<u>>10.0 mg/dL</u>
ALL METHODS	127	14	-	-	-	3	-	47	35	3	-	21	3	-	1
77 Elektronika LabUMat/2	10	-	-	-	-	-	-	4	-	-	-	4	2	-	-
Acon Laboratories	7	3	-	-	-	-	-	4	-	-	-	-	-	-	-
Arkay Aution AU-4050	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Arkay Aution Jet	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-
Arkay Aution Sticks	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Combi-Screen Test Strips	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	3	-	-	-	-	-	-	-	-	-	1	-	-	-
Iris Diagnostics vChem Urine Strips	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Other Dipstick Method	3	1	-	-	-	-	-	2	-	-	-	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Roche Chemstrips / Combur	9	-	-	-	-	-	-	4	4	-	-	-	-	-	1
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Roche cobas u 411	21	1	-	-	-	-	-	14	1	-	-	5	-	-	-
Roche cobas u 601 / 701	6	1	-	-	-	-	-	1	-	-	-	4	-	-	-
Roche Urisys	15	1	-	-	-	-	-	7	-	-	-	7	-	-	-
SD UroColor Reagent Strips	4	1	-	-	-	-	-	3	-	-	-	-	-	-	-
Siemens Clinitek Advantus	14	-	-	-	-	1	-	2	11	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	-	-	-	-	2	-	4	12	-	-	-	-	-	-
Siemens Reagent Strips	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
UriScan Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-2

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>				
		<u>Normal or 0.0 - 0.2 mg/dL or <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	126	48	22	10	37	9
77 Elektronika LabUMat/2	10	-	-	-	6	4
Acon Laboratories	7	4	3	-	-	-
Arkray Aution AU-4050	1	1	-	-	-	-
Arkray Aution Jet	2	-	1	1	-	-
Arkray Aution Sticks	1	-	-	1	-	-
Combi-Screen Test Strips	1	-	-	1	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	5	-	1	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	3	1	2	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-
Roche Chemstrips / Combur	8	3	3	-	1	1
Roche cobas 6500 / u 601	1	1	-	-	-	-
Roche cobas u 411	21	12	8	-	1	-
Roche cobas u 601 / 701	6	5	1	-	-	-
Roche Urisys	15	13	2	-	-	-
SD UroColor Reagent Strips	4	3	-	-	-	1
Siemens Clinitek Advantus	14	-	-	3	11	-
Siemens Clinitek Status / Status+	18	-	-	-	15	3
Siemens Reagent Strips	1	-	-	-	1	-
Sysmex UN Series	1	-	-	-	1	-
Urinometer	1	1	-	-	-	-
UriScan Reagent Strips	1	1	-	-	-	-

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN

Specimen UA-2

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>(5+)</u>	<u>5 - 25</u> <u>Ery/μL</u>	<u>50 -</u> <u>100</u> <u>Ery/μL</u>	<u>200 -</u> <u>300</u> <u>Ery/μL</u>	<u>\pm0.03</u> <u>mg/dL</u>	<u>0.06</u> <u>-</u> <u>0.10</u> <u>mg/</u> <u>dL</u>	<u>0.2 -</u> <u>0.5</u> <u>mg/</u> <u>dL</u>	<u>\geq 1.0</u> <u>mg/</u> <u>dL</u>
ALL METHODS	150	-	-	-	-	2	-	18	51	32	16	-	-	30	-	-	1	-
77 Elektronika LabUMat/2	10	-	-	-	-	-	-	2	2	-	-	-	-	6	-	-	-	-
Acon Laboratories	7	-	-	-	-	-	-	-	1	6	-	-	-	-	-	-	-	-
Arkray Aution AU-4050	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	-	-	-	3	-	-	-	-	-	-	-	-	1	-
Iris Diagnostics vChem Urine Strips	2	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Other Dipstick Method	3	-	-	-	-	-	-	-	2	1	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	21	-	-	-	-	-	-	1	1	18	-	-	-	1	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Roche cobas u 411	22	-	-	-	-	-	-	-	-	-	14	-	-	8	-	-	-	-
Roche cobas u 601 / 701	5	-	-	-	-	-	-	1	-	-	-	-	-	4	-	-	-	-
Roche Miditron Junior/II	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Roche Urisys	15	-	-	-	-	-	-	-	-	5	1	-	-	9	-	-	-	-
SD UroColor Reagent Strips	4	-	-	-	-	-	-	-	4	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	14	-	-	-	-	-	-	2	11	-	-	-	-	1	-	-	-	-
Siemens Clinitek Status / Status+	18	-	-	-	-	2	-	3	13	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	11	-	-	-	-	-	-	-	11	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Urinometer	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-2

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>15 or 25 µL</u>	<u>75 or 100 µL</u>	<u>250 or 500 µL</u>
ALL METHODS	138	138	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	10	10	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	7	7	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution AU-4050	1	1	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	1	1	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	5	5	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	3	3	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	22	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	22	22	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	4	4	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	15	15	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	4	4	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	14	14	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	18	18	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–NITRITE

Specimen UA-2

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	139	138	1
77 Elektronika LabUMat/2	10	10	-
Acon Laboratories	7	7	-
Arkray Aution AU-4050	1	1	-
Arkray Aution Jet	2	2	-
Arkray Aution Sticks	1	1	-
Combi-Screen Test Strips	1	1	-
Iris Diagnostics Aution Max AX-4280	1	1	-
Iris Diagnostics iChem Velocity Strips	5	5	-
Iris Diagnostics vChem Urine Strips	1	1	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-
Other Analyzer Method	1	1	-
Other Dipstick Method	3	3	-
Plasmatec URIPATH	1	1	-
Roche Chemstrips / Combur	20	20	-
Roche cobas 6500 / u 601	1	1	-
Roche cobas u 411	22	22	-
Roche cobas u 601 / 701	5	4	1
Roche SuperUA/ChemstripUA	1	1	-
Roche Urisys	15	15	-
SD UroColor Reagent Strips	4	4	-
Siemens Clinitek Advantus	14	14	-
Siemens Clinitek Status / Status+	18	18	-
Siemens Reagent Strips	1	1	-
Sysmex UN Series	1	1	-
Urinometer	1	1	-
UriScan Reagent Strips	1	1	-

URINALYSIS –MICROALBUMIN (dipstick only)

Specimen UA-2

Participant Results

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

URINALYSIS –URINE hCG

Specimen UA-2

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	107	107	-
77 Elektronika LabUMat/2	1	1	-
Abon (Alere) Biopharm	14	14	-
Acon Laboratories	6	6	-
Alere Aceava hCG-Urine	1	1	-
Alere Clearview hCG Cassette	3	3	-
Alere hCG Combo Cassette	18	18	-
Biosynex	2	2	-
CTK Biotech	3	3	-
JusChek	3	3	-
Other Dipstick Method	2	2	-
SD Bioline hCG	6	6	-
Siemens Clinitek Status / Status+	12	12	-
Stanbio QuStick	1	1	-

MISCELLANEOUS CULTURES

Specimen BA-4 – Sputum Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Burkholderia cepacia	67	35.83%	Acceptable
Burkholderia sp.	10	5.35%	Acceptable
Gram negative bacilli	6	3.21%	Acceptable
Streptococcus mitis	56	29.95%	Acceptable
Streptococcus alpha-hemolytic	17	9.09%	Acceptable
Streptococcus viridans group	8	4.28%	Acceptable
Streptococcus pneumoniae	6	3.21%	

Organism(s) present: *Burkholderia cepacia* and *Streptococcus mitis*

Specimen BA-5 – Stool Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Aeromonas hydrophila	65	34.21%	Acceptable
Aeromonas sp.	17	8.95%	Acceptable
Escherichia coli	103	54.21%	Acceptable
No Salmonella or Shigella isolated	2	1.05%	Acceptable

Organism(s) present: *Aeromonas hydrophila* and *Escherichia coli*

Specimen BA-6 – Ear Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Proteus mirabilis	106	94.64%	Acceptable
Proteus sp.	4	3.57%	Acceptable

Organism(s) present: *Proteus mirabilis*

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen UC-6, CC-6 (SUS-6) Organism(s) present: *Escherichia coli*

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>
	<u>Interpretative category data</u>				<u>Interpretative category data</u>				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Amikacin	25	24	1	-	106	106	-	-	99.24%
Amoxicillin/Clavulanate	31	27	-	4	52	49	2	1	91.57%
Ampicillin	23	2	-	21	122	6	2	114	93.10%
Ampicillin/Sulbactam	15	8	5	2	89	6	36	47	86.54%
Aztreonam	7	7	-	-	29	29	-	-	100.00%
Cefaclor	2	2	-	-	1	1	-	-	100.00%
Cefazolin	14	14	-	-	65	63	1	1	97.47%
Cefdinir	1	1	-	-	-	-	-	-	100.00%
Cefepime	22	22	-	-	122	122	-	-	100.00%
Cefixime	17	16	1	-	3	3	-	-	95.00%
Cefoperazone	10	10	-	-	-	-	-	-	100.00%
Cefotaxime	21	21	-	-	62	61	-	1	98.80%
Cefotetan	-	-	-	-	1	1	-	-	100.00%
Cefoxitin	14	14	-	-	35	35	-	-	100.00%
Cefpodoxime	5	5	-	-	1	1	-	-	100.00%
Ceftaroline	-	-	-	-	1	1	-	-	100.00%
Ceftazidime	24	22	-	2	120	120	-	-	98.61%
Ceftolozane/Tazobactam	-	-	-	-	9	9	-	-	100.00%
Ceftriaxone	22	22	-	-	104	103	1	-	99.21%
Cefuroxime	29	27	2	-	81	78	2	1	95.45%
Ciprofloxacin	36	36	-	-	154	154	-	-	100.00%
Colistin	-	-	-	-	3	1	2	-	100.00%
Doripenem	-	-	-	-	5	5	-	-	100.00%
Doxycycline	2	2	-	-	-	-	-	-	100.00%
Ertapenem	14	14	-	-	87	87	-	-	100.00%
Fosfomycin	17	17	-	-	38	38	-	-	100.00%
Gentamicin	27	26	-	1	135	134	-	1	98.77%
Imipenem	20	20	-	-	67	67	-	-	100.00%
Levofloxacin	18	18	-	-	58	58	-	-	100.00%
Linezolid	1	1	-	-	-	-	-	-	Inappropriate drug ¹

ANTIMICROBIAL SUSCEPTIBILITY TESTING (continued)

Specimen UC-6, CC-6 (SUS-6) Organism(s) present: *Escherichia coli*

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>
	<u>Interpretative category data</u>				<u>Interpretative category data</u>				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Meropenem	19	19	-	-	82	82	-	-	100.00%
Minocycline	2	2	-	-	-	-	-	-	100.00%
Moxifloxacin	2	2	-	-	1	1	-	-	Inappropriate drug ¹
Nalidixic Acid	5	5	-	-	13	13	-	-	100.00%
Netilmicin	4	4	-	-	-	-	-	-	100.00%
Nitrofurantoin	28	26	2	-	116	116	-	-	98.61%
Norfloxacin	6	6	-	-	44	44	-	-	100.00%
Ofloxacin	7	7	-	-	-	-	-	-	100.00%
Piperacillin	1	-	-	1	1	1	-	-	Not graded ²
Piperacillin/Tazobactam	19	18	-	1	87	87	-	-	99.06%
Quinupristin/Dalfopristin	-	-	-	-	1	1	-	-	Inappropriate drug ¹
Tetracycline	7	7	-	-	5	4	-	1	91.67%
Ticarcillin/Clavulanate	-	-	-	-	2	2	-	-	100.00%
Tobramycin	1	1	-	-	21	21	-	-	100.00%
Trimethoprim	-	-	-	-	3	3	-	-	100.00%
Trimethoprim/Sulfamethoxazole	29	29	-	-	144	144	-	-	100.00%

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.

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

² This is an ungraded challenge due to lack of participant consensus

PARASITOLOGY

Specimen FP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	269	90.57%	Acceptable
Root hair artifact	1	0.34%	
Giardia lamblia	6	2.02%	
Endolimax nana	6	2.02%	

Parasite(s) present: No parasite seen

Specimen FP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	285	46.49%	Acceptable
Trichuris trichiura eggs	269	43.88%	Acceptable
Parasite egg or larva seen – no ID	1	0.16%	Acceptable
Entamoeba coli	20	3.26%	
Blastocystis hominis	13	2.12%	
Entamoeba histolytica	7	1.14%	
Hookworm	5	0.82%	

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

PARASITOLOGY (continued)

Specimen FP-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Diphyllobothrium latum	184	47.18%	Acceptable
Parasite egg or larva seen – no ID	3	0.77%	Acceptable
Hookworm	40	10.26%	
Entamoeba histolytica	20	5.13%	
Paragonimus westermani eggs	19	4.87%	
Fasciola hepatica eggs	16	4.10%	
Other parasite found	10	2.56%	
Blastocystis hominis	8	2.05%	
Ascaris lumbricoides eggs	6	1.54%	
Entamoeba coli	6	1.54%	
Enterobius vermicularis eggs	6	1.54%	
Clonorchis sinensis	6	1.54%	

Parasite(s) present: *Diphyllobothrium latum*. This challenge was graded by referee consensus.

Specimen FP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hymenolepis nana eggs	231	75.74%	Acceptable
Parasite egg or larva seen – no ID	3	0.98%	Acceptable
No parasite seen	20	6.56%	
Taenia sp. eggs	17	5.57%	
Endolimax nana	6	1.97%	

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

PARASITOLOGY (continued)

Specimen FP-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	256	91.10%	Acceptable
Plasmodium sp.	7	2.49%	
Babesia sp.	6	2.14%	
Plasmodium vivax	5	1.78%	

Parasite(s) present: No parasite seen

Antinuclear Antibody (ANA) - Qualitative

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	23	-	22	1	1	22
Bio-Rad	1	-	1	-	-	1
BioSystems	2	-	2	-	-	2
Human	1	-	1	-	-	1
Immuno Concepts	2	-	2	-	-	2
INOVA Diagnostics	11	-	10	1	-	11
Kallestad	1	-	1	-	-	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	23	-	2	21
Bio-Rad	1	-	-	1
BioSystems	2	-	-	2
Human	1	-	-	1
Immuno Concepts	2	-	1	1
INOVA Diagnostics	11	-	-	11
Kallestad	1	-	-	1

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

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

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

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

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

ALL METHODS	1	-	-	1	-	2	3	7	-	4	-	1
Bio-Rad	-	-	-	-	-	-	-	-	-	-	-	1
Immuno Concepts	-	-	-	1	-	-	-	2	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	1	3	1	-	4	-	-
Kallestad	-	-	-	-	-	-	-	1	-	-	-	-

Specimen AE-8

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

Specimen AE-9

ALL METHODS	-	-	-	1	-	3	9	1	-	3	2	-
Bio-Rad	-	-	-	-	-	-	-	-	-	-	1	-
Immuno Concepts	-	-	-	1	-	-	2	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	2	4	-	-	3	1	-
Kallestad	-	-	-	-	-	-	1	-	-	-	-	-

Specimen AE-10

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

Anti-dsDNA

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	10	-	22	-	22
BioSystems	2	-	-	2	-	2
Human	1	-	-	1	-	1
Immuno Concepts	1	-	-	1	-	1
INOVA Diagnostics	4	4	-	8	-	8
Kallestad	-	1	-	1	-	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	22	-	22
BioSystems	-	2	-	2
Human	-	1	-	1
Immuno Concepts	-	1	-	1
INOVA Diagnostics	-	8	-	8
Kallestad	-	1	-	1

Anti-RNP

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	2	-	14	-	14
INOVA Diagnostics	9	-	-	9	-	9

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	13	-	14
INOVA Diagnostics	-	9	-	9

Anti-RNP/Sm

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	-	5	-	5
INOVA Diagnostics	1	-	-	1	-	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	-	5
INOVA Diagnostics	-	1	-	1

Anti-SSA

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	-	18	-	1	17
INOVA Diagnostics	11	-	11	-	-	11

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	-	1	17
INOVA Diagnostics	11	-	-	11

Anti-SSB

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	7	18	-	-	18
INOVA Diagnostics	8	3	11	-	-	11

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	-	-	18
INOVA Diagnostics	11	-	-	11

Anti-SSA/SSB

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

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

Anti-Sm

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	1	-	18	-	18
INOVA Diagnostics	11	1	-	12	-	12

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	17	1	17
INOVA Diagnostics	-	12	-	12

Rubella—Qualitative

<u>Method</u>	Specimen RU-6		Specimen RU-7		Specimen RU-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	1	-	17	16	1
Abbott Architect	12	1	-	13	12	1
DiaSorin	1	-	-	1	1	-
Roche cobas 6000 / e 601	1	-	-	1	1	-
Roche cobas e 411	1	-	-	1	1	-
Siemens Atellica	1	-	-	1	1	-

<u>Method</u>	Specimen RU-9		Specimen RU-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	17	16	1
Abbott Architect	-	13	12	1
DiaSorin	-	1	1	-
Roche cobas 6000 / e 601	-	1	1	-
Roche cobas e 411	-	1	1	-
Siemens Atellica	-	1	1	-

Rubella—Quantitative (IU/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen RU-6						
All Method	21	56.70	28.87	50.9	40.1	0.0 - 143.4
Abbott Architect	12	36.93	2.95	8.0	36.1	28.0 - 45.8
Specimen RU-7						
All Method	21	0.10	0.14	146.5	0.0	0.0 - 0.6
Abbott Architect	12	0.02	0.04	233.6	0.0	0.0 - 0.2
Specimen RU-8						
All Method	20	43.47	19.99	46.0	31.7	0.0 - 103.5
Abbott Architect	12	30.10	2.51	8.3	29.7	22.5 - 37.7
Specimen RU-9						
All Method	21	0.10	0.14	146.5	0.0	0.0 - 0.6
Abbott Architect	12	0.02	0.04	233.6	0.0	0.0 - 0.2
Specimen RU-10						
All Method	20	43.16	20.60	47.7	32.1	0.0 - 105.0
Abbott Architect	12	29.36	2.46	8.4	28.8	21.9 - 36.8

Syphilis Serology—Qualitative: VDRL Slide

<u>Method</u>	Specimen SY-6			Specimen SY-7			Specimen SY-8		
	<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	-	-	55	54	-	1	1	-	54
Acon Laboratories	-	-	1	1	-	-	-	-	1
BioSystems	-	-	1	1	-	-	-	-	1
CTK Biotech	-	-	1	1	-	-	-	-	1
Human	-	-	1	1	-	-	-	-	1
Lorne Laboratories	-	-	2	2	-	-	-	-	2
Plasmatec	-	-	5	5	-	-	-	-	5
Roche cobas 6000 / e 601	-	-	1	1	-	-	-	-	1
SPINREACT	-	-	1	1	-	-	-	-	1
Wiener Lab	-	-	36	35	-	1	1	-	35

<u>Method</u>	Specimen SY-9			Specimen SY-10		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	55	-	-	55	-	-
Acon Laboratories	1	-	-	1	-	-
BioSystems	1	-	-	1	-	-
CTK Biotech	1	-	-	1	-	-
Human	1	-	-	1	-	-
Lorne Laboratories	2	-	-	2	-	-
Plasmatec	5	-	-	5	-	-
Roche cobas 6000 / e 601	1	-	-	1	-	-
SPINREACT	1	-	-	1	-	-
Wiener Lab	36	-	-	36	-	-

Syphilis Serology—Semi-Quantitative: VDRL Slide Titer

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>0 dils</u>	<u>1 dil</u>	<u>2 dils</u>	<u>4 dils</u>	<u>8 dils</u>	<u>16 dils</u>	<u>32 dils</u>	<u>>32 dils</u>
Specimen SY-6									
ALL METHODS	49	2	-	-	-	-	-	-	-
BioSystems	1	-	-	-	-	-	-	-	-
Lorne Laboratories	3	-	-	-	-	-	-	-	-
Plasmatec	4	-	-	-	-	-	-	-	-
Roche cobas 6000 / e 601	-	1	-	-	-	-	-	-	-
Wiener Lab	35	1	-	-	-	-	-	-	-
Specimen SY-7									
ALL METHODS	1	1	9	21	14	4	1	-	-
BioSystems	-	-	-	1	-	-	-	-	-
Lorne Laboratories	-	-	1	-	1	-	1	-	-
Plasmatec	-	-	1	1	1	1	-	-	-
Roche cobas 6000 / e 601	-	-	-	1	-	-	-	-	-
Wiener Lab	1	1	6	14	11	3	-	-	-
Specimen SY-8									
ALL METHODS	49	1	-	-	-	-	-	1	-
BioSystems	1	-	-	-	-	-	-	-	-
Lorne Laboratories	3	-	-	-	-	-	-	-	-
Plasmatec	4	-	-	-	-	-	-	-	-
Roche cobas 6000 / e 601	1	-	-	-	-	-	-	-	-
Wiener Lab	34	1	-	-	-	-	-	1	-

Syphilis Serology—Semi-Quantitative : VDRL Slide Titer

Specimen SY-9

ALL METHODS	-	1	9	20	15	3	1	2	-
BioSystems	-	-	-	1	-	-	-	-	-
Lorne Laboratories	-	-	1	-	1	-	-	1	-
Plasmatec	-	-	1	1	1	1	-	-	-
Roche cobas 6000 / e 601	-	-	-	-	1	-	-	-	-
Wiener Lab	-	1	6	16	9	2	1	1	-

Specimen SY-10

ALL METHODS	-	-	3	9	23	10	5	-	1
BioSystems	-	-	-	-	1	-	-	-	-
Lorne Laboratories	-	-	-	1	1	-	1	-	-
Plasmatec	-	-	1	-	1	1	1	-	-
Roche cobas 6000 / e 601	-	-	-	-	-	1	-	-	-
Wiener Lab	-	-	1	7	17	7	3	-	1

Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	10	10	-	-	10
Abbott Architect	-	3	3	-	-	3
Plasmatec	-	2	2	-	-	2
Serodia	-	2	2	-	-	2
Standard Diagnostics	-	2	2	-	-	2

	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	10	-	10	-
Abbott Architect	3	-	3	-
Plasmatec	2	-	2	-
Serodia	2	-	2	-
Standard Diagnostics	2	-	2	-

Syphilis Serology—Qualitative : *Treponema pallidum* Antibodies

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	51	50	1	1	50
Abbott Alinity	-	1	1	-	-	1
Abbott Architect	-	12	12	-	-	12
Atlas Medical	-	1	1	-	-	1
Bio-Rad Evolis	-	1	1	-	-	1
DiaSorin	-	2	2	-	-	2
Human	-	2	2	-	-	2
Roche cobas 6000 / c 501	-	2	2	-	-	2
Roche cobas 8000/e801	-	1	1	-	-	1
Roche cobas e 411	-	1	1	-	-	1
SD Bioline	-	4	4	-	-	4
Serodia	-	8	8	-	-	8
Siemens Immulite 2000	-	1	1	-	-	1
Standard Diagnostics	-	5	4	1	1	4
Zeus	-	2	2	-	-	2

	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	51	-	51	-
Abbott Architect	1	-	1	-
Bio-Rad Evolis	12	-	12	-
bioMerieux	1	-	1	-
DiaSorin	1	-	1	-
Human	2	-	2	-
Plasmatec	2	-	2	-
Roche cobas 6000 / c 501	2	-	2	-
Roche cobas 8000/e801	1	-	1	-
Roche cobas e 411	1	-	1	-
SD Bioline	4	-	4	-
Serodia	8	-	8	-
Siemens Immulite 2000	1	-	1	-
Standard Diagnostics	5	-	5	-
Zeus	2	-	2	-

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	73	72	1	1	72
Acon Laboratories	-	1	1	-	-	1
Atlas Medical	-	2	2	-	-	2
Becton Dickinson	-	3	3	-	-	3
bioMerieux	-	2	2	-	-	2
BioSystems	-	12	12	-	-	12
Human	-	4	4	-	-	4
Lorne Laboratories	-	7	7	-	-	7
Omega Diagnostics	-	3	3	-	-	3
Plasmatec	-	23	23	-	-	23
Pulse Scientific	-	1	1	-	-	1
SPINREACT	-	11	10	1	1	10
Wiener Lab	-	1	1	-	-	1

	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	73	-	73	-
Acon Laboratories	1	-	1	-
Atlas Medical	2	-	2	-
Becton Dickinson	3	-	3	-
bioMerieux	2	-	2	-
BioSystems	12	-	12	-
Human	4	-	4	-
Lorne Laboratories	7	-	7	-
Omega Diagnostics	3	-	3	-
Plasmatec	23	-	23	-
Pulse Scientific	1	-	1	-
SPINREACT	11	-	11	-
Wiener Lab	1	-	1	-

Syphilis Serology—Semi-Quantitative : RPR (Titer)

<u>Specimen/Method</u>	<u>N/A</u> <u>(Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>
Specimen SY-6									
ALL METHODS	62	-	-	-	-	-	-	-	-
Atlas Medical	1	-	-	-	-	-	-	-	-
Becton Dickinson	3	-	-	-	-	-	-	-	-
BioSystems	12	-	-	-	-	-	-	-	-
Human	4	-	-	-	-	-	-	-	-
Lorne Laboratories	5	-	-	-	-	-	-	-	-
Omega Diagnostics	4	-	-	-	-	-	-	-	-
Plasmatec	19	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	10	-	-	-	-	-	-	-	-
Wiener Lab	1	-	-	-	-	-	-	-	-

Specimen SY-7

ALL METHODS	1	3	23	26	6	3	-	-	-
Atlas Medical	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	1	1	1	-	-	-	-
BioSystems	-	-	5	4	3	-	-	-	-
Human	-	-	-	2	1	1	-	-	-
Lorne Laboratories	-	-	4	1	-	-	-	-	-
Omega Diagnostics	-	-	1	2	-	1	-	-	-
Plasmatec	-	2	4	11	1	1	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	1	-	4	5	-	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-	-

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

<u>Specimen/Method</u>	<u>N/A</u> <u>(Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>
Specimen SY-8									
ALL METHODS	61	-	-	-	-	-	1	-	-
Atlas Medical	1	-	-	-	-	-	-	-	-
Becton Dickinson	3	-	-	-	-	-	-	-	-
BioSystems	12	-	-	-	-	-	-	-	-
Human	4	-	-	-	-	-	-	-	-
Lorne Laboratories	5	-	-	-	-	-	-	-	-
Omega Diagnostics	4	-	-	-	-	-	-	-	-
Plasmatec	19	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	9	-	-	-	-	-	1	-	-
Wiener Lab	1	-	-	-	-	-	-	-	-
Specimen SY-9									
ALL METHODS	-	3	25	22	6	3	3	-	-
Atlas Medical	-	1	-	-	-	-	-	-	-
Becton Dickinson	-	-	2	1	-	-	-	-	-
BioSystems	-	-	5	5	1	-	1	-	-
Human	-	-	-	2	-	1	1	-	-
Lorne Laboratories	-	-	3	2	-	-	-	-	-
Omega Diagnostics	-	-	2	-	1	-	1	-	-
Plasmatec	-	1	5	9	3	1	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	-	5	3	1	1	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-	-

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

<u>Specimen/Method</u>	<u>N/A</u> <u>(Neg)</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>
Specimen SY-10									
ALL METHODS	-	-	4	26	18	13	1	-	-
Atlas Medical	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	2	-	1	-	-	-
BioSystems	-	-	1	4	5	2	-	-	-
Human	-	-	-	1	1	1	1	-	-
Lorne Laboratories	-	-	-	4	1	-	-	-	-
Omega Diagnostics	-	-	-	1	-	3	-	-	-
Plasmatec	-	-	1	7	8	3	-	-	-
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	-	-	5	3	2	-	-	-
Wiener Lab	-	-	-	-	-	1	-	-	-

Viral Markers – Anti-HBc (IgM)

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	34	-	-	36	-	7	29	-
Abbott Alinity	-	3	-	-	3	-	-	3	-
Abbott Architect	1	18	-	-	19	-	4	15	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	5	-	-	6	-	-	6	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
Siemens ADVIA	-	2	-	-	2	-	2	-	-
VITROS 3600/4600/5600/7600	-	1	-	-	1	-	-	1	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	35	-	-	36	-
Abbott Alinity	-	3	-	-	3	-
Abbott Architect	1	18	-	-	19	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	6	-	-	6	-
Roche cobas 8000/e801	-	4	-	-	4	-
Siemens ADVIA Centaur	-	2	-	-	2	-
VITROS 3600/4600/5600/7600	-	1	-	-	1	-

Viral Markers – Anti-HBc (Total / IgG)

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	56	-	-	-	56	-	56	-	-
Abbott Alinity	8	-	-	-	8	-	8	-	-
Abbott Architect	28	-	-	-	28	-	28	-	-
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-	1	-	-
DiaSorin	1	-	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	8	-	-	-	8	-	8	-	-
Roche cobas 8000/e801	4	-	-	-	4	-	4	-	-
Roche cobas e 411	1	-	-	-	1	-	1	-	-
Siemens ADVIA	3	-	-	-	3	-	3	-	-
Siemens Atellica	1	-	-	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	1	-	-	-	1	-	1	-	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	56	-	-	1	55	-
Abbott Alinity	8	-	-	-	8	-
Abbott Architect	28	-	-	1	27	-
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-
DiaSorin	1	-	-	-	1	-
Roche cobas 6000 / e 601	8	-	-	-	8	-
Roche cobas 8000/e801	4	-	-	-	4	-
Roche cobas e 411	1	-	-	-	1	-
Siemens ADVIA	3	-	-	-	3	-
Siemens Atellica	1	-	-	-	1	-
VITROS 3600/4600/5600/7600	1	-	-	-	1	-

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	4	149	-	3	150	-	2	150	1
Abbott Alinity	-	10	-	-	10	-	-	10	-
Abbott Architect	-	61	-	-	61	-	-	61	-
Acon Laboratories	1	-	-	-	1	-	-	1	-
Advanced Biotech	-	1	-	-	1	-	-	1	-
Alere Clearview HIV1/2 STAT-PAK	-	2	-	-	2	-	-	2	-
Alere Determine - moderate	-	2	-	-	2	-	-	2	-
Alere Determine - waived	-	2	-	-	2	-	-	2	-
Beckman ACCESS / 2 / Dxl bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-	-	3	-
CTK Biotech	-	2	-	-	2	-	-	2	-
DiaSorin	1	-	-	1	-	-	1	-	-
Human	-	3	-	-	3	-	-	3	-
Roche cobas 6000 / e 601	2	28	-	1	29	-	1	29	-
Roche cobas 8000/e801	-	4	-	-	4	-	-	4	-
Roche cobas e 411	-	10	-	1	9	-	-	9	1
Roche Modular Analytics	-	1	-	-	1	-	-	1	-
Siemens ADVIA	-	6	-	-	6	-	-	6	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
Standard Diagnostics VITROS 3600/4600/5600/7600	-	4	-	-	4	-	-	4	-
	-	2	-	-	2	-	-	2	-

Viral Markers – Anti-HIV- (continued)

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	151	-	151	2	-
Abbott Alinity	-	10	-	10	-	-
Abbott Architect	-	61	-	61	-	-
Acon Laboratories	-	1	-	1	-	-
Advanced Biotech	-	1	-	1	-	-
Alere Clearview HIV1/2						
STAT-PAK	-	2	-	2	-	-
Alere Determine - moderate	-	2	-	2	-	-
Alere Determine - waived	-	2	-	2	-	-
Beckman ACCESS / 2 / Dxl	-	3	-	3	-	-
bioMerieux Vidas, Mini						
Vidas	-	3	-	3	-	-
CTK Biotech	-	2	-	2	-	-
DiaSorin	1	-	-	1	-	-
Human	-	3	-	3	-	-
Roche cobas 6000 / e 601	1	29	-	28	2	-
Roche cobas 8000/e801	-	4	-	4	-	-
Roche cobas e 411	-	10	-	10	-	-
Roche Modular Analytics	-	1	-	1	-	-
Siemens ADVIA	-	6	-	6	-	-
Siemens Atellica	-	1	-	1	-	-
Standard Diagnostics	-	4	-	4	-	-
VITROS						
3600/4600/5600/7600	-	2	-	2	-	-

Viral Markers – Anti-HAV (IgM)

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	50	-	-	50	-	1	49	-
Abbott Alinity	-	2	-	-	2	-	-	2	-
Abbott Architect	-	28	-	-	28	-	1	27	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	6	-	-	6	-	-	6	-
Roche cobas 8000/e801	-	5	-	-	5	-	-	5	-
Roche cobas e 411	-	1	-	-	1	-	-	1	-
Siemens ADVIA	-	2	-	-	2	-	-	2	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
Standard Diagnostics	-	4	-	-	4	-	-	4	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	47	3	-	-	50	-
Abbott Alinity	2	-	-	-	2	-
Abbott Architect	28	-	-	-	28	-
bioMerieux Vidas, Mini Vidas	1	-	-	-	1	-
Roche cobas 6000 / e 601	6	-	-	-	6	-
Roche cobas 8000/e801	5	-	-	-	5	-
Roche cobas e 411	1	-	-	-	1	-
Siemens ADVIA	2	-	-	-	2	-
Siemens Atellica	1	-	-	-	1	-
Standard Diagnostics	1	3	-	-	4	-

Viral Markers – Anti-HAV (Total/IgG)

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	55	-	54	2	-	52	4	-
Abbott Alinity	-	1	-	1	-	-	1	-	-
Abbott Architect	-	29	-	28	1	-	27	2	-
Beckman ACCESS / 2 / DxI	-	1	-	1	-	-	1	-	-
bioMerieux Vidas, Mini Vidas	-	1	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	-	11	-	11	-	-	11	-	-
Roche cobas 8000/e801	-	3	-	3	-	-	3	-	-
Roche cobas e 411	1	3	-	4	-	-	4	-	-
SD Bioline	-	1	-	-	1	-	-	1	-
Siemens ADVIA	-	3	-	3	-	-	3	-	-
Siemens Atellica	-	1	-	1	-	-	1	-	-
VITROS 3600/4600/5600/7600	-	1	-	1	-	-	-	1	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	54	2	-	53	3	-
Abbott Alinity	1	-	-	1	-	-
Abbott Architect	28	1	-	28	1	-
Beckman ACCESS / 2 / DxI	1	-	-	1	-	-
bioMerieux Vidas, Mini Vidas	1	-	-	1	-	-
Roche cobas 6000 / e 601	11	-	-	11	-	-
Roche cobas 8000/e801	3	-	-	3	-	-
Roche cobas e 411	4	-	-	3	1	-
SD Bioline	-	1	-	-	1	-
Siemens ADVIA	3	-	-	3	-	-
Siemens Atellica	1	-	-	1	-	-
VITROS 3600/4600/5600/7600	1	-	-	1	-	-

Viral Markers – HBeAg

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	31	-	-	31	-	31	-	-
Abbott Alinity	-	1	-	-	1	-	1	-	-
Abbott Architect	-	14	-	-	14	-	14	-	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	7	-	-	7	-	7	-	-
Roche cobas 8000/e801	-	5	-	-	5	-	5	-	-
Siemens ADVIA	-	1	-	-	1	-	1	-	-
Siemens Atellica	-	1	-	-	1	-	1	-	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	31	-	1	30	-
Abbott Alinity	-	1	-	-	1	-
Abbott Architect	-	14	-	1	13	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	7	-	-	7	-
Roche cobas 8000/e801	-	5	-	-	5	-
Siemens ADVIA	-	1	-	-	1	-
Siemens Atellica	-	1	-	-	1	-

Viral Markers – Anti-HBs

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	6	92	3	98	3	-	3	96	2
Abbott Alinity	-	6	-	6	-	-	-	6	-
Abbott Architect	1	40	1	42	-	-	-	41	1
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	-	-	2	-
Roche cobas 6000 / e 601	5	19	1	24	1	-	-	25	-
Roche cobas 8000/e801	-	5	-	5	-	-	-	5	-
Roche cobas e 411	-	8	1	9	-	-	1	7	1
Siemens ADVIA	-	5	-	5	-	-	-	5	-
Siemens Atellica	-	1	-	1	-	-	-	1	-
Standard Diagnostics	-	2	-	1	1	-	1	1	-
VITROS									
3600/4600/5600/7600	-	1	-	1	-	-	-	1	-
VITROS Eci	-	1	-	1	-	-	-	1	-

Viral Markers – Anti-HBs

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	97	3	97	4	-
Abbott Alinity	-	6	-	6	-	-
Abbott Architect	-	41	1	42	-	-
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	-
Roche cobas 6000 / e 601	1	24	-	23	2	-
Roche cobas 8000/e801	-	5	-	5	-	-
Roche cobas e 411	-	7	2	9	-	-
Siemens ADVIA	-	5	-	5	-	-
Siemens Atellica	-	1	-	1	-	-
Standard Diagnostics	-	2	-	1	1	-
VITROS						
3600/4600/5600/7600	-	1	-	1	-	-
VITROS Eci	-	1	-	1	-	-

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	149	-	7	143	-	149	1	-
Abbott Alinity	-	11	-	1	10	-	11	-	-
Abbott Architect	-	58	-	-	58	-	57	1	-
Advanced Biotech	-	2	-	-	2	-	2	-	-
Alere Determine - moderate	-	1	-	-	1	-	1	-	-
Beckman ACCESS / 2 / Dxl	-	3	-	-	3	-	3	-	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	1	-	-
CTK Biotech	-	1	-	-	1	-	1	-	-
DiaSorin	-	2	-	-	2	-	2	-	-
Roche cobas 6000 / e 601	-	30	-	1	29	-	30	-	-
Roche cobas 8000/e801	-	5	-	-	5	-	5	-	-
Roche cobas e 411	-	11	-	-	11	-	11	-	-
Roche Modular Analytics	-	1	-	-	1	-	1	-	-
SD Bioline	-	4	-	-	4	-	4	-	-
Siemens ADVIA	1	6	-	5	2	-	7	-	-
Siemens Atellica	-	1	-	-	1	-	1	-	-
Standard Diagnostics	-	5	-	-	5	-	5	-	-
VITROS									
3600/4600/5600/7600	-	2	-	-	2	-	2	-	-

Viral Markers – HBsAg (continued)

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	122	21	7	1	149	-
Abbott Alinity	10	1	-	-	11	-
Abbott Architect	58	-	-	1	57	-
Advanced Biotech	-	2	-	-	2	-
Alere Determine - moderate	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	3	-	-	-	3	-
bioMerieux Vidas, Mini	-	1	-	-	1	-
Vidas	-	1	-	-	1	-
CTK Biotech	-	1	-	-	1	-
DiaSorin	2	-	-	-	2	-
Roche cobas 6000 / e 601	24	1	5	-	30	-
Roche cobas 8000/e801	5	-	-	-	5	-
Roche cobas e 411	8	1	2	-	11	-
Roche Modular Analytics	1	-	-	-	1	-
SD Bioline	-	4	-	-	4	-
Siemens ADVIA	7	-	-	-	7	-
Siemens Atellica	1	-	-	-	1	-
Standard Diagnostics	-	5	-	-	5	-
VITROS	-	-	-	-	-	-
3600/4600/5600/7600	1	1	-	-	2	-

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	134	-	-	134	-	36	95	3
Abbott Alinity	-	10	-	-	10	-	-	10	-
Abbott Architect	-	55	-	-	55	-	-	55	-
Abon (Alere) Biopharm	-	1	-	-	1	-	-	1	-
Advanced Biotech	-	1	-	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-	-	2	-
DiaSorin	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	24	-	-	24	-	22	-	2
Roche cobas 8000/e801	-	5	-	-	5	-	5	-	-
Roche cobas e 411	-	8	-	-	8	-	6	1	1
Roche Modular Analytics	-	1	-	-	1	-	1	-	-
SD Biline	-	2	-	-	2	-	-	2	-
Siemens ADVIA	-	6	-	-	6	-	-	6	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
Standard Diagnostics	-	8	-	-	8	-	1	7	-
VITROS									
3600/4600/5600/7600	-	2	-	-	2	-	-	2	-
VITROS Eci	-	1	-	-	1	-	-	1	-
Wantai BioPharm	-	1	-	-	1	-	-	1	-

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	134	-	-	134	-
Abbott Alinity	-	10	-	-	10	-
Abbott Architect	-	55	-	-	55	-
Abon (Alere) Biopharm	-	1	-	-	1	-
Advanced Biotech	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-
DiaSorin	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	24	-	-	24	-
Roche cobas 8000/e801	-	5	-	-	5	-
Roche cobas e 411	-	8	-	-	8	-
Roche Modular Analytics	-	1	-	-	1	-
SD Bioline	-	2	-	-	2	-
Siemens ADVIA	-	6	-	-	6	-
Siemens Atellica	-	1	-	-	1	-
Standard Diagnostics	-	8	-	-	8	-
VITROS						
3600/4600/5600/7600	-	2	-	-	2	-
VITROS Eci	-	1	-	-	1	-
Wantai BioPharm	-	1	-	-	1	-

Toxoplasma gondii Antibody (IgG) - Qualitative

<u>Method</u>	<u>Specimen TOX-3</u>			<u>Specimen TOX-4</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	19	-	19	-	-
Abbott Architect	-	12	-	12	-	-
bioMerieux Vidas, Mini Vidas	-	2	-	2	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas e 411	-	2	-	2	-	-
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-3						
All Method	24	0.416	0.253	60.8	0.50	0.00 - 1.18
All Roche Instruments	5	0.130	0.001	0.0	0.13	0.12 - 0.14
Abbott Architect	15	0.567	0.159	28.0	0.50	0.09 - 1.05
Roche cobas e 411	3	0.130	0.001	0.0	0.13	0.12 - 0.14
Specimen TOX-4						
All Method	24	86.646	37.776	43.6	66.70	0.00 - 199.98
All Roche Instruments	5	146.420	18.906	12.9	148.00	89.70 - 203.14
Abbott Architect	15	61.500	6.655	10.8	62.20	41.53 - 81.47
Roche cobas e 411	3	152.100	22.179	14.6	162.80	85.56 - 218.64

Toxoplasma gondii Antibody (IgM) - Qualitative

<u>Method</u>	Specimen TOX-3			Specimen TOX-4		
	<u>Positiv e</u>	<u>Negati ve</u>	<u>Equivoc al</u>	<u>Positiv e</u>	<u>Negativ e</u>	<u>Equivoc al</u>
ALL METHODS	-	22	-	22	-	-
Abbott Architect	-	14	-	14	-	-
bioMerieux Vidas, Mini Vidas	-	2	-	2	-	-
DiaSorin	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
Roche cobas e 411	-	2	-	2	-	-
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>
Specimen TOX-3						
All Method	21	0.141	0.069	48.8	0.12	0.00 - 0.35
All Roche Instruments	5	0.248	0.055	22.3	0.22	0.08 - 0.42
Abbott Architect	13	0.108	0.024	22.1	0.11	0.03 - 0.18
Roche cobas e 411	3	0.230	0.026	11.5	0.22	0.15 - 0.31
Specimen TOX-4						
All Method	21	17.385	8.871	51.0	13.55	0.00 - 44.00
All Roche Instruments	5	32.466	1.899	5.8	32.50	26.76 - 38.17
Abbott Architect	13	13.320	1.164	8.7	13.40	9.82 - 16.82
Roche cobas e 411	3	31.870	2.267	7.1	31.26	25.06 - 38.68

Cytomegalovirus (CMV) Antibodies (IgG) - Qualitative

<u>Method</u>	Specimen CMV-3			Specimen CMV-4		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	14	1	-	1	14	-
Abbott Architect	12	-	-	-	12	-
DiaSorin	-	1	-	1	-	-
Roche cobas 6000 / e 601	1	-	-	-	1	-
VITROS 3600/4600/5600/7600	1	-	-	-	1	-

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen CMV-3						
All Method	17	56.786	25.956	45.7	71.30	0.00 - 134.66
Abbott Architect	14	67.193	12.661	18.8	71.70	29.21 - 105.18
Specimen CMV-4						
All Method	17	0.933	0.448	48.0	1.00	0.00 - 2.28
Abbott Architect	14	1.043	0.394	37.7	1.15	0.00 - 2.23

Cytomegalovirus (CMV) Antibodies (IgM) - Qualitative

<u>Method</u>	Specimen CMV-3			Specimen CMV-4		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	19	-	-	6	9	4
Abbott Architect	16	-	-	6	6	4
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>
Specimen CMV-3						
All Method	15	5.842	0.918	15.7	5.97	3.08 - 8.60
Abbott Architect	13	5.813	0.762	13.1	5.97	3.52 - 8.10
Specimen CMV-4						
All Method	15	0.711	0.294	41.3	0.65	0.00 - 1.60
Abbott Architect	13	0.791	0.222	28.1	0.82	0.12 - 1.46

Neonatal Bilirubin, Total (mg/dL)

<u>Method</u>	Specimen NB-6						Specimen NB-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	48	17.88	1.12	6.3	18.2	14.3 - 21.5	42	0.01	0.03	312.0	0.0	0.0 - 0.5
No Reagent Required												
Bilirubinometer / Unistat	38	18.06	1.00	5.6	18.3	14.4 - 21.7	38	0.00	0.01	0.0	0.0	0.0 - 0.4
All Chemistry Instruments	42	18.05	1.03	5.7	18.3	14.4 - 21.7	38	0.00	0.01	0.0	0.0	0.0 - 0.4
<u>Method</u>	Specimen NB-8						Specimen NB-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	48	7.04	0.40	5.6	7.1	5.6 - 8.5	48	18.98	1.34	7.0	19.2	15.1 - 22.8
No Reagent Required												
Bilirubinometer / Unistat	38	7.05	0.37	5.3	7.1	5.6 - 8.5	38	19.26	1.14	5.9	19.5	15.4 - 23.2
All Chemistry Instruments	42	7.09	0.40	5.6	7.1	5.6 - 8.6	42	19.18	1.16	6.0	19.3	15.3 - 23.1
<u>Method</u>	Specimen NB-10											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	48	12.37	0.87	7.1	12.5	9.8 - 14.9						
No Reagent Required												
Bilirubinometer / Unistat	38	12.55	0.70	5.6	12.8	10.0 - 15.1						
All Chemistry Instruments	41	12.56	0.70	5.6	12.7	10.0 - 15.1						

Bilirubin, Direct (mg/dL)

<u>Method</u>	Specimen NB-6						Specimen NB-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	11	6.14	0.65	10.6	5.9	4.8 - 7.5	11	0.12	0.15	122.7	0.1	0.0 - 0.5
<u>Method</u>	Specimen NB-8						Specimen NB-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	11	1.76	0.35	19.8	1.7	1.0 - 2.5	11	4.21	0.67	15.8	4.0	2.8 - 5.6
<u>Method</u>	Specimen NB-10											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	11	5.25	0.78	14.8	5.1	3.6 - 6.9						

Glycohemoglobin (percent)

<u>Method</u>	Specimen GH-3						Specimen GH-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	92	3.77	0.28	7.5	3.8	3.5 - 4.0	114	4.86	0.36	7.4	4.9	4.6 - 5.2
All Bio-Rad Methods	4	-	-	-	3.4	3.1 - 3.6	5	4.85	0.13	2.7	4.9	4.6 - 5.1
All Hemoglobin A1c Methods	91	3.77	0.28	7.4	3.8	3.5 - 4.0	113	4.87	0.36	7.4	4.9	4.6 - 5.2
All Roche Methods	11	4.03	0.13	3.3	4.0	3.8 - 4.3	10	4.35	0.22	5.1	4.4	4.1 - 4.6
All TOSOH Methods	9	3.52	0.14	4.0	3.5	3.3 - 3.7	15	4.98	0.13	2.7	5.0	4.7 - 5.3
Beckman AU A1c	6	2.97	0.19	6.3	3.0	2.8 - 3.2	8	4.29	0.21	4.9	4.3	4.0 - 4.6
Bio-Rad D-10 HbA1C	4	-	-	-	3.4	3.1 - 3.6	5	4.85	0.13	2.7	4.9	4.6 - 5.1
Roche cobas c311 HbA1c	5	4.10	0.17	4.2	4.0	3.8 - 4.4	5	4.30	0.30	7.0	4.3	4.0 - 4.6
Roche cobas c501 HbA1c	6	4.05	0.08	2.1	4.0	3.8 - 4.3	5	4.28	0.16	3.8	4.2	4.0 - 4.5
Siemens DCA Vantage	53	3.85	0.20	5.3	3.9	3.6 - 4.1	54	5.09	0.20	3.9	5.1	4.8 - 5.4
Siemens Dimension HA1C	6	3.63	0.19	5.1	3.7	3.4 - 3.9	9	4.60	0.26	5.6	4.5	4.3 - 4.9
Siemens Dimension HB1C	5	3.77	0.15	4.1	3.8	3.5 - 4.0	7	4.70	0.29	6.3	4.6	4.4 - 5.0
TOSOH G8	9	3.52	0.14	4.0	3.5	3.3 - 3.7	15	4.98	0.13	2.7	5.0	4.7 - 5.3

Whole Blood Glucose (mg/dL)

<u>Method</u>	Specimen WBG-6						Specimen WBG-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	807	70.2	9.6	13.7	72	56 - 85	803	180.8	13.6	7.5	184	144 - 217
All Abbott Methods	45	58.1	6.9	11.8	56	46 - 70	47	162.8	12.9	7.9	163	130 - 196
All Arkray Methods	10	81.2	8.2	10.1	85	64 - 98	8	187.4	16.0	8.5	190	149 - 225
All Bayer Methods	17	50.5	4.8	9.4	49	40 - 61	17	144.1	8.1	5.6	142	115 - 173
All Hemocue Methods	52	91.2	6.3	6.9	92	72 - 110	49	191.6	6.2	3.2	193	153 - 230
All Lifescan Methods	8	60.5	4.7	7.8	61	48 - 73	8	195.4	6.5	3.3	196	156 - 235
All Roche Methods	509	72.2	2.4	3.3	72	57 - 87	505	184.6	4.7	2.5	185	147 - 222
Abbott FreeStyle Freedom	10	61.2	5.9	9.6	62	48 - 74	10	168.6	9.5	5.6	166	134 - 203
Abbott FreeStyle Lite/Freedom Lite	7	63.1	2.4	3.8	63	50 - 76	7	173.6	4.0	2.3	174	138 - 209
Abbott FreeStyle Precision Pro	24	56.2	7.4	13.1	54	44 - 68	24	157.5	13.9	8.8	154	126 - 189
Abbott Precision XceedPro	4	-	-	-	53	42 - 64	6	162.0	9.9	6.1	164	129 - 195
Arkray Platinum	24	85.9	1.9	2.2	86	68 - 104	24	191.0	7.0	3.7	193	152 - 230
Bayer Contour	20	50.6	4.7	9.3	49	40 - 61	21	144.6	8.2	5.7	143	115 - 174
HemoCue Glucose 201	54	91.3	6.3	6.9	92	73 - 110	51	191.9	6.2	3.2	194	153 - 231
Home Diagnostics True Balance / TrueTrack	9	178.0	4.8	2.7	177	142 - 214	9	425.4	12.9	3.0	429	340 - 511
Lifescan One Touch Ultra	17	63.4	4.2	6.6	66	50 - 77	17	202.6	8.2	4.1	209	162 - 244
Medline EvenCare G2 / G3	21	70.4	8.0	11.3	69	56 - 85	21	182.0	21.6	11.8	187	145 - 219
NOVA Biomedical StatStrip	52	55.9	3.8	6.9	56	44 - 68	52	154.2	7.2	4.7	154	123 - 186
Quintet / AC	29	59.5	4.1	6.9	59	47 - 72	30	183.8	7.6	4.1	185	147 - 221
Roche Accu-Chek Inform	10	70.5	0.7	1.0	71	56 - 85	10	183.3	3.7	2.0	183	146 - 220
Roche Accu-Chek Inform II	350	72.0	2.4	3.3	72	57 - 87	346	184.7	4.7	2.6	185	147 - 222
Roche Accu-Chek Performa	146	72.7	2.4	3.2	74	58 - 88	148	184.6	4.6	2.5	185	147 - 222
True Metrix Pro	15	54.8	2.9	5.2	55	43 - 66	15	157.5	7.2	4.6	159	126 - 190

Whole Blood Glucose (mg/dL) (continued)

Specimen WBG-8							Specimen WBG-9					
<u>Method</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	158	288.4	25.5	8.9	293	230 - 347	159	107.1	9.1	8.5	110	85 - 129
All Abbott Methods	10	289.1	31.2	10.8	285	231 - 347	10	101.7	10.4	10.2	100	81 - 123
All Lifescan Methods	3	-	-	-	321	261 - 392	3	-	-	-	115	92 - 139
All Roche Methods	95	296.6	6.5	2.2	296	237 - 356	96	110.9	2.5	2.2	111	88 - 134
Abbott FreeStyle Freedom	10	289.1	31.2	10.8	285	231 - 347	10	101.7	10.4	10.2	100	81 - 123
Lifescan One Touch Ultra	12	341.1	11.6	3.4	346	272 - 410	12	119.7	3.2	2.7	121	95 - 144
NOVA Biomedical StatStrip	34	252.6	12.0	4.8	254	202 - 304	34	94.1	4.8	5.1	94	75 - 113
Roche Accu-Chek Inform	10	297.9	3.2	1.1	299	238 - 358	10	111.1	1.6	1.4	111	88 - 134
Roche Accu-Chek Inform II	79	296.8	6.8	2.3	296	237 - 357	79	110.9	2.6	2.4	111	88 - 134
Roche Accu-Chek Performa	10	279.8	15.2	5.4	288	223 - 336	10	105.6	8.2	7.8	111	84 - 127
True Metrix Pro	1	-	-	-	258	206 - 310	1	-	-	-	97	77 - 117
Specimen WBG-10												
<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	160	327.0	30.4	9.3	331	261 - 393						
All Abbott Methods	10	325.0	14.7	4.5	326	260 - 390						
All Lifescan Methods	3	-	-	-	362	300 - 450						
All Roche Methods	94	333.7	6.8	2.0	334	266 - 401						
Abbott FreeStyle Freedom	10	325.0	14.7	4.5	326	260 - 390						
Lifescan One Touch Ultra	12	400.5	19.9	5.0	409	320 - 481						
NOVA Biomedical StatStrip	34	286.6	10.3	3.6	288	229 - 344						
Roche Accu-Chek Inform	10	332.6	2.6	0.8	332	266 - 400						
Roche Accu-Chek Inform II	77	334.6	6.7	2.0	335	267 - 402						
Roche Accu-Chek Performa	10	316.4	15.6	4.9	324	253 - 380						
True Metrix Pro	1	-	-	-	297	237 - 357						

Folate (ng/mL)

<u>Method</u>	Specimen SC-3						Specimen SC-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	23	7.63	3.38	44.3	8.8	5.3 - 10.0	22	2.34	0.77	32.7	2.6	1.3 - 3.4
All Roche Instruments	8	6.15	1.22	19.8	6.3	4.3 - 8.0	7	1.83	0.50	27.3	2.0	0.8 - 2.9
All Siemens Dimension Instruments	5	5.06	0.70	13.9	5.2	3.5 - 6.6	5	2.22	0.23	10.3	2.2	1.2 - 3.3
All Siemens Dimension Instruments	5	5.06	0.70	13.9	5.2	3.5 - 6.6	5	2.22	0.23	10.3	2.2	1.2 - 3.3
All Siemens Dimension Instruments	5	5.06	0.70	13.9	5.2	3.5 - 6.6	5	2.22	0.23	10.3	2.2	1.2 - 3.3
All Siemens Dimension Instruments	5	5.06	0.70	13.9	5.2	3.5 - 6.6	5	2.22	0.23	10.3	2.2	1.2 - 3.3
All TOSOH Instruments	8	4.20	0.33	7.7	4.1	2.9 - 5.5	8	1.64	0.39	23.5	1.8	0.6 - 2.7
Abbott Architect	6	12.17	2.83	23.2	13.6	8.5 - 15.9	6	3.27	0.60	18.2	3.3	2.2 - 4.3
Beckman ACCESS / 2 / Dxl	24	9.70	0.74	7.6	9.6	6.7 - 12.7	24	3.01	0.31	10.2	3.1	2.0 - 4.1
Roche cobas e 601/ e 602	5	6.04	1.50	24.8	6.5	4.2 - 7.9	5	1.76	0.59	33.8	2.0	0.7 - 2.8

CK-MB - Quantitative (U/L)

<u>Method</u>	Specimen CK-6						Specimen CK-7					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	7	6.30	1.84	29.2	6.3	0.7 - 11.9	7	87.15	17.18	19.7	87.2	35.6 - 138.7
<u>Method</u>	Specimen CK-8						Specimen CK-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	7	27.55	5.02	18.2	27.6	12.4 - 42.7	7	16.35	3.32	20.3	16.4	6.3 - 26.4
<u>Method</u>	Specimen CK-10											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	7	47.50	9.19	19.4	47.5	19.9 - 75.1						

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