

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
2016 MLE-M2**



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EVALUATION CRITERIA

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

Qualitative

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

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

Quantitative

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

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

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

Specimen CL-6							Specimen CL-7					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	64	7.86	0.75	9.5	8.1	6.6 - 9.1	64	3.09	0.40	13.0	3.2	2.6 - 3.6
All Abbott Cell-Dyn Instruments	51	8.15	0.22	2.7	8.2	6.9 - 9.4	53	3.23	0.18	5.5	3.2	2.7 - 3.8
Abbott Cell-Dyn Ruby	43	8.16	0.21	2.6	8.2	6.9 - 9.4	44	3.25	0.17	5.4	3.3	2.7 - 3.8
Orphee Mythic 22	10	6.59	1.03	15.6	6.3	5.6 - 7.6	10	2.34	0.45	19.3	2.2	1.9 - 2.7
Specimen CL-8							Specimen CL-9					
All Method	65	7.85	0.74	9.4	8.1	6.6 - 9.1	65	3.12	0.38	12.2	3.2	2.6 - 3.6
All Abbott Cell-Dyn Instruments	53	8.11	0.26	3.2	8.2	6.8 - 9.4	52	3.23	0.14	4.2	3.3	2.7 - 3.8
Abbott Cell-Dyn Ruby	45	8.10	0.26	3.2	8.2	6.8 - 9.4	43	3.25	0.13	4.0	3.3	2.7 - 3.8
Orphee Mythic 22	10	6.53	1.04	15.9	6.3	5.5 - 7.6	10	2.37	0.37	15.5	2.3	2.0 - 2.8
Specimen CL-10												
All Method	65	24.82	2.05	8.3	25.3	21.0 - 28.6						
All Abbott Cell-Dyn Instruments	53	25.48	0.79	3.1	25.5	21.6 - 29.4						
Abbott Cell-Dyn Ruby	43	25.65	0.63	2.4	25.6	21.8 - 29.6						
Orphee Mythic 22	10	20.65	1.40	6.8	20.4	17.5 - 23.8						

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

Specimen CL-6							Specimen CL-7					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	61	4.548	0.119	2.6	4.57	4.27 - 4.83	61	2.122	0.054	2.5	2.13	1.99 - 2.25
All Abbott Cell-Dyn Instruments	53	4.573	0.102	2.2	4.58	4.29 - 4.85	53	2.132	0.047	2.2	2.13	2.00 - 2.27
Abbott Cell-Dyn Ruby	44	4.589	0.095	2.1	4.60	4.31 - 4.87	44	2.131	0.047	2.2	2.13	2.00 - 2.26
Orphee Mythic 22	9	4.282	0.206	4.8	4.38	4.02 - 4.54	8	2.016	0.081	4.0	2.05	1.89 - 2.14
Specimen CL-8							Specimen CL-9					
All Method	61	4.538	0.106	2.3	4.53	4.26 - 4.82	61	2.118	0.054	2.6	2.12	1.99 - 2.25
All Abbott Cell-Dyn Instruments	53	4.550	0.090	2.0	4.55	4.27 - 4.83	53	2.130	0.046	2.1	2.13	2.00 - 2.26
Abbott Cell-Dyn Ruby	45	4.568	0.101	2.2	4.57	4.29 - 4.85	44	2.128	0.048	2.2	2.13	2.00 - 2.26
Orphee Mythic 22	9	4.271	0.199	4.7	4.34	4.01 - 4.53	8	2.008	0.084	4.2	2.03	1.88 - 2.13
Specimen CL-10												
All Method	62	6.421	0.167	2.6	6.44	6.03 - 6.81						
All Abbott Cell-Dyn Instruments	53	6.469	0.127	2.0	6.49	6.08 - 6.86						
Abbott Cell-Dyn Ruby	44	6.492	0.120	1.9	6.51	6.10 - 6.89						
Orphee Mythic 22	9	6.006	0.263	4.4	6.11	5.64 - 6.37						

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

Specimen CL-6							Specimen CL-7					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	64	13.07	0.58	4.4	13.2	12.1 - 14.0	64	5.36	0.30	5.7	5.5	4.9 - 5.8
All Abbott Cell-Dyn Instruments	53	13.29	0.30	2.2	13.3	12.3 - 14.3	52	5.46	0.12	2.2	5.5	5.0 - 5.9
Abbott Cell-Dyn Ruby	44	13.30	0.31	2.3	13.3	12.3 - 14.3	43	5.44	0.11	2.1	5.5	5.0 - 5.9
Orphee Mythic 22	10	11.92	0.25	2.1	11.9	11.0 - 12.8	10	4.86	0.39	8.1	4.8	4.5 - 5.3
Specimen CL-8							Specimen CL-9					
All Method	65	13.00	0.53	4.0	13.1	12.0 - 14.0	64	5.36	0.30	5.5	5.5	4.9 - 5.8
All Abbott Cell-Dyn Instruments	54	13.20	0.21	1.6	13.2	12.2 - 14.2	53	5.47	0.13	2.3	5.5	5.0 - 5.9
Abbott Cell-Dyn Ruby	45	13.21	0.22	1.6	13.2	12.2 - 14.2	44	5.45	0.12	2.3	5.5	5.0 - 5.9
Orphee Mythic 22	10	11.88	0.27	2.2	11.8	11.0 - 12.8	10	4.80	0.31	6.5	4.7	4.4 - 5.2
Specimen CL-10												
All Method	65	19.22	0.71	3.7	19.4	17.8 - 20.6						
All Abbott Cell-Dyn Instruments	54	19.45	0.49	2.5	19.5	18.0 - 20.9						
Abbott Cell-Dyn Ruby	44	19.50	0.41	2.1	19.5	18.1 - 20.9						
Orphee Mythic 22	10	18.01	0.54	3.0	17.8	16.7 - 19.3						

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

Specimen CL-6							Specimen CL-7					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	64	37.29	1.54	4.1	37.0	35.0 - 39.6	60	15.64	0.55	3.5	15.6	14.7 - 16.6
All Abbott Cell-Dyn Instruments	48	36.98	0.97	2.6	37.0	34.7 - 39.3	49	15.53	0.48	3.1	15.5	14.5 - 16.5
Abbott Cell-Dyn Ruby	43	37.03	0.96	2.6	37.0	34.8 - 39.3	44	15.52	0.50	3.2	15.5	14.5 - 16.5
Orphee Mythic 22	10	37.79	2.07	5.5	38.7	35.5 - 40.1	10	16.35	1.09	6.7	16.1	15.3 - 17.4
Specimen CL-8							Specimen CL-9					
All Method	63	37.12	1.37	3.7	37.0	34.8 - 39.4	64	15.72	0.60	3.8	15.8	14.7 - 16.7
All Abbott Cell-Dyn Instruments	48	36.70	0.84	2.3	36.9	34.5 - 39.0	49	15.59	0.41	2.7	15.7	14.6 - 16.6
Abbott Cell-Dyn Ruby	44	36.80	0.98	2.7	37.0	34.5 - 39.1	44	15.56	0.41	2.7	15.6	14.6 - 16.5
Orphee Mythic 22	10	37.72	1.87	5.0	38.6	35.4 - 40.0	10	16.01	0.71	4.4	16.0	15.0 - 17.0
Specimen CL-10												
All Method	65	53.78	2.18	4.1	53.9	50.5 - 57.1						
All Abbott Cell-Dyn Instruments	50	53.28	1.58	3.0	53.5	50.0 - 56.5						
Abbott Cell-Dyn Ruby	45	53.36	1.60	3.0	53.8	50.1 - 56.6						
Orphee Mythic 22	10	54.06	2.57	4.8	55.1	50.8 - 57.4						

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

Specimen CL-6							Specimen CL-7					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	63	280.2	19.7	7.0	277	210 - 351	64	88.2	9.8	11.1	87	66 - 111
All Abbott Cell-Dyn Instruments	51	281.1	17.0	6.1	280	210 - 352	52	84.9	7.0	8.2	85	63 - 107
Abbott Cell-Dyn Ruby	44	284.7	18.1	6.4	282	213 - 356	44	85.1	6.6	7.7	85	63 - 107
Orphee Mythic 22	10	273.8	20.4	7.5	277	205 - 343	10	102.0	4.3	4.3	102	76 - 128
Specimen CL-8							Specimen CL-9					
All Method	63	274.7	18.5	6.7	276	206 - 344	63	86.3	8.8	10.2	85	64 - 108
All Abbott Cell-Dyn Instruments	51	275.3	15.9	5.8	276	206 - 345	52	83.5	6.0	7.1	83	62 - 105
Abbott Cell-Dyn Ruby	43	277.9	13.6	4.9	277	208 - 348	44	83.3	5.4	6.5	83	62 - 105
Orphee Mythic 22	10	272.1	16.8	6.2	274	204 - 341	9	-	-	-	100	74 - 124
Specimen CL-10												
All Method	63	509.2	38.3	7.5	514	381 - 637						
All Abbott Cell-Dyn Instruments	53	518.0	32.3	6.2	523	388 - 648						
Abbott Cell-Dyn Ruby	44	526.3	26.1	5.0	527	394 - 658						
Orphee Mythic 22	10	462.6	34.4	7.4	463	346 - 579						

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

Specimen CL-6							Specimen CL-7					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	62	60.99	1.56	2.6	61.4	56.2 - 65.7	62	50.37	2.14	4.2	50.9	43.9 - 56.8
All Abbott Cell-Dyn Instruments	51	61.50	0.79	1.3	61.6	59.1 - 63.9	51	51.08	1.34	2.6	51.0	47.0 - 55.1
Abbott Cell-Dyn Ruby	44	61.53	0.80	1.3	61.6	59.1 - 64.0	43	51.10	1.35	2.6	51.0	47.0 - 55.2
Orphee Mythic 22	10	57.16	2.78	4.9	58.0	48.8 - 65.6	10	46.55	1.22	2.6	46.5	42.9 - 50.2
Specimen CL-8							Specimen CL-9					
All Method	61	61.26	1.49	2.4	61.5	56.7 - 65.8	62	50.51	2.23	4.4	50.4	43.8 - 57.3
All Abbott Cell-Dyn Instruments	51	61.69	0.90	1.5	61.6	58.9 - 64.4	51	51.12	1.71	3.4	50.8	45.9 - 56.3
Abbott Cell-Dyn Ruby	43	61.59	0.87	1.4	61.6	58.9 - 64.2	43	51.31	1.66	3.2	51.0	46.3 - 56.3
Orphee Mythic 22	10	57.58	2.68	4.7	58.5	49.5 - 65.7	10	47.10	1.26	2.7	47.4	43.3 - 50.9
Specimen CL-10												
All Method	62	74.60	1.31	1.8	74.8	70.6 - 78.6						
All Abbott Cell-Dyn Instruments	51	75.02	0.95	1.3	75.0	72.1 - 77.9						
Abbott Cell-Dyn Ruby	42	75.10	0.67	0.9	75.0	73.0 - 77.2						
Orphee Mythic 22	10	70.44	6.94	9.9	72.5	49.6 - 91.3						

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

Specimen CL-6							Specimen CL-7					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	59	27.12	2.66	9.8	28.0	19.1 - 35.1	61	37.25	3.79	10.2	38.5	25.8 - 48.7
All Abbott Cell-Dyn Instruments	50	27.91	0.88	3.1	28.0	25.2 - 30.6	51	38.61	1.89	4.9	39.0	32.9 - 44.3
Abbott Cell-Dyn Ruby	43	28.01	0.72	2.6	28.0	25.8 - 30.2	43	38.42	1.89	4.9	39.0	32.7 - 44.1
Orphee Mythic 22	9	19.57	3.12	15.9	19.2	10.2 - 29.0	9	29.34	3.40	11.6	30.2	19.1 - 39.6
Specimen CL-8							Specimen CL-9					
All Method	60	27.08	2.58	9.5	27.7	19.3 - 34.9	61	36.81	3.95	10.7	38.4	24.9 - 48.7
All Abbott Cell-Dyn Instruments	52	27.64	1.20	4.3	28.0	24.0 - 31.3	51	38.13	2.35	6.1	38.6	31.0 - 45.2
Abbott Cell-Dyn Ruby	44	27.86	1.13	4.1	28.1	24.4 - 31.3	43	38.02	2.44	6.4	38.6	30.7 - 45.4
Orphee Mythic 22	9	19.40	3.11	16.0	18.8	10.0 - 28.8	9	28.99	3.99	13.8	29.2	17.0 - 41.0
Specimen CL-10												
All Method	60	17.61	1.50	8.5	18.0	13.1 - 22.2						
All Abbott Cell-Dyn Instruments	51	18.08	0.84	4.6	18.1	15.5 - 20.7						
Abbott Cell-Dyn Ruby	43	18.07	0.78	4.3	18.1	15.7 - 20.5						
Orphee Mythic 22	9	13.96	1.72	12.3	14.3	8.8 - 19.2						

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

Specimen CL-6							Specimen CL-7					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	62	8.67	4.65	53.6	6.7	0.0 - 22.7	62	8.68	5.44	62.7	6.2	0.0 - 25.0
All Abbott Cell-Dyn Instruments	51	6.72	0.78	11.6	6.6	4.3 - 9.1	51	6.43	1.47	22.9	6.0	2.0 - 10.9
Abbott Cell-Dyn Ruby	43	6.61	0.48	7.3	6.6	5.1 - 8.1	43	6.59	1.44	21.9	6.2	2.2 - 11.0
Orphee Mythic 22	10	19.29	2.49	12.9	19.0	11.8 - 26.8	10	20.59	3.37	16.4	21.0	10.4 - 30.8
Specimen CL-8							Specimen CL-9					
All Method	63	8.44	4.30	50.9	6.7	0.0 - 21.4	62	8.65	4.62	53.4	7.1	0.0 - 22.6
All Abbott Cell-Dyn Instruments	52	6.69	0.72	10.8	6.6	4.5 - 8.9	52	6.90	1.60	23.2	7.0	2.0 - 11.8
Abbott Cell-Dyn Ruby	43	6.59	0.58	8.8	6.6	4.8 - 8.4	44	6.85	1.60	23.4	6.8	2.0 - 11.7
Orphee Mythic 22	10	19.07	2.13	11.2	18.9	12.6 - 25.5	10	20.77	3.20	15.4	19.9	11.1 - 30.4
Specimen CL-10												
All Method	62	5.38	2.61	48.4	4.7	0.0 - 13.3						
All Abbott Cell-Dyn Instruments	49	4.51	0.46	10.2	4.6	3.1 - 5.9						
Abbott Cell-Dyn Ruby	43	4.56	0.33	7.1	4.6	3.5 - 5.6						
Orphee Mythic 22	9	11.93	1.45	12.1	12.3	7.5 - 16.3						

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

Specimen CL-6							Specimen CL-7					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	58	3.57	0.50	13.9	3.7	2.0 - 5.1	60	3.36	0.62	18.5	3.4	1.5 - 5.3
All Abbott Cell-Dyn Instruments	51	3.69	0.25	6.7	3.7	2.9 - 4.5	50	3.46	0.41	11.8	3.4	2.2 - 4.7
Abbott Cell-Dyn Ruby	43	3.69	0.25	6.7	3.7	2.9 - 4.5	42	3.51	0.38	10.9	3.5	2.3 - 4.7
Orphee Mythic 22	9	2.36	1.03	43.8	2.2	0.0 - 5.5	9	2.57	0.95	37.0	2.4	0.0 - 5.5
Specimen CL-8							Specimen CL-9					
All Method	58	3.56	0.60	16.8	3.6	1.7 - 5.4	62	3.22	0.75	23.4	3.4	0.9 - 5.5
All Abbott Cell-Dyn Instruments	50	3.70	0.29	7.8	3.7	2.8 - 4.6	51	3.45	0.46	13.5	3.5	2.0 - 4.9
Abbott Cell-Dyn Ruby	41	3.69	0.30	8.2	3.7	2.7 - 4.6	43	3.47	0.47	13.5	3.5	2.0 - 4.9
Orphee Mythic 22	9	2.38	1.32	55.5	2.3	0.0 - 6.4	9	2.39	0.96	40.3	2.0	0.0 - 5.3
Specimen CL-10												
All Method	59	1.89	0.28	14.7	1.9	1.0 - 2.8						
All Abbott Cell-Dyn Instruments	51	1.95	0.16	8.3	1.9	1.4 - 2.5						
Abbott Cell-Dyn Ruby	42	1.94	0.15	7.9	1.9	1.4 - 2.4						
Orphee Mythic 22	9	1.03	0.53	51.0	1.0	0.0 - 2.7						

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

Specimen CL-6							Specimen CL-7					
<u>Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	60	0.11	0.17	163.6	0.0	0.0 - 0.7	59	0.19	0.26	137.2	0.1	0.0 - 1.0
All Abbott Cell-Dyn Instruments	48	0.03	0.06	199.8	0.0	0.0 - 0.3	48	0.12	0.16	133.9	0.1	0.0 - 0.6
Abbott Cell-Dyn Ruby	42	0.02	0.04	181.1	0.0	0.0 - 0.2	40	0.10	0.11	119.1	0.1	0.0 - 0.5
Orphee Mythic 22	10	0.66	0.78	118.3	0.4	0.0 - 3.1	10	0.66	0.96	145.2	0.4	0.0 - 3.6
Specimen CL-8							Specimen CL-9					
All Method	60	0.12	0.17	148.3	0.0	0.0 - 0.7	60	0.22	0.25	113.1	0.1	0.0 - 1.0
All Abbott Cell-Dyn Instruments	49	0.05	0.08	162.1	0.0	0.0 - 0.3	51	0.19	0.25	130.6	0.1	0.0 - 1.0
Abbott Cell-Dyn Ruby	41	0.03	0.06	178.9	0.0	0.0 - 0.3	43	0.19	0.24	127.0	0.1	0.0 - 1.0
Orphee Mythic 22	10	0.69	0.78	112.4	0.5	0.0 - 3.1	10	0.69	0.97	140.3	0.4	0.0 - 3.6
Specimen CL-10												
All Method	61	0.34	0.19	55.2	0.3	0.0 - 0.9						
All Abbott Cell-Dyn Instruments	51	0.31	0.16	51.9	0.3	0.0 - 0.8						
Abbott Cell-Dyn Ruby	42	0.32	0.15	47.9	0.3	0.0 - 0.8						
Orphee Mythic 22	10	0.59	0.48	80.9	0.5	0.0 - 2.1						

BLOOD BANK
ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-6	Group A	137	99.28%	Acceptable
	Group O	1	0.72%	
BB-7	Group B	138	100%	Acceptable
BB-8	Group O	137	100%	Acceptable
BB-9	Group A	136	99.27%	Acceptable
	Group O	1	0.73%	
BB-10	Group O	138	100%	Acceptable

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-6	Rh Positive	136	99.27%	Acceptable
	Rh Negative	1	0.74%	
BB-7	Rh Negative	134	97.81%	Acceptable
	Rh Positive	3	2.19%	
BB-8	Rh Positive	135	99.26%	Acceptable
	Rh Negative	1	0.74%	
BB-9	Rh Negative	135	99.26%	Acceptable
	Rh Positive	1	0.74%	
BB-10	Rh Negative	136	99.27%	Acceptable
	Rh Positive	1	0.73%	

BLOOD BANK

UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	Unexpected antibody detected	108	95.58%	Acceptable
	No unexpected antibody detected	5	4.42%	
AB-7	No unexpected antibody detected	109	96.46%	Acceptable
	Unexpected antibody detected	4	3.54%	
AB-8	No unexpected antibody detected	111	98.23%	Acceptable
	Unexpected antibody detected	2	1.77%	
AB-9	No unexpected antibody detected	109	97.32%	Acceptable
	Unexpected antibody detected	3	2.68%	
AB-10	Unexpected antibody detected	111	98.23%	Acceptable
	No unexpected antibody detected	2	1.77%	

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	Anti-E	48	94.12%	Acceptable
	Anti-K	1	1.96%	
	Other antibody not listed	1	1.96%	
	Anti-D	1	1.96%	
AB-7	No antibody detected	50	100%	Acceptable
AB-8	No antibody detected	50	100%	Acceptable
AB-9	No antibody detected	50	100%	Acceptable
AB-10	Anti-D	47	92.16%	Acceptable
	Anti-E	1	1.96%	
	Anti-Fy(b)	1	1.96%	
	Anti-Le(b)	1	1.96%	
	Unable to identify referred	1	1.96%	

Specimens AB-6 and AB-10 were graded by 100% referee consensus.

BLOOD BANK

COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	Compatible	101	96.19%	Acceptable
	Not Compatible	4	3.81%	
AB-7	Compatible	101	97.12%	Acceptable
	Not Compatible	3	2.88%	
AB-8	Compatible	102	98.08%	Acceptable
	Not Compatible	2	1.92%	
AB-9	Compatible	98	94.23%	Acceptable
	Not Compatible	6	5.77%	
AB-10	Not Compatible	101	97.12%	Acceptable
	Compatible	3	2.88%	

Specimen AB-9 was graded by 100% referee consensus.

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	108	30.20	5.59	18.5	30.7	25.6 - 34.8	101	55.07	11.75	21.3	54.3	46.8 - 63.4
Dade Innovin												
Dade Behring BFT II	5	26.40	1.59	6.0	25.9	22.4 - 30.4	5	49.84	1.61	3.2	49.3	42.3 - 57.4
Sysmex CA-500/600 series	22	25.50	1.18	4.6	25.4	21.6 - 29.4	22	45.79	2.76	6.0	45.6	38.9 - 52.7
All Coagulation Instruments	31	25.54	1.32	5.2	25.5	21.7 - 29.4	32	46.28	2.94	6.3	46.2	39.3 - 53.3
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STA Compact	4	31.78	1.30	4.1	31.8	27.0 - 36.6	4	55.50	5.65	10.2	56.8	47.1 - 63.9
Diagnostica Stago STart 4/8	6	33.37	3.64	10.9	34.2	28.3 - 38.4	4	71.53	7.51	10.5	71.8	60.7 - 82.3
RAL Clot-SP	18	34.06	1.39	4.1	34.0	28.9 - 39.2	18	64.44	2.33	3.6	64.5	54.7 - 74.2
All Coagulation Instruments	33	33.63	1.97	5.9	33.8	28.5 - 38.7	32	65.17	5.98	9.2	64.7	55.3 - 75.0
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	28.78	2.12	7.4	29.2	24.4 - 33.2	6	53.92	4.18	7.7	54.1	45.8 - 62.1
IL TEST PT Fibrinogen												
IL ACL, all models	6	21.43	0.71	3.3	21.6	18.2 - 24.7	6	35.42	1.89	5.3	35.3	30.1 - 40.8
IL TEST PT-FIB HS PLUS												
IL ACL, all models	17	35.29	3.07	8.7	35.1	29.9 - 40.6	12	62.27	6.12	9.8	64.7	52.9 - 71.7

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-8						Specimen CG-9					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	110	12.14	1.55	12.8	12.5	10.3 - 14.0	108	11.83	1.61	13.6	11.9	10.0 - 13.7
Dade Innovin												
Dade Behring BFT II	5	9.70	0.51	5.3	9.6	8.2 - 11.2	5	8.92	0.66	7.4	8.8	7.5 - 10.3
Sysmex CA-500/600 series	23	10.57	0.26	2.5	10.6	8.9 - 12.2	22	10.23	0.22	2.2	10.3	8.6 - 11.8
All Coagulation Instruments	32	10.43	0.47	4.5	10.6	8.8 - 12.0	32	9.99	0.65	6.5	10.3	8.4 - 11.5
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STA Compact	4	12.90	0.42	3.3	12.9	10.9 - 14.9	3	-	-	-	12.5	11.1 - 15.1
Diagnostica Stago STart 4/8	6	12.68	0.60	4.7	12.9	10.7 - 14.6	6	12.53	0.73	5.9	12.5	10.6 - 14.5
RAL Clot-SP	17	13.43	0.32	2.4	13.4	11.4 - 15.5	18	13.42	0.46	3.4	13.3	11.4 - 15.5
All Coagulation Instruments	33	13.20	0.61	4.6	13.2	11.2 - 15.2	32	13.10	0.73	5.6	13.2	11.1 - 15.1
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	11.22	0.31	2.7	11.3	9.5 - 12.9	6	11.18	0.13	1.2	11.2	9.5 - 12.9
IL TEST PT Fibrinogen												
IL ACL, all models	6	11.78	1.08	9.1	11.4	10.0 - 13.6	6	11.13	0.65	5.8	11.0	9.4 - 12.9
IL TEST PT-FIB HS PLUS												
IL ACL, all models	17	13.34	0.85	6.4	13.2	11.3 - 15.4	16	12.78	0.50	3.9	12.7	10.8 - 14.7

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	108	13.68	1.40	10.2	13.5	11.6 - 15.8
Dade Innovin						
Dade Behring BFT II	5	11.92	0.37	3.1	11.9	10.1 - 13.8
Sysmex CA-500/600 series	22	12.58	0.36	2.8	12.7	10.6 - 14.5
All Coagulation Instruments	32	12.41	0.58	4.7	12.6	10.5 - 14.3
Diag Stago STA Neoplastine Cl+						
Diagnostica Stago STA Compact	4	14.10	0.62	4.4	14.1	11.9 - 16.3
Diagnostica Stago STart 4/8	6	13.82	0.80	5.8	14.0	11.7 - 15.9
RAL Clot-SP	18	14.94	0.40	2.7	15.0	12.6 - 17.2
All Coagulation Instruments	33	14.56	0.70	4.8	14.7	12.3 - 16.8
HemosIL RecombiPlasTin 2G						
IL ACL, all models	6	12.57	0.42	3.3	12.7	10.6 - 14.5
IL TEST PT Fibrinogen						
IL ACL, all models	6	13.08	0.97	7.4	12.9	11.1 - 15.1
IL TEST PT-FIB HS PLUS						
IL ACL, all models	17	14.54	1.10	7.5	14.8	12.3 - 16.8

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	106	2.84	0.48	17.0	2.8	2.2 - 3.5	101	5.85	1.75	29.8	5.4	4.6 - 7.1
Dade Innovin												
Dade Behring BFT II	5	2.52	0.04	1.8	2.5	2.0 - 3.1	5	4.30	0.19	4.4	4.3	3.4 - 5.2
Sysmex CA-500/600 series	22	2.47	0.15	6.2	2.5	1.9 - 3.0	22	4.37	0.30	6.9	4.4	3.4 - 5.3
All Coagulation Instruments	32	2.45	0.17	7.0	2.5	1.9 - 3.0	32	4.33	0.30	6.9	4.4	3.4 - 5.3
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STA Compact	4	3.03	0.51	16.7	3.1	2.4 - 3.7	3	-	-	-	7.0	5.9 - 9.0
Diagnostica Stago STart 4/8	7	3.24	0.55	17.0	3.2	2.5 - 3.9	5	8.30	1.27	15.3	8.0	6.6 - 10.0
RAL Clot-SP	17	3.38	0.30	9.0	3.3	2.7 - 4.1	17	7.72	0.53	6.9	7.7	6.1 - 9.3
All Coagulation Instruments	31	3.28	0.39	12.0	3.3	2.6 - 4.0	29	7.85	0.94	12.0	7.9	6.2 - 9.5
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	2.62	0.32	12.2	2.7	2.0 - 3.2	6	5.05	0.67	13.3	5.2	4.0 - 6.1
IL TEST PT Fibrinogen												
IL ACL, all models	6	2.82	0.51	18.2	3.0	2.2 - 3.4	6	6.72	1.07	16.0	6.9	5.3 - 8.1
IL TEST PT-FIB HS PLUS												
IL ACL, all models	17	2.97	0.37	12.5	2.8	2.3 - 3.6	13	5.68	1.50	26.3	5.4	4.5 - 6.9

PROTHROMBIN TIME-INTERNATIONAL NORMALIZED RATIO (INR)

<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	108	1.00	0.11	10.6	1.0	0.7 - 1.2	104	0.97	0.09	9.5	1.0	0.7 - 1.2
Dade Innovin												
Dade Behring BFT II	5	1.08	0.04	4.1	1.1	0.8 - 1.3	5	1.00	0.01	0.0	1.0	0.8 - 1.2
Sysmex CA-500/600 series	23	1.04	0.06	5.7	1.0	0.8 - 1.3	22	1.00	0.05	4.8	1.0	0.8 - 1.3
All Coagulation Instruments	33	1.05	0.06	5.4	1.1	0.8 - 1.3	32	1.01	0.04	4.3	1.0	0.8 - 1.3
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STA Compact	4	0.93	0.10	10.4	1.0	0.7 - 1.2	3	-	-	-	1.0	0.7 - 1.2
Diagnostica Stago STart 4/8	7	0.93	0.10	10.2	0.9	0.7 - 1.2	7	0.93	0.11	12.0	0.9	0.7 - 1.2
RAL Clot-SP	17	1.01	0.07	6.5	1.0	0.8 - 1.3	17	1.00	0.08	7.9	1.0	0.8 - 1.2
All Coagulation Instruments	31	0.97	0.09	8.8	1.0	0.7 - 1.2	30	0.97	0.10	10.2	1.0	0.7 - 1.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	0.93	0.08	8.7	1.0	0.7 - 1.2	6	0.97	0.08	8.4	1.0	0.7 - 1.2
IL TEST PT Fibrinogen												
IL ACL, all models	6	0.98	0.15	15.0	1.0	0.7 - 1.2	6	0.90	0.15	17.2	1.0	0.7 - 1.1
IL TEST PT-FIB HS PLUS												
IL ACL, all models	17	0.96	0.10	10.5	0.9	0.7 - 1.2	17	0.89	0.08	8.8	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	106	1.14	0.13	11.8	1.2	0.9 - 1.4
Dade Innovin						
Dade Behring BFT II	5	1.28	0.04	3.5	1.3	1.0 - 1.6
Sysmex CA-500/600 series	22	1.23	0.06	4.6	1.2	0.9 - 1.5
All Coagulation Instruments	32	1.23	0.06	5.2	1.2	0.9 - 1.5
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STA Compact	4	1.08	0.15	14.0	1.1	0.8 - 1.3
Diagnostica Stago STart 4/8	7	1.04	0.11	10.9	1.1	0.8 - 1.3
RAL Clot-SP	17	1.13	0.06	5.2	1.1	0.9 - 1.4
All Coagulation Instruments	31	1.10	0.10	8.9	1.1	0.8 - 1.4
HemosIL RecombiPlasTin 2G						
IL ACL, all models	6	1.10	0.11	10.0	1.1	0.8 - 1.4
IL TEST PT Fibrinogen						
IL ACL, all models	6	1.18	0.19	16.4	1.3	0.9 - 1.5
IL TEST PT-FIB HS PLUS						
IL ACL, all models	17	1.06	0.14	13.0	1.0	0.8 - 1.3

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	60	53.8	9.8	18.3	51	45 - 62	59	75.9	14.0	18.4	72	64 - 88
Dade Actin												
All Coagulation Instruments	3	72.7	9.6	13.2	71	61 - 84	3	114.7	15.5	13.5	110	97 - 132
Dade Actin FSL												
Sysmex CA-500/600 series	8	49.8	1.0	2.1	50	42 - 58	8	70.9	2.2	3.1	71	60 - 82
All Coagulation Instruments	10	50.3	1.6	3.3	50	42 - 58	10	71.3	2.9	4.0	71	60 - 82
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	4	52.5	2.6	5.0	52	44 - 61	4	74.0	1.4	1.9	75	62 - 86
Diagnostica Stago STart 4/8	4	51.5	5.8	11.3	51	43 - 60	4	68.3	10.1	14.9	68	58 - 79
All Coagulation Instruments	11	56.2	8.9	15.8	53	47 - 65	11	75.5	16.0	21.2	74	64 - 87
Diagnostica Stago STA-PTT												
All Coagulation Instruments	2	-	-	-	53	45 - 61	3	74.3	3.1	4.1	75	63 - 86
Hemoliance SynthASil												
IL ACL, all models	4	65.5	2.1	3.2	66	55 - 76	4	90.8	4.9	5.4	89	77 - 105
IL TEST APTT-SP												
IL ACL, all models	23	47.5	4.6	9.6	48	40 - 55	22	69.9	3.4	4.9	70	59 - 81

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

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	63	29.3	3.3	11.2	29	24 - 34	60	28.9	2.9	10.1	28	24 - 34
Dade Actin												
All Coagulation Instruments	3	29.0	2.6	9.1	28	24 - 34	3	30.7	2.1	6.8	30	26 - 36
Dade Actin FSL												
Sysmex CA-500/600 series	8	25.6	0.7	2.9	26	21 - 30	8	25.9	0.8	3.2	26	21 - 30
All Coagulation Instruments	10	26.1	1.2	4.6	26	22 - 31	10	26.3	1.2	4.4	26	22 - 31
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	4	30.5	1.3	4.2	31	25 - 36	4	31.0	1.8	5.9	31	26 - 36
Diagnostica Stago STart 4/8	4	27.8	5.4	19.6	30	23 - 32	3	29.7	2.5	8.5	30	25 - 35
All Coagulation Instruments	11	29.6	3.4	11.6	31	25 - 35	10	31.0	2.5	8.2	31	26 - 36
Diagnostica Stago STA-PTT												
All Coagulation Instruments	3	31.3	1.2	3.7	32	26 - 37	3	30.7	0.6	1.9	31	26 - 36
Hemoliance SynthASil												
IL ACL, all models	4	30.3	1.5	5.0	30	25 - 35	4	28.5	2.1	7.3	29	24 - 33
IL TEST APTT-SP												
IL ACL, all models	23	28.4	1.6	5.6	28	24 - 33	23	27.4	1.3	4.9	27	23 - 32
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	62	32.5	3.4	10.4	33	27 - 38						
Dade Actin												
All Coagulation Instruments	3	34.0	2.6	7.8	33	28 - 40						
Dade Actin FSL												
Sysmex CA-500/600 series	8	26.4	0.7	2.8	26	22 - 31						
All Coagulation Instruments	10	26.9	1.3	4.8	26	22 - 31						
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STA Compact	4	34.5	1.3	3.7	35	29 - 40						
Diagnostica Stago STart 4/8	4	32.5	1.7	5.3	33	27 - 38						
All Coagulation Instruments	11	33.7	2.4	7.2	33	28 - 39						
Diagnostica Stago STA-PTT												
All Coagulation Instruments	3	34.0	0.1	0.0	34	28 - 40						
Hemoliance SynthASil												
IL ACL, all models	4	33.5	2.5	7.5	33	28 - 39						
IL TEST APTT-SP												
IL ACL, all models	23	32.6	1.6	4.9	33	27 - 38						

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	28	352.0	70.9	20.2	344	281 - 423	29	324.9	109.2	33.6	305	259 - 390
Dade Thrombin												
All Coagulation Instruments	3	236.7	37.2	15.7	226	189 - 285	3	221.7	28.7	13.0	212	177 - 267
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	3	312.3	6.1	2.0	311	249 - 375	4	295.0	12.8	4.3	296	236 - 354
All Coagulation Instruments	5	321.4	17.8	5.5	318	257 - 386	6	288.2	18.3	6.3	289	230 - 346
IL Fibrinogen-C												
All Coagulation Instruments	2	-	-	-	334	266 - 401	3	296.0	12.5	4.2	292	236 - 356
IL TEST PT-FIB HS PLUS												
IL ACL, all models	12	399.3	44.5	11.2	417	319 - 480	11	423.8	69.4	16.4	411	339 - 509
IL TEST PT-FIB Recombinant												
IL ACL, all models	3	403.3	79.7	19.8	439	322 - 484	2	-	-	-	351	259 - 390
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	33	301.7	45.5	15.1	298	241 - 363	33	528.3	91.4	17.3	534	422 - 634
Dade Thrombin												
All Coagulation Instruments	3	232.0	19.1	8.2	222	185 - 279	3	360.7	80.1	22.2	364	288 - 433
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	4	268.0	27.4	10.2	273	214 - 322	4	486.8	35.5	7.3	483	389 - 585
All Coagulation Instruments	6	275.8	25.3	9.2	281	220 - 331	6	484.5	47.5	9.8	483	387 - 582
IL Fibrinogen-C												
All Coagulation Instruments	3	319.0	23.5	7.4	318	255 - 383	3	611.3	72.0	11.8	610	489 - 734
IL TEST PT-FIB HS PLUS												
IL ACL, all models	15	319.8	38.5	12.0	312	255 - 384	15	560.9	53.5	9.5	558	448 - 674
IL TEST PT-FIB Recombinant												
IL ACL, all models	3	357.3	17.0	4.8	364	285 - 429	3	612.3	86.0	14.0	644	489 - 735
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	29	130.7	25.8	19.8	127	104 - 157						
Dade Thrombin												
All Coagulation Instruments	3	98.7	13.3	13.5	102	78 - 119						
Diagnostica Stago STA Fibrinogen												
Diagnostica Stago STA Compact	4	127.0	5.0	3.9	126	101 - 153						
All Coagulation Instruments	6	125.0	7.1	5.7	126	100 - 150						
IL Fibrinogen-C												
All Coagulation Instruments	3	129.7	13.1	10.1	134	103 - 156						
IL TEST PT-FIB HS PLUS												
IL ACL, all models	11	142.9	24.5	17.2	137	114 - 172						
IL TEST PT-FIB Recombinant												
IL ACL, all models	3	157.0	30.5	19.4	166	125 - 189						

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	386	1.0167	0.0072	0.7	1.020	1.006 - 1.027
All Roche Methods	142	1.0114	0.0064	0.6	1.010	1.001 - 1.022
All Siemens Methods	44	1.0239	0.0021	0.2	1.025	1.013 - 1.034
77 Elektronika LabUMat/2	10	1.0220	0.0044	0.4	1.023	1.012 - 1.032
Arkray Aution Sticks	14	1.0170	0.0039	0.4	1.015	1.007 - 1.027
Combi-Screen Test Strips	11	1.0141	0.0030	0.3	1.015	1.004 - 1.025
DIRUI H-100 / H-500 Urine Analyzer	19	1.0213	0.0041	0.4	1.020	1.011 - 1.032
Other Analyzer Method	12	1.0204	0.0055	0.5	1.022	1.010 - 1.031
Roche Chemstrips / Combur	18	1.0075	0.0025	0.3	1.008	0.997 - 1.018
Roche cobas u 411	83	1.0093	0.0031	0.3	1.010	0.999 - 1.020
Roche Urisys	57	1.0144	0.0083	0.8	1.010	1.004 - 1.025
SD UroColor Reagent Strips	17	1.0197	0.0041	0.4	1.020	1.009 - 1.030
Siemens Clinitek Advantus	33	1.0236	0.0023	0.2	1.025	1.013 - 1.034
UriScan Reagent Strips	31	1.0234	0.0033	0.3	1.025	1.013 - 1.034

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	406	-	-	-	4	1	3	63	270	57	8	-	-
77 Elektronika LabUMat/2	9	-	-	-	-	-	-	8	1	-	-	-	-
Acon Laboratories	7	-	-	-	-	-	-	-	5	-	2	-	-
Analyticon CombiScan 500	3	-	-	-	-	-	-	-	3	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	1	1	-	-	-
Arkray Aution Sticks	15	-	-	-	-	-	-	-	10	5	-	-	-
Arkray PocketChem UA	2	-	-	-	-	-	-	-	1	1	-	-	-
Combi-Screen Test Strips	11	-	-	-	-	-	-	6	5	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	20	-	-	-	2	-	1	7	6	4	-	-	-
DIRUI H-800 Urine Analyzer	7	-	-	-	-	-	-	2	5	-	-	-	-
HUMAN Combilyzer	1	-	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	-	1	-	-	-
Iris Diagnostics iChem Velocity Strips	8	-	-	-	-	-	-	7	1	-	-	-	-
Other Analyzer Method	12	-	-	-	-	-	-	7	3	2	-	-	-
Other Dipstick Method	3	-	-	-	-	-	-	1	1	1	-	-	-
Plasmatec URIPATH	2	-	-	-	-	-	-	-	2	-	-	-	-
Roche Chemstrips / Combur	20	-	-	-	-	-	-	-	14	4	2	-	-
Roche cobas 6500 / u 601	2	-	-	-	-	-	-	-	2	-	-	-	-
Roche cobas u 411	88	-	-	-	2	-	1	-	84	-	1	-	-
Roche Mditron Junior/II	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche Urilux S	2	-	-	-	-	-	-	-	2	-	-	-	-
Roche Urisys	57	-	-	-	-	-	-	1	55	-	1	-	-
SD UroColor Reagent Strips	18	-	-	-	-	1	-	6	7	4	-	-	-
Siemens Clinitek 500	2	-	-	-	-	-	-	-	1	1	-	-	-
Siemens Clinitek Advantus	33	-	-	-	-	-	-	-	13	20	-	-	-
Siemens Clinitek Atlas	5	-	-	-	-	-	-	-	4	1	-	-	-
Siemens Clinitek Status / Status+	7	-	-	-	-	-	-	1	6	-	-	-	-
Siemens Multistix Pro	1	-	-	-	-	-	-	-	1	-	-	-	-
Siemens Reagent Strips	15	-	-	-	-	-	-	-	5	10	-	-	-
Urinometer	2	-	-	-	-	-	-	-	2	-	-	-	-
UriScan Pro/II	9	-	-	-	-	-	-	5	4	-	-	-	-
UriScan Reagent Strips	33	-	-	-	-	-	1	12	19	1	-	-	-
URIT Medical Uritest 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	406	2	-	6	73	108	8	2	7	1	146	50	3
77 Elektronika LabUMat/2	10	1	-	-	4	1	-	-	-	-	4	-	-
Acon Laboratories	7	-	-	-	4	2	1	-	-	-	-	-	-
Analyticon CombiScan 500	3	-	-	-	-	-	-	-	-	-	3	-	-
Arkray Aution Jet	2	1	-	-	-	1	-	-	-	-	-	-	-
Arkray Aution Sticks	16	-	-	-	2	7	-	-	-	-	2	5	-
Arkray PocketChem UA	1	-	-	-	-	1	-	-	-	-	-	-	-
Combi-Screen Test Strips	11	-	-	-	1	1	-	-	-	-	-	9	-
DIRUI H-100 / H-500 Urine Analyzer	21	-	-	-	2	14	-	-	-	-	2	3	-
DIRUI H-800 Urine Analyzer	6	-	-	-	-	5	-	-	-	-	-	1	-
HUMAN Combilyzer	1	-	-	-	-	-	-	-	-	-	1	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	1	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	-	-	4	-	-	-	-	4	-	-	-	-
Other Analyzer Method	13	-	-	-	-	4	-	-	-	-	6	2	1
Other Dipstick Method	4	-	-	-	1	-	-	1	-	-	1	1	-
Plasmatec URIPATH	2	-	-	-	2	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	21	-	-	1	4	11	-	-	1	-	4	-	-
Roche cobas 6500 / u 601	2	-	-	-	-	-	-	-	-	-	2	-	-
Roche cobas u 411	87	-	-	-	3	8	2	-	1	1	66	6	-
Roche Miditron Junior/II	1	-	-	-	-	-	-	-	-	-	1	-	-
Roche Urilux S	2	-	-	-	-	2	-	-	-	-	-	-	-
Roche Urisys	56	-	-	-	4	9	1	-	-	-	33	9	-
SD UroColor Reagent Strips	18	-	-	-	11	3	-	-	1	-	2	1	-
Siemens Clinitek 500	2	-	-	-	1	-	-	-	-	-	1	-	-
Siemens Clinitek Advantus	33	-	-	-	14	8	-	-	-	-	6	5	-
Siemens Clinitek Atlas	5	-	-	-	-	3	-	-	-	-	1	1	-
Siemens Clinitek Status / Status+	7	-	-	-	-	6	-	-	-	-	-	1	-
Siemens Multistix Pro	1	-	-	-	-	-	-	-	-	-	1	-	-
Siemens Reagent Strips	14	-	-	-	4	9	-	-	-	-	-	1	-
Urinometer	2	-	-	-	2	-	-	-	-	-	-	-	-
UriScan Pro/II	9	-	-	1	1	-	1	-	-	-	3	2	1
UriScan Reagent Strips	33	-	-	-	13	9	3	1	-	-	5	1	1
URIT Medical Uritest Reagent Strips	1	-	-	-	-	1	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-2

<u>Method</u>	<u>Labs</u>	<u>Negative</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	408	2	-	7	49	80	54	6	35	45	130
77 Elektronika LabUMat/2	10	-	-	-	-	4	2	-	-	3	1
Acon Laboratories	7	-	-	-	3	-	3	-	1	-	-
Analyticon CombiScan 500	3	-	-	-	-	-	-	-	-	3	-
Arkray Aution Jet	2	-	-	-	-	2	-	-	-	-	-
Arkray Aution Sticks	16	-	-	-	-	9	-	-	4	1	2
Arkray PocketChem UA	2	-	-	-	-	1	-	-	1	-	-
Combi-Screen Test Strips	10	-	-	-	1	-	1	-	-	3	5
DIRUI H-100 / H-500 Urine Analyzer	21	-	-	1	1	12	-	-	-	5	2
DIRUI H-800 Urine Analyzer	6	-	-	-	2	3	-	-	1	-	-
HUMAN Combilyzer	1	-	-	-	-	-	-	-	-	-	1
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	1	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	-	-	1	1	-	-	5	1	-	-
Other Analyzer Method	13	-	-	-	-	4	-	-	1	7	1
Other Dipstick Method	4	-	-	-	-	1	-	-	-	1	2
Plasmatec URIPATH	2	-	-	-	1	1	-	-	-	-	-
Roche Chemstrips / Combur	20	-	-	-	-	1	14	-	-	-	5
Roche cobas 6500 / u 601	2	-	-	-	-	-	-	-	2	-	-
Roche cobas u 411	89	2	-	-	-	1	11	-	8	1	66
Roche Mditron Junior/II	1	-	-	-	-	-	-	-	-	-	1
Roche Urilux S	2	-	-	-	-	-	2	-	-	-	-
Roche Urisys	57	-	-	-	-	7	8	1	12	1	28
SD UroColor Reagent Strips	18	-	-	-	3	6	4	-	-	3	2
Siemens Clinitek 500	2	-	-	1	-	-	-	-	-	1	-
Siemens Clinitek Advantus	33	-	-	-	19	3	-	-	1	10	-
Siemens Clinitek Atlas	5	-	-	-	1	1	1	-	1	1	-
Siemens Clinitek Status / Status+	7	-	-	1	3	2	-	-	-	1	-
Siemens Multistix Pro	1	-	-	-	-	-	-	-	-	-	1
Siemens Reagent Strips	15	-	-	3	6	4	1	-	-	-	1
Urinometer	2	-	-	-	1	-	1	-	-	-	-
UriScan Pro/II	9	-	-	-	-	2	1	-	-	-	6
UriScan Reagent Strips	32	-	-	-	5	14	5	-	2	2	4
URIT Medical Uritest Reagent Strips	1	-	-	-	1	-	-	-	-	-	-

URINALYSIS DIPSTICK–KETONES

Specimen UA-2

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>Participant Results</u>								
							(1+)	(2+)	(3+)	(4+)	<u>5 - 10</u> <u>mg/dL</u>	<u>15 - 20</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	408	17	6	1	-	-	53	95	29	1	12	41	139	12	2
77 Elektronika LabUMat/2	9	1	-	-	-	-	4	-	1	-	-	2	1	-	-
Acon Laboratories	7	2	-	-	-	-	-	4	-	-	-	1	-	-	-
Analyticon CombiScan 500	3	-	-	-	-	-	-	-	-	-	-	1	-	2	-
Arkray Aution Jet	2	-	-	-	-	-	-	2	-	-	-	-	-	-	-
Arkray Aution Sticks	16	2	-	-	-	-	4	3	-	-	-	4	3	-	-
Arkray PocketChem UA	2	-	-	-	-	-	-	1	-	-	-	-	1	-	-
Combi-Screen Test Strips	11	-	-	-	-	-	2	1	-	-	-	-	-	8	-
DIRUI H-100 / H-500 Urine Analyzer	21	-	-	-	-	-	11	4	-	-	-	3	3	-	-
DIRUI H-800 Urine Analyzer	6	-	2	-	-	-	-	3	-	-	1	-	-	-	-
HUMAN Combilyzer	1	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	8	-	-	-	-	-	1	1	-	-	-	4	2	-	-
Other Analyzer Method	14	1	-	-	-	-	5	-	1	-	1	4	2	-	-
Other Dipstick Method	4	1	-	-	-	-	-	1	1	-	1	-	-	-	-
Plasmatec URIPATH	2	1	-	-	-	-	-	1	-	-	-	-	-	-	-
Roche Chemstrips / Combur	20	-	3	-	-	-	2	8	2	-	-	-	5	-	-
Roche cobas 6500 / u 601	2	-	-	-	-	-	-	-	-	-	-	-	2	-	-
Roche cobas u 411	89	1	-	-	-	-	2	2	9	-	1	3	69	-	2
Roche Miditron Junior/II	1	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Roche Urilux S	2	-	-	-	-	-	1	-	1	-	-	-	-	-	-
Roche Urisys	56	1	-	-	-	-	1	9	5	-	-	6	34	-	-
SD UroColor Reagent Strips	18	1	-	-	-	-	2	11	-	-	2	-	2	-	-
Siemens Clinitek 500	2	-	-	-	-	-	1	-	-	-	-	1	-	-	-
Siemens Clinitek Advantus	33	1	-	1	-	-	12	8	-	-	-	9	2	-	-
Siemens Clinitek Atlas	5	-	-	-	-	-	-	4	-	-	-	-	-	1	-
Siemens Clinitek Status / Status+	6	2	-	-	-	-	-	2	1	-	-	-	1	-	-
Siemens Multistix Pro	1	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Siemens Reagent Strips	14	-	-	-	-	-	-	7	6	-	-	-	1	-	-
Urinometer	2	-	-	-	-	-	-	2	-	-	-	-	-	-	-
UriScan Pro/II	9	1	-	-	-	-	1	1	-	-	2	-	3	1	-
UriScan Reagent Strips	33	2	-	-	-	-	2	18	2	1	2	1	5	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–BILIRUBIN

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>0.5 - 1.0</u> <u>mg/dL</u>	<u>2.0 - 4.0</u> <u>mg/dL</u>	<u>6.0 - 10.0</u> <u>mg/dL</u>	<u>>10.0</u> <u>mg/dL</u>
ALL METHODS	396	58	-	-	15	-	34	62	60	2	21	17	127	-
77 Elektronika LabUMat/2	8	2	-	-	-	-	-	-	3	-	1	-	2	-
Acon Laboratories	7	1	-	-	-	-	-	4	2	-	-	-	-	-
Analyticon CombiScan 500	4	-	-	-	-	-	-	-	-	1	-	3	-	-
Arkray Aution Jet	2	-	-	-	-	-	2	-	-	-	-	-	-	-
Arkray Aution Sticks	16	-	-	-	-	-	7	3	-	-	5	-	1	-
Arkray PocketChem UA	2	-	-	-	-	-	1	-	-	-	1	-	-	-
Combi-Screen Test Strips	10	-	-	-	-	-	1	-	2	1	-	6	-	-
DIRUI H-100 / H-500 Urine Analyzer	21	2	-	-	-	-	12	1	1	-	4	1	-	-
DIRUI H-800 Urine Analyzer	6	-	-	-	-	-	1	4	-	-	-	1	-	-
HUMAN Combilyzer	1	-	-	-	-	-	-	-	-	-	1	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	1	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	9	9	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	14	1	-	-	-	-	2	4	2	-	2	-	3	-
Other Dipstick Method	4	-	-	-	-	-	-	-	2	-	1	-	1	-
Plasmatec URIPATH	2	-	-	-	-	-	-	2	-	-	-	-	-	-
Roche Chemstrips / Combur	19	-	-	-	-	-	-	2	13	-	-	-	4	-
Roche cobas 6500 / u 601	2	-	-	-	-	-	-	-	-	-	-	-	2	-
Roche cobas u 411	89	3	-	-	-	-	-	3	9	-	-	1	73	-
Roche Mditron Junior/II	1	-	-	-	-	-	-	-	-	-	-	-	1	-
Roche Urilux S	2	-	-	-	-	-	-	1	1	-	-	-	-	-
Roche Urisys	57	-	-	-	-	-	-	1	14	-	-	3	39	-
SD UroColor Reagent Strips	17	2	-	-	-	-	1	7	2	-	3	1	1	-
Siemens Clinitek 500	2	-	-	-	1	-	-	1	-	-	-	-	-	-
Siemens Clinitek Advantus	33	1	-	-	11	-	-	20	1	-	-	-	-	-
Siemens Clinitek Atlas	5	-	-	-	1	-	2	-	1	-	-	1	-	-
Siemens Clinitek Status / Status+	7	-	-	-	2	-	-	3	2	-	-	-	-	-
Siemens Multistix Pro	1	-	-	-	-	-	-	1	-	-	-	-	-	-
Siemens Reagent Strips	4	1	-	-	-	-	-	2	1	-	-	-	-	-
Urinometer	2	1	-	-	-	-	-	1	-	-	-	-	-	-
UriScan Pro/II	9	9	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	32	25	-	-	-	-	3	1	1	-	2	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	-	1	-	-	-	-	-	-

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-2

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Neg or 0.0 - 0.2 mg/dL</u>	<u>1.0 or <2.0 mg/dL</u>	<u>2.0/3.0 mg/dL</u>	<u>4.0 or 4.0/6.0 mg/dL</u>	<u>≥8.0 or ≥12.0 mg/dL</u>
ALL METHODS	395	54	49	55	106	131
77 Elektronika LabUMat/2	10	1	-	-	1	8
Acon Laboratories	7	2	4	1	-	-
Analyticon CombiScan 500	3	-	-	-	-	3
Arkray Aution Jet	2	2	-	-	-	-
Arkray Aution Sticks	15	11	1	2	1	-
Arkray PocketChem UA	2	1	1	-	-	-
Combi-Screen Test Strips	11	1	-	-	-	10
DIRUI H-100 / H-500 Urine Analyzer	21	13	7	-	1	-
DIRUI H-800 Urine Analyzer	6	5	1	-	-	-
HUMAN Combilyzer	1	-	1	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	9	-	-	7	2	-
Other Analyzer Method	13	4	1	-	2	6
Other Dipstick Method	4	-	-	2	-	2
Plasmatec URIPATH	2	-	-	2	-	-
Roche Chemstrips / Combur	19	1	4	3	3	8
Roche cobas 6500 / u 601	2	-	-	-	1	1
Roche cobas u 411	88	2	-	3	33	50
Roche Miditron Junior/II	1	-	-	-	1	-
Roche Urilux S	2	-	-	2	-	-
Roche Urisys	57	-	10	1	29	17
SD UroColor Reagent Strips	18	4	8	-	2	4
Siemens Clinitek 500	2	-	-	1	1	-
Siemens Clinitek Advantus	33	1	5	20	7	-
Siemens Clinitek Atlas	5	-	1	4	-	-
Siemens Clinitek Status / Status+	6	-	-	-	6	-
Siemens Multistix Pro	1	-	1	-	-	-
Siemens Reagent Strips	4	-	-	4	-	-
Urinometer	2	1	-	-	1	-
UriScan Pro/II	9	1	1	-	4	3
UriScan Reagent Strips	32	1	1	3	9	18
URIT Medical Uritest 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>250</u> <u>Ery/μL</u>	<u>± 0.03</u> <u>mg/dL</u>	<u>0.06</u> <u>-</u> <u>0.10</u> <u>mg/</u> <u>dL</u>	<u>0.2 -</u> <u>0.5</u> <u>mg/</u> <u>dL</u>	<u>≥ 1.0</u> <u>mg/</u> <u>dL</u>
ALL METHODS	408	1	-	-	1	2	1	22	146	28	16	-	7	176	1	-	2	5
77 Elektronika LabUMat/2	10	1	-	-	-	-	-	3	4	-	-	-	2	-	-	-	-	-
Acon Laboratories	7	-	-	-	-	-	-	-	7	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	3	-	-	-	-	-	-	-	-	-	-	-	-	3	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	16	-	-	-	-	-	-	3	7	1	-	-	-	1	-	-	2	2
Arkray PocketChem UA	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	11	-	-	-	-	-	-	-	3	1	-	-	-	6	1	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	21	-	-	-	-	-	-	-	15	1	-	-	-	5	-	-	-	-
DIRUI H-800 Urine Analyzer	6	-	-	-	-	-	-	-	5	-	-	-	-	1	-	-	-	-
HUMAN Combilyzer	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	9	-	-	-	-	-	-	4	3	-	-	-	-	-	-	-	-	2
Other Analyzer Method	13	-	-	-	-	-	-	1	9	-	-	-	1	2	-	-	-	-
Other Dipstick Method	4	-	-	-	-	-	-	-	1	-	-	-	-	3	-	-	-	-
Plasmatec URIPATH	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	19	-	-	-	-	-	-	1	3	10	1	-	-	4	-	-	-	-
Roche cobas 6500 / u 601	2	-	-	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-
Roche cobas u 411	89	-	-	-	-	-	-	-	-	-	10	-	2	77	-	-	-	-
Roche Mditron Junior/II	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Roche Urilux S	2	-	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-
Roche Urisys	57	-	-	-	-	-	-	1	-	9	4	-	-	43	-	-	-	-
SD UroColor Reagent Strips	18	-	-	-	-	-	1	2	11	2	-	-	1	1	-	-	-	-
Siemens Clinitek 500	2	-	-	-	-	-	-	-	1	-	-	-	-	1	-	-	-	-
Siemens Clinitek Advantus	33	-	-	-	-	-	-	-	23	1	-	-	-	9	-	-	-	-
Siemens Clinitek Atlas	5	-	-	-	-	1	-	-	2	1	-	-	-	1	-	-	-	-
Siemens Clinitek Status / Status+	6	-	-	-	1	1	-	-	4	-	-	-	-	-	-	-	-	-
Siemens Multistix Pro	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	15	-	-	-	-	-	-	-	14	-	-	-	-	1	-	-	-	-
Urinometer	2	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	-	-
UriScan Pro/II	9	-	-	-	-	-	-	-	4	-	-	-	-	5	-	-	-	-
UriScan Reagent Strips	32	-	-	-	-	-	-	5	19	1	-	-	-	7	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-2

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>											
		<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>25 µL</u>	<u>75 or 100 µL</u>	<u>250 or 500 µL</u>
ALL METHODS	389	1	2	1	2	-	26	55	91	1	1	23	186
77 Elektronika LabUMat/2	10	-	-	-	-	-	-	1	7	-	-	-	2
Acon Laboratories	7	-	-	-	-	-	1	5	1	-	-	-	-
Analyticon CombiScan 500	3	-	-	-	-	-	-	-	-	-	-	1	2
Arkray Aution Jet	1	-	-	-	-	-	-	-	-	-	-	-	1
Arkray Aution Sticks	15	-	-	-	-	-	-	1	-	-	-	1	13
Arkray PocketChem UA	2	-	-	-	-	-	-	-	-	-	-	-	2
Combi-Screen Test Strips	11	-	-	-	-	-	-	1	1	-	-	-	9
DIRUI H-100 / H-500 Urine Analyzer	20	-	2	-	-	-	6	7	1	-	-	4	-
DIRUI H-800 Urine Analyzer	6	-	-	-	-	-	-	-	5	-	-	-	1
HUMAN Combilyzer	1	-	-	-	-	-	-	-	-	-	-	1	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	-	-	-	-	1
Iris Diagnostics iChem Velocity Strips	9	-	-	-	-	-	-	-	7	-	-	-	2
Other Analyzer Method	13	-	-	-	-	-	-	2	3	-	1	-	7
Other Dipstick Method	4	-	-	-	-	-	-	1	-	-	-	-	3
Plasmatec URIPATH	2	-	-	-	-	-	-	-	2	-	-	-	-
Roche Chemstrips / Combur	18	-	-	-	-	-	-	3	10	-	-	-	5
Roche cobas 6500 / u 601	2	-	-	-	-	-	-	-	-	-	-	-	2
Roche cobas u 411	87	-	-	-	-	-	-	-	10	-	-	-	77
Roche Miditron Junior/II	1	-	-	-	-	-	-	-	-	-	-	-	1
Roche Urilux S	2	-	-	-	-	-	-	-	2	-	-	-	-
Roche Urisys	57	-	-	-	-	-	-	1	12	-	-	-	44
SD UroColor Reagent Strips	18	-	-	-	-	-	2	5	7	-	-	4	-
Siemens Clinitek 500	2	-	-	-	-	-	1	-	-	-	-	1	-
Siemens Clinitek Advantus	33	-	-	-	-	-	11	14	1	-	-	7	-
Siemens Clinitek Atlas	5	-	-	-	1	-	-	-	3	-	-	1	-
Siemens Clinitek Status / Status+	6	-	-	1	1	-	1	3	-	-	-	-	-
Siemens Multistix Pro	1	-	-	-	-	-	1	-	-	-	-	-	-
Siemens Reagent Strips	4	-	-	-	-	-	3	-	-	-	-	1	-
Urinometer	2	-	-	-	-	-	-	2	-	-	-	-	-
UriScan Pro/II	9	-	-	-	-	-	-	2	2	-	-	-	5
UriScan Reagent Strips	30	1	-	-	-	-	-	6	16	1	-	1	5
URIT Medical Uritest 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	397	390	7
77 Elektronika LabUMat/2	10	10	-
Acon Laboratories	8	8	-
Analyticon CombiScan 500	3	3	-
Arkray Aution Jet	2	2	-
Arkray Aution Sticks	15	15	-
Arkray PocketChem UA	2	2	-
Combi-Screen Test Strips	11	10	1
DIRUI H-100 / H-500 Urine Analyzer	21	19	2
DIRUI H-800 Urine Analyzer	6	6	-
HUMAN Combilyzer	1	1	-
Iris Diagnostics Aution Max AX-4280	1	1	-
Iris Diagnostics iChem Velocity Strips	9	9	-
Other Analyzer Method	13	13	-
Other Dipstick Method	4	4	-
Plasmatec URIPATH	2	2	-
Roche Chemstrips / Combur	19	19	-
Roche cobas 6500 / u 601	2	2	-
Roche cobas u 411	89	88	1
Roche Mditron Junior/II	1	1	-
Roche Urilux S	2	2	-
Roche Urisys	57	57	-
SD UroColor Reagent Strips	19	18	1
Siemens Clinitek 500	2	2	-
Siemens Clinitek Advantus	33	33	-
Siemens Clinitek Atlas	4	4	-
Siemens Clinitek Status / Status+	6	6	-
Siemens Multistix Pro	1	1	-
Siemens Reagent Strips	3	3	-
Urinometer	2	2	-
UriScan Pro/II	9	9	-
UriScan Reagent Strips	32	30	2
URIT Medical Uritest 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	17	-	1	1	-	1	-	1	9	-	4
Beckman Coulter ICON microALB	1	-	-	-	-	-	-	-	1	-	-
DIRUI H-100 / H-500 Urine Analyzer	2	-	-	-	-	-	-	-	1	-	1
Other Analyzer Method	4	-	-	-	-	-	-	-	1	-	3
Roche Integra	2	-	-	-	-	-	-	-	2	-	-
Roche Micral - 1 minute	2	-	-	1	-	-	-	1	-	-	-
Roche Urisys	1	-	-	-	-	-	-	-	1	-	-
Siemens Clinitek Microalbumin	2	-	-	-	-	-	-	-	2	-	-

URINALYSIS –URINE hCG

Specimen UA-2

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	98	98	-
Acon Laboratories	9	9	-
Alere Acceava hCG-Urine	2	2	-
Alere Clearview hCG Cassette	6	6	-
Biotron 1-Step	7	7	-
CONSULT diagnostics hCG Combo	1	1	-
Other Dipstick Method	3	3	-
Quidel QuickVue One-Step Combo	17	17	-
RefuAH hCG Dipstick	1	1	-
Roche cobas u 411	1	1	-
Stanbio QuStick	1	1	-
Sure-Vue hCG - 25mIU	2	2	-

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen SUS-6

Specimen SUS-6	-----Disk Diffusion-----				-----MIC-----				Acceptable (%)
	Interpretative category data				Interpretative category data				
<u>Antimicrobial</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	45	44	1	-	145	144	-	1	99.02%
Amoxicillin/Clavulanate	47	44	-	3	76	75	1	-	96.75%
Ampicillin	28	2	1	25	104	3	2	99	94.41%
Ampicillin/Sulbactam	27	25	1	1	83	80	-	3	95.87%
Aztreonam	17	16	1	-	50	50	-	-	98.61%
Cefaclor	10	9	-	1	-	-	-	-	90.00%
Cefazolin	9	9	-	-	55	53	-	2	97.10%
Cefepime	37	37	-	-	134	131	-	3	98.35%
Cefixime	25	24	-	1	20	20	-	-	97.78%
Cefoperazone	11	11	-	-	-	-	-	-	100.00%
Cefotaxime	38	35	2	1	73	72	-	1	96.67%
Cefotetan	-	-	-	-	3	3	-	-	100.00%
Cefoxitin	7	7	-	-	61	61	-	-	100.00%
Cefpodoxime	6	6	-	-	2	2	-	-	100.00%
Ceftazidime	43	41	1	1	146	144	-	2	98.03%
Ceftizoxime	3	3	-	-	-	-	-	-	100.00%
Ceftriaxone	44	43	1	-	128	126	-	2	98.38%
Cefuroxime	43	42	1	-	97	97	-	-	99.33%
Cephalexin	5	4	1	-	1	1	-	-	83.33%
Cephalothin	9	7	-	2	44	44	-	-	96.67%
Ciprofloxacin	57	57	-	-	176	175	-	1	99.60%
Ciprofloxacin	69	41	18	10	176	83	86	7	93.33%
Daptomycin	-	-	-	-	1	1	-	-	Inappropriate drug ¹
Doxycycline	6	4	2	-	-	-	-	-	66.67%
Ertapenem	17	17	-	-	122	122	-	-	100.00%
Fosfomycin	9	7	-	2	26	6	-	20	Inappropriate drug ¹
Gentamicin	50	48	1	1	163	162	-	1	98.68%
Imipenem	41	39	1	1	105	105	-	-	98.04%
Kanamycin	1	1	-	-	-	-	-	-	Not graded ²
Levofloxacin	33	33	-	-	54	53	-	1	98.92%

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

² This is an ungraded challenge due to lack of comparison group.

ANTIMICROBIAL SUSCEPTIBILITY TESTING (cont'd)
Specimen SUS-6

Specimen SUS-6					-----Disk Diffusion-----				-----MIC-----				
	Interpretative category data				Interpretative category data								
<u>Antimicrobial</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>	<u>Acceptable (%)</u>				
Linezolid	1	-	-	1	-	-	-	-	Inappropriate drug ¹				
Lomefloxacin	1	1	-	-	-	-	-	-	Not graded ²				
Meropenem	37	36	-	1	130	129	-	1	98.86%				
Minocycline	2	2	-	-	-	-	-	-	Not graded ²				
Moxifloxacin	7	7	-	-	-	-	-	-	Inappropriate drug ¹				
Nalidixic Acid	11	10	1	-	6	5	1	-	89.47%				
Netilmicin	8	8	-	-	1	1	-	-	100.00%				
Nitrofurantoin	42	38	1	3	124	108	15	1	88.20%				
Norfloxacin	21	21	-	-	38	38	-	-	100.00%				
Ofloxacin	22	22	-	-	1	1	-	-	100.00%				
Oxacillin	1	-	-	1	-	-	-	-	Inappropriate drug ¹				
Penicillin	3	-	-	3	1	1	-	-	Inappropriate drug ¹				
Piperacillin	7	5	1	1	14	10	2	2	71.43% ³				
Piperacillin/Tazobactam	37	32	1	4	111	111	-	-	96.15%				
Sulfisoxazole	2	2	-	-	-	-	-	-	Not graded ²				
Teicoplanin	2	-	-	2	-	-	-	-	Inappropriate drug ¹				
Tetracycline	5	5	-	-	11	11	-	-	100.00%				
Ticarcillin/Clavulanate	-	-	-	-	9	8	1	-	90.91%				
Tobramycin	9	7	1	1	38	37	1	-	94.12%				
Trimethoprim	2	2	-	-	2	1	-	1	80.00%				
Trimethoprim/Sulfamethoxazole	49	49	-	-	163	162	-	1	99.56%				
Vancomycin	2	-	-	2	-	-	-	-	Inappropriate drug ¹				

Organism present in specimen SUS-6: *Klebsiella pneumoniae*

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³ This is challenge graded by referee consensus.

PARASITOLOGY (PA Specimens)

Specimen PA-6

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

Parasite present in specimen PA-6: *Chilomastix mesnili*. Specimen PA-6 is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	2	50.00%	Unacceptable
Entamoeba histolytica	1	25.00%	Unacceptable
Iodamoeba butschlii	1	25.00%	Unacceptable

Parasite present in specimen PA-7: *Entamoeba coli*. Specimen PA-7 is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Clonorchis sinensis	5	41.67%	Unacceptable
No parasite seen	4	33.33%	Unacceptable
Ascaris lumbricoides eggs	1	8.33%	Unacceptable
Enterobius vermicularis eggs	1	8.33%	Unacceptable
Taenia sp. eggs	1	8.33%	Unacceptable

Parasite present in specimen PA-8: *Clonorchis sinensis*. Specimen PA-8 is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	12	63.16%	Acceptable
Trichuris trichiura eggs	5	26.32%	Acceptable
Hookworm	1	5.26%	
Strongyloides stercoralis larvae	1	5.26%	

Parasite present in specimen PA-9: *Ascaris lumbricoides* eggs.

Specimen PA-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hymenolepis nana eggs	10	71.43%	Acceptable
Taenia sp. eggs	1	7.14%	
Ascaris lumbricoides eggs	1	7.14%	
Entamoeba coli	1	7.14%	
Hymenolepis diminuta eggs	1	7.14%	

Parasite present in specimen PA-10: *Hymenolepis nana* eggs. (Graded by US consensus)

PARASITOLOGY (FP Specimens)

Specimen FP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Balantidium coli	308	85.95%	Acceptable
Parasite egg seen but no ID	1	0.41%	Acceptable
No parasite seen	12	4.96%	
Ascaris lumbricoides eggs	4	1.65%	
Taenia sp. eggs	2	0.85%	
Blastocystis hominis	2	0.85%	
Cryptosporidium sp., oocysts	1	0.41%	
Diphyllobothrium latum	1	0.41%	
Entamoeba hartmanni	1	0.41%	
Enterobius vermicularis eggs	1	0.41%	
Fasciola hepatica eggs	1	0.41%	
Hookworm	1	0.41%	
Isospora belli oocysts	1	0.41%	
Paragonimus westermani eggs	1	0.41%	
Schistosoma sp. eggs, NOS	1	0.41%	
Schistosoma japonicum eggs	1	0.41%	
Schistosoma mansoni eggs	1	0.41%	
Trichuris trichiura eggs	1	0.41%	
Cyclospora cayetanensis	1	0.41%	

Parasite present in specimen FP-6: *Balantidium coli*.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. eggs	191	59.69%	Acceptable
Blastocystis hominis	60	18.75%	
Endolimax nana	21	6.56%	
Ascaris lumbricoides eggs	15	4.69%	
Giardia lamblia	8	2.50%	
No parasite seen	6	1.88%	
Hookworm	4	1.25%	
Hymenolepis diminuta eggs	3	0.94%	
Hymenolepis nana eggs	3	0.94%	
Entamoeba coli	2	0.63%	
Entamoeba histolytica	2	0.63%	
Entamoeba hartmanni	2	0.63%	
Iodamoeba butschlii	1	0.31%	
Chilomastix mesnili	1	0.31%	
Dientamoeba fragilis	1	0.31%	

Parasite present in specimen FP-7: *Taenia sp. eggs*. This challenge was graded by 85% referee consensus.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hymenolepis nana eggs	204	80.95%	Acceptable
Hymenolepis diminuta eggs	20	7.94%	
Taenia sp. eggs	6	2.38%	
Endolimax nana	5	1.98%	
Hookworm	3	1.19%	
Giardia lamblia	2	0.79%	
Entamoeba coli	2	0.79%	
Enterobius vermicularis eggs	2	0.79%	
Ascaris lumbricoides eggs	2	0.79%	
No parasite seen	2	0.79%	
Trichuris trichiura eggs	1	0.40%	
Blastocystis hominis	1	0.40%	
Fasciola hepatica eggs	1	0.40%	
Iodamoeba butschlii	1	0.40%	

Parasite present in specimen FP-8: *Hymenolepis nana* eggs.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Paragonimus westermani eggs	118	48.56%	Acceptable
Diphylobothrium latum	62	25.51%	
Fasciola hepatica eggs	20	8.23%	
No parasite seen	15	6.17%	
Clonorchis sinensis	6	2.47%	
Hookworm	5	2.06%	
Ascaris lumbricoides eggs	5	2.06%	
Balantidium coli	2	0.82%	
Endolimax nana	2	0.82%	
Trichuris trichiura eggs	2	0.82%	
Parasite larva seen but no ID	1	0.41%	
Other parasite seen but no ID	1	0.41%	
Strongyloides stercoralis larvae	1	0.41%	
Taenia sp. eggs	1	0.41%	
Iodamoeba butschlii	1	0.41%	
Blastocystis hominis	1	0.41%	

Parasites present in specimen FP-9: *Paragonimus westermani* eggs. This challenge was graded by 85% referee consensus.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	213	93.83%	Acceptable
Plasmodium vivax	4	1.76%	
Trypanosoma cruzi	2	0.88%	
Microfilaria-Loa loa	2	0.88%	
Plasmodium sp., NOS	2	0.88%	
Plasmodium falciparum	2	0.88%	
Plasmodium malariae	1	0.44%	
Babesia sp.	1	0.44%	

Parasite present in specimen FP-10: No parasite present.

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	11	1	11	1	2	10
Immuno Concepts	1	-	1	-	-	1
INOVA Diagnostics	6	-	5	1	2	4
Kallestad	1	-	1	-	-	1
Phadia EliA	1	-	1	-	-	1
Zeus	1	-	1	-	-	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	10	11	1
Immuno Concepts	-	1	1	-
INOVA Diagnostics	2	4	6	-
Kallestad	-	1	1	-
Phadia EliA	-	1	1	-
Zeus	-	1	1	-

Antinuclear Antibody (ANA)—Quantitative (Titer)

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

ALL METHODS	-	-	1	-	-	4	2	-	1	-	-	-
Immuno Concepts	-	-	1	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	2	1	-	1	-	-	-
Kallestad	-	-	-	-	-	-	1	-	-	-	-	-
Zeus	-	-	-	-	-	1	-	-	-	-	-	-

Antinuclear Antibody (ANA)—Quantitative (Titer)

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

ALL METHODS	-	-	1	-	-	-	2	-	3	1	1	-
Immuno Concepts	-	-	1	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	2	-	-	1	1	-
Kallestad	-	-	-	-	-	-	-	-	1	-	-	-
Zeus	-	-	-	-	-	-	-	-	1	-	-	-

Specimen AE-8

ALL METHODS	-	-	1	-	-	-	-	-	-	-	-	7
Immuno Concepts	-	-	1	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	-	-	4
Kallestad	-	-	-	-	-	-	-	-	-	-	-	1
Zeus	-	-	-	-	-	-	-	-	-	-	-	1

Specimen AE-9

ALL METHODS	-	-	1	-	-	-	-	-	-	-	-	7
Immuno Concepts	-	-	1	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	-	-	4
Kallestad	-	-	-	-	-	-	-	-	-	-	-	1
Zeus	-	-	-	-	-	-	-	-	-	-	-	1

Specimen AE-10

ALL METHODS	-	-	1	-	2	2	1	-	-	2	-	-
Immuno Concepts	-	-	1	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	1	1	-	-	-	2	-	-
Kallestad	-	-	-	-	-	-	1	-	-	-	-	-
Zeus	-	-	-	-	-	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	-	11	10	1	-	11
BioSystems	-	1	1	-	-	1
INOVA Diagnostics	-	6	5	1	-	6
Zeus	-	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	-	11	2	9
BioSystems	-	1	-	1
INOVA Diagnostics	-	6	2	4
Zeus	-	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	7	-	7	-	-	7
INOVA Diagnostics	6	-	6	-	-	6

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7
INOVA Diagnostics	-	6	-	6

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	3	-	3	-	-	3

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	3	-	3

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	-	10	10	-	-	10
INOVA Diagnostics	-	6	6	-	-	6

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	10	-	10
INOVA Diagnostics	-	6	-	6

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	-	10	7	3	-	10
INOVA Diagnostics	-	6	6	-	-	6

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	10	-	10
INOVA Diagnostics	-	6	-	6

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	-	1	1	-	-	1

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

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	2	8	6	4	-	10
INOVA Diagnostics	2	8	6	1	-	7

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	10	-	10
INOVA Diagnostics	-	7	-	7

Specimen AE-7 is an ungraded challenge due to less than 80% participant consensus.

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	22	-	1	21	1	21
Abbott Architect	12	-	-	12	-	12
bioMerieux Vidas, Mini Vidas	1	-	-	1	-	1
Roche cobas 6000 / e 601	1	-	-	1	-	1
Roche cobas 6000/e601 - IgG	1	-	-	1	-	1
Roche cobas e 411	2	-	1	1	1	1
Siemens ADVIA Centaur	1	-	-	1	-	1
Siemens Immulite 2000	2	-	-	2	-	2
VITROS ECI	2	-	-	2	-	2

<u>Method</u>	Specimen RU-9		Specimen RU-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	21	22	-
Abbott Architect	-	12	12	-
bioMerieux Vidas, Mini Vidas	-	1	1	-
Roche cobas 6000 / e 601	-	1	1	-
Roche cobas 6000/e601 - IgG	-	1	1	-
Roche cobas e 411	1	1	2	-
Siemens ADVIA Centaur	-	1	1	-
Siemens Immulite 2000	-	2	2	-
VITROS ECI	-	2	2	-

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	31	37.02	29.49	79.7	17.5	0.0 - 125.5
Abbott Architect	17	16.50	1.29	7.8	16.9	12.6 - 20.4
Specimen RU-7						
All Method	31	0.13	0.36	275.0	0.0	0.0 - 1.3
Abbott Architect	16	0.00	0.01	0.0	0.0	0.0 - 0.1
Specimen RU-8						
All Method	30	0.08	0.13	151.4	0.0	0.0 - 0.5
Abbott Architect	16	0.00	0.01	0.0	0.0	0.0 - 0.1
Specimen RU-9						
All Method	31	0.07	0.12	155.5	0.0	0.0 - 0.5
Abbott Architect	17	0.00	0.01	0.0	0.0	0.0 - 0.1
Specimen RU-10						
All Method	30	52.80	40.68	77.0	26.4	0.0 - 174.9
Abbott Architect	17	24.85	2.04	8.2	25.2	18.7 - 31.0

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	-	-	35	34	-	1	1	-	34
Abbott Architect	-	-	1	1	-	-	-	-	1
Omega Diagnostics	-	-	2	2	-	-	-	-	2
Plasmatec	-	-	3	3	-	-	-	-	3
SPINREACT	-	-	1	1	-	-	-	-	1
Standard Diagnostics	-	-	3	3	-	-	-	-	3
Wiener Lab	-	-	23	22	-	1	1	-	22

<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	35	-	-	35	-	-
Abbott Architect	1	-	-	1	-	-
Omega Diagnostics	2	-	-	2	-	-
Plasmatec	3	-	-	3	-	-
SPINREACT	1	-	-	1	-	-
Standard Diagnostics	3	-	-	3	-	-
Wiener Lab	23	-	-	23	-	-

Syphilis Serology—Quantitative: VDRL Slide Titer

<u>Specimen/Method</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>	<u>N/A</u> <u>(Neg)</u>
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Specimen SY-6

ALL METHODS	2	-	-	-	-	-	-	-	26
Human	1	-	-	-	-	-	-	-	-
Omega Diagnostics	-	-	-	-	-	-	-	-	1
Plasmatec	-	-	-	-	-	-	-	-	1
Wiener Lab	1	-	-	-	-	-	-	-	23

Specimen SY-7

ALL METHODS	1	2	6	17	1	1	-	-	-
Human	-	1	-	-	-	-	-	-	-
Omega Diagnostics	-	-	-	1	-	-	-	-	-
Plasmatec	-	-	1	-	-	-	-	-	-
Wiener Lab	1	1	5	16	-	1	-	-	-

Specimen SY-8

ALL METHODS	1	1	-	-	-	-	-	-	26
Human	1	-	-	-	-	-	-	-	-
Omega Diagnostics	-	-	-	-	-	-	-	-	1
Plasmatec	-	-	-	-	-	-	-	-	1
Wiener Lab	-	1	-	-	-	-	-	-	23

Syphilis Serology—Quantitative: VDRL Slide Titer

<u>Specimen/Method</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>	<u>N/A (Neg)</u>
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Specimen SY-9

ALL METHODS	-	1	11	10	4	2	-	-	-
Human	-	1	-	-	-	-	-	-	-
Omega Diagnostics	-	-	1	-	-	-	-	-	-
Plasmatec	-	-	1	-	-	-	-	-	-
Wiener Lab	-	-	9	10	4	1	-	-	-

Specimen SY-10

ALL METHODS	-	-	4	15	8	1	-	-	-
Human	-	-	1	-	-	-	-	-	-
Omega Diagnostics	-	-	-	-	1	-	-	-	-
Plasmatec	-	-	-	1	-	-	-	-	-
Wiener Lab	-	-	3	14	7	-	-	-	-

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	-	14	14	-	-	14
Abbott Architect	-	2	2	-	-	2
Human	-	2	2	-	-	2
Omega Diagnostics	-	3	3	-	-	3
Serodia	-	1	1	-	-	1
SPINREACT	-	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	14	-	14	-
Abbott Architect	2	-	2	-
Human	2	-	2	-
Omega Diagnostics	3	-	3	-
Serodia	1	-	1	-
SPINREACT	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	-	40	39	1	-	40
Abbott Architect	-	5	5	-	-	5
bioMerieux	-	1	1	-	-	1
Human	-	1	1	-	-	1
Omega Diagnostics	-	3	3	-	-	3
Plasmatec	-	3	3	-	-	3
Roche cobas 6000 / c 501	-	1	1	-	-	1
Roche cobas e 411	-	1	1	-	-	1
Serodia	-	13	13	-	-	13
SPINREACT	-	1	1	-	-	1
Standard Diagnostics	-	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	39	1	39	1
Abbott Architect	5	-	5	-
bioMerieux	1	-	1	-
Human	1	-	1	-
Omega Diagnostics	3	-	3	-
Plasmatec	3	-	3	-
Roche cobas 6000 / c 501	1	-	1	-
Roche cobas e 411	1	-	1	-
Serodia	13	-	13	-
SPINREACT	1	-	1	-
Standard Diagnostics	1	-	1	-

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	2	82	83	1	-	84
Abbott Architect	-	2	2	-	-	2
Becton Dickinson	-	2	2	-	-	2
bioMerieux	-	4	4	-	-	4
BioSystems	-	4	4	-	-	4
Human	1	10	11	-	-	11
Immunostics Inc.	-	1	1	-	-	1
Omega Diagnostics	-	14	14	-	-	14
Plasmatec	-	13	13	-	-	13
Pulse Scientific	-	1	1	-	-	1
Siemens ADVIA Centaur	-	1	1	-	-	1
SPINREACT	1	20	20	1	-	21
Standard Diagnostics	-	1	1	-	-	1
VITROS 3600/4600/5600	-	1	1	-	-	1
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	83	1	83	1
Abbott Architect	2	-	2	-
Becton Dickinson	2	-	2	-
bioMerieux	4	-	4	-
BioSystems	4	-	4	-
Human	11	-	11	-
Immunostics Inc.	1	-	1	-
Omega Diagnostics	14	-	14	-
Plasmatec	13	-	13	-
Pulse Scientific	1	-	1	-
Siemens ADVIA Centaur	1	-	1	-
SPINREACT	20	1	20	1
Standard Diagnostics	1	-	1	-
VITROS 3600/4600/5600	1	-	1	-
Wiener Lab	1	-	1	-

Syphilis Serology—Quantitative: RPR (Titer)

<u>Specimen/Method</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>	<u>N/A</u> <u>(Neg)</u>
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Specimen SY-6

ALL METHODS	3	-	-	-	-	-	-	-	66
Becton Dickinson	-	-	-	-	-	-	-	-	2
bioMerieux	-	-	-	-	-	-	-	-	3
BioSystems	-	-	-	-	-	-	-	-	4
Human	3	-	-	-	-	-	-	-	8
Immunostics Inc.	-	-	-	-	-	-	-	-	1
Omega Diagnostics	-	-	-	-	-	-	-	-	12
Plasmatec	-	-	-	-	-	-	-	-	10
Pulse Scientific	-	-	-	-	-	-	-	-	1
SPINREACT	-	-	-	-	-	-	-	-	19
Wiener Lab	-	-	-	-	-	-	-	-	1

Specimen SY-7

ALL METHODS	8	38	12	5	1	-	-	2	2
Becton Dickinson	-	1	1	-	-	-	-	-	-
bioMerieux	2	1	-	-	-	-	-	-	-
BioSystems	1	-	1	-	-	-	-	1	-
Human	-	7	2	2	-	-	-	-	-
Immunostics Inc.	-	-	-	-	1	-	-	-	-
Omega Diagnostics	1	8	1	-	-	-	-	1	1
Plasmatec	4	6	-	-	-	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	-	12	4	2	-	-	-	-	1
Wiener Lab	-	-	1	-	-	-	-	-	-

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

<u>Specimen/Method</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>	<u>N/A</u> <u>(Neg)</u>
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Specimen SY-8

ALL METHODS	2	-	-	-	-	-	-	-	67
Becton Dickinson	-	-	-	-	-	-	-	-	2
bioMerieux	-	-	-	-	-	-	-	-	3
BioSystems	-	-	-	-	-	-	-	-	4
Human	2	-	-	-	-	-	-	-	9
Immunostics Inc.	-	-	-	-	-	-	-	-	1
Omega Diagnostics	-	-	-	-	-	-	-	-	12
Plasmatec	-	-	-	-	-	-	-	-	10
Pulse Scientific	-	-	-	-	-	-	-	-	1
SPINREACT	-	-	-	-	-	-	-	-	19
Wiener Lab	-	-	-	-	-	-	-	-	1

Specimen SY-9

ALL METHODS	15	29	12	5	3	-	-	2	2
Becton Dickinson	-	1	1	-	-	-	-	-	-
bioMerieux	2	1	-	-	-	-	-	-	-
BioSystems	1	-	1	-	-	-	-	1	-
Human	2	5	2	2	-	-	-	-	-
Immunostics Inc.	-	-	-	-	1	-	-	-	-
Omega Diagnostics	2	6	2	-	-	-	-	1	1
Plasmatec	5	4	1	-	-	-	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	1	11	3	2	1	-	-	-	1
Wiener Lab	-	-	-	-	1	-	-	-	-

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

<u>Specimen/Method</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>	<u>N/A</u> <u>(Neg)</u>
Specimen SY-10									
ALL METHODS	-	21	27	14	3	-	-	2	2
Becton Dickinson	-	-	1	1	-	-	-	-	-
bioMerieux	-	2	1	-	-	-	-	-	-
BioSystems	-	2	1	-	-	-	-	1	-
Human	-	3	4	3	1	-	-	-	-
Immunostics Inc.	-	-	-	1	-	-	-	-	-
Omega Diagnostics	-	2	6	2	-	-	-	1	1
Plasmatec	-	7	3	-	-	-	-	-	-
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	3	9	5	1	-	-	-	1
Wiener Lab	-	-	-	1	-	-	-	-	-

Viral Markers – Anti-HBc (IgM)

Specimen VM-6				Specimen VM-7			Specimen VM-8		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	59	-	36	22	1	-	59	-
Abbott Architect	-	25	-	22	3	-	-	25	-
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	-	-	2	-
bioMerieux Vidas, Mini Vidas	-	3	-	3	-	-	-	3	-
Roche cobas 6000 / e 601	-	13	-	-	13	-	-	13	-
Roche cobas e 411	-	2	-	-	2	-	-	2	-
Siemens ADVIA Centaur	-	7	-	7	-	-	-	7	-
VITROS 3600/4600/5600	-	3	-	-	2	1	-	3	-
VITROS Eci	-	1	-	-	1	-	-	1	-

Specimen VM-9				Specimen VM-10		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	59	-	-	59	-
Abbott Architect	-	25	-	-	25	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-
Roche cobas 6000 / e 601	-	13	-	-	13	-
Roche cobas e 411	-	2	-	-	2	-
Siemens ADVIA Centaur	-	7	-	-	7	-
VITROS 3600/4600/5600	-	3	-	-	3	-
VITROS Eci	-	1	-	-	1	-

Viral Markers – Anti-HBc (Total / IgG)

Specimen VM-6				Specimen VM-7			Specimen VM-8		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	3	80	1	82	2	-	13	68	3
Abbott Architect	-	39	-	38	1	-	-	39	-
Beckman ACCESS / 2 / Dxl	3	-	-	3	-	-	2	1	-
Bio-Rad Evolis	-	1	-	1	-	-	-	1	-
bioMerieux Vidas, Mini									
Vidas	-	2	-	2	-	-	-	1	1
DiaSorin	-	1	-	1	-	-	-	1	-
Human	-	1	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	14	-	14	-	-	6	8	-
Roche cobas e 411	-	6	-	6	-	-	3	2	1
Roche Modular Analytics	-	1	-	1	-	-	1	-	-
Siemens ADVIA Centaur	-	8	-	8	-	-	-	8	-
VITROS 3600/4600/5600	-	2	-	2	-	-	-	2	-
VITROS ECI	-	2	-	2	-	-	-	2	-

Specimen VM-9				Specimen VM-10		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	83	1	-	-	83	1
Abbott Architect	39	-	-	-	39	-
Beckman ACCESS / 2 / Dxl	3	-	-	-	3	-
Bio-Rad Evolis	1	-	-	-	1	-
bioMerieux Vidas, Mini						
Vidas	2	-	-	-	2	-
DiaSorin	1	-	-	-	1	-
Human	1	-	-	-	1	-
Roche cobas 6000 / e 601	14	-	-	-	14	-
Roche cobas e 411	6	-	-	-	6	-
Roche Modular Analytics	1	-	-	-	1	-
Siemens ADVIA Centaur	8	-	-	-	8	-
VITROS 3600/4600/5600	2	-	-	-	2	-
VITROS ECI	2	-	-	-	2	-

Viral Markers – Anti-HIV

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	209	1	1	209	1	-	210	1
Abbott Architect	-	60	-	-	60	-	-	60	-
Abbott Architect - Total	-	1	-	-	1	-	-	1	-
Alere Determine HIV 1/2									
Ag/Ab Combo	-	1	-	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	6	-	-	6	-	-	6	-
Bio-Rad Evolis	-	1	-	-	1	-	-	1	-
bioMerieux Vidas, Mini									
Vidas	-	11	-	-	11	-	-	11	-
DiaSorin	-	1	-	-	1	-	-	1	-
Human	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	42	-	-	42	-	-	42	-
Roche cobas e 411	1	21	-	1	21	-	-	22	-
Roche Modular Analytics	-	4	-	-	4	-	-	4	-
Siemens ADVIA Centaur	-	25	1	-	25	1	-	25	1
Standard Diagnostics	-	3	-	-	3	-	-	3	-
VITROS 3600/4600/5600	-	4	-	-	4	-	-	4	-
VITROS ECI	-	12	-	-	12	-	-	12	-

Viral Markers – Anti-HIV- cont'd

<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	211	-	-	26	166	19
Abbott Architect	60	-	-	-	59	1
Abbott Architect - Total	1	-	-	-	1	-
Alere Determine HIV 1/2						
Ag/Ab Combo	1	-	-	-	1	-
Beckman ACCESS / 2 / DxI	6	-	-	-	6	-
Bio-Rad Evolis	1	-	-	1	-	-
bioMerieux Vidas, Mini						
Vidas	11	-	-	4	7	-
DiaSorin	1	-	-	-	1	-
Human	2	-	-	-	2	-
Roche cobas 6000 / e 601	42	-	-	15	17	10
Roche cobas e 411	22	-	-	5	12	5
Roche Modular Analytics	4	-	-	1	-	3
Siemens ADVIA Centaur	26	-	-	-	26	-
Standard Diagnostics	3	-	-	-	3	-
VITROS 3600/4600/5600	4	-	-	-	4	-
VITROS ECI	12	-	-	-	12	-

Viral Markers – Anti-HAV (IgM)

Specimen VM-6				Specimen VM-7			Specimen VM-8		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	79	3	1	1	82	-	-	83	-
Abbott Architect	27	1	-	1	27	-	-	28	-
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-	-	1	-
bioMerieux Vidas, Mini									
Vidas	6	-	-	-	6	-	-	6	-
Roche cobas 6000 / e 601	19	1	-	-	20	-	-	20	-
Roche cobas e 411	4	-	-	-	4	-	-	4	-
Roche Modular Analytics	1	-	-	-	1	-	-	1	-
Siemens ADVIA Centaur	11	1	-	-	12	-	-	12	-
Standard Diagnostics	2	-	-	-	2	-	-	2	-
VITROS 3600/4600/5600	-	-	1	-	1	-	-	1	-
VITROS ECI	4	-	-	-	4	-	-	4	-

Specimen VM-9				Specimen VM-10		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	81	1	2	81	-
Abbott Architect	-	28	-	-	28	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-
bioMerieux Vidas, Mini						
Vidas	-	6	-	-	6	-
Roche cobas 6000 / e 601	-	20	-	-	20	-
Roche cobas e 411	-	4	-	-	4	-
Roche Modular Analytics	-	1	-	-	1	-
Siemens ADVIA Centaur	-	11	1	1	11	-
Standard Diagnostics	-	2	-	-	2	-
VITROS 3600/4600/5600	-	1	-	-	1	-
VITROS ECI	-	4	-	-	4	-

Viral Markers – Anti-HAV (Total/IgG)

	Specimen VM-6			Specimen VM-7			Specimen VM-8		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	74	3	-	18	58	1	1	76	-
Abbott Architect	29	-	-	2	27	-	-	29	-
Beckman ACCESS / 2 / Dxl	1	-	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	6	-	-	1	5	-	-	6	-
Roche cobas 6000 / e 601	15	-	-	10	5	-	-	15	-
Roche cobas e 411	6	-	-	2	4	-	-	6	-
Roche Elecsys 1010 / 2010	1	-	-	1	-	-	-	1	-
Roche Modular Analytics	1	-	-	-	1	-	-	1	-
Siemens ADVIA Centaur	9	-	-	1	8	-	-	9	-
Standard Diagnostics	-	1	-	-	1	-	-	1	-
VITROS ECI	2	-	-	-	1	1	-	2	-

	Specimen VM-9			Specimen VM-10		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	75	2	-	73	4	-
Abbott Architect	29	-	-	28	1	-
Beckman ACCESS / 2 / Dxl	1	-	-	1	-	-
bioMerieux Vidas, Mini Vidas	6	-	-	6	-	-
Roche cobas 6000 / e 601	15	-	-	15	-	-
Roche cobas e 411	6	-	-	6	-	-
Roche Elecsys 1010 / 2010	1	-	-	1	-	-
Roche Modular Analytics	1	-	-	1	-	-
Siemens ADVIA Centaur	9	-	-	8	1	-
Standard Diagnostics	-	1	-	-	1	-
VITROS ECI	2	-	-	2	-	-

Viral Markers – HBeAg

Specimen VM-6				Specimen VM-7			Specimen VM-8		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	49	1	-	50	-	1	49	-
Abbott Architect	-	20	-	-	20	-	-	20	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-	-	3	-
DiaSorin	-	1	-	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	14	-	-	14	-	1	13	-
Roche cobas e 411	-	1	-	-	1	-	-	1	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	-	1	-
Roche Modular Analytics	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	4	1	-	5	-	-	5	-

Specimen VM-9				Specimen VM-10		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	50	-	-	50	-
Abbott Architect	-	20	-	-	20	-
bioMerieux Vidas, Mini Vidas	-	3	-	-	3	-
DiaSorin	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	14	-	-	14	-
Roche cobas e 411	-	1	-	-	1	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-
Roche Modular Analytics	-	1	-	-	1	-
Siemens ADVIA Centaur	-	5	-	-	5	-

Viral Markers – Anti-HBs

Specimen VM-6				Specimen VM-7			Specimen VM-8		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	3	146	-	1	148	-	147	2	-
Abbott Architect	-	46	-	-	46	-	46	-	-
Beckman ACCESS / 2 / Dxl	-	3	-	-	3	-	3	-	-
bioMerieux Vidas, Mini									
Vidas	-	5	-	-	5	-	5	-	-
Roche cobas 6000 / e 601	1	36	-	1	36	-	37	-	-
Roche cobas e 411	-	15	-	-	15	-	14	1	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	1	-	-
Roche Modular Analytics	-	2	-	-	2	-	2	-	-
Siemens ADVIA Centaur	1	21	-	-	22	-	22	-	-
VITROS 3600/4600/5600	-	5	-	-	5	-	5	-	-
VITROS ECI	-	5	-	-	5	-	5	-	-

Specimen VM-9				Specimen VM-10		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	149	-	-	149	-	-
Abbott Architect	46	-	-	46	-	-
Beckman ACCESS / 2 / Dxl	3	-	-	3	-	-
bioMerieux Vidas, Mini						
Vidas	5	-	-	5	-	-
Roche cobas 6000 / e 601	37	-	-	37	-	-
Roche cobas e 411	15	-	-	15	-	-
Roche Elecsys 1010 / 2010	1	-	-	1	-	-
Roche Modular Analytics	2	-	-	2	-	-
Siemens ADVIA Centaur	22	-	-	22	-	-
VITROS 3600/4600/5600	5	-	-	5	-	-
VITROS ECI	5	-	-	5	-	-

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	3	205	2	194	13	3	1	208	1
Abbott Architect	-	60	-	59	-	1	-	60	-
Abbott Architect - Total	-	1	-	1	-	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	6	-	6	-	-	-	6	-
Bio-Rad Evolis	-	1	-	1	-	-	-	1	-
bioMerieux Vidas, Mini									
Vidas	-	8	-	8	-	-	-	8	-
DiaSorin	-	1	-	1	-	-	-	1	-
Human	-	1	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	-	40	1	40	1	-	-	41	-
Roche cobas e 411	2	20	1	23	-	-	1	22	-
Roche Elecsys 1010 / 2010	-	1	-	1	-	-	-	1	-
Roche Modular Analytics	-	3	-	3	-	-	-	2	1
Siemens ADVIA Centaur	-	26	-	24	-	2	-	26	-
Standard Diagnostics	-	2	-	-	2	-	-	2	-
VITROS 3600/4600/5600	-	4	-	4	-	-	-	4	-
VITROS ECI	-	13	-	13	-	-	-	13	-

<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	208	1	8	199	3
Abbott Architect	-	60	-	-	60	-
Abbott Architect - Total	-	1	-	-	1	-
Beckman ACCESS / 2 / Dxl	-	6	-	-	6	-
Bio-Rad Evolis	-	1	-	-	1	-
bioMerieux Vidas, Mini						
Vidas	-	8	-	-	8	-
DiaSorin	-	1	-	-	1	-
Human	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	41	-	-	40	1
Roche cobas e 411	1	21	1	1	21	1
Roche Elecsys 1010 / 2010	-	1	-	-	1	-
Roche Modular Analytics	-	3	-	-	3	-
Siemens ADVIA Centaur	-	26	-	-	26	-
Standard Diagnostics	-	2	-	-	2	-
VITROS 3600/4600/5600	-	4	-	2	1	1
VITROS ECI	-	13	-	4	9	-

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	55	129	-	50	131	3	183	1	-
Abbott Architect	1	55	-	1	55	-	55	1	-
Abbott Architect - Total	-	1	-	-	1	-	1	-	-
Beckman ACCESS / 2 / DxI	-	4	-	-	4	-	4	-	-
Bio-Rad Evolis	-	1	-	-	1	-	1	-	-
bioMerieux Vidas, Mini Vidas	-	6	-	-	6	-	6	-	-
DiaSorin	-	1	-	-	1	-	1	-	-
Human	-	1	-	-	1	-	1	-	-
Roche cobas 6000 / e 601	33	1	-	33	1	-	34	-	-
Roche cobas e 411	12	3	-	10	3	2	15	-	-
Roche Elecsys 1010 / 2010	2	-	-	1	-	1	2	-	-
Roche Modular Analytics	3	-	-	3	-	-	3	-	-
Siemens ADVIA Centaur	-	25	-	-	25	-	25	-	-
Standard Diagnostics	-	4	-	-	4	-	4	-	-
VITROS 3600/4600/5600	-	4	-	-	4	-	4	-	-
VITROS ECI	-	10	-	-	10	-	10	-	-

<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	3	181	-	170	11	3
Abbott Architect	-	56	-	52	1	3
Abbott Architect - Total	-	1	-	1	-	-
Beckman ACCESS / 2 / DxI	-	4	-	4	-	-
Bio-Rad Evolis	-	1	-	1	-	-
bioMerieux Vidas, Mini Vidas	-	6	-	2	4	-
DiaSorin	-	1	-	1	-	-
Human	-	1	-	1	-	-
Roche cobas 6000 / e 601	1	33	-	34	-	-
Roche cobas e 411	1	14	-	15	-	-
Roche Elecsys 1010 / 2010	-	2	-	2	-	-
Roche Modular Analytics	-	3	-	2	1	-
Siemens ADVIA Centaur	-	25	-	24	1	-
Standard Diagnostics	1	3	-	3	1	-
VITROS 3600/4600/5600	-	4	-	4	-	-
VITROS ECI	-	10	-	10	-	-

Toxoplasma gondii Antibody (IgG) - Qualitative

<u>Method</u>	Specimen TOX-3		Specimen TOX-4	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	21	-	-	21
Abbott Architect	10	-	-	10
Beckman ACCESS / 2 / Dxl	3	-	-	3
bioMerieux Vidas, Mini Vidas	2	-	-	2
Roche cobas 6000 / e 601	2	-	-	2
Roche cobas e 411	2	-	-	2
Siemens Immulite 2000	1	-	-	1

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	391.350	253.473	64.8	275.00	0.00 - 898.30
Abbott Architect	12	322.467	286.023	88.7	200.00	0.00 - 894.52
Beckman ACCESS / 2 / Dxl	3	461.000	14.526	3.2	462.00	431.94 - 490.06
Roche cobas 6000 / e 601	2	-	-	-	654.50	0.00 - 898.30
Specimen TOX-4						
All Method	26	0.607	0.854	140.7	0.35	0.00 - 2.32
Abbott Architect	14	0.436	0.150	34.4	0.40	0.13 - 0.74
Beckman ACCESS / 2 / Dxl	3	3.170	2.236	70.5	2.30	0.00 - 7.65
Roche cobas 6000 / e 601	4	0.130	0.001	0.0	0.13	0.12 - 0.14

Toxoplasma gondii Antibody (IgM) - Qualitative

<u>Method</u>	Specimen TOX-3		Specimen TOX-4	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	24	1	-	25
Abbott Architect	10	-	-	10
Beckman ACCESS / 2 / Dxl	2	-	-	2
bioMerieux Vidas, Mini Vidas	2	-	-	2
Roche cobas 6000 / e 601	4	-	-	4
Roche cobas e 411	3	-	-	3
Siemens Immulite 2000	1	-	-	1
VITROS ECI	1	-	-	1

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	5.460	4.599	84.2	3.42	0.00 - 14.66	5.460
Abbott Architect	2.863	0.354	12.4	2.83	2.15 - 3.58	2.863
Roche cobas 6000 / e 601	5.267	0.577	11.0	5.16	4.11 - 6.43	5.267
Specimen TOX-4						
All Method	21	0.162	0.074	45.3	0.17	0.01 - 0.31
Abbott Architect	10	0.149	0.061	40.9	0.15	0.02 - 0.28
Roche cobas 6000 / e 601	3	0.193	0.023	11.9	0.18	0.14 - 0.24

Cytomegalovirus (CMV) Antibodies (IgG) - Qualitative

<u>Method</u>	<u>Specimen CMV-3</u>		<u>Specimen CMV-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	-	-	17
Abbott Architect	10	-	-	10
Beckman ACCESS / 2 / Dxl	1	-	-	1
bioMerieux Vidas, Mini Vidas	1	-	-	1
Roche cobas 6000 / e 601	1	-	-	1
Roche cobas e 411	2	-	-	2
Siemens Immulite 2000	2	-	-	2

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	21	55.605	39.776	71.5	79.10	0.00 - 135.16
Abbott Architect	11	90.918	7.718	8.5	89.60	75.48 - 106.36
Specimen CMV-4						
All Method	22	1.560	1.562	100.1	0.95	0.00 - 4.69
Abbott Architect	12	1.808	1.492	82.5	1.15	0.00 - 4.80

Cytomegalovirus (CMV) Antibodies (IgM) - Qualitative

<u>Method</u>	<u>Specimen CMV-3</u>		<u>Specimen CMV-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	19	1	-	20
Abbott Architect	10	-	-	10
Beckman ACCESS / 2 / Dxl	1	-	-	1
bioMerieux Vidas, Mini Vidas	1	-	-	1
Roche cobas 6000 / e 601	2	-	-	2
Roche cobas e 411	2	-	-	2
Siemens Immulite 2000	3	-	-	3

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

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen CMV-3						
All Method	17	5.808	1.307	22.5	6.28	3.19 - 8.43
Abbott Architect	9	6.542	0.598	9.1	6.52	5.34 - 7.74
Specimen CMV-4						
All Method	17	0.192	0.060	31.0	0.21	0.07 - 0.32
Abbott Architect	9	0.211	0.026	12.2	0.21	0.15 - 0.27

CK-MB - Quantitative (U/L)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen CK-6						
All Method	10	17.40	3.16	18.2	16.1	7.9 - 26.9
Roche cobas 6000 / c 501	6	15.67	0.43	2.8	15.7	14.3 - 17.0
Specimen CK-7						
All Method	10	49.53	10.72	21.6	45.1	17.3 - 81.7
Roche cobas 6000 / c 501	6	43.98	1.02	2.3	44.0	40.9 - 47.1
Specimen CK-8						
All Method	10	7.64	1.85	24.3	7.1	2.0 - 13.3
Roche cobas 6000 / c 501	6	6.55	0.81	12.3	6.9	4.1 - 9.0
Specimen CK-9						
All Method	10	28.01	4.78	17.1	26.0	13.6 - 42.4
Roche cobas 6000 / c 501	6	25.68	0.74	2.9	25.8	23.4 - 27.9
Specimen CK-10						
All Method	10	92.05	19.51	21.2	83.0	33.5 - 150.6
Roche cobas 6000 / c 501	6	82.57	1.80	2.2	82.6	77.1 - 88.0

Medical Laboratory Evaluation
25 Massachusetts Ave NW Ste 700
Washington, DC 20001-7401
800-338-2746 • 202-261-4500 • Fax: 202-835-0440
www.acponline.org/mle