MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

Medical Laboratory Evaluation

International Data Supplement
2022 MLE-M3

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Immunology

Chemistry

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 ± 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	± 15%
Automated Differential	± 3 SD
Bilirubin, Neonatal (Total)	± 0.4 mg/dL or 20% *
Bilirubin, Direct	± 2 SD
Cytomegalovirus	
Fibrinogen	± 3 SD
Glucose, Whole Blood	± 6 mg/dL or ± 20%*
Glycohemoglobin	± 8%
Hematocrit	± 6%
Hemoglobin	± 7%
International Normalized Ratio (INR)	± 15%
Platelet Count	± 25%
Prothrombin Time	± 15%
Red Blood Cell Count	± 6%
Rubella	± 3 SD
Sedimentation Rate	± 3 SD
Specific Gravity	± 0.010
Toxoplasma	± 3 SD
White Blood Cell Count	± 15%

*Whichever is greater

SEDIMENTATION RATE (MM/HR)

	Specimen ES-5						Specimen ES-6					
Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	126	59.0	14.7	24.9	56	14 - 104	129	12.4	3.9	31.0	12	0 - 24
All Automated Methods	23	74.1	13.9	18.7	74	32 - 116	25	14.5	4.7	32.5	14	0 - 29
All Diesse Methods	10	72.3	20.0	27.7	79	12 - 133	11	17.1	3.8	22.3	16	5 - 29
All Manual Methods	94	57.0	11.6	20.3	55	22 - 92	95	12.4	3.2	25.9	12	2 - 23
All Vital Diagnostics Methods	10	74.9	10.1	13.5	73	44 - 106	10	11.4	3.4	30.2	13	1 - 22
Ves-Matic Easy Diesse	5	84.2	11.6	13.8	88	49 - 120	5	16.4	2.6	15.9	15	8 - 25
Vital Diagnostics Excyte M/10	5	78.8	12.9	16.4	78	40 - 118	5	11.6	3.7	32.0	13	0 - 23
Westergren - diluted	76	58.0	11.6	20.0	55	23 - 93	76	12.0	3.1	26.0	11	2 - 22
Westergren - undiluted	16	53.5	10.5	19.6	53	22 - 85	16	13.9	3.5	24.9	14	3 - 25

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

	Specimen CL-11						Specimen CL-12					
Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	15	6.86	0.83	12.2	6.5	5.8 - 7.9	15	2.52	0.37	14.7	2.4	2.1 - 2.9
All Abbott Cell-Dyn Instruments	12	7.78	0.70	9.1	7.6	6.6 - 9.0	12	2.93	0.19	6.5	2.9	2.4 - 3.4
Abbott Cell-Dyn Ruby	8	7.78	0.70	9.1	7.6	6.6 - 9.0	8	2.93	0.19	6.5	2.9	2.4 - 3.4
Orphee Mythic 22	6	6.37	0.22	3.4	6.4	5.4 - 7.4	6	2.30	0.21	9.1	2.3	1.9 - 2.7

	Specimen CL-13						Specimen CL-14					
All Method	15	6.70	0.61	9.2	6.6	5.6 - 7.8	15	18.93	1.48	7.8	18.5	16.0 - 21.8
All Abbott Cell-Dyn Instruments	12	7.43	0.17	2.3	7.5	6.3 - 8.6	12	20.58	0.97	4.7	20.7	17.4 - 23.7
Abbott Cell-Dyn Ruby	8	7.43	0.17	2.3	7.5	6.3 - 8.6	8	20.58	0.97	4.7	20.7	17.4 - 23.7
Orphee Mythic 22	6	6.28	0.28	4.4	6.3	5.3 - 7.3	6	17.93	0.63	3.5	17.9	15.2 - 20.7

	Specimen CL-15					
All Method	15	2.75	0.52	18.8	2.6	2.3 - 3.2
All Abbott Cell-Dyn Instruments	12	3.18	0.15	4.7	3.2	2.6 - 3.7
Abbott Cell-Dyn Ruby	8	3.18	0.15	4.7	3.2	2.6 - 3.7
Orphee Mythic 22	6	2.33	0.16	7.0	2.3	1.9 - 2.7

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

	Specimen CL-11						Specimen CL-12					
Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	15	4.545	0.125	2.7	4.55	4.27 - 4.82	15	2.136	0.065	3.0	2.11	2.00 - 2.27
All Abbott Cell-Dyn Instruments	12	4.683	0.081	1.7	4.67	4.40 - 4.97	12	2.183	0.062	2.9	2.20	2.05 - 2.32
Abbott Cell-Dyn Ruby	8	4.683	0.081	1.7	4.67	4.40 - 4.97	8	2.183	0.062	2.9	2.20	2.05 - 2.32
Orphee Mythic 22	6	4.507	0.073	1.6	4.52	4.23 - 4.78	6	2.122	0.048	2.3	2.11	1.99 - 2.25
	Specimen CL-13						**Specimen CL-14**					
All Method	15	4.570	0.158	3.5	4.58	4.29 - 4.85	15	5.135	0.208	4.0	5.15	4.82 - 5.45
All Abbott Cell-Dyn Instruments	12	4.715	0.105	2.2	4.72	4.43 - 5.00	12	5.338	0.119	2.2	5.39	5.01 - 5.66
Abbott Cell-Dyn Ruby	8	4.715	0.105	2.2	4.72	4.43 - 5.00	8	5.338	0.119	2.2	5.39	5.01 - 5.66
Orphee Mythic 22	6	4.503	0.120	2.7	4.51	4.23 - 4.78	6	5.025	0.160	3.2	5.06	4.72 - 5.33
	Specimen CL-15											
All Method	15	2.300	0.501	21.8	2.15	2.16 - 2.44						
All Abbott Cell-Dyn Instruments	12	2.193	0.057	2.6	2.21	2.06 - 2.33						
Abbott Cell-Dyn Ruby	8	2.193	0.057	2.6	2.21	2.06 - 2.33						
Orphee Mythic 22	6	2.122	0.044	2.1	2.13	1.99 - 2.25						

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

	Specimen CL-11						Specimen CL-12					
Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	15	12.58	1.08	8.6	12.2	11.6 - 13.5	15	4.84	0.59	12.2	4.6	4.4 - 5.2
All Abbott Cell-Dyn Instruments	12	14.03	0.31	2.2	14.1	13.0 - 15.1	12	5.55	0.13	2.3	5.6	5.1 - 6.0
Abbott Cell-Dyn Ruby	8	14.03	0.31	2.2	14.1	13.0 - 15.1	8	5.55	0.13	2.3	5.6	5.1 - 6.0
Orphee Mythic 22	6	11.93	0.50	4.2	12.1	11.0 - 12.8	6	4.43	0.23	5.1	4.5	4.1 - 4.8
	Specimen CL-13						**Specimen CL-14**					
All Method	15	12.57	1.02	8.1	12.1	11.6 - 13.5	15	15.89	0.90	5.7	15.5	14.7 - 17.1
All Abbott Cell-Dyn Instruments	12	13.75	0.30	2.2	13.7	12.7 - 14.8	12	16.93	0.10	0.6	17.0	15.7 - 18.2
Abbott Cell-Dyn Ruby	8	13.75	0.30	2.2	13.7	12.7 - 14.8	8	16.93	0.10	0.6	17.0	15.7 - 18.2
Orphee Mythic 22	6	11.87	0.53	4.4	12.1	11.0 - 12.7	6	15.28	0.51	3.3	15.4	14.2 - 16.4
	Specimen CL-15											
All Method	15	5.19	1.21	23.2	4.5	4.8 - 5.6						
All Abbott Cell-Dyn Instruments	12	5.63	0.10	1.7	5.7	5.2 - 6.1						
Abbott Cell-Dyn Ruby	8	5.63	0.10	1.7	5.7	5.2 - 6.1						
Orphee Mythic 22	6	4.38	0.19	4.4	4.5	4.0 - 4.7						

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

	Specimen CL-11						Specimen CL-12					
Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	15	39.91	1.67	4.2	39.8	37.5 - 42.4	15	16.31	0.81	4.9	16.3	15.3 - 17.3
All Abbott Cell-Dyn Instruments	12	38.43	1.12	2.9	38.0	36.1 - 40.8	12	15.60	0.51	3.3	15.5	14.6 - 16.6
Abbott Cell-Dyn Ruby	8	38.43	1.12	2.9	38.0	36.1 - 40.8	8	15.60	0.51	3.3	15.5	14.6 - 16.6
Orphee Mythic 22	6	40.90	1.26	3.1	40.9	38.4 - 43.4	6	16.87	0.56	3.3	17.0	15.8 - 17.9
	Specimen CL-13						**Specimen CL-14**					
All Method	15	39.85	1.68	4.2	39.9	37.4 - 42.3	15	45.89	1.28	2.8	46.3	43.1 - 48.7
All Abbott Cell-Dyn Instruments	12	38.58	0.96	2.5	38.4	36.2 - 40.9	12	45.20	0.84	1.9	45.1	42.4 - 48.0
Abbott Cell-Dyn Ruby	8	38.58	0.96	2.5	38.4	36.2 - 40.9	8	45.20	0.84	1.9	45.1	42.4 - 48.0
Orphee Mythic 22	6	40.87	1.53	3.7	40.8	38.4 - 43.4	6	46.27	1.51	3.3	46.8	43.4 - 49.1
	Specimen CL-15											
All Method	15	17.57	3.89	22.1	16.7	16.5 - 18.7						
All Abbott Cell-Dyn Instruments	12	15.73	0.48	3.0	15.7	14.7 - 16.7						
Abbott Cell-Dyn Ruby	8	15.73	0.48	3.0	15.7	14.7 - 16.7						
Orphee Mythic 22	6	16.88	0.44	2.6	16.8	15.8 - 17.9						

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

	Specimen CL-11						Specimen CL-12					
Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	15	272.6	22.1	8.1	267	204 - 341	15	91.9	14.5	15.8	95	68 - 115
All Abbott Cell-Dyn Instruments	12	258.8	7.5	2.9	260	194 - 324	12	76.5	4.4	5.8	77	57 - 96
Abbott Cell-Dyn Ruby	8	258.8	7.5	2.9	260	194 - 324	8	76.5	4.4	5.8	77	57 - 96
Orphee Mythic 22	6	286.0	21.3	7.4	281	214 - 358	6	103.3	7.4	7.2	103	77 - 130
	Specimen CL-13						**Specimen CL-14**					
All Method	15	262.7	20.7	7.9	258	197 - 329	15	482.6	38.4	8.0	482	361 - 604
All Abbott Cell-Dyn Instruments	12	250.3	7.3	2.9	248	187 - 313	12	462.5	28.4	6.1	469	346 - 579
Abbott Cell-Dyn Ruby	8	250.3	7.3	2.9	248	187 - 313	8	462.5	28.4	6.1	469	346 - 579
Orphee Mythic 22	6	275.7	18.6	6.7	272	206 - 345	6	503.5	35.0	6.9	496	377 - 630
	Specimen CL-15											
All Method	15	94.8	19.7	20.8	104	71 - 119						
All Abbott Cell-Dyn Instruments	12	73.5	7.5	10.2	74	55 - 92						
Abbott Cell-Dyn Ruby	8	73.5	7.5	10.2	74	55 - 92						
Orphee Mythic 22	6	110.8	7.0	6.3	110	83 - 139						

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

	Specimen CL-11						Specimen CL-12					
Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	15	60.07	2.89	4.8	59.4	51.4 - 68.8	15	49.12	1.76	3.6	48.8	43.8 - 54.5
All Abbott Cell-Dyn Instruments	12	63.33	1.29	2.0	63.4	59.4 - 67.3	12	50.95	0.97	1.9	51.3	48.0 - 53.9
Abbott Cell-Dyn Ruby	8	63.33	1.29	2.0	63.4	59.4 - 67.3	8	50.95	0.97	1.9	51.3	48.0 - 53.9
Orphee Mythic 22	6	58.38	1.45	2.5	58.4	54.0 - 62.8	6	48.13	1.19	2.5	48.6	44.5 - 51.8
	Specimen CL-13						**Specimen CL-14**					
All Method	15	59.93	3.26	5.4	58.8	50.1 - 69.7	15	71.12	2.69	3.8	70.4	63.0 - 79.3
All Abbott Cell-Dyn Instruments	12	63.80	0.71	1.1	63.6	61.6 - 66.0	12	74.25	0.62	0.8	74.4	72.3 - 76.2
Abbott Cell-Dyn Ruby	8	63.80	0.71	1.1	63.6	61.6 - 66.0	8	74.25	0.62	0.8	74.4	72.3 - 76.2
Orphee Mythic 22	6	57.85	1.38	2.4	58.2	53.7 - 62.0	6	69.35	1.40	2.0	69.9	65.1 - 73.6
	Specimen CL-15											
All Method	15	49.79	2.85	5.7	50.3	41.2 - 58.4						
All Abbott Cell-Dyn Instruments	12	51.78	0.46	0.9	51.7	50.3 - 53.2						
Abbott Cell-Dyn Ruby	8	51.78	0.46	0.9	51.7	50.3 - 53.2						
Orphee Mythic 22	6	47.73	2.01	4.2	47.5	41.6 - 53.8						

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

	Specimen CL-11						Specimen CL-12					
Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	15	23.64	2.18	9.2	24.0	17.1 - 30.2	15	33.92	3.39	10.0	33.0	23.7 - 44.1
All Abbott Cell-Dyn Instruments	12	25.65	1.25	4.9	25.3	21.8 - 29.5	12	37.60	1.13	3.0	38.0	34.2 - 41.0
Abbott Cell-Dyn Ruby	8	25.65	1.25	4.9	25.3	21.8 - 29.5	8	37.60	1.13	3.0	38.0	34.2 - 41.0
Orphee Mythic 22	6	22.70	1.25	5.5	22.1	18.9 - 26.5	6	31.78	1.25	3.9	31.9	28.0 - 35.6
	Specimen CL-13						**Specimen CL-14**					
All Method	15	23.54	2.50	10.6	23.8	16.0 - 31.1	15	15.43	1.93	12.5	14.9	9.6 - 21.3
All Abbott Cell-Dyn Instruments	12	24.85	0.81	3.2	24.9	22.4 - 27.3	12	13.90	0.84	6.1	14.1	11.3 - 16.5
Abbott Cell-Dyn Ruby	8	24.85	0.81	3.2	24.9	22.4 - 27.3	8	13.90	0.84	6.1	14.1	11.3 - 16.5
Orphee Mythic 22	6	23.16	2.98	12.9	22.5	14.2 - 32.2	6	16.98	1.35	8.0	17.3	12.9 - 21.1
	Specimen CL-15											
All Method	15	33.58	4.34	12.9	33.5	20.5 - 46.7						
All Abbott Cell-Dyn Instruments	12	37.03	1.66	4.5	37.5	32.0 - 42.1						
Abbott Cell-Dyn Ruby	8	37.03	1.66	4.5	37.5	32.0 - 42.1						
Orphee Mythic 22	6	32.44	3.25	10.0	31.2	22.6 - 42.2						

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

	Specimen CL-11						Specimen CL-12					
Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	15	10.54	5.38	51.1	13.4	0.0 - 26.7	15	13.59	5.20	38.3	15.7	0.0 - 29.2
All Abbott Cell-Dyn Instruments	12	4.38	0.72	16.4	4.5	2.2 - 6.6	12	7.73	0.42	5.4	7.9	6.4 - 9.0
Abbott Cell-Dyn Ruby	8	4.38	0.72	16.4	4.5	2.2 - 6.6	8	7.73	0.42	5.4	7.9	6.4 - 9.0
Orphee Mythic 22	6	14.64	1.22	8.3	15.3	10.9 - 18.3	6	17.28	1.74	10.1	17.3	12.0 - 22.6
	Specimen CL-13						**Specimen CL-14**					
All Method	15	11.13	5.83	52.4	14.4	0.0 - 28.7	15	8.15	3.73	45.7	9.7	0.0 - 19.4
All Abbott Cell-Dyn Instruments	12	4.48	0.38	8.4	4.5	3.3 - 5.7	12	3.93	0.32	8.2	4.0	2.9 - 4.9
Abbott Cell-Dyn Ruby	8	4.48	0.38	8.4	4.5	3.3 - 5.7	8	3.93	0.32	8.2	4.0	2.9 - 4.9
Orphee Mythic 22	6	15.74	1.52	9.7	15.2	11.1 - 20.4	6	11.30	0.75	6.7	11.5	9.0 - 13.6
	Specimen CL-15											
All Method	15	13.19	5.17	39.2	15.0	0.0 - 28.8						
All Abbott Cell-Dyn Instruments	12	7.60	1.68	22.1	6.9	2.5 - 12.7						
Abbott Cell-Dyn Ruby	8	7.60	1.68	22.1	6.9	2.5 - 12.7						
Orphee Mythic 22	6	17.20	2.34	13.6	17.2	10.1 - 24.3						

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

	Specimen CL-11						Specimen CL-12					
Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	15	5.80	1.74	30.1	6.3	0.5 - 11.1	15	2.84	0.85	29.8	3.2	0.3 - 5.4
All Abbott Cell-Dyn Instruments	12	6.50	0.56	8.6	6.4	4.8 - 8.2	12	3.05	0.49	16.2	3.1	1.5 - 4.6
Abbott Cell-Dyn Ruby	8	6.50	0.56	8.6	6.4	4.8 - 8.2	8	3.05	0.49	16.2	3.1	1.5 - 4.6
Orphee Mythic 22	6	4.70	2.16	46.1	4.8	0.0 - 11.2	6	2.58	1.04	40.3	2.8	0.0 - 5.8
	Specimen CL-13						**Specimen CL-14**					
All Method	15	5.34	2.11	39.5	6.5	0.0 - 11.7	15	5.58	2.57	46.1	7.2	0.0 - 13.3
All Abbott Cell-Dyn Instruments	12	6.75	0.31	4.6	6.7	5.8 - 7.7	12	7.48	0.31	4.1	7.4	6.5 - 8.5
Abbott Cell-Dyn Ruby	8	6.75	0.31	4.6	6.7	5.8 - 7.7	8	7.48	0.31	4.1	7.4	6.5 - 8.5
Orphee Mythic 22	6	3.30	1.20	36.3	3.0	0.0 - 6.9	6	3.23	2.05	63.7	3.3	0.0 - 9.4
	Specimen CL-15											
All Method	15	2.98	0.69	23.1	2.9	0.9 - 5.1						
All Abbott Cell-Dyn Instruments	12	3.03	0.40	13.3	2.9	1.8 - 4.3						
Abbott Cell-Dyn Ruby	8	3.03	0.40	13.3	2.9	1.8 - 4.3						
Orphee Mythic 22	6	2.70	0.69	25.4	2.8	0.6 - 4.8						

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

	Specimen CL-11						Specimen CL-12					
Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	15	0.33	0.23	71.1	0.4	0.0 - 1.1	15	0.54	0.27	50.2	0.5	0.0 - 1.4
All Abbott Cell-Dyn Instruments	12	0.13	0.19	151.4	0.1	0.0 - 0.7	12	0.60	0.42	70.7	0.7	0.0 - 1.9
Abbott Cell-Dyn Ruby	8	0.13	0.19	151.4	0.1	0.0 - 0.7	8	0.60	0.42	70.7	0.7	0.0 - 1.9
Orphee Mythic 22	6	0.45	0.19	41.6	0.4	0.0 - 1.1	6	0.53	0.15	28.2	0.5	0.0 - 1.0
	Specimen CL-13						**Specimen CL-14**					
All Method	15	0.29	0.16	56.4	0.3	0.0 - 0.8	15	0.45	0.24	54.4	0.5	0.0 - 1.2
All Abbott Cell-Dyn Instruments	12	0.13	0.10	76.6	0.2	0.0 - 0.5	12	0.43	0.29	67.6	0.6	0.0 - 1.3
Abbott Cell-Dyn Ruby	8	0.13	0.10	76.6	0.2	0.0 - 0.5	8	0.43	0.29	67.6	0.6	0.0 - 1.3
Orphee Mythic 22	6	0.40	0.11	27.4	0.4	0.0 - 0.8	6	0.48	0.25	51.4	0.5	0.0 - 1.3
	Specimen CL-15											
All Method	15	0.65	0.23	34.4	0.6	0.0 - 1.4						
All Abbott Cell-Dyn Instruments	12	0.58	0.19	32.9	0.7	0.0 - 1.2						
Abbott Cell-Dyn Ruby	8	0.58	0.19	32.9	0.7	0.0 - 1.2						
Orphee Mythic 22	6	0.72	0.26	36.8	0.8	0.0 - 1.6						

BLOOD BANK

ABO GROUP

Specimen	Results	Labs	Percent	Performance
BB-11	Group O	21	95.45%	Acceptable
	Group A	1	4.55%	
BB-12	Group A	21	95.45%	Acceptable
	Group O	1	4.55%	
BB-13	Group B	21	95.45%	Acceptable
	Group O	1	4.55%	
BB-14	Group A	22	100%	Acceptable
BB-15	Group O	20	90.91%	Acceptable
	Group A	1	4.55%	
	Group B	1	4.55%	

RH FACTOR (D TYPE)

Specimen	Results	Labs	Percent	Performance
BB-11	Rh Positive	22	100%	Acceptable
BB-12	Rh Negative	21	95.45%	Acceptable
	Rh Positive	1	4.55%	
BB-13	Rh Positive	22	100%	Acceptable
BB-14	Rh Positive	21	95.45%	Acceptable
	Rh Negative	1	4.55%	
BB-15	Rh Negative	22	100%	Acceptable

UNEXPECTED ANTIBODY DETECTION

Specimen	Results	Labs	Percent	Performance
AB-11	Unexpected antibody detected	20	95.24%	Acceptable
	No unexpected antibody detected	1	4.76%	
AB-12	No unexpected antibody detected	21	100%	Acceptable
AB-13	No unexpected antibody detected	19	90.48%	Acceptable
	Unexpected antibody detected	2	9.52%	
AB-14	Unexpected antibody detected	20	95.24%	Acceptable
	No unexpected antibody detected	1	4.76%	
AB-15	No unexpected antibody detected	20	95.24%	Acceptable
	Unexpected antibody detected	1	4.76%	

BLOOD BANK

ANTIBODY IDENTIFICATION

Specimen	Identification	Labs	Percent	Performance
AB-11	Anti-K	13	92.86%	Acceptable
	No antibody detected	1	7.14%	
AB-12	No antibody detected	14	100%	Acceptable
AB-13	No antibody detected	14	100%	Acceptable
AB-14	Anti-Fy(a)	14	100%	Acceptable
AB-15	No antibody detected	14	100%	Acceptable

COMPATIBILITY TESTING

Specimen	Results	Labs	Percent	Performance
AB-11	Compatible	18	100%	Acceptable
AB-12	Compatible	18	100%	Acceptable
AB-13	Compatible	17	94.44%	Acceptable
	Not Compatible	1	5.56%	
AB-14	Not Compatible	17	94.44%	Acceptable
	Compatible	1	5.56%	
AB-15	Compatible	18	100%	Acceptable

Coagulation

PROTHROMBIN TIME (seconds)

	Specimen CG-11						Specimen CG-12					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	43	13.80	1.70	12.3	13.3	11.7 - 15.9	43	33.68	6.96	20.7	32.4	28.6 - 38.8
Dade Innovin												
Dade Behring BFT II	5	11.95	0.21	1.8	12.0	10.1 - 13.8	5	29.05	2.05	7.1	29.1	24.6 - 33.5
Sysmex CA-500/600 series	12	12.27	0.44	3.6	12.1	10.4 - 14.2	12	26.47	0.85	3.2	26.5	22.4 - 30.5
All Coagulation Instruments	18	12.31	0.52	4.3	12.1	10.4 - 14.2	18	26.93	1.35	5.0	26.9	22.8 - 31.0
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	5	15.54	0.60	3.9	15.6	13.2 - 17.9	5	42.18	1.40	3.3	41.8	35.8 - 48.6
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	10	15.74	0.93	5.9	15.5	13.3 - 18.2	10	40.98	2.13	5.2	42.0	34.8 - 47.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	12.94	0.78	6.1	13.0	10.9 - 14.9	5	33.16	2.52	7.6	33.4	28.1 - 38.2

	Specimen CG-13						Specimen CG-14					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	43	24.24	4.60	19.0	23.1	20.6 - 27.9	43	12.69	1.86	14.7	11.8	10.7 - 14.6
Dade Innovin												
Dade Behring BFT II	5	20.55	1.06	5.2	20.6	17.4 - 23.7	5	10.90	0.14	1.3	10.9	9.2 - 12.6
Sysmex CA-500/600 series	12	19.35	0.56	2.9	19.3	16.4 - 22.3	12	11.08	0.57	5.1	11.0	9.4 - 12.8
All Coagulation Instruments	18	19.61	0.79	4.0	19.4	16.6 - 22.6	18	10.98	0.31	2.8	11.0	9.3 - 12.7
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	5	29.18	0.75	2.6	28.8	24.8 - 33.6	5	14.84	0.67	4.5	14.6	12.6 - 17.1
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	10	29.54	1.40	4.8	29.2	25.1 - 34.0	10	14.71	0.65	4.4	14.6	12.5 - 17.0
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	23.44	1.58	6.7	23.3	19.9 - 27.0	5	11.38	0.37	3.3	11.3	9.6 - 13.1

PROTHROMBIN TIME (seconds)

Specimen CG-15

Reagent/Instrument	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
All Method	43	12.74	2.03	15.9	11.6	10.8 - 14.7
Dade Innovin						
Dade Behring BFT II	5	10.75	0.07	0.7	10.8	9.1 - 12.4
Sysmex CA-500/600 series	12	10.93	0.22	2.0	11.0	9.2 - 12.6
All Coagulation Instruments	18	10.94	0.24	2.2	11.0	9.2 - 12.6
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	5	15.38	0.22	1.4	15.5	13.0 - 17.7
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STart Max	10	15.06	0.21	1.4	15.1	12.8 - 17.4
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	11.34	0.38	3.3	11.2	9.6 - 13.1

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

	Specimen CG-11						Specimen CG-12					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	43	1.18	0.10	8.8	1.2	1.0 - 1.4	43	3.16	0.64	20.2	2.9	2.6 - 3.7
Dade Innovin												
Dade Behring BFT II	5	1.25	0.07	5.7	1.3	1.0 - 1.5	5	2.70	0.28	10.5	2.7	2.2 - 3.2
Sysmex CA-500/600 series	12	1.21	0.07	5.5	1.2	1.0 - 1.4	12	2.68	0.13	4.7	2.7	2.2 - 3.1
All Coagulation Instruments	18	1.22	0.07	5.5	1.2	1.0 - 1.5	18	2.69	0.14	5.1	2.7	2.2 - 3.1
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	5	1.20	0.07	5.9	1.2	1.0 - 1.4	5	3.84	0.34	8.8	3.9	3.2 - 4.5
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	10	1.21	0.08	6.5	1.2	1.0 - 1.4	10	3.94	0.12	3.1	4.0	3.3 - 4.6
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	1.08	0.08	7.7	1.1	0.9 - 1.3	5	2.84	0.26	9.2	2.9	2.4 - 3.3

	Specimen CG-13						Specimen CG-14					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	43	2.20	0.35	15.8	2.1	1.8 - 2.6	43	1.08	0.11	10.3	1.1	0.9 - 1.3
Dade Innovin												
Dade Behring BFT II	5	2.00	0.14	7.1	2.0	1.7 - 2.3	5	1.15	0.07	6.1	1.2	0.9 - 1.4
Sysmex CA-500/600 series	12	1.95	0.09	4.6	1.9	1.6 - 2.3	12	1.08	0.06	5.8	1.1	0.9 - 1.3
All Coagulation Instruments	18	1.96	0.09	4.6	1.9	1.6 - 2.3	18	1.09	0.06	5.9	1.1	0.9 - 1.3
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart Max	5	2.54	0.11	4.5	2.5	2.1 - 3.0	5	1.14	0.05	4.8	1.1	0.9 - 1.4
Diagnostica Stago Neoplastine CI Plus												
Diagnostica Stago STart Max	10	2.62	0.15	5.6	2.6	2.2 - 3.1	10	1.11	0.06	5.4	1.1	0.9 - 1.3
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	2.00	0.16	7.9	2.0	1.7 - 2.3	5	0.96	0.05	5.7	1.0	0.8 - 1.2

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

Specimen CG-15

Reagent/Instrument	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
All Method	43	1.09	0.11	9.9	1.1	0.9 - 1.3
Dade Innovin						
Dade Behring BFT II	5	1.15	0.07	6.1	1.2	0.9 - 1.4
Sysmex CA-500/600 series	12	1.08	0.05	4.2	1.1	0.9 - 1.3
All Coagulation Instruments	18	1.08	0.06	5.2	1.1	0.9 - 1.3
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart Max	5	1.18	0.04	3.8	1.2	1.0 - 1.4
Diagnostica Stago Neoplastine CI Plus						
Diagnostica Stago STart Max	10	1.17	0.05	4.3	1.2	0.9 - 1.4
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	0.94	0.05	5.8	0.9	0.7 - 1.1

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

	Specimen CG-11						Specimen CG-12					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	22	29.6	5.6	18.9	27	25 - 35	22	43.8	4.4	10.0	43	37 - 51
Dade Actin FSL												
Sysmex CA-500/600 series	7	25.0	1.2	4.6	25	21 - 29	7	43.4	5.0	11.4	44	36 - 50
All Coagulation Instruments	8	25.1	1.1	4.5	25	21 - 29	8	43.1	4.7	10.8	43	36 - 50
HemosIL APTT-SP												
IL ACL, all models	5	32.7	1.5	4.7	33	27 - 38	5	44.3	3.2	7.3	43	37 - 51
IL TEST APTT-SP												
IL ACL, all models	5	33.0	0.1	0.0	33	28 - 38	5	45.0	2.8	6.3	45	38 - 52

	Specimen CG-13						Specimen CG-14					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	22	37.5	4.3	11.5	38	31 - 44	22	27.5	4.5	16.5	27	23 - 32
Dade Actin FSL												
Sysmex CA-500/600 series	7	37.3	5.6	15.1	36	31 - 43	7	24.3	1.4	5.7	24	20 - 28
All Coagulation Instruments	8	37.0	5.3	14.3	36	31 - 43	8	24.3	1.3	5.3	24	20 - 28
HemosIL APTT-SP												
IL ACL, all models	5	38.0	1.7	4.6	39	32 - 44	5	29.3	0.6	2.0	29	24 - 34
IL TEST APTT-SP												
IL ACL, all models	5	38.0	0.1	0.0	38	32 - 44	5	30.5	0.7	2.3	31	25 - 36

	Specimen CG-15					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	22	28.9	5.7	19.7	27	24 - 34
Dade Actin FSL						
Sysmex CA-500/600 series	7	24.7	1.3	5.1	25	21 - 29
All Coagulation Instruments	8	24.6	1.2	4.8	25	20 - 29
HemosIL APTT-SP						
IL ACL, all models	5	35.0	5.0	14.3	35	29 - 41
IL TEST APTT-SP						
IL ACL, all models	5	34.0	1.4	4.2	34	28 - 40

FIBRINOGEN (mg/dL)

	Specimen CG-11						Specimen CG-12					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	11	153.6	10.8	7.0	151	122 - 185	11	232.2	14.0	6.0	239	185 - 279
IL Fibrinogen-C												
IL ACL, all models	5	160.0	7.9	5.0	163	128 - 192	5	237.7	7.6	3.2	241	190 - 286

	Specimen CG-13						Specimen CG-14					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	11	243.8	27.4	11.2	250	195 - 293	11	182.2	17.1	9.4	186	145 - 219
IL Fibrinogen-C												
IL ACL, all models	5	258.7	11.0	4.2	255	206 - 311	5	189.7	7.2	3.8	186	151 - 228

	Specimen CG-15					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	11	433.8	50.5	11.7	419	347 - 521
IL Fibrinogen-C						
IL ACL, all models	5	443.0	43.3	9.8	419	354 - 532

PROTHROMBIN TIME (seconds) – XS Samples

	Specimen XS-11						Specimen XS-12					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	28	15.28	0.35	2.3	15.4	12.9 - 17.6	28	22.28	1.04	4.7	22.7	18.9 - 25.7
All Roche CoaguChek XS Plus Instruments	14	15.16	0.43	2.9	15.1	12.8 - 17.5	14	21.81	1.12	5.1	21.9	18.5 - 25.1
Roche CoaguChek Pro II	14	15.41	0.19	1.2	15.4	13.0 - 17.8	14	22.74	0.72	3.2	23.0	19.3 - 26.2
Roche CoaguChek XS Plus - Waived	9	15.13	0.47	3.1	15.0	12.8 - 17.5	9	21.88	1.15	5.2	21.9	18.5 - 25.2
Roche CoaguChek XS Plus	5	15.20	0.41	2.7	15.2	12.9 - 17.5	5	21.68	1.19	5.5	21.9	18.4 - 25.0

	Specimen XS-13						Specimen XS-14					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	10	32.48	2.82	8.7	32.5	27.6 - 37.4	10	22.63	1.50	6.6	22.8	19.2 - 26.1
All Roche CoaguChek XS Plus Instruments	10	32.48	2.82	8.7	32.5	27.6 - 37.4	10	22.63	1.50	6.6	22.8	19.2 - 26.1
Roche CoaguChek XS Plus - Waived	5	30.75	2.47	8.0	30.8	26.1 - 35.4	5	21.55	1.20	5.6	21.6	18.3 - 24.8
Roche CoaguChek XS Plus	5	34.20	2.40	7.0	34.2	29.0 - 39.4	5	23.70	0.85	3.6	23.7	20.1 - 27.3

	Specimen XS-15					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	9	35.13	1.29	3.7	34.6	29.8 - 40.5
All Roche CoaguChek XS Plus Instruments	9	35.13	1.29	3.7	34.6	29.8 - 40.5
Roche CoaguChek XS Plus - Waived	4	-	-	-	34.2	29.0 - 39.4
Roche CoaguChek XS Plus	5	35.60	1.41	4.0	35.6	30.2 - 41.0

INTERNATIONAL NORMALIZED RATIO (INR)– XS Samples

	Specimen XS-11						Specimen XS-12					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	58	1.28	0.04	3.1	1.3	1.0 - 1.5	57	1.86	0.10	5.3	1.9	1.5 - 2.2
All Roche CoaguChek XS Plus Instruments	32	1.27	0.05	3.8	1.3	1.0 - 1.5	31	1.84	0.11	5.7	1.9	1.5 - 2.2
Roche CoaguChek Pro II	26	1.30	0.01	0.0	1.3	1.1 - 1.5	26	1.88	0.08	4.4	1.9	1.6 - 2.2
Roche CoaguChek XS Plus - Waived	25	1.27	0.05	3.8	1.3	1.0 - 1.5	25	1.84	0.11	5.9	1.9	1.5 - 2.2
Roche CoaguChek XS Plus	7	1.26	0.05	4.3	1.3	1.0 - 1.5	6	1.80	0.09	5.0	1.8	1.5 - 2.1

	Specimen XS-13						Specimen XS-14					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	18	2.91	0.20	6.9	3.0	2.4 - 3.4	18	1.99	0.11	5.5	2.0	1.6 - 2.3
All Roche CoaguChek XS Plus Instruments	7	2.73	0.21	7.6	2.7	2.3 - 3.2	7	1.90	0.11	5.8	1.9	1.6 - 2.2
Roche CoaguChek Pro II	11	3.01	0.11	3.8	3.0	2.5 - 3.5	11	2.05	0.07	3.4	2.0	1.7 - 2.4
Roche CoaguChek XS Plus - Waived	5	2.68	0.21	7.7	2.7	2.2 - 3.1	5	1.88	0.13	6.7	1.9	1.5 - 2.2
Roche CoaguChek XS Plus	2	-	-	-	2.9	2.4 - 3.3	2	-	-	-	2.0	1.6 - 2.3

	Specimen XS-15					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	18	2.95	0.11	3.7	3.0	2.5 - 3.4
All Roche CoaguChek XS Plus Instruments	7	2.82	0.08	3.0	2.8	2.3 - 3.3
Roche CoaguChek Pro II	11	3.01	0.05	1.8	3.0	2.5 - 3.5
Roche CoaguChek XS Plus - Waived	5	2.80	0.10	3.6	2.8	2.3 - 3.3
Roche CoaguChek XS Plus	2	-	-	-	2.9	2.4 - 3.3

URINALYSIS DIPSTICK–SPECIFIC GRAVITY

Specimen UA-3

Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
All Method	145	1.0228	0.0059	0.6	1.025	1.012 - 1.033
All Iris Diagnostics Methods	6	1.0260	0.0006	0.1	1.026	1.016 - 1.036
All Refractive Index Methods	9	1.0254	0.0034	0.3	1.026	1.015 - 1.036
All Roche Methods	49	1.0167	0.0035	0.3	1.015	1.006 - 1.027
All Siemens Methods	36	1.0260	0.0023	0.2	1.025	1.015 - 1.036
77 Elektronika LabUMat/2	21	1.0300	0.0014	0.1	1.030	1.020 - 1.041
Acon Laboratories	9	1.0240	0.0023	0.2	1.025	1.014 - 1.034
Roche Chemstrips / Combur	8	1.0175	0.0037	0.4	1.015	1.007 - 1.028
Roche cobas u 411	28	1.0168	0.0027	0.3	1.015	1.006 - 1.027
Roche cobas u 601 / 701	6	1.0278	0.0064	0.6	1.030	1.017 - 1.038
Roche Urisys	17	1.0150	0.0001	0.0	1.015	1.005 - 1.025
Siemens Clinitek Advantus	14	1.0250	0.0001	0.0	1.025	1.015 - 1.035
Siemens Clinitek Status / Status+	20	1.0270	0.0025	0.2	1.025	1.017 - 1.037

URINALYSIS DIPSTICK–pH

Specimen UA-3

Participant Results

Method	***Labs***	***≤3.5***	***4.0***	***4.5***	***5.0***	***5.5***	***6.0***	***6.5***	***7.0***	***7.5***	***8.0***	***8.5***	***≥9.0***
ALL METHODS	171	-	-	-	-	-	32	112	27	-	-	-	-
77 Elektronika LabStrip (U Series)	1	-	-	-	-	-	-	1	-	-	-	-	-
77 Elektronika LabUMat/2	22	-	-	-	-	-	1	21	-	-	-	-	-
Acon Laboratories	9	-	-	-	-	-	2	1	6	-	-	-	-
Arkray Aution AU-4050	2	-	-	-	-	-	-	1	1	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	1	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	-	-	-	4	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	-	-	-	2	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	1	-	-	-	-	-
Other Dipstick Method	1	-	-	-	-	-	1	-	-	-	-	-	-
Roche Chemstrips / Combur	22	-	-	-	-	-	19	3	-	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	1	-	-	-	-	-
Roche cobas u 411	28	-	-	-	-	-	1	27	-	-	-	-	-
Roche cobas u 601 / 701	6	-	-	-	-	-	-	6	-	-	-	-	-
Roche Urisys	18	-	-	-	-	-	7	11	-	-	-	-	-
Siemens Clinitek Advantus	16	-	-	-	-	-	-	15	1	-	-	-	-
Siemens Clinitek Status / Status+	20	-	-	-	-	-	-	1	19	-	-	-	-
Siemens Reagent Strips	12	-	-	-	-	-	-	12	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	1	-	-	-	-	-
Urinometer	2	-	-	-	-	-	-	2	-	-	-	-	-
UriScan Pro/II	1	-	-	-	-	-	1	-	-	-	-	-	-

URINALYSIS DIPSTICK–PROTEIN QUALITATIVE

Specimen UA-3

Participant Results

Method	***Labs***	***Negative***	***Trace***	***(1+)***	***(2+)***	***(3+)***	***(4+)***	***10 - 20 mg/dL***	***30 - 70 mg/dL***	***75 mg/dL***	***100 - 200 mg/dL***	***≥300 - 600 mg/dL***	***>600 or ≥1000 mg/dL***
ALL METHODS	171	1	-	12	92	38	-	-	4	1	22	1	-
77 Elektronika LabStrip (U Series)	1	-	-	-	1	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	22	-	-	5	12	-	-	-	2	-	3	-	-
Acon Laboratories	9	-	-	5	4	-	-	-	-	-	-	-	-
Arkray Aution AU-4050	2	-	-	-	2	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	3	-	-	-	-	-	1	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	2	-	-	-	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	1	-	-	-	-
Other Dipstick Method	1	-	-	1	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	-	-	-	20	1	-	-	-	-	1	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	1	-	-	-	-	-	-	-
Roche cobas u 411	28	1	-	-	2	18	-	-	-	-	7	-	-
Roche cobas u 601 / 701	6	-	-	-	-	-	-	-	-	-	6	-	-
Roche Urisys	18	-	-	-	2	13	-	-	-	1	2	-	-
Siemens Clinitek Advantus	16	-	-	-	15	-	-	-	-	-	1	-	-
Siemens Clinitek Status / Status+	20	-	-	-	14	5	-	-	-	-	-	1	-
Siemens Reagent Strips	12	-	-	-	12	-	-	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	-	-	1	-	-
Urinometer	2	-	-	-	2	-	-	-	-	-	-	-	-
UriScan Pro/II	1	-	-	-	1	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-3

Method	Labs	Participant Results									
		Negative or Normal	Trace	(1+)	(2+)	(3+)	(4+)	30 - 100 mg/dL	150 - 300 mg/dL	500 mg/dL	>500 or ≥1000 or ≥2000 mg/dL
ALL METHODS	171	-	-	1	9	44	89	-	1	1	26
77 Elektronika LabStrip (U Series)	1	-	-	-	-	-	1	-	-	-	-
77 Elektronika LabUMat/2	22	-	-	-	-	1	16	-	-	-	5
Acon Laboratories	9	-	-	-	-	-	9	-	-	-	-
Arkray Aution AU-4050	2	-	-	-	-	-	2	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	1
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	-	-	-	-	3	-	-	-	1	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	-	1	1	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	1
Other Dipstick Method	1	-	-	-	-	-	1	-	-	-	-
Roche Chemstrips / Combur	22	-	-	-	-	2	19	-	-	-	1
Roche cobas 6500 / u 601	1	-	-	-	-	-	1	-	-	-	-
Roche cobas u 411	28	-	-	-	-	-	21	-	-	-	7
Roche cobas u 601 / 701	6	-	-	-	-	-	-	-	-	-	6
Roche Urisys	18	-	-	-	-	1	14	-	-	-	3
Siemens Clinitek Advantus	16	-	-	-	-	14	1	-	-	-	1
Siemens Clinitek Status / Status+	20	-	-	1	8	10	-	-	1	-	-
Siemens Reagent Strips	12	-	-	-	1	11	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	-	-	1
Urinometer	2	-	-	-	-	1	1	-	-	-	-
UriScan Pro/II	1						1				

URINALYSIS DIPSTICK–KETONES

Specimen UA-3

		Participant Results												
Method	***Labs***	***Negative***	***Trace***	***Small***	***Moderate***	***Large***	***(1+)***	***(2+)***	***(3+)***	***(4+)***	***5 - 10 mg/dL***	***15 - 25 mg/dL***	***40 - 60 mg/dL***	***≥80 - 100 mg/dL***	***≥150 mg/dL***
ALL METHODS	171	171	-	-	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabStrip (U Series)	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	22	22	-	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution AU-4050	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	22	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	28	28	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	6	6	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	18	18	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	20	20	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	12	12	-	-	-	-	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-3

Method	Labs	Participant Results: Negative	Positive (Ictotest ONLY)	Trace	Small	Moderate	Large	(1+)	(2+)	(3+)	(4+)	0.5 - 1.0 mg/dL	2.0 - 4.0 mg/dL	6.0 - 10.0 mg/dL	>10.0 mg/dL
ALL METHODS	147	147	-	-	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabStrip (U Series)	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	22	22	-	-	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution AU-4050	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	28	28	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 601 / 701	6	6	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	18	18	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	16	16	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	20	20	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-3

Participant Results

Method	*Labs*	*Normal or 0.0 - 0.2 mg/dL or <3.2 µmol/L*	*1.0 or <2.0 mg/dL or 16 or 17 µmol/L*	*2.0/3.0 mg/dL or 34 or 35 µmol/L*	*4.0 or 4.0/6.0 mg/dL or 70 µmol/L*	*≥8.0 or ≥12.0 mg/dL or ≥140 or 200 µmol/L*
ALL METHODS	146	145	1	-	-	-
77 Elektronika LabStrip (U Series)	1	1	-	-	-	-
77 Elektronika LabUMat/2	22	22	-	-	-	-
Acon Laboratories	9	9	-	-	-	-
Arkray Aution AU-4050	2	2	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	2	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-
Other Dipstick Method	1	1	-	-	-	-
Roche Chemstrips / Combur	9	9	-	-	-	-
Roche cobas 6500 / u 601	1	1	-	-	-	-
Roche cobas u 411	28	28	-	-	-	-
Roche cobas u 601 / 701	6	5	1	-	-	-
Roche Urisys	17	17	-	-	-	-
Siemens Clinitek Advantus	16	16	-	-	-	-
Siemens Clinitek Status / Status+	20	20	-	-	-	-
Siemens Reagent Strips	1	1	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-
Urinometer	2	2	-	-	-	-
UriScan Pro/II	1	1	-	-	-	-

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN

Specimen UA-3

		Participant Results																
Method	***Labs***	***Negative***	***Trace***	***Small***	***Moderate***	***Large***	***(1+)***	***(2+)***	***(3+)***	***(4+)***	***(5+)***	***5 - 25 Ery/µL***	***50 - 100 Ery/µL***	***200 - 300 Ery/µL***	***±0.03 mg/dL***	***0.06 - 0.10 mg/dL***	***0.2 - 0.5 mg/dL***	***≥ 1.0 mg/dL***
ALL METHODS	171	1	-	1	-	1	1	2	69	53	16	-	1	25	-	-	-	1
77 Elektronika LabStrip (U Series)	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	22	-	-	-	-	-	-	-	15	1	-	-	-	6	-	-	-	-
Acon Laboratories	9	-	-	-	-	-	1	-	-	8	-	-	-	-	-	-	-	-
Arkray Aution AU-4050	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	3	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	1
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	2	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Other Dipstick Method	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	21	-	-	-	-	-	-	-	-	20	-	-	1	-	-	-	-	-
Roche cobas 6500 / u 601	1	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Roche cobas u 411	28	1	-	-	-	-	-	-	-	5	15	-	-	7	-	-	-	-
Roche cobas u 601 / 701	6	-	-	-	-	-	-	-	-	-	-	-	-	6	-	-	-	-
Roche Miditron Junior/II	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Roche Urisys	18	-	-	-	-	-	-	-	-	15	-	-	-	3	-	-	-	-
Siemens Clinitek Advantus	16	-	-	-	-	-	-	1	14	-	-	-	-	1	-	-	-	-
Siemens Clinitek Status / Status+	20	-	-	1	-	1	-	-	18	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	12	-	-	-	-	-	-	-	12	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Urinometer	2	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	-
UriScan Pro/II	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-3

		Participant Results											
Method	***Labs***	***Negative***	***Trace***	***Small***	***Moderate***	***Large***	***(1+)***	***(2+)***	***(3+)***	***(4+)***	***15 or 25 µL***	***75 or 100 µL***	***250 or 500 µL***
ALL METHODS	159	158	-	-	-	-	1	-	-	-	-	-	-
77 Elektronika LabStrip (U Series)	1	1	-	-	-	-	-	-	-	-	-	-	-
77 Elektronika LabUMat/2	22	22	-	-	-	-	-	-	-	-	-	-	-
Acon Laboratories	9	9	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution AU-4050	2	2	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	4	4	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	1	-	-	-	-	-	-	-	-	-	-	-
Iris Ichem VELOCITY Urine Chemistry System	1	1	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	22	22	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	28	27	-	-	-	-	1	-	-	-	-	-	-
Roche cobas u 601 / 701	6	6	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	18	18	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	16	16	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	20	20	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-
Sysmex UN Series	1	1	-	-	-	-	-	-	-	-	-	-	-
Urinometer	2	2	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	1	1	-	-	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–NITRITE

Specimen UA-3

Participant Results

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	160	1	159
77 Elektronika LabStrip (U Series)	1	-	1
77 Elektronika LabUMat/2	22	-	22
Acon Laboratories	9	-	9
Arkray Aution AU-4050	2	-	2
DIRUI H-800 Urine Analyzer	1	-	1
Iris Diagnostics Aution Max AX-4280	1	-	1
Iris Diagnostics iChem Velocity Strips	4	-	4
Iris Ichem VELOCITY Urine Chemistry System	2	-	2
Other Analyzer Method	1	-	1
Other Dipstick Method	1	-	1
Roche Chemstrips / Combur	22	-	22
Roche cobas 6500 / u 601	1	-	1
Roche cobas u 411	28	1	27
Roche cobas u 601 / 701	6	-	6
Roche Urisys	18	-	18
Siemens Clinitek Advantus	16	-	16
Siemens Clinitek Status / Status+	20	-	20
Siemens Reagent Strips	1	-	1
Sysmex UN Series	1	-	1
Urinometer	2	-	2
UriScan Pro/II	1	-	1

URINALYSIS –MICROALBUMIN (dipstick only)

Specimen UA-3

Participant Results

Method	*Labs*	*Negative*	*10 mg/L*	*20 mg/L*	*30 mg/L*	*50 mg/L*	*80 mg/L*	*100 mg/L*	*150 mg/L*	*+ (4 - 8 mg/dL)*	*++ (>8 mg/dL)*
ALL METHODS	10	2	-	-	-	-	-	1	5	-	2
Other Analyzer Method	1	-	-	-	-	-	-	-	1	-	-
Other Dipstick Method	2	1	-	-	-	-	-	-	-	-	1
Roche Micral - 1 minute	3	-	-	-	-	-	-	1	2	-	-

URINALYSIS –URINE hCG

Specimen UA-3

Participant Results

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	110	-	110
77 Elektronika LabUMat/2	1	-	1
Abon (Alere) Biopharm	2	-	2
Acon Laboratories	5	-	5
Alere hCG Combo Cassette	1	-	1
Biosynex	4	-	4
CTK Biotech	1	-	1
JusChek	5	-	5
Ms. Tellme hCG Rapid Test Cassette	19	-	19
NOVA Test One Step Pregnancy Test	10	-	10
Other Dipstick Method	11	-	11
ProDetect hCG Test	4	-	4
SD Bioline hCG	2	-	2
Siemens Clinitek Status / Status+	15	-	15

MISCELLANEOUS CULTURES

Specimen BA-7 – Blood Culture

Identification	*Labs*	*Percent*	*Performance*
Plesiomonas shigelloides	103	89.57%	Acceptable
Gram negative bacilli	1	0.87%	Acceptable
Plesiomonas sp.	1	0.87%	Acceptable

Organism(s) present: *Plesiomonas shigelloides.*

Specimen BA-8 – Sputum Culture

Identification	*Labs*	*Percent*	*Performance*
Pasteurella multocida	74	47.74%	Acceptable
Streptococcus mutans	32	20.65%	Acceptable
Pasteurella sp.	10	6.45%	Acceptable
Gram negative bacilli	2	1.29%	Acceptable
Gram negative coccobacilli	2	1.29%	Acceptable
Gram positive cocci	1	0.65%	Acceptable
Streptococcus alpha-hemolytic	1	0.65%	Acceptable
Haemophilus parainfluenza	13	8.39%	

Organism(s) present: *Pasteurella multocida* and *Streptococcus mutans.*

Specimen BA-9 – Wound Culture

Identification	*Labs*	*Percent*	*Performance*
Streptococcus agalactiae	106	53.81%	Acceptable
Staphylococcus epidermidis	57	28.83%	Acceptable
Staph – coagulase negative	10	5.08%	Acceptable
Staphylococcus sp.	7	3.55%	Acceptable
Strep – beta hemo: not Grp A	3	1.52%	Acceptable
Staphylococcus hominis	6	3.05%	

Organism(s) present: *Streptococcus agalactiae* and *Staphylococcus epidermidis.*

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen UC-11, CC-11 (SUS-11) Organism(s) present: *Providencia stuartii*

	------Disk Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Amikacin	21	2	4	15	115	20	50	45	83.83%
Amoxicillin/Clavulanate	19	-	-	19	16	-	-	16	100.00%
Ampicillin	16	-	-	16	45	1	-	44	98.36%
Ampicillin/Sulbactam	15	1	-	14	80	-	-	80	98.95%
Aztreonam	4	2	1	1	21	2	-	19	80.00%
Cefazolin	8	1	-	7	42	-	-	42	98.00%
Cefepime	21	10	4	7	115	29	18	68	83.00%
Cefixime	7	-	-	7	2	-	-	2	100.00%
Cefoperazone	9	-	2	7	1	1	-	-	90.00%
Cefotaxime	19	4	1	14	19	2	1	16	87.00%
Cefoxitin	5	-	-	5	29	-	-	29	100.00%
Cefpodoxime	2	-	-	2	-	-	-	-	100.00%
Ceftaroline	-	-	-	-	3	-	-	3	100.00%
Ceftazidime	17	3	-	14	88	8	-	80	89.52%
Ceftazidime-Avibactam	-	-	-	-	10	10	-	-	100.00%
Ceftizoxime	-	-	-	-	2	-	-	2	100.00%
Ceftolozane/Tazobactam	-	-	-	-	19	11	3	5	84.00%
Ceftriaxone	13	2	1	10	89	3	6	80	88.24%
Cefuroxime	18	1	-	17	33	1	-	32	96.08%
Ciprofloxacin	24	1	-	23	148	1	-	147	98.84%
Colistin	-	-	-	-	5	-	-	5	100.00%
Daptomycin	-	-	-	-	3	1	-	2	Inappropriate drug[1]
Doripenem	1	-	-	1	1	-	-	1	100.00%
Doxycycline	3	-	-	3	-	-	-	-	100.00%
Ertapenem	7	-	-	7	121	1	-	120	99.22%
Fosfomycin	7	4	-	3	23	2	-	21	Inappropriate drug[1]
Gentamicin	23	1	-	22	113	-	-	113	99.26%

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

ANTIMICROBIAL SUSCEPTIBILIY TESTING (continued)

Specimen UC-6, CC-6 (SUS-6) Organism(s) present: *Providencia stuartii*

	------Disk Diffusion------				------MIC------				
	Interpretative category data				Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Imipenem	17	2	2	13	60	4	6	50	92.72%
Levofloxacin	15	1	-	14	42	2	-	40	94.74%
Linezolid	-	-	-	-	2	-	-	2	Inappropriate drug[1]
Meropenem	13	2	3	8	127	7	3	117	89.29%
Minocycline	1	-	-	1	1	-	-	1	100.00%
Moxifloxacin	-	-	-	-	2	-	-	2	Inappropriate drug[1]
Nalidixic Acid	2	1	-	1	8	-	-	8	90.00%
Netilmicin	2	-	-	2	-	-	-	-	100.00%
Nitrofurantoin	22	1	-	21	80	1	-	79	98.04%
Norfloxacin	5	1	-	4	52	1	-	51	96.49%
Ofloxacin	3	-	-	3	1	-	-	1	100.00%
Oxacillin	-	-	-	-	1	-	-	1	Inappropriate drug[1]
Penicillin	-	-	-	-	2	1	-	1	Inappropriate
Piperacillin	1	-	-	1	1	-	-	1	100.00%
Piperacillin/Tazobactam	23	13	5	5	64	46	8	10	82.76%
Polymyxin B	-	-	-	-	1	-	-	1	100.00%
Rifampin	-	-	-	-	2	1	-	1	Inappropriate drug[1]
Teicoplanin	-	-	-	-	1	1	-	-	Inappropriate drug[1]
Tetracycline	6	-	-	6	9	1	-	8	93.33%
Ticarcillin/Clavulanate	-	-	-	-	1	-	1	-	100.00%
Tobramycin	4	-	-	4	8	-	-	8	100.00%
Trimethoprim	1	-	-	1	1	-	-	1	100.00%
Trimethoprim/Sulfamethoxazole	20	1	-	19	134	2	-	132	98.05%
Vancomycin	-	-	-	-	4	1	-	3	Inappropriate drug[1]

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

PARASITOLOGY

Specimen FP-11

Identification	***Labs***	***Percent***	***Performance***
Balantidium coli	234	45.88%	Acceptable
Enterobius vermicularis eggs	134	26.27%	Acceptable
Strongyloides stercoralis larvae	84	16.47%	Acceptable
Parasite egg or larvae seen -no	2	0.39%	Acceptable
No parasite seen	11	2.16%	
Hookworm	6	1.18%	
Paragonimus westermani eggs	6	1.18%	
Ascaris lumbricoides eggs	6	1.18%	
Fasciola hepatica eggs	5	0.98%	
Giardia lamblia	5	0.98%	
Diphyllobothrium latum	5	0.98%	
Endolimax nana	5	0.98%	

Parasite(s) present: *Balantidium coli, Enterobius vermicularis eggs* and *Strongyloides stercoralis larvae.*

Specimen FP-12

Identification	***Labs***	***Percent***	***Performance***
No parasite seen	271	93.45%	Acceptable

Parasite(s) present: Negative for parasites.

PARASITOLOGY (continued)

Specimen FP-13

Identification	***Labs***	***Percent***	***Performance***
Clonorchis sinensis	86	17.84%	Ungraded
Ascaris lumbricoides eggs	176	36.51%	
Giardia lamblia	119	24.69%	
Trichuris trichiura eggs	44	9.13%	
No parasite seen	16	3.32%	
Hookworm	6	1.24%	
Paragonimus westermani eggs	6	1.24%	
Taenia sp. eggs	5	1.04%	

Parasite(s) present: *Clonorchis sinensis.* This is an ungraded challenge due to lack of participant consensus.

Specimen FP-14

Identification	***Labs***	***Percent***	***Performance***
Entamoeba coli	206	32.44%	Acceptable
Taenia sp. eggs	202	31.81%	Acceptable
Entamoeba histolytica	131	20.62%	Acceptable
Protozoan cyst or trophozoite	1	0.16%	Acceptable
Parasite egg or larvae seen – no	1	0.16%	Acceptable
Endolimax nana	26	4.09%	
Blastocystis hominis	24	3.78%	
Ascaris lumbricoides eggs	12	1.89%	
Hymenolepis nana eggs	11	1.77%	
Iodamoeba butschlii	8	1.26%	
Giardia lamblia	5	0.79%	

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

PARASITOLOGY (continued)

Specimen FP-15

Identification	***Labs***	***Percent***	***Performance***
Babesia sp.	56	19.18%	Acceptable
Plasmodium falciparum	105	35.96%	
Plasmodium sp.	83	28.42%	
Plasmodium vivax	30	10.27%	
No parasite seen	6	2.05%	
Plasmodium ovale	5	1.77%	

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

Antinuclear Antibody (ANA) - Qualitative

Method	Specimen AE-11 Positive	Specimen AE-11 Negative	Specimen AE-12 Positive	Specimen AE-12 Negative	Specimen AE-13 Positive	Specimen AE-13 Negative
ALL METHODS	-	22	22	-	21	1
Alegria by ORGENTEC	-	1	1	-	1	-
Bio-Rad	-	2	2	-	2	-
BioSystems	-	2	2	-	2	-
Human	-	1	1	-	1	-
Immuno Concepts	-	3	3	-	2	1
INOVA Diagnostics	-	8	8	-	8	-
Kallestad	-	1	1	-	1	-

Method	Specimen AE-14 Positive	Specimen AE-14 Negative	Specimen AE-15 Positive	Specimen AE-15 Negative
ALL METHODS	-	22	21	1
Alegria by ORGENTEC	-	1	1	-
Bio-Rad	-	2	2	-
BioSystems	-	2	2	-
Human	-	1	1	-
Immuno Concepts	-	3	3	-
INOVA Diagnostics	-	8	7	1
Kallestad	-	1	1	-

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

Specimen/Method	N/A (Neg)	8/ 10	16/ 20	32/ 40	64/ 80	128/ 160	256/ 320	512/ 640	>640	1024/ 1280	2048/ 2560	≥2560
Specimen AE-11												
ALL METHODS	16	-	-	1	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
BioSystems	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	7	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-

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

Specimen/Method	*N/A (Neg)*	*8/ 10*	*16/ 20*	*32/ 40*	*64/ 80*	*128/ 160*	*256/ 320*	*512/ 640*	*>640*	*1024/ 1280*	*2048/ 2560*	*≥2560*
Specimen AE-12												
ALL METHODS	-	-	-	1	1	2	3	8	-	2	-	-
Bio-Rad	-	-	-	-	-	-	2	-	-	-	-	-
BioSystems	-	-	-	-	-	-	-	2	-	-	-	-
Immuno Concepts	-	-	-	1	-	2	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	1	-	1	4	-	1	-	-
Kallestad	-	-	-	-	-	-	-	-	-	1	-	-
Specimen AE-13												
ALL METHODS	-	-	-	1	3	3	3	5	-	2	-	-
Bio-Rad	-	-	-	-	-	1	-	1	-	-	-	-
BioSystems	-	-	-	-	-	-	-	1	-	1	-	-
Immuno Concepts	-	-	-	1	2	-	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	1	2	2	2	-	-	-	-
Kallestad	-	-	-	-	-	-	-	-	-	1	-	-
Specimen AE-14												
ALL METHODS	16	-	-	1	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
BioSystems	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	7	-	-	-	-	-	-	-	-	-	-	-
Kallestad	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-15												
ALL METHODS	-	-	-	1	-	1	2	6	2	3	2	-
Bio-Rad	-	-	-	-	-	-	-	2	-	-	-	-
BioSystems	-	-	-	-	-	-	-	-	1	1	-	-
Immuno Concepts	-	-	-	1	-	-	2	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	1	-	3	1	1	1	-
Kallestad	-	-	-	-	-	-	-	-	-	1	-	-

Anti-dsDNA

Method	Specimen AE-11 Positive	Specimen AE-11 Negative	Specimen AE-12 Positive	Specimen AE-12 Negative	Specimen AE-13 Positive	Specimen AE-13 Negative
ALL METHODS	1	17	18	-	15	3
Alegria by ORGENTEC	1	-	1	-	1	-
Bio-Rad	-	1	1	-	-	1
BioSystems	-	2	2	-	2	-
Human	-	1	1	-	1	-
INOVA Diagnostics	-	8	8	-	8	-

Method	Specimen AE-14 Positive	Specimen AE-14 Negative	Specimen AE-15 Positive	Specimen AE-15 Negative
ALL METHODS	1	17	2	16
Alegria by ORGENTEC	-	1	-	1
Bio-Rad	-	1	-	1
BioSystems	-	2	1	1
Human	-	1	-	1
INOVA Diagnostics	1	7	1	7

Anti-RNP

Method	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	Positive	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	-	12	5	6	7	5
BioSystems	-	1	-	1	-	1
Diesse Chorus ANA Screen	-	1	-	1	-	1
INOVA Diagnostics	-	7	5	2	7	-

Method	Specimen AE-14		Specimen AE-15	
	Positive	*Negative*	*Positive*	*Negative*
ALL METHODS	-	12	9	3
BioSystems	-	1	-	1
Diesse Chorus ANA Screen	-	1	-	1
INOVA Diagnostics	-	7	7	-

Specimen AE-12 is an ungraded challenge due to lack of participant consensus.
Specimen AE-13 and Specimen AE-15 was graded by referee consensus.

Anti-RNP/Sm

Method	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	Positive	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	7	2	5	2	5
Alegria by ORGENTEC	-	3	-	3	1	2
INOVA Diagnostics	-	1	-	1	-	1

Method	Specimen AE-14		Specimen AE-15	
	Positive	***Negative***	***Positive***	***Negative***
ALL METHODS	-	7	7	-
BioSystems	-	3	3	-
INOVA Diagnostics	-	1	1	-

Specimen AE-12 and Specimen AE-13 is an ungraded challenge due to lack of participant consensus.

Anti-SSA

Method	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	Positive	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	18	17	-	-	18
Alegria by ORGENTEC	-	3	3	-	-	3
BioSystems	-	1	1	-	-	1
Diesse Chorus ANA Screen	-	1	1	-	-	1
INOVA Diagnostics	-	6	6	-	-	6

Method	Specimen AE-14		Specimen AE-15	
	Positive	***Negative***	***Positive***	***Negative***
ALL METHODS	-	18	-	18
Alegria by ORGENTEC	-	3	-	3
BioSystems	-	1	-	1
Diesse Chorus ANA Screen	-	1	-	1
INOVA Diagnostics	-	6	-	6

Anti-SSB

Method	**Specimen AE-11**		**Specimen AE-12**		**Specimen AE-13**	
	Positive	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	20	-	19	-	20
Alegria by ORGENTEC	-	3	-	3	-	3
BioSystems	-	1	-	1	-	1
Diesse Chorus ANA Screen	-	1	-	1	-	1
INOVA Diagnostics	-	8	-	8	-	8

Method	**Specimen AE-14**		**Specimen AE-15**	
	Positive	***Negative***	***Positive***	***Negative***
ALL METHODS	-	20	-	20
Alegria by ORGENTEC	-	3	-	3
BioSystems	-	1	-	1
Diesse Chorus ANA Screen	-	1	-	1
INOVA Diagnostics	-	8	-	8

Anti-Sm

Method	Specimen AE-11 Positive	Specimen AE-11 Negative	Specimen AE-12 Positive	Specimen AE-12 Negative	Specimen AE-13 Positive	Specimen AE-13 Negative
ALL METHODS	-	20	2	17	16	4
Alegria by ORGENTEC	-	3	-	3	2	1
BioSystems	-	1	1	-	1	-
Diesse Chorus ANA Screen	-	1	-	1	1	-
INOVA Diagnostics	-	9	1	8	9	-

Method	Specimen AE-14 Positive	Specimen AE-14 Negative	Specimen AE-15 Positive	Specimen AE-15 Negative
ALL METHODS	-	20	19	1
Alegria by ORGENTEC	-	3	3	-
BioSystems	-	1	1	-
Diesse Chorus ANA Screen	-	1	1	-
INOVA Diagnostics	-	9	9	-

Rubella—Qualitative

Method	Specimen RU-11 Positive	Specimen RU-11 Negative	Specimen RU-12 Positive	Specimen RU-12 Negative	Specimen RU-13 Positive	Specimen RU-13 Negative
ALL METHODS	17	-	-	17	17	-
Abbott Architect	13	-	-	13	13	-
Roche cobas 6000 / e 601	1	-	-	1	1	-
Roche cobas e 411	1	-	-	1	1	-
Siemens Atellica	1	-	-	1	1	-

Method	Specimen RU-14 Positive	Specimen RU-14 Negative	Specimen RU-15 Positive	Specimen RU-15 Negative
ALL METHODS	-	17	17	-
Abbott Architect	-	13	13	-
Roche cobas 6000 / e 601	-	1	1	-
Roche cobas e 411	-	1	1	-
Siemens Atellica	-	1	1	-

Rubella—Quantitative (IU/mL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen RU-11						
All Method	19	51.30	23.84	46.5	40.2	3.6 - 99.0
All Roche Methods	5	89.08	6.38	7.2	91.6	69.9 - 108.3
Abbott Architect	13	39.00	3.25	8.3	39.2	29.2 - 48.8
Specimen RU-12						
All Method	19	0.17	0.24	144.2	0.0	0.0 - 0.7
All Roche Methods	5	0.50	0.20	40.0	0.6	0.0 - 1.1
Abbott Architect	11	0.00	0.01	0.0	0.0	0.0 - 0.1
Specimen RU-13						
All Method	19	44.39	22.33	50.3	34.1	0.0 - 89.1
All Roche Methods	5	80.08	5.25	6.6	80.8	64.3 - 95.9
Abbott Architect	13	32.39	3.14	9.7	33.0	22.9 - 41.9
Specimen RU-14						
All Method	19	0.16	0.24	147.6	0.0	0.0 - 0.7
All Roche Methods	5	0.50	0.20	40.0	0.6	0.0 - 1.1
Abbott Architect	13	0.02	0.06	259.6	0.0	0.0 - 0.3
Specimen RU-15						
All Method	19	45.41	24.01	52.9	33.5	0.0 - 93.5
All Roche Methods	5	83.04	11.76	14.2	81.8	47.7 - 118.4
Abbott Architect	13	32.70	3.10	9.5	32.7	23.4 - 42.0

Syphilis Serology—Qualitative: VDRL Slide

	Specimen SY-11			Specimen SY-12			Specimen SY-13		
Method	***Reactive***	***Weakly Reactive***	***Non-Reactive***	***Reactive***	***Weakly Reactive***	***Non-Reactive***	***Reactive***	***Weakly Reactive***	***Non-Reactive***
ALL METHODS	33	-	1	-	-	34	34	-	-
Acon Laboratories	1	-	-	-	-	1	1	-	-
CTK Biotech	1	-	-	-	-	1	1	-	-
Lorne Laboratories	1	-	-	-	-	1	1	-	-
Plasmatec	-	-	1	-	-	1	1	-	-
Roche cobas 6000 / e 601	1	-	-	-	-	1	1	-	-
Standard Diagnostics	1	-	-	-	-	1	1	-	-
Wiener Lab	24	-	-	-	-	24	24	-	-

	Specimen SY-14			Specimen SY-15		
Method	***Reactive***	***Weakly Reactive***	***Non-Reactive***	***Reactive***	***Weakly Reactive***	***Non-Reactive***
ALL METHODS	32	1	1	1	-	33
Acon Laboratories	1	-	-	-	-	1
CTK Biotech	1	-	-	-	-	1
Lorne Laboratories	1	-	-	-	-	1
Plasmatec	-	1	-	-	-	1
Roche cobas 6000 / e 601	1	-	-	-	-	1
Standard Diagnostics	1	-	-	-	-	1
Wiener Lab	23	-	1	1	-	23

Syphilis Serology—Semi-Quantitative: VDRL Slide Titer

Specimen/Method	*N/A (Neg)*	*0 dils*	*1 dil*	*2 dils*	*4 dils*	*8 dils*	*16 dils*	*32 dils*	*>32 dils*
Specimen SY-11									
ALL METHODS	1	2	3	19	3	4	-	-	-
Lorne Laboratories	-	-	-	-	-	1	-	-	-
Plasmatec	1	-	-	-	-	-	-	-	-
Wiener Lab	-	2	3	14	3	3	-	-	-
Specimen SY-12									
ALL METHODS	31	1	-	-	-	-	-	-	-
Lorne Laboratories	1	-	-	-	-	-	-	-	-
Plasmatec	1	-	-	-	-	-	-	-	-
Wiener Lab	24	1	-	-	-	-	-	-	-
Specimen SY-13									
ALL METHODS	-	-	-	6	21	2	2	1	-
Lorne Laboratories	-	-	-	-	-	1	-	-	-
Plasmatec	-	-	-	-	1	-	-	-	-
Wiener Lab	-	-	-	5	16	1	2	1	-

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

Specimen SY-14

ALL METHODS	-	-	5	18	5	3	1	-	-
Lorne Laboratories	-	-	-	-	-	1	-	-	-
Plasmatec	-	-	1	-	-	-	-	-	-
Wiener Lab	-	-	4	13	5	2	1	-	-

Specimen SY-15

ALL METHODS	31	1	-	-	-	-	-	-	-
Lorne Laboratories	1	-	-	-	-	-	-	-	-
Plasmatec	1	-	-	-	-	-	-	-	-
Wiener Lab	24	1	-	-	-	-	-	-	-

Syphilis Serology—Qualitative: MHA-TP

	Specimen SY-11		Specimen SY-12		Specimen SY-13	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	5	1	-	6	6	-
Abbott Architect	1	-	-	1	1	-
Atlas Medical	1	-	-	1	1	-
Plasmatec	2	1	-	3	3	-
Serodia	1	-	-	1	1	-

	Specimen SY-14		Specimen SY-15	
	Reactive	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	6	-	-	6
Abbott Architect	1	-	-	1
Atlas Medical	1	-	-	1
Plasmatec	3	-	-	3
Serodia	1	-	-	1

Syphilis Serology—Qualitative : *Treponema pallidum* Antibodies

	Specimen SY-11		Specimen SY-12		Specimen SY-13	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	48	2	-	50	50	-
Abbott Alinity	5	-	-	5	5	-
Abbott Architect	8	-	-	8	8	-
Abon (Alere) Biopharm	2	-	-	2	2	-
Advanced Biotech	1	-	-	1	1	-
CTK Biotech	2	-	-	2	2	-
DiaSorin	1	1	-	2	2	-
Human	1	-	-	1	1	-
Plasmatec	-	1	-	1	1	-
Roche cobas 6000 / c 501	1	-	-	1	1	-
Roche cobas 8000 / e801	1	-	-	1	1	-
Roche cobas e 411	1	-	-	1	1	-
SD Bioline	6	-	-	6	6	-
Serodia	9	-	-	9	9	-
Siemens Immulite 2000	1	-	-	1	1	-
Standard Diagnostics	3	-	-	3	3	-
Zeus	1	-	-	1	1	-

Syphilis Serology—Qualitative : *Treponema pallidum* Antibodies (cont'd)

	Specimen SY-14		Specimen SY-15	
	Reactive	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	49	1	-	50
Abbott Alinity	5	-	-	5
Abbott Architect	8	-	-	8
Abon (Alere) Biopharm	2	-	-	2
Advanced Biotech	1	-	-	1
CTK Biotech	2	-	-	2
DiaSorin	1	1	-	2
Human	1	-	-	1
Plasmatec	1	-	-	1
Roche cobas 6000 / c 501	1	-	-	1
Roche cobas 8000 / e801	1	-	-	1
Roche cobas e 411	1	-	-	1
SD Bioline	6	-	-	6
Serodia	9	-	-	9
Siemens Immulite 2000	1	-	-	1
Standard Diagnostics	3	-	-	3
Zeus	1	-	-	1

Syphilis Serology—Qualitative: RPR

	Specimen SY-11		Specimen SY-12		Specimen SY-13	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	41	2	1	42	43	-
Atlas Medical	1	-	-	1	1	-
Becton Dickinson	4	-	-	4	4	-
BioSystems	8	-	1	7	8	-
Human	3	-	-	3	3	-
Lorne Laboratories	5	-	-	5	5	-
Omega Diagnostics	2	-	-	2	2	-
Plasmatec	1	2	-	3	3	-
Pulse Scientific	1	-	-	1	1	-
SPINREACT	9	-	-	9	9	-

	Specimen SY-14		Specimen SY-15	
	Reactive	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	43	-	-	43
Atlas Medical	1	-	-	1
Becton Dickinson	4	-	-	4
BioSystems	8	-	-	8
Human	3	-	-	3
Lorne Laboratories	5	-	-	5
Omega Diagnostics	2	-	-	2
Plasmatec	3	-	-	3
Pulse Scientific	1	-	-	1
SPINREACT	9	-	-	9

Syphilis Serology—Semi-Quantitative : RPR (Titer)

Specimen/Method	*N/A (Neg)*	*1*	*2*	*4*	*8*	*16*	*32*	*64*	*>64*
Specimen SY-11									
ALL METHODS	1	4	20	10	1	1	-	-	-
Atlas Medical	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	3	1	-	-	-	-	-
BioSystems	-	-	7	1	-	-	-	-	-
Human	-	-	2	1	-	-	-	-	-
Lorne Laboratories	-	1	2	1	-	-	-	-	-
Omega Diagnostics	-	-	-	1	1	-	-	-	-
Plasmatec	1	-	-	-	-	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	1	3	4	-	-	-	-	-
Specimen SY-12									
ALL METHODS	36	1	-	-	-	-	-	-	-
Atlas Medical	1	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-
BioSystems	7	1	-	-	-	-	-	-	-
Human	3	-	-	-	-	-	-	-	-
Lorne Laboratories	4	-	-	-	-	-	-	-	-
Omega Diagnostics	2	-	-	-	-	-	-	-	-
Plasmatec	1	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	8	-	-	-	-	-	-	-	-

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

Specimen/Method	*N/A (Neg)*	*1*	*2*	*4*	*8*	*16*	*32*	*64*	*>64*
Specimen SY-13									
ALL METHODS	-	1	6	19	10	-	-	1	-
Atlas Medical	-	-	-	1	-	-	-	-	-
Becton Dickinson	-	-	-	2	2	-	-	-	-
BioSystems	-	-	1	6	1	-	-	-	-
Human	-	-	1	1	1	-	-	-	-
Lorne Laboratories	-	-	1	2	-	-	-	1	-
Omega Diagnostics	-	-	-	1	1	-	-	-	-
Plasmatec	-	-	-	1	-	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	1	-	3	4	-	-	-	-
Specimen SY-14									
ALL METHODS	-	5	23	6	2	-	-	1	-
Atlas Medical	-	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	2	2	-	-	-	-	-
BioSystems	-	-	7	1	-	-	-	-	-
Human	-	-	3	-	-	-	-	-	-
Lorne Laboratories	-	1	2	-	-	-	-	1	-
Omega Diagnostics	-	-	1	-	1	-	-	-	-
Plasmatec	-	1	-	-	-	-	-	-	-
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	1	5	1	1	-	-	-	-

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

Specimen/Method	*N/A (Neg)*	*1*	*2*	*4*	*8*	*16*	*32*	*64*	*>64*
Specimen SY-15									
ALL METHODS	37	-	-	-	-	-	-	-	-
Atlas Medical	1	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-
BioSystems	8	-	-	-	-	-	-	-	-
Human	3	-	-	-	-	-	-	-	-
Lorne Laboratories	4	-	-	-	-	-	-	-	-
Omega Diagnostics	2	-	-	-	-	-	-	-	-
Plasmatec	1	-	-	-	-	-	-	-	-
Pulse Scientific	1	-	-	-	-	-	-	-	-
SPINREACT	8	-	-	-	-	-	-	-	-

Viral Markers – Anti-HBc (IgM)

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	1	41	-	-	42	-	-	42	-
Abbott Alinity	-	4	-	-	4	-	-	4	-
Abbott Architect	1	17	-	-	18	-	-	18	-
Beckman ACCESS / 2 / DxI	-	1	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	7	-	-	7	-	-	7	-
Roche cobas 8000 / e602	-	1	-	-	1	-	-	1	-
Roche cobas 8000 / e801	-	4	-	-	4	-	-	4	-
Siemens ADVIA	-	1	-	-	1	-	-	1	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-	-	4	-

	Specimen VM-14			Specimen VM-15		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	42	-	42	-	-
Abbott Alinity	-	4	-	4	-	-
Abbott Architect	-	18	-	18	-	-
Beckman ACCESS / 2 / DxI	-	1	-	1	-	-
bioMerieux Vidas, Mini Vidas	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	7	-	7	-	-
Roche cobas 8000 / e602	-	1	-	1	-	-
Roche cobas 8000 / e801	-	4	-	4	-	-
Siemens ADVIA	-	1	-	1	-	-
Siemens Atellica	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	-	4	-	4	-	-

Viral Markers – Anti-HBc (Total / IgG)

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	56	2	-	2	56	-	1	57	-
Abbott Alinity	8	-	-	-	8	-	-	8	-
Abbott Architect	27	-	-	-	27	-	-	27	-
Beckman ACCESS / 2 / DxI	1	1	-	2	-	-	1	1	-
DiaSorin	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	6	-	-	-	6	-	-	6	-
Roche cobas 8000 / e801	4	-	-	-	4	-	-	4	-
Roche cobas e 411	2	-	-	-	2	-	-	2	-
Siemens ADVIA	2	-	-	-	2	-	-	2	-
Siemens Atellica	2	-	-	-	2	-	-	2	-
VITROS 3600/4600/5600/7600	4	-	-	-	4	-	-	4	-

	Specimen VM-14			Specimen VM-15		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	58	-	57	1	-
Abbott Alinity	-	8	-	8	-	-
Abbott Architect	-	27	-	27	-	-
Beckman ACCESS / 2 / DxI	-	2	-	1	1	-
DiaSorin	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	6	-	6	-	-
Roche cobas 8000 / e801	-	4	-	4	-	-
Roche cobas e 411	-	2	-	2	-	-
Siemens ADVIA	-	2	-	2	-	-
Siemens Atellica	-	2	-	2	-	-
VITROS 3600/4600/5600/7600	-	4	-	4	-	-

Viral Markers – Anti-HIV

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	120	-	-	120	-	120	-	-
Abbott Alinity	-	13	-	-	13	-	13	-	-
Abbott Architect	-	47	-	-	47	-	47	-	-
Abbott IMx	-	1	-	-	1	-	1	-	-
Acon Laboratories	-	1	-	-	1	-	1	-	-
ad-bio Rapid Test	-	2	-	-	2	-	2	-	-
Alere Determine - moderate	-	2	-	-	2	-	2	-	-
Beckman ACCESS / 2 / DxI	-	4	-	-	4	-	4	-	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-	3	-	-
DiaSorin	-	1	-	-	1	-	1	-	-
Human	-	2	-	-	2	-	2	-	-
Roche cobas 6000 / e 601	-	11	-	-	11	-	11	-	-
Roche cobas 8000 / e801	-	7	-	-	7	-	7	-	-
Roche cobas e 411	-	7	-	-	7	-	7	-	-
SD Bioline	-	6	-	-	6	-	6	-	-
Siemens ADVIA	-	1	-	-	1	-	1	-	-
Siemens Atellica	-	2	-	-	2	-	2	-	-
Snibe MAGLUMI 600	-	1	-	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-	4	-	-
VITROS ECi	-	1	-	-	1	-	1	-	-
Wondfo	-	1	-	-	1	-	1	-	-

Viral Markers – Anti-HIV- (continued)

	Specimen VM-14			Specimen VM-15		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	120	-	-	120	-
Abbott Alinity	-	13	-	-	13	-
Abbott Architect	-	47	-	-	47	-
Abbott IMx	-	1	-	-	1	-
Acon Laboratories	-	1	-	-	1	-
ad-bio Rapid Test	-	2	-	-	2	-
Alere Determine - moderate	-	2	-	-	2	-
Beckman ACCESS / 2 / DxI	-	4	-	-	4	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-
DiaSorin	-	1	-	-	1	-
Human	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	11	-	-	11	-
Roche cobas 8000 / e801	-	7	-	-	7	-
Roche cobas e 411	-	7	-	-	7	-
SD Bioline	-	6	-	-	6	-
Siemens ADVIA	-	1	-	-	1	-
Siemens Atellica	-	2	-	-	2	-
Snibe MAGLUMI 600	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-
VITROS ECi	-	1	-	-	1	-
Wondfo	-	1	-	-	1	-

Viral Markers – Anti-HAV (IgM)

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	49	-	-	49	-	-	49	-
Abbott Alinity	-	5	-	-	5	-	-	5	-
Abbott Architect	-	23	-	-	23	-	-	23	-
bioMerieux Vidas, Mini Vidas	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	8	-	-	8	-	-	8	-
Roche cobas 8000 / e801	-	4	-	-	4	-	-	4	-
SD Bioline	-	2	-	-	2	-	-	2	-
Siemens ADVIA	-	1	-	-	1	-	-	1	-
Siemens Atellica	-	2	-	-	2	-	-	2	-
Standard Diagnostics	-	2	-	-	2	-	-	2	-

	Specimen VM-14			Specimen VM-15		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	49	-	-	49	-
Abbott Alinity	-	5	-	-	5	-
Abbott Architect	-	23	-	-	23	-
bioMerieux Vidas, Mini Vidas	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	8	-	-	8	-
Roche cobas 8000 / e801	-	4	-	-	4	-
SD Bioline	-	2	-	-	2	-
Siemens ADVIA	-	1	-	-	1	-
Siemens Atellica	-	2	-	-	2	-
Standard Diagnostics	-	2	-	-	2	-

Viral Markers – Anti-HAV (Total/IgG)

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	36	-	-	36	-	34	2	-
Abbott Alinity	-	3	-	-	3	-	3	-	-
Abbott Architect	-	17	-	-	17	-	17	-	-
Beckman ACCESS / 2 / DxI	-	1	-	-	1	-	1	-	-
bioMerieux Vidas, Mini Vidas	-	2	-	-	2	-	2	-	-
Roche cobas 6000 / e 601	-	2	-	-	2	-	1	1	-
Roche cobas 8000 / e602	-	1	-	-	1	-	1	-	-
Roche cobas 8000 / e801	-	3	-	-	3	-	3	-	-
Roche cobas e 411	-	2	-	-	2	-	2	-	-
SD Bioline	-	1	-	-	1	-	-	1	-
Siemens ADVIA	-	2	-	-	2	-	2	-	-
Siemens Atellica	-	1	-	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	-	1	-	-	1	-	1	-	-

	Specimen VM-14			Specimen VM-15		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	9	27	-	-	35	1
Abbott Alinity	1	2	-	-	3	-
Abbott Architect	8	9	-	-	17	-
Beckman ACCESS / 2 / DxI	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	2	-	-	1	1
Roche cobas 6000 / e 601	-	2	-	-	2	-
Roche cobas 8000 / e602	-	1	-	-	1	-
Roche cobas 8000 / e801	-	3	-	-	3	-
Roche cobas e 411	-	2	-	-	2	-
SD Bioline	-	1	-	-	1	-
Siemens ADVIA	-	2	-	-	2	-
Siemens Atellica	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	-	1	-	-	1	-

Viral Markers – HBeAg

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	30	-	-	30	-	-	30	-
Abbott Alinity	-	4	-	-	4	-	-	4	-
Abbott Architect	-	11	-	-	11	-	-	11	-
Roche cobas 6000 / e 601	-	6	-	-	6	-	-	6	-
Roche cobas 8000 / e602	-	1	-	-	1	-	-	1	-
Roche cobas 8000 / e801	-	5	-	-	5	-	-	5	-
Siemens ADVIA	-	1	-	-	1	-	-	1	-
Siemens Atellica	-	1	-	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	-	1	-	-	1	-	-	1	-

	Specimen VM-14			Specimen VM-15		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	30	-	2	28	-
Abbott Alinity	-	4	-	-	4	-
Abbott Architect	-	11	-	-	11	-
Roche cobas 6000 / e 601	-	6	-	-	6	-
Roche cobas 8000 / e602	-	1	-	-	1	-
Roche cobas 8000 / e801	-	5	-	-	5	-
Siemens ADVIA	-	1	-	1	-	-
Siemens Atellica	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	-	1	-	-	1	-

Viral Markers – Anti-HBs

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	2	72	-	73	1	-	72	2	-
Abbott Alinity	-	8	-	8	-	-	8	-	-
Abbott Architect	-	31	-	31	-	-	31	-	-
Beckman ACCESS / 2 / DxI	1	2	-	3	-	-	2	1	-
bioMerieux Vidas, Mini Vidas	-	1	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	-	8	-	8	-	-	8	-	-
Roche cobas 8000 / e801	-	7	-	7	-	-	7	-	-
Roche cobas e 411	-	6	-	6	-	-	6	-	-
SD Bioline	1	-	-	-	1	-	-	1	-
Siemens ADVIA	-	3	-	3	-	-	3	-	-
Siemens Atellica	-	2	-	2	-	-	2	-	-
VITROS 3600/4600/5600/7600	-	3	-	3	-	-	3	-	-
VITROS ECi	-	1	-	1	-	-	1	-	-

	Specimen VM-14			Specimen VM-15		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	74	-	2	72	-
Abbott Alinity	-	8	-	-	8	-
Abbott Architect	-	31	-	-	31	-
Beckman ACCESS / 2 / DxI	-	3	-	1	2	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	8	-	-	8	-
Roche cobas 8000 / e801	-	7	-	-	7	-
Roche cobas e 411	-	6	-	-	6	-
SD Bioline	-	1	-	1	-	-
Siemens ADVIA	-	3	-	-	3	-
Siemens Atellica	-	2	-	-	2	-
VITROS 3600/4600/5600/7600	-	3	-	-	3	-
VITROS ECi	-	1	-	-	1	-

Viral Markers – HBsAg

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	116	1	-	69	44	4	3	114	-
Abbott Alinity	15	-	-	13	2	-	1	14	-
Abbott Architect	44	-	-	43	-	1	1	43	-
Abbott IMx	1	-	-	-	1	-	-	1	-
ad-bio Rapid Test	1	-	-	-	1	-	-	1	-
Beckman ACCESS / 2 / DxI	3	-	-	-	3	-	-	3	-
bioMerieux Vidas, Mini Vidas	3	-	-	-	3	-	-	3	-
CTK Biotech	1	-	-	-	1	-	-	1	-
DiaSorin	-	1	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	13	-	-	3	9	1	-	13	-
Roche cobas 8000 / e801	6	-	-	-	5	1	1	5	-
Roche cobas e 411	8	-	-	3	4	1	-	8	-
SD Bioline	6	-	-	-	6	-	-	6	-
Siemens ADVIA	2	-	-	1	1	-	-	2	-
Siemens Atellica	2	-	-	1	1	-	-	2	-
Snibe MAGLUMI 600	1	-	-	-	1	-	-	1	-
Standard Diagnostics	1	-	-	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	4	-	-	4	-	-	-	4	-

Specimen AE-12 is an ungraded challenge due to lack of participant consensus.

Viral Markers – HBsAg (continued)

	Specimen VM-14			Specimen VM-15		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	6	108	2	115	1	-
Abbott Alinity	1	14	-	15	-	-
Abbott Architect	3	41	-	44	-	-
Abbott IMx	-	1	-	1	-	-
ad-bio Rapid Test	-	1	-	1	-	-
Beckman ACCESS / 2 / DxI	-	3	-	3	-	-
bioMerieux Vidas, Mini Vidas	-	3	-	3	-	-
CTK Biotech	-	1	-	1	-	-
DiaSorin	1	-	-	1	-	-
Roche cobas 6000 / e 601	1	10	1	12	-	-
Roche cobas 8000 / e801	-	6	-	6	-	-
Roche cobas e 411	-	7	1	8	-	-
SD Bioline	-	6	-	6	-	-
Siemens ADVIA	-	2	-	2	-	-
Siemens Atellica	-	2	-	2	-	-
Snibe MAGLUMI 600	-	1	-	1	-	-
Standard Diagnostics	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	-	4	-	4	-	-

Viral Markers – Anti-HCV

	Specimen VM-11			Specimen VM-12			Specimen VM-13		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	1	108	-	107	1	-	-	109	-
Abbott Alinity	-	14	-	14	-	-	-	14	-
Abbott Architect	-	43	-	42	1	-	-	43	-
Abbott IMx	-	2	-	2	-	-	-	2	-
ad-bio Rapid Test	1	2	-	3	-	-	-	3	-
Beckman ACCESS / 2 / DxI	-	3	-	3	-	-	-	3	-
DiaSorin	-	1	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	11	-	11	-	-	-	11	-
Roche cobas 8000 / e801	-	5	-	5	-	-	-	5	-
Roche cobas e 411	-	8	-	8	-	-	-	8	-
SD Bioline	-	5	-	5	-	-	-	5	-
Siemens ADVIA	-	2	-	2	-	-	-	2	-
Siemens Atellica	-	2	-	2	-	-	-	2	-
Standard Diagnostics	-	2	-	2	-	-	-	2	-
VITROS 3600/4600/5600/7600	-	4	-	3	-	-	-	4	-
VITROS ECi	-	1	-	1	-	-	-	1	-
Wantai BioPharm	-	1	-	1	-	-	-	1	-

Viral Markers – Anti-HCV

	Specimen VM-14			Specimen VM-15		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	109	-	22	86	1
Abbott Alinity	-	14	-	-	14	-
Abbott Architect	-	43	-	2	41	-
Abbott IMx	-	2	-	-	2	-
ad-bio Rapid Test	-	3	-	-	3	-
Beckman ACCESS / 2 / DxI	-	3	-	-	3	-
DiaSorin	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	11	-	10	1	-
Roche cobas 8000 / e801	-	5	-	5	-	-
Roche cobas e 411	-	8	-	5	2	1
SD Bioline	-	5	-	-	5	-
Siemens ADVIA	-	2	-	-	2	-
Siemens Atellica	-	2	-	-	2	-
Standard Diagnostics	-	2	-	-	2	-
VITROS 3600/4600/5600/7600	-	4	-	-	4	-
VITROS ECi	-	1	-	-	1	-
Wantai BioPharm	-	1	-	-	1	-

Toxoplasma gondii Antibody (IgG) - Qualitative

	Specimen TOX-5			Specimen TOX-6		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	2	16	-	17	1	-
Abbott Architect	1	11	-	11	1	-
bioMerieux Vidas, Mini Vidas	-	1	-	1	-	-
Roche cobas e 411	1	-	-	1	-	-
VITROS 3600/4600/5600/7600	-	2	-	2	-	-

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

Specimen/Method	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
Specimen TOX-5						
All Method	30	0.787	0.613	77.9	0.60	0.00 - 2.63
All Roche Instruments	10	0.130	0.001	0.0	0.13	0.12 - 0.14
Abbott Architect	13	0.877	0.464	52.9	0.70	0.00 - 2.27
Roche cobas 6000 / e 601	5	0.130	0.001	0.0	0.13	0.12 - 0.14
Roche cobas e 411	5	0.130	0.001	0.0	0.13	0.12 - 0.14
VITROS 3600/4600/5600/7600	5	0.350	0.057	16.2	0.35	0.18 - 0.52
Specimen TOX-6						
All Method	30	451.510	557.030	123.4	200.00	0.00 - 2122.60
All Roche Instruments	10	1306.875	791.805	60.6	1306.50	0.00 - 3682.29
Abbott Architect	13	200.000	0.001	0.0	200.00	199.99 - 200.01
Roche cobas 6000 / e 601	5	621.750	39.952	6.4	621.75	501.89 - 741.61
Roche cobas e 411	5	1992.000	41.012	2.1	1992.00	1868.96 - 2115.04
VITROS 3600/4600/5600/7600	5	323.000	16.971	5.3	323.00	272.08 - 373.92

Toxoplasma gondii Antibody (IgM) - Qualitative

	Specimen TOX-5			Specimen TOX-6		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	-	19	-	19	-	-
Abbott Architect	-	12	-	12	-	-
bioMerieux Vidas, Mini Vidas	-	1	-	1	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
Roche cobas e 411	-	1	-	1	-	-
VITROS 3600/4600/5600/7600	-	2	-	2	-	-

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

Specimen/Method	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
Specimen TOX-5						
All Method	21	0.130	0.075	58.1	0.09	0.00 - 0.36
All Roche Instruments	5	0.245	0.042	17.2	0.25	0.11 - 0.38
Abbott Architect	12	0.082	0.029	35.0	0.08	0.00 - 0.17
Specimen TOX-6						
All Method	21	1.859	0.489	26.3	1.81	0.39 - 3.33
All Roche Instruments	5	2.618	0.206	7.9	2.68	1.99 - 3.24
Abbott Architect	12	1.683	0.211	12.6	1.77	1.04 - 2.32

Cytomegalovirus (CMV) Antibodies (IgG) - Qualitative

	Specimen CMV-5			Specimen CMV-6		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	14	2	-	2	14	-
Abbott Architect	13	1	-	2	12	-
DiaSorin	-	1	-	-	1	-
VITROS 3600/4600/5600/7600	1	-	-	-	1	-

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

Specimen/Method	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
Specimen CMV-5						
All Method	16	357.963	183.555	51.3	250.00	0.00 - 908.63
Abbott Architect	14	338.764	179.339	52.9	250.00	0.00 - 876.79
Specimen CMV-6						
All Method	17	1.532	0.843	55.0	1.70	0.00 - 4.07
Abbott Architect	15	1.727	0.684	39.6	1.90	0.00 - 3.78

Cytomegalovirus (CMV) Antibodies (IgM) - Qualitative

	Specimen CMV-5			Specimen CMV-6		
Method	***Positive***	***Negative***	***Equivocal***	***Positive***	***Negative***	***Equivocal***
ALL METHODS	5	14	1	16	4	-
Abbott Architect	4	12	1	16	1	-
Roche cobas 6000 / e 601	1	1	-	-	2	-
VITROS 3600/4600/5600/7600	-	1	-	-	1	-

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

Specimen/Method	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
Specimen CMV-5						
All Method	16	0.691	0.215	31.1	0.68	0.04 - 1.34
Abbott Architect	14	0.741	0.164	22.1	0.73	0.24 - 1.24
Specimen CMV-6						
All Method	16	2.030	0.858	42.3	2.28	0.00 - 4.61
Abbott Architect	14	2.230	0.692	31.0	2.40	0.15 - 4.31

Neonatal Bilirubin, Total (mg/dL)

Method	Specimen NB-11 Labs	Mean	SD	CV	Median	Range	Specimen NB-12 Labs	Mean	SD	CV	Median	Range
All Method	43	5.33	0.49	9.2	5.4	4.2 - 6.4	43	10.14	0.74	7.3	10.3	8.1 - 12.2
No Reagent Required												
Bilirubinometer / Reichart UNISTAT	36	5.29	0.49	9.2	5.4	4.2 - 6.4	36	10.23	0.72	7.1	10.4	8.1 - 12.3
All Chemistry Instruments	40	5.32	0.50	9.4	5.4	4.2 - 6.4	40	10.20	0.72	7.0	10.4	8.1 - 12.3

Method	Specimen NB-13 Labs	Mean	SD	CV	Median	Range	Specimen NB-14 Labs	Mean	SD	CV	Median	Range
All Method	43	17.34	0.95	5.5	17.5	13.8 - 20.9	39	0.01	0.03	350.9	0.0	0.0 - 0.5
No Reagent Required												
Bilirubinometer / Reichart UNISTAT	36	17.49	0.90	5.1	17.7	13.9 - 21.0	35	0.00	0.01	0.0	0.0	0.0 - 0.4
All Chemistry Instruments	40	17.35	0.97	5.6	17.5	13.8 - 20.9	36	0.00	0.02	600.3	0.0	0.0 - 0.5

Method	Specimen NB-15 Labs	Mean	SD	CV	Median	Range
All Method	43	14.63	0.89	6.1	14.8	11.7 - 17.6
No Reagent Required						
Bilirubinometer / Reichart UNISTAT	36	14.72	0.88	6.0	14.9	11.7 - 17.7
All Chemistry Instruments	40	14.70	0.89	6.0	14.9	11.7 - 17.7

Bilirubin, Direct (mg/dL)

Method	Specimen NB-11 Labs	Mean	SD	CV	Median	Range	Specimen NB-12 Labs	Mean	SD	CV	Median	Range
All Method	10	1.06	0.35	32.6	1.0	0.3 - 1.8	10	3.85	0.75	19.6	3.7	2.3 - 5.4

Method	Specimen NB-13 Labs	Mean	SD	CV	Median	Range	Specimen NB-14 Labs	Mean	SD	CV	Median	Range
All Method	10	3.34	0.77	23.2	3.2	1.7 - 4.9	10	0.09	0.14	155.0	0.1	0.0 - 0.4

Method	Specimen NB-15 Labs	Mean	SD	CV	Median	Range
All Method	10	4.64	0.87	18.9	4.4	2.8 - 6.4

Glycohemoglobin (percent)

	Specimen GH-5						Specimen GH-6					
Method	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	106	5.12	0.21	4.1	5.1	4.7 - 5.6	106	7.02	0.22	3.1	7.0	6.4 - 7.6
All Bio-Rad Methods	5	5.20	0.26	5.1	5.1	4.7 - 5.7	5	6.93	0.23	3.3	6.8	6.3 - 7.5
All Enzymatic A1c Methods	6	4.90	0.34	7.0	4.8	4.5 - 5.3	6	6.69	0.48	7.2	6.6	6.1 - 7.3
All Hemoglobin A1c Methods	90	5.15	0.18	3.5	5.1	4.7 - 5.6	90	7.04	0.20	2.8	7.0	6.4 - 7.6
All Roche Methods	7	4.97	0.14	2.8	4.9	4.5 - 5.4	7	7.04	0.13	1.8	7.1	6.4 - 7.7
All TOSOH Methods	13	5.35	0.13	2.4	5.3	4.9 - 5.8	13	6.91	0.15	2.2	7.0	6.3 - 7.5
Beckman AU A1c	5	5.10	0.16	3.1	5.1	4.6 - 5.6	5	6.96	0.15	2.2	6.9	6.4 - 7.6
Bio-Rad D-10 HbA1C	5	5.20	0.26	5.1	5.1	4.7 - 5.7	5	6.93	0.23	3.3	6.8	6.3 - 7.5
Roche cobas c501 HbA1c	5	4.90	0.10	2.0	4.9	4.5 - 5.3	5	7.10	0.10	1.4	7.1	6.5 - 7.7
Roche Integra A1C	5	5.03	0.15	3.0	5.0	4.6 - 5.5	5	7.00	0.14	2.0	7.1	6.4 - 7.6
Siemens DCA Vantage	45	5.12	0.13	2.6	5.1	4.7 - 5.6	45	7.13	0.17	2.3	7.1	6.5 - 7.7
Siemens Dimension HA1C	10	5.05	0.14	2.7	5.1	4.6 - 5.5	10	6.90	0.16	2.3	6.9	6.3 - 7.5
Siemens Dimension HB1C	5	5.10	0.17	3.4	5.0	4.6 - 5.6	5	6.90	0.17	2.5	6.8	6.3 - 7.5
TOSOH G8	13	5.35	0.13	2.4	5.3	4.9 - 5.8	13	6.91	0.15	2.2	7.0	6.3 - 7.5

Whole Blood Glucose (mg/dL)

	Specimen WBG-11						Specimen WBG-12					
Method	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	919	108.3	11.3	10.4	110	86 - 131	909	343.0	21.1	6.1	348	274 - 412
All Abbott Methods	60	95.9	6.4	6.6	96	76 - 116	60	330.3	22.1	6.7	332	264 - 397
All Arkray Methods	5	126.8	5.0	3.9	127	101 - 153	3	-	-	-	362	289 - 435
All Bayer Methods	14	85.4	8.3	9.7	83	68 - 103	15	274.1	24.9	9.1	274	219 - 329
All Hemocue Methods	52	128.4	6.1	4.7	129	102 - 155	55	347.8	9.0	2.6	348	278 - 418
All Lifescan Methods	6	107.5	5.3	4.9	107	86 - 129	6	382.5	65.2	17.1	356	306 - 459
All Roche Methods	502	111.0	2.6	2.3	112	88 - 134	509	350.7	7.6	2.2	351	280 - 421
Abbott FreeStyle Freedom	10	95.2	3.2	3.4	95	76 - 115	10	334.8	12.1	3.6	332	267 - 402
Abbott FreeStyle Lite/Freedom Lite	6	99.5	2.5	2.5	100	79 - 120	6	336.0	11.5	3.4	333	268 - 404
Abbott FreeStyle Precision Pro	27	94.5	7.3	7.7	95	75 - 114	27	323.7	27.9	8.6	317	258 - 389
Abbott Precis. Xtra/Optium	13	96.2	7.3	7.6	94	76 - 116	13	332.2	21.1	6.3	338	265 - 399
Abbott Precision XceedPro	13	91.7	6.0	6.5	88	73 - 111	13	309.9	23.7	7.7	293	247 - 372
Arkray Platinum	23	126.8	4.1	3.2	126	101 - 153	21	367.0	12.4	3.4	366	293 - 441
Bayer Contour / Plus	15	83.9	7.6	9.0	83	67 - 101	16	267.6	22.9	8.5	266	214 - 322
CareSens	33	125.4	11.5	9.2	126	100 - 151	42	346.1	28.1	8.1	346	276 - 416
GlucoQuick GD50	5	107.2	5.0	4.6	109	85 - 129	5	346.2	25.4	7.3	341	276 - 416
HemoCue Glucose 201	52	128.3	6.0	4.7	129	102 - 154	55	348.1	9.1	2.6	348	278 - 418
Home Diagnostics True Balance / TrueTrack	5	280.2	15.7	5.6	279	224 - 337	5	551.0	47.5	8.6	568	440 - 662
Lifescan One Touch Ultra	6	107.5	5.3	4.9	107	86 - 129	6	382.5	65.2	17.1	356	306 - 459
Medline EvenCare G2 / G3	25	114.8	11.1	9.7	114	91 - 138	23	296.1	21.1	7.1	297	236 - 356
NOVA Biomedical StatStrip	50	94.5	7.5	7.9	95	75 - 114	50	306.4	20.6	6.7	308	245 - 368
Quintet / AC	25	105.3	4.1	3.9	106	84 - 127	25	369.4	19.8	5.4	372	295 - 444
Roche Accu-Chek Inform	10	108.9	1.4	1.3	109	87 - 131	10	341.9	4.9	1.4	341	273 - 411
Roche Accu-Chek Inform II	361	111.0	2.6	2.3	112	88 - 134	364	351.0	7.2	2.1	351	280 - 422
Roche Accu-Chek Instant / Plus	5	94.0	0.1	0.0	94	75 - 113	5	314.8	3.5	1.1	315	251 - 378
Roche Accu-Chek Performa	132	111.0	2.6	2.3	112	88 - 134	137	350.4	9.6	2.7	351	280 - 421
Tru-Life Health Care	5	105.0	6.3	6.0	107	84 - 126	5	307.2	24.6	8.0	303	245 - 369
True Metrix Pro	70	93.0	5.7	6.1	92	74 - 112	70	327.2	16.3	5.0	331	261 - 393

Whole Blood Glucose (mg/dL) (continued)

	Specimen WBG-13						Specimen WBG-14					
Method	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	193	401.2	25.3	6.3	406	320 - 482	193	312.3	23.9	7.7	318	249 - 375
All Abbott Methods	11	400.1	22.7	5.7	406	320 - 481	11	304.0	10.3	3.4	300	243 - 365
All Lifescan Methods	3	-	-	-	405	323 - 486	3	-	-	-	328	260 - 391
All Roche Methods	92	413.1	11.6	2.8	415	330 - 496	90	320.7	8.1	2.5	321	256 - 385
Abbott FreeStyle Freedom	10	405.2	16.0	3.9	408	324 - 487	10	303.9	10.9	3.6	300	243 - 365
Abbott Precis. Xtra/Optium	1	-	-	-	349	279 - 419	1	-	-	-	305	244 - 366
CareSens	23	402.1	35.2	8.7	402	321 - 483	23	351.1	25.2	7.2	358	280 - 422
GlucoQuick GD50	5	418.0	33.5	8.0	416	334 - 502	5	320.8	29.4	9.2	321	256 - 385
Lifescan One Touch Ultra	3	-	-	-	405	323 - 486	3	-	-	-	328	260 - 391
NOVA Biomedical StatStrip	23	376.3	24.0	6.4	379	301 - 452	23	288.5	12.0	4.2	289	230 - 347
Roche Accu-Chek Inform	10	402.6	5.2	1.3	403	322 - 484	10	313.0	4.4	1.4	313	250 - 376
Roche Accu-Chek Inform II	71	415.0	9.0	2.2	416	331 - 498	71	321.5	6.6	2.1	323	257 - 386
Roche Accu-Chek Performa	17	403.9	25.4	6.3	413	323 - 485	17	310.5	22.3	7.2	319	248 - 373
Tru-Life Health Care	5	355.6	25.1	7.1	363	284 - 427	5	272.4	15.9	5.8	278	217 - 327
True Metrix Pro	20	379.8	23.6	6.2	391	303 - 456	20	281.6	5.9	2.1	280	225 - 338

	Specimen WBG-15					
Method	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	193	203.1	19.4	9.6	206	162 - 244
All Abbott Methods	11	191.4	7.0	3.7	194	153 - 230
All Lifescan Methods	3	-	-	-	209	166 - 251
All Roche Methods	90	209.1	4.9	2.3	209	167 - 251
Abbott FreeStyle Freedom	10	193.1	4.2	2.2	194	154 - 232
Abbott Precis. Xtra/Optium	1	-	-	-	174	139 - 209
CareSens	24	242.3	24.3	10.0	243	193 - 291
GlucoQuick GD50	5	199.6	11.8	5.9	196	159 - 240
Lifescan One Touch Ultra	3	-	-	-	209	166 - 251
NOVA Biomedical StatStrip	23	184.0	7.9	4.3	185	147 - 221
Roche Accu-Chek Inform	10	206.4	3.4	1.6	207	165 - 248
Roche Accu-Chek Inform II	71	209.3	4.1	1.9	209	167 - 252
Roche Accu-Chek Performa	17	202.1	15.2	7.5	208	161 - 243
Tru-Life Health Care	5	193.6	13.4	6.9	199	154 - 233
True Metrix Pro	20	177.5	8.5	4.8	178	142 - 213

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