

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-M1**



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EVALUATION CRITERIA

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

Qualitative

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	$\pm$ 3 SD
CK-MB (U/L)	$\pm$ 3 SD
Cytomegalovirus	$\pm$ 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	$\pm$ 3 SD
Specific Gravity	$\pm$ 0.010
Toxoplasma	$\pm$ 2 SD
White Blood Cell Count	$\pm$ 15%

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

Specimen CL-1							Specimen CL-2					
<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	65	2.294	0.080	3.5	2.31	2.15 - 2.44	64	4.693	0.160	3.4	4.71	4.41 - 4.98
All Abbott Cell-Dyn Instruments	57	2.315	0.053	2.3	2.32	2.17 - 2.46	55	4.739	0.105	2.2	4.74	4.45 - 5.03
Abbott Cell-Dyn Ruby	42	2.316	0.056	2.4	2.32	2.17 - 2.46	41	4.758	0.094	2.0	4.76	4.47 - 5.05
Specimen CL-3							Specimen CL-4					
All Method	62	5.219	0.167	3.2	5.23	4.90 - 5.54	63	5.241	0.145	2.8	5.26	4.92 - 5.56
All Abbott Cell-Dyn Instruments	55	5.250	0.134	2.6	5.24	4.93 - 5.57	57	5.267	0.114	2.2	5.26	4.95 - 5.59
Abbott Cell-Dyn Ruby	40	5.281	0.133	2.5	5.28	4.96 - 5.60	42	5.289	0.103	2.0	5.28	4.97 - 5.61
Specimen CL-5												
All Method	64	2.286	0.081	3.5	2.30	2.14 - 2.43						
All Abbott Cell-Dyn Instruments	56	2.307	0.053	2.3	2.31	2.16 - 2.45						
Abbott Cell-Dyn Ruby	41	2.309	0.057	2.5	2.31	2.17 - 2.45						

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

Specimen CL-1							Specimen CL-2					
<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	5.54	0.27	4.8	5.6	5.1 - 6.0	63	13.44	0.67	5.0	13.6	12.4 - 14.4
All Abbott Cell-Dyn Instruments	57	5.60	0.14	2.4	5.6	5.2 - 6.0	55	13.62	0.37	2.7	13.6	12.6 - 14.6
Abbott Cell-Dyn Ruby	42	5.56	0.11	2.0	5.6	5.1 - 6.0	40	13.67	0.24	1.8	13.7	12.7 - 14.7
Specimen CL-3							Specimen CL-4					
All Method	63	16.41	0.63	3.8	16.5	15.2 - 17.6	63	16.45	0.54	3.3	16.5	15.2 - 17.7
All Abbott Cell-Dyn Instruments	55	16.57	0.37	2.2	16.6	15.4 - 17.8	57	16.54	0.39	2.4	16.5	15.3 - 17.7
Abbott Cell-Dyn Ruby	40	16.63	0.25	1.5	16.6	15.4 - 17.8	42	16.59	0.30	1.8	16.6	15.4 - 17.8
Specimen CL-5												
All Method	63	5.48	0.32	5.8	5.5	5.0 - 5.9						
All Abbott Cell-Dyn Instruments	55	5.57	0.15	2.7	5.6	5.1 - 6.0						
Abbott Cell-Dyn Ruby	40	5.52	0.12	2.2	5.5	5.1 - 6.0						

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

Specimen CL-1							Specimen CL-2					
<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	65	16.13	0.75	4.6	16.0	15.1 - 17.2	63	39.05	2.01	5.2	38.5	36.7 - 41.4
All Abbott Cell-Dyn Instruments	49	15.91	0.50	3.2	16.0	14.9 - 16.9	46	38.41	1.08	2.8	38.3	36.1 - 40.8
Abbott Cell-Dyn Ruby	42	15.88	0.52	3.3	16.0	14.9 - 16.9	40	38.49	1.07	2.8	38.3	36.1 - 40.9
Specimen CL-3							Specimen CL-4					
All Method	63	45.33	2.31	5.1	44.8	42.6 - 48.1	64	45.39	2.31	5.1	44.7	42.6 - 48.2
All Abbott Cell-Dyn Instruments	47	44.45	1.48	3.3	44.3	41.7 - 47.2	48	44.48	1.36	3.1	44.1	41.8 - 47.2
Abbott Cell-Dyn Ruby	40	44.63	1.49	3.3	44.4	41.9 - 47.4	41	44.55	1.35	3.0	44.1	41.8 - 47.3
Specimen CL-5												
All Method	64	16.07	0.76	4.7	16.0	15.1 - 17.1						
All Abbott Cell-Dyn Instruments	48	15.83	0.48	3.0	15.9	14.8 - 16.8						
Abbott Cell-Dyn Ruby	41	15.81	0.48	3.0	15.9	14.8 - 16.8						

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

Specimen CL-1							Specimen CL-2					
<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	72.5	6.7	9.2	72	54 - 91	63	273.4	14.9	5.5	274	205 - 342
All Abbott Cell-Dyn Instruments	57	71.1	4.5	6.3	71	53 - 89	56	273.8	14.3	5.2	274	205 - 343
Abbott Cell-Dyn Ruby	42	70.5	4.0	5.6	71	52 - 89	41	278.5	12.4	4.5	277	208 - 349
Specimen CL-3							Specimen CL-4					
All Method	64	509.2	31.3	6.1	509	381 - 637	64	508.6	27.2	5.4	508	381 - 636
All Abbott Cell-Dyn Instruments	55	509.1	25.8	5.1	509	381 - 637	56	510.3	24.9	4.9	510	382 - 638
Abbott Cell-Dyn Ruby	41	519.2	26.6	5.1	513	389 - 650	41	518.7	22.2	4.3	516	388 - 649
Specimen CL-5												
All Method	62	72.8	7.6	10.5	71	54 - 91						
All Abbott Cell-Dyn Instruments	57	71.2	5.3	7.5	71	53 - 89						
Abbott Cell-Dyn Ruby	42	71.1	5.0	7.1	70	53 - 89						

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

Specimen CL-1							Specimen CL-2					
<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	48.46	1.81	3.7	48.3	43.0 - 53.9	62	61.35	1.24	2.0	61.5	57.6 - 65.1
All Abbott Cell-Dyn Instruments	56	48.68	1.74	3.6	48.3	43.4 - 53.9	52	61.60	0.64	1.0	61.7	59.6 - 63.6
Abbott Cell-Dyn Ruby	41	48.79	1.60	3.3	48.3	43.9 - 53.6	40	61.61	0.54	0.9	61.7	59.9 - 63.3
Specimen CL-3							Specimen CL-4					
All Method	62	72.78	1.24	1.7	73.0	69.0 - 76.5	63	72.77	1.16	1.6	72.9	69.3 - 76.3
All Abbott Cell-Dyn Instruments	54	73.03	0.92	1.3	73.1	70.2 - 75.8	53	72.97	0.76	1.0	73.0	70.6 - 75.3
Abbott Cell-Dyn Ruby	39	73.02	0.63	0.9	73.0	71.1 - 75.0	40	72.95	0.59	0.8	73.0	71.1 - 74.8
Specimen CL-5												
All Method	64	49.59	1.92	3.9	49.7	43.8 - 55.4						
All Abbott Cell-Dyn Instruments	55	49.88	1.46	2.9	49.9	45.4 - 54.3						
Abbott Cell-Dyn Ruby	40	50.15	1.39	2.8	50.1	45.9 - 54.4						

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

Specimen CL-1							Specimen CL-2					
<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	37.98	2.95	7.8	38.4	29.1 - 46.9	59	25.55	1.22	4.8	25.6	21.8 - 29.3
All Abbott Cell-Dyn Instruments	56	38.26	2.53	6.6	38.6	30.6 - 45.9	56	25.66	0.79	3.1	25.7	23.2 - 28.1
Abbott Cell-Dyn Ruby	41	37.95	2.49	6.6	38.2	30.4 - 45.5	41	25.63	0.75	2.9	25.7	23.3 - 27.9
Specimen CL-3							Specimen CL-4					
All Method	63	15.26	1.81	11.9	15.2	9.8 - 20.7	64	14.94	1.71	11.4	15.1	9.8 - 20.1
All Abbott Cell-Dyn Instruments	53	15.35	1.06	6.9	15.3	12.1 - 18.6	52	15.39	0.80	5.2	15.3	12.9 - 17.8
Abbott Cell-Dyn Ruby	39	15.37	0.76	5.0	15.2	13.0 - 17.7	39	15.28	0.91	5.9	15.2	12.5 - 18.1
Specimen CL-5												
All Method	59	37.58	2.24	6.0	38.0	30.8 - 44.3						
All Abbott Cell-Dyn Instruments	56	37.78	1.91	5.1	38.0	32.0 - 43.6						
Abbott Cell-Dyn Ruby	41	37.53	1.90	5.1	37.5	31.8 - 43.3						

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

Specimen CL-1							Specimen CL-2					
<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	8.93	4.81	53.9	7.6	0.0 - 23.4	62	7.71	3.57	46.4	6.6	0.0 - 18.5
All Abbott Cell-Dyn Instruments	53	7.82	1.75	22.3	7.5	2.5 - 13.1	53	6.62	0.59	8.9	6.5	4.8 - 8.4
Abbott Cell-Dyn Ruby	38	8.11	1.61	19.8	8.0	3.2 - 13.0	40	6.56	0.47	7.2	6.5	5.1 - 8.0
Specimen CL-3							Specimen CL-4					
All Method	62	5.06	2.41	47.5	4.5	0.0 - 12.3	61	4.99	2.07	41.5	4.4	0.0 - 11.2
All Abbott Cell-Dyn Instruments	53	4.35	0.75	17.2	4.4	2.1 - 6.6	53	4.46	0.65	14.7	4.3	2.4 - 6.5
Abbott Cell-Dyn Ruby	39	4.46	0.56	12.6	4.5	2.7 - 6.2	38	4.40	0.35	8.1	4.4	3.3 - 5.5
Specimen CL-5												
All Method	60	8.33	4.04	48.5	7.2	0.0 - 20.5						
All Abbott Cell-Dyn Instruments	55	7.35	1.25	17.0	7.1	3.6 - 11.2						
Abbott Cell-Dyn Ruby	40	7.37	1.04	14.1	7.3	4.2 - 10.5						

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

Specimen CL-1							Specimen CL-2					
<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	4.62	0.46	9.9	4.6	3.2 - 6.0	60	5.83	0.38	6.5	5.9	4.6 - 7.0
All Abbott Cell-Dyn Instruments	56	4.66	0.40	8.6	4.6	3.4 - 5.9	54	5.89	0.31	5.2	5.9	4.9 - 6.9
Abbott Cell-Dyn Ruby	41	4.70	0.42	8.9	4.8	3.4 - 6.0	39	5.91	0.33	5.5	5.9	4.9 - 6.9
Specimen CL-3							Specimen CL-4					
All Method	60	6.66	0.58	8.8	6.8	4.9 - 8.5	59	6.84	0.41	6.0	6.9	5.5 - 8.1
All Abbott Cell-Dyn Instruments	55	6.80	0.33	4.9	6.9	5.8 - 7.8	56	6.91	0.27	4.0	6.9	6.0 - 7.8
Abbott Cell-Dyn Ruby	40	6.85	0.30	4.4	6.9	5.9 - 7.8	41	6.95	0.27	3.9	7.0	6.1 - 7.8
Specimen CL-5												
All Method	61	4.65	0.38	8.2	4.6	3.5 - 5.8						
All Abbott Cell-Dyn Instruments	56	4.72	0.40	8.4	4.7	3.5 - 6.0						
Abbott Cell-Dyn Ruby	41	4.75	0.43	9.0	4.7	3.4 - 6.1						

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

Specimen CL-1							Specimen CL-2					
<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	0.44	0.50	113.9	0.3	0.0 - 2.0	62	0.25	0.18	73.3	0.2	0.0 - 0.8
All Abbott Cell-Dyn Instruments	56	0.43	0.50	115.5	0.3	0.0 - 2.0	55	0.23	0.17	75.4	0.2	0.0 - 0.8
Abbott Cell-Dyn Ruby	39	0.33	0.35	104.2	0.2	0.0 - 1.4	41	0.22	0.16	74.2	0.2	0.0 - 0.8
Specimen CL-3							Specimen CL-4					
All Method	63	0.32	0.26	79.9	0.3	0.0 - 1.2	62	0.28	0.20	71.8	0.3	0.0 - 0.9
All Abbott Cell-Dyn Instruments	55	0.28	0.22	78.5	0.3	0.0 - 1.0	54	0.25	0.16	65.8	0.3	0.0 - 0.8
Abbott Cell-Dyn Ruby	40	0.29	0.21	73.1	0.3	0.0 - 1.0	39	0.25	0.16	66.5	0.3	0.0 - 0.8
Specimen CL-5												
All Method	62	0.29	0.27	93.7	0.2	0.0 - 1.1						
All Abbott Cell-Dyn Instruments	55	0.28	0.28	98.3	0.2	0.0 - 1.2						
Abbott Cell-Dyn Ruby	41	0.25	0.25	101.1	0.2	0.0 - 1.1						

BLOOD BANK
ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-1	Group O	114	99.13%	Acceptable
	Group AB	1	0.87%	
BB-2	Group A	119	99.17%	Acceptable
	Group AB	1	0.83%	
BB-3	Group O	114	97.44%	Acceptable
	Group AB	2	1.71%	
BB-4	Group A	1	0.85%	Acceptable
	Group B	119	98.35%	
BB-5	Group AB	2	1.65%	Acceptable
	Group A	117	96.69%	
	Group O	3	2.48%	
	Group AB	1	0.85%	

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-1	Rh Positive	114	99.13%	Acceptable
	Rh Negative	1	0.87%	
BB-2	Rh Negative	119	99.17%	Acceptable
	Rh Positive	1	0.85%	
BB-3	Rh Positive	114	97.44%	Acceptable
	Rh Negative	3	2.56%	
BB-4	Rh Negative	116	95.87%	Acceptable
	Rh Positive	5	4.13%	
BB-5	Rh Positive	120	99.17%	Acceptable
	Rh Negative	1	0.85%	

BLOOD BANK

UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	Unexpected antibody detected	92	98.92%	Acceptable
	No unexpected antibody detected	1	1.08%	
AB-2	No unexpected antibody detected	92	98.92%	Acceptable
	Unexpected antibody detected	1	1.08%	
AB-3	No unexpected antibody detected	88	94.62%	Acceptable
	Unexpected antibody detected	5	5.38%	
AB-4	Unexpected antibody detected	90	96.77%	Acceptable
	No unexpected antibody detected	3	3.23%	
AB-5	No unexpected antibody detected	91	97.85%	Acceptable
	Unexpected antibody detected	2	2.15%	

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	Anti-Fy(a)	33	73.33%	Acceptable
	Unable to identify, referred	7	15.56%	Acceptable
	No antibody detected	2	4.44%	
	Anti-e	2	4.44%	
	Anti-Jk(b)	1	2.22%	
AB-2	No antibody detected	45	100%	Acceptable
AB-3	No antibody detected	45	100%	Acceptable
AB-4	Anti-K	44	97.78%	Acceptable
	Anti-Le(a)	1	2.22%	
AB-5	No antibody detected	45	100%	Acceptable

Specimen AB-1 was 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-1	Not Compatible	60	62.50%	Acceptable
	Compatible	36	37.50%	
AB-2	Compatible	91	94.79%	Acceptable
	Not Compatible	5	5.25%	
AB-3	Compatible	88	91.67%	Acceptable
	Not Compatible	8	8.33%	
AB-4	Compatible	90	93.75%	Acceptable
	Not Compatible	6	6.25%	
AB-5	Compatible	92	96.84%	Acceptable
	Not Compatible	3	3.16%	

Specimen AB-1 was graded by 100% referee consensus.

Coagulation

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-1						Specimen CG-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	117	56.17	10.59	18.9	57.6	47.7 - 64.6	120	12.02	1.45	12.0	12.4	10.2 - 13.9
Dade Innovin												
Dade Behring BFT II	5	50.08	4.28	8.6	49.7	42.5 - 57.6	5	9.04	0.57	6.3	8.9	7.6 - 10.4
Sysmex CA-500/600 series	24	47.94	2.13	4.4	47.6	40.7 - 55.2	24	10.56	0.26	2.4	10.5	8.9 - 12.2
All Coagulation Instruments	34	47.94	2.73	5.7	47.6	40.7 - 55.2	34	10.35	0.67	6.5	10.4	8.7 - 11.9
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	5	69.80	6.89	9.9	72.1	59.3 - 80.3	5	13.34	0.75	5.6	13.1	11.3 - 15.4
Diagnostica Stago STart 4/8	8	64.31	4.15	6.4	64.3	54.6 - 74.0	8	13.08	0.45	3.5	13.1	11.1 - 15.1
RAL Clot-SP	18	64.31	2.08	3.2	64.5	54.6 - 74.0	18	13.41	0.41	3.0	13.4	11.3 - 15.5
All Coagulation Instruments	35	65.83	4.74	7.2	64.7	55.9 - 75.8	37	13.22	0.52	4.0	13.2	11.2 - 15.3
Diagon Dia-PT												
Coalyzer-410	5	54.88	7.21	13.1	52.3	46.6 - 63.2	6	12.97	0.66	5.1	12.9	11.0 - 15.0
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	53.64	7.64	14.2	56.7	45.5 - 61.7	5	11.02	1.09	9.9	11.3	9.3 - 12.7
IL TEST PT Fibrinogen												
IL ACL, all models	6	34.60	1.69	4.9	34.6	29.4 - 39.8	6	10.83	0.27	2.5	11.0	9.2 - 12.5
IL TEST PT-FIB HS PLUS												
IL ACL, all models	16	63.28	4.64	7.3	64.1	53.7 - 72.8	16	12.79	0.40	3.1	12.8	10.8 - 14.8

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-3						Specimen CG-4					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	120	13.74	1.44	10.4	14.1	11.6 - 15.9	120	12.08	1.44	11.9	12.4	10.2 - 13.9
Dade Innovin												
Dade Behring BFT II	5	11.28	0.70	6.2	11.2	9.5 - 13.0	5	9.42	0.53	5.6	9.3	8.0 - 10.9
Sysmex CA-500/600 series	23	12.34	0.24	1.9	12.4	10.4 - 14.2	24	10.54	0.20	1.9	10.6	8.9 - 12.2
All Coagulation Instruments	34	12.23	0.70	5.7	12.3	10.3 - 14.1	34	10.39	0.51	4.9	10.5	8.8 - 12.0
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	5	15.10	0.78	5.2	14.9	12.8 - 17.4	5	13.56	0.87	6.4	13.3	11.5 - 15.6
Diagnostica Stago STart 4/8	8	14.40	0.51	3.5	14.4	12.2 - 16.6	8	12.83	0.51	4.0	12.8	10.9 - 14.8
RAL Clot-SP	18	15.22	0.63	4.1	15.2	12.9 - 17.5	18	13.50	0.32	2.4	13.5	11.4 - 15.6
All Coagulation Instruments	37	14.86	0.72	4.8	14.9	12.6 - 17.1	37	13.23	0.59	4.5	13.3	11.2 - 15.3
Diagon Dia-PT												
Coalyzer-410	6	14.90	1.22	8.2	14.5	12.6 - 17.2	6	12.92	1.21	9.3	12.6	10.9 - 14.9
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	12.54	0.72	5.7	12.8	10.6 - 14.5	5	11.20	0.91	8.2	11.6	9.5 - 12.9
IL TEST PT Fibrinogen												
IL ACL, all models	6	12.78	0.24	1.9	12.9	10.8 - 14.8	6	11.28	0.29	2.5	11.3	9.5 - 13.0
IL TEST PT-FIB HS PLUS												
IL ACL, all models	15	14.73	0.43	2.9	14.9	12.5 - 17.0	16	13.20	0.54	4.1	13.3	11.2 - 15.2

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-5					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	120	31.37	5.37	17.1	32.1	26.6 - 36.1
Dade Innovin						
Dade Behring BFT II	5	26.36	2.47	9.4	25.7	22.4 - 30.4
Sysmex CA-500/600 series	24	26.91	1.17	4.3	26.7	22.8 - 31.0
All Coagulation Instruments	34	26.72	1.37	5.1	26.4	22.7 - 30.8
Diag Stago STA Neoplastine Cl+						
bioMerieux Thrombolyzer Compact X/XR	5	39.02	1.24	3.2	39.0	33.1 - 44.9
Diagnostica Stago STart 4/8	8	34.19	5.08	14.9	35.6	29.0 - 39.4
RAL Clot-SP	18	36.08	1.25	3.5	35.9	30.6 - 41.5
All Coagulation Instruments	36	36.44	2.23	6.1	36.5	30.9 - 42.0
Diagon Dia-PT						
Coalyzer-410	6	31.28	1.98	6.3	31.5	26.5 - 36.0
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	29.50	3.42	11.6	30.8	25.0 - 34.0
IL TEST PT Fibrinogen						
IL ACL, all models	6	20.92	0.64	3.1	20.8	17.7 - 24.1
IL TEST PT-FIB HS PLUS						
IL ACL, all models	16	34.84	1.74	5.0	34.9	29.6 - 40.1

PROTHROMBIN TIME-INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-1						Specimen CG-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	116	5.99	1.58	26.4	5.6	4.7 - 7.2	116	1.00	0.08	7.7	1.0	0.7 - 1.2
Dade Innovin												
Dade Behring BFT II	5	4.30	0.31	7.2	4.3	3.4 - 5.2	5	1.02	0.04	4.4	1.0	0.8 - 1.3
Sysmex CA-500/600 series	24	4.54	0.18	3.9	4.6	3.6 - 5.5	24	1.04	0.05	4.8	1.0	0.8 - 1.3
All Coagulation Instruments	33	4.47	0.24	5.3	4.5	3.5 - 5.4	34	1.03	0.05	5.2	1.0	0.8 - 1.3
Dade Thromborel S												
All Coagulation Instruments	3	-	-	-	5.3	4.4 - 6.8	4	1.05	0.10	9.5	1.1	0.8 - 1.3
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	5	8.38	1.30	15.5	8.2	6.7 - 10.1	5	1.00	0.10	10.0	1.0	0.8 - 1.2
Diagnostica Stago STart 4/8	8	7.60	1.16	15.2	7.5	6.0 - 9.2	8	1.00	0.11	10.7	1.0	0.8 - 1.2
RAL Clot-SP	17	7.75	0.57	7.4	7.6	6.2 - 9.4	17	1.00	0.05	5.0	1.0	0.8 - 1.2
All Coagulation Instruments	34	7.88	0.98	12.4	7.8	6.3 - 9.5	35	0.99	0.07	7.5	1.0	0.7 - 1.2
Diagon Dia-PT												
Coalyzer-410	4	5.35	0.76	14.2	5.4	4.2 - 6.5	5	0.96	0.05	5.7	1.0	0.7 - 1.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	5.08	0.62	12.2	5.3	4.0 - 6.1	6	1.02	0.10	9.7	1.1	0.8 - 1.3
IL TEST PT Fibrinogen												
IL ACL, all models	6	6.92	1.27	18.4	7.2	5.5 - 8.4	6	0.92	0.12	12.8	1.0	0.7 - 1.2
IL TEST PT-FIB HS PLUS												
IL ACL, all models	16	5.71	0.64	11.2	6.0	4.5 - 6.9	16	0.93	0.07	7.4	0.9	0.7 - 1.2
IL TEST PT-FIB Recombinant												
IL ACL, all models	4	5.65	0.90	15.9	5.5	4.5 - 6.8	4	0.90	0.16	18.1	0.9	0.7 - 1.1

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-3						Specimen CG-4					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	119	1.15	0.10	8.4	1.2	0.9 - 1.4	116	1.00	0.08	7.7	1.0	0.8 - 1.2
Dade Innovin												
Dade Behring BFT II	5	1.22	0.04	3.7	1.2	0.9 - 1.5	5	1.04	0.05	5.3	1.0	0.8 - 1.3
Sysmex CA-500/600 series	23	1.20	0.05	4.0	1.2	0.9 - 1.5	24	1.04	0.06	5.5	1.0	0.8 - 1.3
All Coagulation Instruments	34	1.20	0.07	5.6	1.2	0.9 - 1.5	34	1.04	0.06	5.8	1.0	0.8 - 1.3
Dade Thromborel S												
All Coagulation Instruments	4	1.10	0.08	7.4	1.1	0.8 - 1.4	4	1.03	0.13	12.3	1.0	0.8 - 1.3
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	5	1.16	0.11	9.8	1.2	0.9 - 1.4	5	1.00	0.10	10.0	1.0	0.8 - 1.2
Diagnostica Stago STart 4/8	8	1.13	0.13	11.4	1.1	0.9 - 1.4	8	0.98	0.09	9.1	1.0	0.7 - 1.2
RAL Clot-SP	17	1.17	0.08	7.3	1.2	0.9 - 1.5	17	0.99	0.06	5.6	1.0	0.7 - 1.2
All Coagulation Instruments	35	1.15	0.10	8.8	1.1	0.9 - 1.4	35	0.98	0.07	7.6	1.0	0.7 - 1.2
Diagon Dia-PT												
Coalyzer-410	5	1.16	0.09	7.7	1.1	0.9 - 1.4	5	0.96	0.05	5.7	1.0	0.7 - 1.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	1.17	0.05	4.4	1.2	0.9 - 1.5	6	1.02	0.10	9.7	1.1	0.8 - 1.3
IL TEST PT Fibrinogen												
IL ACL, all models	6	1.20	0.15	12.9	1.3	0.9 - 1.5	6	1.00	0.15	15.5	1.1	0.8 - 1.2
IL TEST PT-FIB HS PLUS												
IL ACL, all models	16	1.10	0.07	6.6	1.1	0.8 - 1.4	16	0.94	0.07	7.7	0.9	0.7 - 1.2
IL TEST PT-FIB Recombinant												
IL ACL, all models	4	1.05	0.13	12.3	1.1	0.8 - 1.3	4	0.90	0.14	15.7	1.0	0.7 - 1.1

PROTHROMBIN TIME-INTERNATIONAL NORMALIZED RATIO (INR)

Specimen CG-5

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	118	3.04	0.56	18.5	2.9	2.4 - 3.7
Dade Innovin						
Dade Behring BFT II	5	2.52	0.19	7.6	2.5	2.0 - 3.1
Sysmex CA-500/600 series	24	2.58	0.11	4.1	2.6	2.0 - 3.1
All Coagulation Instruments	33	2.56	0.12	4.9	2.6	2.0 - 3.1
Dade Thromborel S						
All Coagulation Instruments	4	3.38	0.89	26.4	3.0	2.7 - 4.1
Diag Stago STA Neoplastine CI+						
bioMerieux Thrombolyzer Compact X/XR	5	3.98	0.57	14.3	4.2	3.1 - 4.8
Dagnostica Stago STart 4/8	7	3.70	0.59	16.0	3.8	2.9 - 4.5
RAL Clot-SP	17	3.59	0.20	5.7	3.6	2.8 - 4.4
All Coagulation Instruments	34	3.70	0.41	11.2	3.6	2.9 - 4.5
Diagon Dia-PT						
Coalyzer-410	5	3.08	0.22	7.0	3.1	2.4 - 3.7
HemosIL RecombiPlasTin 2G						
IL ACL, all models	6	2.77	0.24	8.8	2.8	2.2 - 3.4
IL TEST PT Fibrinogen						
IL ACL, all models	6	2.88	0.43	14.8	3.0	2.3 - 3.5
IL TEST PT-FIB HS PLUS						
IL ACL, all models	16	2.93	0.24	8.2	2.9	2.3 - 3.6
IL TEST PT-FIB Recombinant						
IL ACL, all models	4	2.78	0.17	6.2	2.8	2.2 - 3.4

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

<u>Reagent/Instrument</u>	Specimen CG-1						Specimen CG-2					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	61	78.2	13.8	17.7	74	66 - 90	72	31.2	2.9	9.3	31	26 - 36
Dade Actin												
Sysmex CA-500/600 series	2	-	-	-	100	86 - 117	3	32.0	4.0	12.5	32	27 - 37
All Coagulation Instruments	3	101.7	3.5	3.5	102	86 - 117	5	32.4	3.6	11.0	32	27 - 38
Dade Actin FSL												
Sysmex CA-500/600 series	10	71.4	1.4	2.0	71	60 - 83	10	29.0	0.7	2.3	29	24 - 34
All Coagulation Instruments	11	71.5	1.4	2.0	71	60 - 83	11	29.2	0.9	3.0	29	24 - 34
Diagnostica Stago STA C.K. Prest												
bioMerieux Thrombolyzer Compact X/XR	4	80.3	2.2	2.8	81	68 - 93	4	34.5	1.3	3.7	35	29 - 40
Diagnostica Stago STA Compact	2	-	-	-	80	66 - 90	3	33.0	1.7	5.2	34	28 - 38
Diagnostica Stago STart 4/8	3	74.3	0.6	0.8	74	63 - 86	5	32.8	4.0	12.3	33	27 - 38
All Coagulation Instruments	9	78.2	4.4	5.6	77	66 - 90	12	33.4	2.7	8.2	34	28 - 39
Diagnostica Stago STA-PTT												
All Coagulation Instruments	3	73.7	8.4	11.4	78	62 - 85	4	33.0	3.4	10.2	33	28 - 38
Diagon Dia-PTT												
Coalyzer-410	2	-	-	-	214	181 - 247	3	33.3	4.0	12.1	34	28 - 39
Hemoliance SynthASil												
IL ACL, all models	4	93.5	8.5	9.1	97	79 - 108	4	30.5	0.6	1.9	31	25 - 36
IL TEST APTT-SP												
IL ACL, all models	22	71.1	3.6	5.1	72	60 - 82	23	29.5	1.6	5.3	29	25 - 34

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

<u>Reagent/Instrument</u>	Specimen CG-3						Specimen CG-4					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	70	37.6	4.2	11.2	38	31 - 44	70	28.2	2.7	9.4	28	23 - 33
Dade Actin												
Sysmex CA-500/600 series	3	34.0	4.6	13.5	33	28 - 40	3	27.0	2.6	9.8	28	22 - 32
All Coagulation Instruments	5	35.2	4.2	12.0	34	29 - 41	5	27.2	2.6	9.5	28	23 - 32
Dade Actin FSL												
Sysmex CA-500/600 series	10	31.3	0.7	2.2	31	26 - 36	10	24.9	0.7	3.0	25	21 - 29
All Coagulation Instruments	11	31.5	0.8	2.6	31	26 - 37	11	25.1	0.9	3.8	25	21 - 29
Diagnostica Stago STA C.K. Prest												
bioMerieux Thrombolyzer Compact X/XR	4	43.3	2.1	4.8	43	36 - 50	4	31.8	1.3	4.0	32	26 - 37
Diagnostica Stago STA Compact	3	39.3	2.1	5.3	40	33 - 46	3	29.7	1.5	5.1	30	25 - 35
Diagnostica Stago STart 4/8	4	41.3	4.8	11.6	40	35 - 48	5	29.2	4.8	16.3	28	24 - 34
All Coagulation Instruments	11	41.5	3.4	8.2	41	35 - 48	12	30.2	3.2	10.7	30	25 - 35
Diagnostica Stago STA-PTT												
All Coagulation Instruments	4	41.8	3.0	7.2	41	35 - 49	4	31.3	1.9	6.1	31	26 - 36
Diagon Dia-PTT												
Coalyzer-410	3	39.0	1.0	2.6	39	33 - 45	3	28.3	2.5	8.9	28	24 - 33
Hemoliance SynthASil												
IL ACL, all models	4	39.3	1.0	2.4	40	33 - 46	4	30.5	0.6	1.9	31	25 - 36
IL TEST APTT-SP												
IL ACL, all models	22	37.3	1.8	4.9	37	31 - 43	22	27.6	1.2	4.4	28	23 - 32

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

Specimen CG-5

<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	59	54.0	8.1	15.1	51	45 - 63
Dade Actin						
Sysmex CA-500/600 series	2	-	-	-	64	54 - 74
All Coagulation Instruments	3	64.3	1.5	2.4	64	54 - 74
Dade Actin FSL						
Sysmex CA-500/600 series	10	50.1	1.1	2.2	50	42 - 58
All Coagulation Instruments	11	50.5	1.6	3.1	50	42 - 59
Diagnostica Stago STA C.K. Prest						
bioMerieux Thrombolyzer Compact X/XR	4	54.5	4.4	8.0	57	46 - 63
Diagnostica Stago STA Compact	3	52.7	6.0	11.4	52	44 - 61
Diagnostica Stago STart 4/8	3	61.7	11.0	17.8	68	52 - 71
All Coagulation Instruments	10	56.1	7.5	13.4	57	47 - 65
Diagnostica Stago STA-PTT						
All Coagulation Instruments	3	54.7	2.1	3.8	54	46 - 63
Diagon Dia-PTT						
Coalyzer-410	3	122.0	21.1	17.3	124	103 - 141
Hemoliance SynthASil						
IL ACL, all models	4	65.3	3.9	5.9	66	55 - 76
IL TEST APTT-SP						
IL ACL, all models	20	48.7	2.5	5.1	49	41 - 57

FIBRINOGEN (mg/dL)

Specimen CG-1							Specimen CG-2					
<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	37	321.5	62.3	19.4	301	257 - 386	37	527.2	82.4	15.6	524	421 - 633
Dade Thrombin												
All Coagulation Instruments	3	250.7	60.5	24.1	281	200 - 301	3	382.0	77.9	20.4	338	305 - 459
Diagnostica Stago STA Fibrinogen												
bioMerieux Thrombolyzer Compact												
X/XR	3	272.7	11.0	4.0	269	218 - 328	3	559.3	37.7	6.7	555	447 - 672
Diagnostica Stago STA Compact	3	276.3	17.4	6.3	270	221 - 332	3	529.3	36.2	6.8	521	423 - 636
All Coagulation Instruments	8	280.3	15.5	5.5	278	224 - 337	8	560.3	52.6	9.4	553	448 - 673
IL Fibrinogen-C												
All Coagulation Instruments	3	291.0	14.9	5.1	297	232 - 350	3	637.0	94.3	14.8	655	509 - 765
IL TEST PT-FIB HS PLUS												
IL ACL, all models	14	379.5	40.8	10.8	376	303 - 456	14	546.9	57.5	10.5	532	437 - 657
IL TEST PT-FIB Recombinant												
IL ACL, all models	4	346.3	56.8	16.4	355	277 - 416	4	518.0	42.6	8.2	510	414 - 622

Specimen CG-3							Specimen CG-4					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	38	141.9	21.4	15.1	140	113 - 171	35	306.9	29.1	9.5	307	245 - 369
Dade Thrombin												
All Coagulation Instruments	3	137.7	44.8	32.5	150	110 - 166	3	252.3	58.4	23.1	283	201 - 303
Diagnostica Stago STA Fibrinogen												
bioMerieux Thrombolyzer Compact												
X/XR	3	126.7	10.0	7.9	126	101 - 153	3	304.0	20.7	6.8	310	243 - 365
Diagnostica Stago STA Compact	3	150.0	18.0	12.0	150	120 - 180	3	299.3	32.6	10.9	309	239 - 360
All Coagulation Instruments	8	141.1	16.8	11.9	140	112 - 170	8	305.5	22.8	7.5	310	244 - 367
IL Fibrinogen-C												
All Coagulation Instruments	3	133.3	5.7	4.3	135	106 - 160	3	382.3	119.4	31.2	320	305 - 459
IL TEST PT-FIB HS PLUS												
IL ACL, all models	14	147.2	17.7	12.0	147	117 - 177	14	318.4	31.6	9.9	310	254 - 383
IL TEST PT-FIB Recombinant												
IL ACL, all models	4	150.3	20.6	13.7	149	120 - 181	4	315.3	28.7	9.1	317	252 - 379

FIBRINOGEN (mg/dL)

Specimen CG-5						
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	34	330.9	59.3	17.9	325	264 - 398
Dade Thrombin						
All Coagulation Instruments	3	260.7	66.0	25.3	291	208 - 313
Diagnostica Stago STA Fibrinogen						
bioMerieux Thrombolyzer Compact						
X/XR	3	292.3	21.5	7.4	300	233 - 351
Diagnostica Stago STA Compact	3	313.0	12.8	4.1	316	250 - 376
All Coagulation Instruments	8	301.9	17.1	5.7	304	241 - 363
IL Fibrinogen-C						
All Coagulation Instruments	3	379.7	93.1	24.5	331	303 - 456
IL TEST PT-FIB HS PLUS						
IL ACL, all models	11	375.6	33.2	8.8	365	300 - 451
IL TEST PT-FIB Recombinant						
IL ACL, all models	4	340.0	34.9	10.3	340	272 - 408

URINALYSIS DIPSTICK–SPECIFIC GRAVITY

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	375	1.0166	0.0051	0.5	1.015	1.006 - 1.027
All Roche Methods	136	1.0149	0.0039	0.4	1.015	1.004 - 1.025
All Siemens Methods	49	1.0150	0.0039	0.4	1.015	1.005 - 1.025
Arkray Aution Sticks	17	1.0236	0.0047	0.5	1.025	1.013 - 1.034
Combi-Screen Test Strips	10	1.0165	0.0024	0.2	1.015	1.006 - 1.027
DIRUI H-100 / H-500 Urine Analyzer	12	1.0150	0.0001	0.0	1.015	1.005 - 1.025
Other Analyzer Method	17	1.0207	0.0048	0.5	1.022	1.010 - 1.031
Roche Chemstrips / Combur	18	1.0125	0.0025	0.2	1.013	1.002 - 1.023
Roche cobas u 411	80	1.0140	0.0028	0.3	1.015	1.004 - 1.024
Roche Urisys	55	1.0167	0.0051	0.5	1.016	1.006 - 1.027
SD UroColor Reagent Strips	17	1.0238	0.0057	0.6	1.025	1.013 - 1.034
Siemens Clinitek Advantus	31	1.0131	0.0030	0.3	1.015	1.003 - 1.024
Siemens Clinitek Status / Status+	10	1.0170	0.0035	0.3	1.018	1.007 - 1.027
UriScan Reagent Strips	36	1.0191	0.0043	0.4	1.020	1.009 - 1.030

URINALYSIS DIPSTICK–pH

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>≤3.5</u>	<u>4.0</u>	<u>4.5</u>	<u>5.0</u>	<u>5.5</u>	<u>6.0</u>	<u>6.5</u>	<u>7.0</u>	<u>7.5</u>	<u>8.0</u>	<u>8.5</u>	<u>≥9.0</u>
ALL METHODS	391	-	-	-	-	1	19	126	241	4	-	-	-
Acon Laboratories	7	-	-	-	-	-	1	2	4	-	-	-	-
Analyticon CombiScan 500	2	-	-	-	-	-	-	-	2	-	-	-	-
Arkray Aution Sticks	18	-	-	-	-	-	-	14	4	-	-	-	-
Arkray PocketChem UA	1	-	-	-	-	-	-	-	1	-	-	-	-
Combi-Screen Test Strips	10	-	-	-	-	-	2	1	6	1	-	-	-
CYBOW Urine Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	14	-	-	-	-	-	1	9	3	1	-	-	-
DIRUI H-800 Urine Analyzer	7	-	-	-	-	-	-	4	3	-	-	-	-
HUMAN Combilyzer	2	-	-	-	-	-	-	1	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	-	2	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	9	-	-	-	-	-	-	8	1	-	-	-	-
Other Analyzer Method	18	-	-	-	-	-	1	14	3	-	-	-	-
Other Dipstick Method	7	-	-	-	-	-	1	4	2	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	1	-	-	-	-	-
Roche Chemstrip 101	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche Chemstrips / Combur	19	-	-	-	-	-	1	1	17	-	-	-	-
Roche cobas u 411	84	-	-	-	-	-	-	4	80	-	-	-	-
Roche Mditron Junior/II	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche Urilux S	2	-	-	-	-	-	-	1	1	-	-	-	-
Roche Urisys	54	-	-	-	-	-	1	8	45	-	-	-	-
SD UroColor Reagent Strips	17	-	-	-	-	-	1	14	2	-	-	-	-
Siemens Clinitek 500	2	-	-	-	-	-	-	-	2	-	-	-	-
Siemens Clinitek Advantus	31	-	-	-	-	-	1	4	26	-	-	-	-
Siemens Clinitek Atlas	6	-	-	-	-	-	-	3	3	-	-	-	-
Siemens Clinitek Status / Status+	10	-	-	-	-	-	-	-	9	1	-	-	-
Siemens Multistix Pro	2	-	-	-	-	-	-	-	1	1	-	-	-
Siemens Reagent Strips	14	-	-	-	-	-	-	5	9	-	-	-	-
Urinometer	1	-	-	-	-	-	-	1	-	-	-	-	-
UriScan Pro/II	6	-	-	-	-	-	-	4	2	-	-	-	-
UriScan Reagent Strips	36	-	-	-	-	1	9	18	8	-	-	-	-

URINALYSIS DIPSTICK–PROTEIN QUALITATIVE

Specimen UA-1

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	390	384	-	-	2	-	-	1	2	-	-	1	-
Acon Laboratories	7	7	-	-	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	2	2	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	18	18	-	-	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	1	1	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	9	8	-	-	-	-	-	1	-	-	-	-	-
CYBOW Urine Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	14	14	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	7	7	-	-	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	2	2	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	9	9	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	19	18	-	-	-	-	-	-	1	-	-	-	-
Other Dipstick Method	8	8	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrip 101	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	20	19	-	-	1	-	-	-	-	-	-	-	-
Roche cobas u 411	84	83	-	-	-	-	-	-	-	-	-	1	-
Roche Miditron Junior/II	1	1	-	-	-	-	-	-	-	-	-	-	-
Roche Urilux S	2	2	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	53	53	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	17	17	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	2	2	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	30	29	-	-	1	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	7	7	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	11	11	-	-	-	-	-	-	-	-	-	-	-
Siemens Multistix Pro	2	2	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	13	13	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	6	6	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	35	34	-	-	-	-	-	-	1	-	-	-	-
UriScan Reagent Strips	390	384	-	-	2	-	-	1	2	-	-	1	-

URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-1

<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	390	1	-	10	49	45	80	1	13	35	156
Acon Laboratories	8	-	-	1	2	1	3	-	1	-	-
Analyticon CombiScan 500	2	1	-	-	-	-	-	-	-	-	1
Arkray Aution Sticks	18	-	-	-	-	1	7	-	-	3	7
Arkray PocketChem UA	1	-	-	-	-	-	1	-	-	-	-
Combi-Screen Test Strips	8	-	-	-	1	-	-	-	-	-	7
CYBOW Urine Reagent Strips	1	-	-	-	1	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	14	-	-	-	4	5	-	-	5	-	-
DIRUI H-800 Urine Analyzer	6	-	-	-	2	1	2	-	-	1	-
HUMAN Combilyzer	2	-	-	-	-	-	-	-	-	1	1
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	1	-	-	-	1
Iris Diagnostics iChem Velocity Strips	9	-	-	-	1	-	-	-	-	8	-
Other Analyzer Method	18	-	-	-	-	-	8	-	2	3	5
Other Dipstick Method	8	-	-	-	-	1	3	-	-	1	3
Plasmatec URIPATH	1	-	-	1	-	-	-	-	-	-	-
Roche Chemstrip 101	1	-	-	-	-	-	-	-	-	-	1
Roche Chemstrips / Combur	20	-	-	-	-	2	13	-	-	-	5
Roche cobas u 411	84	-	-	-	-	2	13	1	-	-	68
Roche Mditron Junior/II	1	-	-	-	-	-	1	-	-	-	-
Roche Urilux S	2	-	-	-	-	1	1	-	-	-	-
Roche Urisys	54	-	-	-	-	4	15	-	-	-	35
SD UroColor Reagent Strips	17	-	-	-	7	4	2	-	-	1	3
Siemens Clinitek 500	2	-	-	-	-	-	-	-	1	1	-
Siemens Clinitek Advantus	30	-	-	-	15	4	-	-	1	6	4
Siemens Clinitek Atlas	7	-	-	-	-	4	-	-	-	-	3
Siemens Clinitek Status / Status+	11	-	-	3	2	2	1	-	-	3	-
Siemens Multistix Pro	2	-	-	-	-	-	-	-	-	1	1
Siemens Reagent Strips	14	-	-	4	8	-	1	-	1	-	-
Urinometer	1	-	-	-	-	1	-	-	-	-	-
UriScan Pro/II	6	-	-	-	-	1	1	-	-	1	3
UriScan Reagent Strips	35	-	-	1	5	11	5	-	2	3	8

URINALYSIS DIPSTICK–KETONES

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Participant Results</u>													
		<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>5 - 10</u> <u>mg/dL</u>	<u>15 - 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	390	1	-	-	-	1	-	22	112	67	-	2	8	43	134
Acon Laboratories	8	-	-	-	-	-	-	-	5	2	-	-	-	-	1
Analyticon CombiScan 500	2	1	-	-	-	-	-	-	-	-	-	-	-	-	1
Arkray Aution Sticks	18	-	-	-	-	-	-	-	-	12	-	-	1	1	4
Arkray PocketChem UA	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Combi-Screen Test Strips	9	-	-	-	-	-	-	2	1	-	-	-	-	-	6
CYBOW Urine Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	13	-	-	-	-	-	-	-	8	2	-	-	-	3	-
DIRUI H-800 Urine Analyzer	7	-	-	-	-	-	-	1	4	1	-	-	1	-	-
HUMAN Combilyzer	2	-	-	-	-	-	-	-	1	-	-	-	-	1	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	-	-	-	1	-	-	-	-	1
Iris Diagnostics iChem Velocity Strips	9	-	-	-	-	-	-	-	-	1	-	-	-	5	3
Other Analyzer Method	18	-	-	-	-	-	-	1	5	4	-	-	1	2	5
Other Dipstick Method	8	-	-	-	-	-	-	-	3	2	-	-	-	1	2
Plasmatec URIPATH	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Roche Chemstrip 101	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Roche Chemstrips / Combur	20	-	-	-	-	-	-	-	15	2	-	-	-	-	3
Roche cobas u 411	84	-	-	-	-	-	-	-	2	13	-	1	-	-	68
Roche Mditron Junior/II	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Roche Urilux S	2	-	-	-	-	-	-	-	1	1	-	-	-	-	-
Roche Urisys	53	-	-	-	-	-	-	2	12	5	-	-	1	2	31
SD UroColor Reagent Strips	17	-	-	-	-	-	-	6	7	-	-	-	1	3	-
Siemens Clinitek 500	2	-	-	-	-	1	-	-	-	-	-	-	-	1	-
Siemens Clinitek Advantus	30	-	-	-	-	-	-	-	18	-	-	-	-	12	-
Siemens Clinitek Atlas	7	-	-	-	-	-	-	-	1	3	-	-	-	1	2
Siemens Clinitek Status / Status+	10	-	-	-	-	-	-	-	4	3	-	-	1	-	2
Siemens Multistix Pro	2	-	-	-	-	-	-	-	-	-	-	-	-	-	2
Siemens Reagent Strips	13	-	-	-	-	-	-	-	-	12	-	-	-	-	1
Urinometer	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-
UriScan Pro/II	6	-	-	-	-	-	-	2	2	-	-	-	-	2	-
UriScan Reagent Strips	36	-	-	-	-	-	-	7	15	2	-	-	2	9	1

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Participant Results</u>					<u>0.5 - 1.0 mg/dL</u>	<u>2.0 - 4.0 mg/dL</u>	<u>6.0 - 10.0 mg/dL</u>	<u>>10.0 mg/dL</u>
						<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>				
ALL METHODS	378	376	-	-	-	-	-	-	1	-	1	-	-	-
Acon Laboratories	8	8	-	-	-	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	18	18	-	-	-	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	8	8	-	-	-	-	-	-	-	-	-	-	-	-
CYBOW Urine Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	13	13	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	7	7	-	-	-	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	9	9	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	18	18	-	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	8	8	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrip 101	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	20	20	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	82	82	-	-	-	-	-	-	-	-	-	-	-	-
Roche Mditron Junior/II	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urilux S	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	55	55	-	-	-	-	-	-	-	-	-	-	-	-
SD UroColor Reagent Strips	16	16	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	30	29	-	-	-	-	-	-	1	-	-	-	-	-
Siemens Clinitek Atlas	7	7	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	10	10	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Multistix Pro	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	3	3	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	6	6	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	36	35	-	-	-	-	-	-	-	-	1	-	-	-

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>				
		<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	378	375	-	2	1	-
Acon Laboratories	8	8	-	-	-	-
Analyticon CombiScan 500	3	3	-	-	-	-
Arkray Aution Sticks	17	17	-	-	-	-
Arkray PocketChem UA	1	1	-	-	-	-
Combi-Screen Test Strips	7	7	-	-	-	-
CYBOW Urine Reagent Strips	1	1	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	14	14	-	-	-	-
DIRUI H-800 Urine Analyzer	7	7	-	-	-	-
HUMAN Combilyzer	2	2	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-
Iris Diagnostics iChem Velocity Strips	9	9	-	-	-	-
Other Analyzer Method	18	18	-	-	-	-
Other Dipstick Method	8	8	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-
Roche Chemstrip 101	1	1	-	-	-	-
Roche Chemstrips / Combur	20	20	-	-	-	-
Roche cobas u 411	82	82	-	-	-	-
Roche Mditron Junior/II	1	1	-	-	-	-
Roche Urilux S	2	2	-	-	-	-
Roche Urisys	54	54	-	-	-	-
SD UroColor Reagent Strips	17	17	-	-	-	-
Siemens Clinitek 500	2	2	-	-	-	-
Siemens Clinitek Advantus	30	30	-	-	-	-
Siemens Clinitek Atlas	7	6	-	1	-	-
Siemens Clinitek Status / Status+	10	9	-	1	-	-
Siemens Multistix Pro	2	2	-	-	-	-
Siemens Reagent Strips	3	3	-	-	-	-
Urinometer	1	1	-	-	-	-
UriScan Pro/II	6	6	-	-	-	-
UriScan Reagent Strips	36	35	-	-	1	-

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN
Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>(5+)</u>	<u>5 - 25</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	392	385	2	-	-	-	1	1	-	-	-	3	-	-	-	-	-	-
Acon Laboratories	8	8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	18	18	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Arkray PocketChem UA	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	8	7	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
CYBOW Urine Reagent Strips	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	14	14	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DIRUI H-800 Urine Analyzer	7	7	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	9	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Analyzer Method	18	17	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Other Dipstick Method	8	8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrip 101	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Chemstrips / Combur	20	20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche cobas u 411	83	82	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Roche Mditron Junior/II	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urilux S	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Roche Urisys	54	53	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
SD UroColor Reagent Strips	17	17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek 500	2	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Advantus	30	30	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Atlas	7	7	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Clinitek Status / Status+	10	10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Multistix Pro	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Siemens Reagent Strips	14	14	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Pro/II	6	6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
UriScan Reagent Strips	36	35	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-1

<u>Method</u>	<i>Participant Results</i>												
	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small</u>	<u>Moderate</u>	<u>Large</u>	<u>(1+)</u>	<u>(2+)</u>	<u>(3+)</u>	<u>(4+)</u>	<u>25 µL</u>	<u>75 or 100 µL</u>	<u>250 or 500 µL</u>
ALL METHODS	376	2	-	2	-	3	8	59	112	5	1	9	175
Acon Laboratories	8	-	-	-	-	-	2	4	1	-	-	1	-
Analyticon CombiScan 500	2	1	-	-	-	-	-	-	-	-	-	-	1
Arkray Aution Sticks	18	-	-	-	-	-	-	-	-	-	-	1	17
Arkray PocketChem UA	1	-	-	-	-	-	-	-	-	-	-	-	1
Combi-Screen Test Strips	9	-	-	-	-	-	-	1	-	-	-	-	8
CYBOW Urine Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	14	-	-	-	-	-	1	7	3	1	-	1	1
DIRUI H-800 Urine Analyzer	7	-	-	-	-	-	-	-	5	1	-	-	1
HUMAN Combilyzer	2	-	-	-	-	-	-	-	1	-	-	1	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	-	-	-	-	-	-	2
Iris Diagnostics iChem Velocity Strips	9	-	-	-	-	-	-	-	4	-	-	-	5
Other Analyzer Method	16	1	-	-	-	-	-	2	4	1	-	1	7
Other Dipstick Method	8	-	-	-	-	-	-	1	4	-	-	-	3
Plasmatec URIPATH	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche Chemstrip 101	2	-	-	-	-	-	-	1	1	-	-	-	-
Roche Chemstrips / Combur	17	-	-	-	-	-	-	2	11	1	-	-	3
Roche cobas u 411	83	-	-	-	-	-	-	-	15	-	-	-	68
Roche Miditron Junior/II	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche Urilux S	2	-	-	-	-	-	-	1	1	-	-	-	-
Roche Urisys	54	-	-	-	-	-	-	2	15	-	-	1	36
SD UroColor Reagent Strips	17	-	-	-	-	-	-	5	8	-	-	-	4
Siemens Clinitek 500	2	-	-	-	-	-	-	1	-	-	-	-	1
Siemens Clinitek Advantus	30	-	-	-	-	1	1	21	2	-	-	2	3
Siemens Clinitek Atlas	7	-	-	-	-	1	-	-	4	-	-	-	2
Siemens Clinitek Status / Status+	10	-	-	2	-	1	3	-	3	1	-	-	-
Siemens Multistix Pro	2	-	-	-	-	-	-	2	-	-	-	-	-
Siemens Reagent Strips	3	-	-	-	-	-	1	-	2	-	-	-	-
Urinometer	1	-	-	-	-	-	-	1	-	-	-	-	-
UriScan Pro/II	6	-	-	-	-	-	-	-	4	-	-	-	2
UriScan Reagent Strips	35	-	-	-	-	-	-	7	18	-	1	1	8

URINALYSIS DIPSTICK–NITRITE

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	380	376	4
Acon Laboratories	9	9	-
Analyticon CombiScan 500	3	2	1
Arkray Aution Sticks	17	16	1
Arkray PocketChem UA	1	1	-
Combi-Screen Test Strips	8	8	-
CYBOW Urine Reagent Strips	1	1	-
DIRUI H-100 / H-500 Urine Analyzer	14	14	-
DIRUI H-800 Urine Analyzer	7	7	-
HUMAN Combilyzer	2	2	-
Iris Diagnostics Aution Max AX-4280	2	2	-
Iris Diagnostics iChem Velocity Strips	9	9	-
Other Analyzer Method	18	18	-
Other Dipstick Method	8	8	-
Plasmatec URIPATH	1	1	-
Roche Chemstrip 101	1	1	-
Roche Chemstrips / Combur	19	19	-
Roche cobas u 411	83	83	-
Roche Mditron Junior/II	1	1	-
Roche Urilux S	2	2	-
Roche Urisys	54	53	1
SD UroColor Reagent Strips	18	17	1
Siemens Clinitek 500	2	2	-
Siemens Clinitek Advantus	30	30	-
Siemens Clinitek Atlas	6	6	-
Siemens Clinitek Status / Status+	10	10	-
Siemens Multistix Pro	2	2	-
Siemens Reagent Strips	2	2	-
Urinometer	1	1	-
UriScan Pro/II	6	6	-
UriScan Reagent Strips	36	36	-

URINALYSIS –MICROALBUMIN (dipstick only)

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>10 mg/L</u>	<u>20 mg/L</u>	<u>30 mg/L</u>	<u>50 mg/L</u>	<u>80 mg/L</u>	<u>100 mg/L</u>	<u>150 mg/L</u>	<u>+ (4 - 8 mg/dL)</u>	<u>++ (>8 mg/dL)</u>
ALL METHODS	28	16	8	-	3	-	1	-	-	-	-
Beckman Coulter ICON microALB	1	1	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	1	1	-	-	-	-	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	2	2	-	-	-	-	-	-	-	-	-
HUMAN Combilyzer	1	1	-	-	-	-	-	-	-	-	-
Other Analyzer Method	1	1	-	-	-	-	-	-	-	-	-
Roche Micral - 1 minute	5	3	-	-	2	-	-	-	-	-	-
Siemens Clinitek Microalbumin	7	-	6	-	1	-	-	-	-	-	-
UriScan Pro/II	1	-	-	-	-	-	1	-	-	-	-

URINALYSIS –URINE hCG

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	107	1	106
Acon Laboratories	10	-	10
Alere Acceava hCG-Urine	2	-	2
Alere Clearview hCG Cassette	6	-	6
bioMerieux VIKIA hCG-D	1	-	1
Biotron 1-Step	7	-	7
CONSULT diagnostics hCG Combo	1	-	1
Other Dipstick Method	2	-	2
Quidel QuickVue + One-Step	1	-	1
Quidel QuickVue One-Step Combo	19	-	19
Quidel QuickVue One-Step Urine	4	-	4
RefuAH hCG Dipstick	1	-	1
Siemens Clinitek Status / Status+	1	-	1
Stanbio QuStick	1	-	1
Sure-Vue hCG - 25mIU	2	-	2

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen SUS-1

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</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	54	53	1	-	129	129	-	-	99.48%
Amoxicillin/Clavulanate	52	34	10	8	71	47	6	18	65.85% ¹
Ampicillin	37	-	-	37	138	3	1	134	97.81%
Ampicillin/Sulbactam	32	18	6	8	91	3	33	55	83.72% ²
Aztreonam	24	23	1	-	43	43	-	-	98.55%
Carbenicillin	-	-	-	-	1	1	-	-	Inappropriate drug ³
Cefaclor	9	6	-	3	-	-	-	-	Not graded ²
Cefazolin	17	14	2	1	46	45	-	1	93.94%
Cefepime	37	37	-	-	127	125	1	1	98.84%
Cefixime	21	20	1	-	17	17	-	-	97.37%
Cefoperazone	11	10	-	1	1	1	-	-	91.67%
Cefotaxime	37	36	-	1	79	78	-	1	98.33%
Cefotetan	-	-	-	-	3	3	-	-	100.00%
Cefoxitin	12	11	1	-	59	58	-	1	97.33%
Cefpodoxime	5	5	-	-	3	3	-	-	100.00%
Ceftazidime	46	46	-	-	134	131	2	1	98.40%
Ceftizoxime	1	1	-	-	2	2	-	-	100.00%
Ceftriaxone	52	51	1	-	128	125	1	2	97.89%
Ceftriaxone	52	51	1	-	128	125	1	2	97.89%
Cephalexin	7	4	2	1	4	3	1	-	90.91%
Cephalothin	14	6	5	3	54	50	3	1	83.10%
Ciprofloxacin	59	58	1	-	156	156	-	-	99.56%
Doxycycline	5	4	1	-	-	-	-	-	80.00%
Ertapenem	16	16	-	-	110	110	-	-	100.00%
Fosfomycin	16	15	-	1	39	39	-	-	98.21%
Gatifloxacin	1	-	-	1	2	2	-	-	Not graded ²
Gentamicin	52	51	1	-	157	157	-	-	99.54%
Imipenem	40	40	-	-	89	89	-	-	100.00%
Kanamycin	1	1	-	-	-	-	-	-	100.00%
Levofloxacin	28	28	-	-	50	50	-	-	100.00%

¹ This specimen was graded by 82% referee consensus.

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

³ This is an inappropriate drug for organism and/or source.

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	2	-	-	2	1	1	-	-	Inappropriate drug ³
Lomefloxacin	1	1	-	-	1	1	-	-	100.00%
Meropenem	39	38	-	1	120	120	-	-	99.38%
Methicillin	-	-	-	-	1	-	-	1	Inappropriate drug ³
Minocycline	1	1	-	-	1	1	-	-	100.00%
Moxifloxacin	8	8	-	-	1	1	-	-	Inappropriate drug ³
Nalidixic Acid	15	15	-	-	10	10	-	-	100.00%
Netilmicin	7	7	-	-	3	3	-	-	100.00%
Nitrofurantoin	53	52	-	1	130	129	-	1	98.96%
Norfloxacin	23	23	-	-	45	45	-	-	100.00%
Ofloxacin	17	17	-	-	2	2	-	-	100.00%
Oxacillin	3	-	-	3	1	-	-	1	Inappropriate drug ³
Penicillin	3	-	-	3	1	-	-	1	Inappropriate drug ³
Piperacillin	7	4	1	2	16	-	2	14	84.61%
Piperacillin/Tazobactam	38	37	1	-	98	93	5	-	94.41%
Rifampin	1	-	-	1	1	-	1	-	Inappropriate drug ³
Sulfisoxazole	2	2	-	-	-	-	-	-	100.00%
Teicoplanin	3	1	-	2	1	1	-	-	Inappropriate drug ³
Tetracycline	9	8	-	1	13	12	-	1	91.67%
Ticarcillin	1	1	-	-	-	-	-	-	Inappropriate drug ³
Ticarcillin/Clavulanate	3	3	-	-	7	5	2	-	80.00%
Tobramycin	13	12	1	-	37	37	-	-	98.11%
Trimethoprim	1	1	-	-	2	2	-	-	100.00%
Trimethoprim/Sulfamethoxazole	58	58	-	-	160	160	-	-	100.00%
Vancomycin	1	-	-	1	1	1	-	-	Inappropriate drug ³

Organism present in specimen SUS-1: *Escherichia coli*.

³ This is an inappropriate drug for organism and/or source.

PARASITOLOGY (PA Specimens)

Specimen PA-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	4	66.67%	Acceptable
Blastocystic hominis	1	16.67%	
Entamoeba coli	1	16.67%	

Parasite present in specimen PA-1: No parasite seen. (Graded by US consensus).

Specimen PA-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba histolytica	3	60.00%	Acceptable
Entamoeba coli	2	40.00%	

Parasite present in specimen PA-2: *Entamoeba histolytica*. (Graded by US consensus).

Specimen PA-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	13	86.67%	Acceptable
No parasite seen	1	6.67%	
Entamoeba coli	1	6.67%	

Parasite present in specimen PA-3: *Hookworm*. (Graded by US consensus).

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. eggs	12	80.00%	Acceptable
Endolimax nana	1	6.67%	
No parasite seen	1	6.67%	
Ascaris lumbricoides eggs	1	6.67%	

Parasites present in specimen PA-4: *Taenia sp. eggs* and *Giardia lamblia*. (Graded by US consensus)

Specimen PA-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Microfilaria, NOS	2	16.67%	Unacceptable
Microfilaria-Loa loa	2	16.67%	Unacceptable
Microfilaria-Mansonella perstans	3	25.00%	Unacceptable
Microfilaria-Wuchereria bancrofti	2	16.67%	Unacceptable
No parasite seen	1	8.33%	Unacceptable
Microfilaria-Mansonella ozzardi	1	8.33%	Unacceptable
Microfilaria-Onchocerca volvulus	1	8.33%	Unacceptable

Parasite present in specimen PA-5: *Microfilaria-Loa loa*. Specimen PA-5 is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY (FP Specimens)

Specimen FP-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Diphyllbothrium latum	181	72.40%	Acceptable
Fasciola hepatica eggs	18	7.20%	
Paragonimus westermani eggs	17	6.80%	
Endolimax nana	12	4.80%	
Hookworm	5	2.00%	
Blastocystis hominis	4	1.60%	
Ascaris lumbricoides eggs	3	1.20%	
Schistosma sp. eggs, NOS	2	0.80%	
Clonorchis sinensis	2	0.80%	
No parasite seen	1	0.40%	
Entamoeba histolytica	1	0.40%	
Trichostrongylus sp. eggs	1	0.40%	
Entamoeba coli	1	0.40%	
Balantidium coli	1	0.40%	
Trichuris trichiura eggs	1	0.40%	

Parasite present in specimen FP-1: *Diphyllbothrium latum*. This challenge is graded by 80% referee consensus.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	208	88.14%	Acceptable
Strongyloides stercoralis larvae	12	5.08%	
Parasite larvae seen but no ID	2	0.85%	
Blastocystis hominis	2	0.85%	
Taenia sp. eggs	2	0.85%	
Other parasite seen but no ID	2	0.85%	
Hookworm	2	0.85%	
Protozoan seen but no ID	1	0.42%	
Endolimax nana	1	0.42%	
Ascaris lumbricoides eggs	1	0.42%	
Trichinella spiralis	1	0.42%	
Entamoeba coli	1	0.42%	
Parasite egg seen but no ID	1	0.42%	

Parasite present in specimen FP-2: No parasite seen.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Clonorchis sinensis	99	41.25%	Acceptable
Parasite egg seen but no ID	5	2.08%	Acceptable
No parasite seen	90	37.50%	
Taenia sp. eggs	16	6.67%	
Giardia lamblia	7	2.92%	
Strongyloides stercoralis larvae	4	1.67%	
Enterobius vermicularis eggs	3	1.25%	
Trichuris trichiurs eggs	3	1.25%	
Hookworm	3	1.25%	
Schistosoma japonicum eggs	2	0.83%	
Endolimax nana	2	0.83%	
Parasite larvae seen but no ID	1	0.42%	
Isospora belli oocysts	1	0.42%	
Hymenolepis diminuta eggs	1	0.42%	
Diphyllobothrium latum	1	0.42%	
Ascaris lumbricoides eggs	1	0.42%	
Cryptosporidium sp., oocysts	1	0.42%	

Parasite present in specimen FP-3: *Clonorchis sinensis*.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	218	74.66%	Acceptable
Trichuris trichiura eggs	59	20.21%	Acceptable
Parasite egg seen but no ID	2	0.68%	Acceptable
No parasite eggs	7	2.40%	
Parasite egg seen but no ID	2	0.68%	
Hookworm	2	0.68%	
Taenia sp. eggs	1	0.34%	
Balantidium coli	1	0.34%	
Paragonimus westermani eggs	1	0.34%	
Schistosoma japonicum eggs	1	0.34%	

Parasites present in specimen FP-4: *Ascaris lumbricoides* eggs.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Trypanosoma cruzi	144	61.80%	Acceptable
Trypanosoma sp., NOS	77	33.05%	Acceptable
Plasmodium vivax	4	1.72%	
Microfilaria, NOS	2	0.86%	
Trypanosoma brucei	2	0.86%	
Plasmodium sp., NOS	1	0.43%	
Leishmania sp.	1	0.43%	
Plasmodium falciparum	1	0.43%	
Toxoplasma gondii	1	0.43%	

Parasite present in specimen FP-5: *Trypanosoma cruzi* and *Trypanosoma sp., NOS*.

Antinuclear Antibody (ANA) - Qualitative

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	2	1	12	13	-
INOVA Diagnostics	7	-	1	6	7	-
Kallestad	1	-	-	1	1	-
Zeus	1	-	-	1	1	-

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	-	1	12
INOVA Diagnostics	7	-	1	6
Kallestad	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-1

ALL METHODS	-	-	-	-	2	3	2	-	-	1	1	-
INOVA Diagnostics	-	-	-	-	2	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-2

ALL METHODS	-	-	1	-	-	-	-	-	-	-	-	8
INOVA Diagnostics	-	-	1	-	-	-	-	-	-	-	-	5
Kallestad	-	-	-	-	-	-	-	-	-	-	-	1
Zeus	-	-	-	-	-	-	-	-	-	-	-	1

Specimen AE-3

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

Specimen AE-4

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

Specimen AE-5

ALL METHODS	-	1	-	-	-	-	-	-	-	-	-	8
INOVA Diagnostics	-	1	-	-	-	-	-	-	-	-	-	5
Kallestad	-	-	-	-	-	-	-	-	-	-	-	1
Zeus	-	-	-	-	-	-	-	-	-	-	-	1

Anti-dsDNA

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	12	-	12	12	-
BioSystems	-	1	-	1	1	-
INOVA Diagnostics	-	6	-	6	6	-
Zeus	-	1	-	1	1	-

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	12	1	11
BioSystems	-	1	-	1
INOVA Diagnostics	-	6	-	6
Zeus	-	1	-	1

Anti-RNP

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	-	8	5	3
INOVA Diagnostics	-	6	-	6	5	1

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	8	-	8
INOVA Diagnostics	-	6	-	6

AE-3 is an ungraded challenge due to less than 80% participant consensus.

Anti-RNP/Sm

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

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

AE-3 is an ungraded challenge due to less than 80% participant consensus.

Anti-SSA

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	9	-	11	11	-
INOVA Diagnostics	-	6	-	6	6	-
Zeus	-	1	-	1	1	-

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	-	-	11
INOVA Diagnostics	6	-	-	6
Zeus	1	-	-	1

Anti-SSB

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	11	-	11	9	2
INOVA Diagnostics	-	6	-	6	6	-
Zeus	-	1	-	1	1	-

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	-	-	11
INOVA Diagnostics	6	-	-	6
Zeus	1	-	-	1

Anti-SSA/SSB

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

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	-	-	2

Anti-Sm

<u>Method</u>	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	11	-	11	4	7
INOVA Diagnostics	-	6	-	6	3	3
Zeus	-	1	-	1	1	-

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	11	-	11
INOVA Diagnostics	-	6	-	6
Zeus	-	1	-	1

AE-3 is graded to US consensus.

Rubella—Qualitative

<u>Method</u>	Specimen RU-1		Specimen RU-2		Specimen RU-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	20	20	-	20	-
Abbott Architect	-	10	10	-	10	-
bioMerieux Vidas, Mini Vidas	-	1	1	-	1	-
Roche cobas 6000 / e 601	-	2	2	-	2	-
Roche cobas 6000/e601 - IgG	-	1	1	-	1	-
Roche cobas e 411	-	1	1	-	1	-
Siemens ADVIA Centaur - IgG	-	1	1	-	1	-
Siemens Immulite 2000	-	2	2	-	2	-
VITROS ECI	-	1	1	-	1	-

<u>Method</u>	Specimen RU-4		Specimen RU-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	20	20	-
Abbott Architect	-	10	10	-
bioMerieux Vidas, Mini Vidas	-	1	1	-
Roche cobas 6000 / e 601	-	2	2	-
Roche cobas 6000/e601 - IgG	-	1	1	-
Roche cobas e 411	-	1	1	-
Siemens ADVIA Centaur - IgG	-	1	1	-
Siemens Immulite 2000	-	2	2	-
VITROS ECI	-	1	1	-

Rubella—Quantitative (IU/mL)

<u><i>Specimen/Method</i></u>	<u><i>Labs</i></u>	<u><i>Mean</i></u>	<u><i>SD</i></u>	<u><i>CV</i></u>	<u><i>Median</i></u>	<u><i>Range</i></u>
Specimen RU-1						
All Method	25	0.08	0.12	140.4	0.0	0.0 - 0.5
Abbott Architect	12	0.00	0.01	0.0	0.0	0.0 - 0.1
Specimen RU-2						
All Method	28	33.62	9.98	29.7	28.6	3.6 - 63.6
Abbott Architect	13	25.70	2.16	8.4	25.8	19.2 - 32.2
Specimen RU-3						
All Method	27	102.31	35.68	34.9	83.1	0.0 - 209.4
Abbott Architect	13	79.42	6.94	8.7	78.2	58.6 - 100.3
Specimen RU-4						
All Method	26	0.16	0.28	178.6	0.0	0.0 - 1.1
Abbott Architect	13	0.00	0.01	0.0	0.0	0.0 - 0.1
Specimen RU-5						
All Method	28	48.15	14.77	30.7	41.8	3.8 - 92.5
Abbott Architect	13	37.06	3.79	10.2	36.3	25.6 - 48.5

Syphilis Serology—Qualitative: VDRL Slide

<u>Method</u>	Specimen SY-1			Specimen SY-2			Specimen SY-3		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>
ALL METHODS	1	-	29	1	-	29	1	-	29
Omega Diagnostics	-	-	1	-	-	1	-	-	1
Plasmatec	-	-	2	-	-	2	-	-	2
Siemens ADVIA									
Centaur	-	-	1	-	-	1	-	-	1
SPINREACT	-	-	1	-	-	1	-	-	1
Standard Diagnostics	-	-	4	-	-	4	-	-	4
Wiener Lab	1	-	17	1	-	17	1	-	17

<u>Method</u>	Specimen SY-4			Specimen SY-5		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>
ALL METHODS	30	-	-	30	-	-
Omega Diagnostics	1	-	-	1	-	-
Plasmatec	2	-	-	2	-	-
Siemens ADVIA						
Centaur	1	-	-	1	-	-
SPINREACT	1	-	-	1	-	-
Standard Diagnostics	4	-	-	4	-	-
Wiener Lab	18	-	-	18	-	-

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-1

ALL METHODS	3	1	-	-	-	-	-	-	20
Omega Diagnostics	-	-	-	-	-	-	-	-	1
Plasmatec	-	-	-	-	-	-	-	-	1
SPINREACT	-	-	-	-	-	-	-	-	1
Wiener Lab	1	1	-	-	-	-	-	-	15

Specimen SY-2

ALL METHODS	3	1	-	-	-	-	-	-	20
Omega Diagnostics	-	-	-	-	-	-	-	-	1
Plasmatec	-	-	-	-	-	-	-	-	1
SPINREACT	-	-	-	-	-	-	-	-	1
Wiener Lab	1	1	-	-	-	-	-	-	15

Specimen SY-3

ALL METHODS	3	-	-	1	-	-	-	-	20
Omega Diagnostics	-	-	-	-	-	-	-	-	1
Plasmatec	-	-	-	-	-	-	-	-	1
SPINREACT	-	-	-	-	-	-	-	-	1
Wiener Lab	1	-	-	1	-	-	-	-	15

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-4

ALL METHODS	-	1	4	5	6	5	3	-	-
Omega Diagnostics	-	-	-	-	-	-	1	-	-
Plasmatec	-	-	-	-	-	1	-	-	-
SPINREACT	-	-	1	-	-	-	-	-	-
Wiener Lab	-	1	2	5	5	3	1	-	-

Specimen SY-5

ALL METHODS	2	2	7	8	3	2	-	-	-
Omega Diagnostics	-	-	-	-	-	1	-	-	-
Plasmatec	-	-	-	1	-	-	-	-	-
SPINREACT	-	-	-	1	-	-	-	-	-
Wiener Lab	2	2	6	6	1	-	-	-	-

Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	15	1	14	1	14
Abbott Architect	-	3	-	3	-	3
Human	-	1	-	1	1	-
Omega Diagnostics	-	1	1	-	-	1
Plasmatec	-	3	-	3	-	3
Serodia	-	2	-	2	-	2
SPINREACT	-	1	-	1	-	1

	Specimen SY-4		Specimen SY-5	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	15	-	15	-
Abbott Architect	3	-	3	-
Human	1	-	1	-
Omega Diagnostics	1	-	1	-
Plasmatec	3	-	3	-
Serodia	2	-	2	-
SPINREACT	1	-	1	-

Syphilis Serology—Qualitative: *Treponema pallidum* Antibodies

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	33	2	31	-	33
Abbott Architect	-	4	-	4	-	4
Human	-	1	-	1	-	1
Omega Diagnostics	-	3	1	2	-	3
Plasmatec	-	4	1	3	-	4
Serodia	-	13	-	13	-	13
Zeus	-	1	-	1	-	1

	Specimen SY-4		Specimen SY-5	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	33	-	32	1
Abbott Architect	4	-	4	-
Human	1	-	-	1
Omega Diagnostics	3	-	3	-
Plasmatec	4	-	4	-
Serodia	13	-	13	-
Zeus	1	-	1	-

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-1		Specimen SY-2		Specimen SY-3	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	75	1	74	-	75
Becton Dickinson	-	3	-	3	-	3
Biokit	-	1	-	1	-	1
bioMerieux	-	6	-	6	-	6
BioSystems	-	4	-	4	-	4
Human	-	12	-	12	-	12
Omega Diagnostics	-	14	1	13	-	14
Plasmatec	-	16	-	16	-	16
Pulse Scientific	-	1	-	1	-	1
SPINREACT	-	9	-	9	-	9
Standard Diagnostics	-	1	-	1	-	1
Wiener Lab	-	1	-	1	-	1

	Specimen SY-4		Specimen SY-5	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	75	-	75	-
Becton Dickinson	3	-	3	-
Biokit	1	-	1	-
bioMerieux	6	-	6	-
BioSystems	4	-	4	-
Human	12	-	12	-
Omega Diagnostics	14	-	14	-
Plasmatec	16	-	16	-
Pulse Scientific	1	-	1	-
SPINREACT	9	-	9	-
Standard Diagnostics	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-1

ALL METHODS	3	-	-	-	-	-	-	-	54
Becton Dickinson	-	-	-	-	-	-	-	-	2
bioMerieux	-	-	-	-	-	-	-	-	3
BioSystems	-	-	-	-	-	-	-	-	4
Human	1	-	-	-	-	-	-	-	7
Omega Diagnostics	-	-	-	-	-	-	-	-	13
Plasmatec	1	-	-	-	-	-	-	-	11
Pulse Scientific	-	-	-	-	-	-	-	-	1
SPINREACT	1	-	-	-	-	-	-	-	7
Wiener Lab	-	-	-	-	-	-	-	-	1

Specimen SY-2

ALL METHODS	3	1	-	-	-	-	-	-	53
Becton Dickinson	-	-	-	-	-	-	-	-	2
bioMerieux	-	-	-	-	-	-	-	-	3
BioSystems	-	-	-	-	-	-	-	-	4
Human	1	-	-	-	-	-	-	-	7
Omega Diagnostics	-	1	-	-	-	-	-	-	12
Plasmatec	1	-	-	-	-	-	-	-	11
Pulse Scientific	-	-	-	-	-	-	-	-	1
SPINREACT	1	-	-	-	-	-	-	-	7
Wiener Lab	-	-	-	-	-	-	-	-	1
Wiener Lab	3	1	-	-	-	-	-	-	53

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-3									
ALL METHODS	3	-	-	-	-	-	-	-	54
Becton Dickinson	-	-	-	-	-	-	-	-	2
bioMerieux	-	-	-	-	-	-	-	-	3
BioSystems	-	-	-	-	-	-	-	-	4
Human	1	-	-	-	-	-	-	-	7
Omega Diagnostics	-	-	-	-	-	-	-	-	13
Plasmatec	1	-	-	-	-	-	-	-	11
Pulse Scientific	-	-	-	-	-	-	-	-	1
SPINREACT	1	-	-	-	-	-	-	-	7
Wiener Lab	-	-	-	-	-	-	-	-	1
Specimen SY-4									
ALL METHODS	1	8	23	23	3	-	-	1	1
Becton Dickinson	-	-	-	2	-	-	-	-	-
bioMerieux	-	1	2	-	-	-	-	-	-
BioSystems	-	1	2	1	-	-	-	-	-
Human	-	2	3	3	-	-	-	-	-
Omega Diagnostics	-	-	6	5	-	-	-	1	1
Plasmatec	-	3	4	4	1	-	-	-	-
Pulse Scientific	-	-	-	1	-	-	-	-	-
SPINREACT	-	-	3	3	2	-	-	-	-
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 (Neg)</u>
Specimen SY-5									
ALL METHODS	14	22	16	3	1	1	-	-	1
Becton Dickinson	-	2	-	-	-	-	-	-	-
bioMerieux	1	1	1	-	-	-	-	-	-
BioSystems	-	3	1	-	-	-	-	-	-
Human	4	3	1	-	-	-	-	-	-
Omega Diagnostics	2	4	5	-	1	-	-	-	1
Plasmatec	4	4	3	-	-	1	-	-	-
Pulse Scientific	-	-	1	-	-	-	-	-	-
SPINREACT	2	2	2	2	-	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-	-

Viral Markers – Anti-HBc (IgM)

Specimen VM-1				Specimen VM-2			Specimen VM-3		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	53	10	47	17	1	-	64	-
Abbott Architect	-	26	-	26	-	-	-	26	-
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	-	-	2	-
bioMerieux Vidas, Mini Vidas	-	1	3	4	-	-	-	4	-
Roche cobas 6000 / e 601	-	10	-	-	10	-	-	9	-
Roche cobas e 411	-	6	-	-	6	-	-	6	-
Roche Modular Analytics	-	1	-	-	1	-	-	1	-
Siemens ADVIA Centaur	-	4	7	11	-	-	-	11	-
VITROS 3600/4600/5600	-	1	-	-	-	1	-	1	-
VITROS Eci	-	1	-	1	-	-	-	1	-

Specimen VM-4				Specimen VM-5		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	64	-	-	64	-
Abbott Architect	-	26	-	-	26	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-
bioMerieux Vidas, Mini Vidas	-	4	-	-	4	-
Roche cobas 6000 / e 601	-	9	-	-	9	-
Roche cobas e 411	-	6	-	-	6	-
Roche Modular Analytics	-	1	-	-	1	-
Siemens ADVIA Centaur	-	11	-	-	11	-
VITROS 3600/4600/5600	-	1	-	-	1	-
VITROS Eci	-	1	-	-	1	-

Viral Markers – Anti-HBc (Total / IgG)

	Specimen VM-1			Specimen VM-2			Specimen VM-3		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	87	2	-	88	1	-	8	79	2
Abbott Architect	38	-	-	38	-	-	-	38	-
Beckman ACCESS / 2 / Dxl	2	-	-	2	-	-	2	-	-
Bio-Rad Evolis	-	1	-	1	-	-	1	-	-
bioMerieux Vidas, Mini Vidas	4	1	-	4	1	-	1	3	1
DiaSorin	1	-	-	1	-	-	-	1	-
Roche cobas 6000 / e 601	11	-	-	11	-	-	1	10	-
Roche cobas e 411	8	-	-	8	-	-	3	5	-
Roche Modular Analytics	3	-	-	3	-	-	-	3	-
Siemens ADVIA Centaur	12	-	-	12	-	-	-	12	-
VITROS 3600/4600/5600	2	-	-	2	-	-	-	2	-
VITROS ECI	2	-	-	2	-	-	-	2	-

	Specimen VM-4			Specimen VM-5		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	3	86	-	7	81	1
Abbott Architect	-	38	-	-	38	-
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-
Bio-Rad Evolis	1	-	-	-	1	-
bioMerieux Vidas, Mini Vidas	1	4	-	1	4	-
DiaSorin	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	11	-	1	10	-
Roche cobas e 411	1	7	-	2	6	-
Roche Modular Analytics	-	3	-	-	3	-
Siemens ADVIA Centaur	-	12	-	2	9	1
VITROS 3600/4600/5600	-	2	-	-	2	-
VITROS ECI	-	2	-	-	2	-

Viral Markers – Anti-HIV

	Specimen VM-1			Specimen VM-2			Specimen VM-3		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	218	-	-	218	-	1	219	-
Abbott Architect	-	64	-	-	64	-	-	64	-
Acon Laboratories	-	1	-	-	1	-	-	1	-
Alere Determine HIV 1/2									
Ag/Ab Combo	-	1	-	-	1	-	-	1	-
Beckman ACCESS / 2 / DxI	-	6	-	-	5	-	-	6	-
Bio-Rad Evolis	-	1	-	-	1	-	1	-	-
bioMerieux Vidas, Mini									
Vidas	-	14	-	-	14	-	-	14	-
DiaSorin	-	1	-	-	1	-	-	1	-
Human	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	40	-	-	40	-	-	40	-
Roche cobas e 411	-	22	-	-	22	-	-	23	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	-	1	-
Roche Modular Analytics	-	5	-	-	5	-	-	5	-
Siemens ADVIA Centaur	1	28	-	-	29	-	-	29	-
Standard Diagnostics	-	2	-	-	2	-	-	2	-
VITROS 3600/4600/5600	-	3	-	-	3	-	-	3	-
VITROS ECI	-	11	-	-	11	-	-	11	-

Viral Markers – Anti-HIV- cont'd

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	2	217	1	213	7	-
Abbott Architect	-	64	-	64	-	-
Acon Laboratories	-	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	1	13	-	13	1	-
DiaSorin	-	1	-	1	-	-
Human	-	2	-	1	1	-
Roche cobas 6000 / e 601	-	40	-	38	2	-
Roche cobas e 411	-	22	1	23	-	-
Roche Elecsys 1010 / 2010	-	1	-	1	-	-
Roche Modular Analytics	-	5	-	5	-	-
Siemens ADVIA Centaur	1	28	-	28	1	-
Standard Diagnostics	-	2	-	2	-	-
VITROS 3600/4600/5600	-	3	-	3	-	-
VITROS ECI	-	11	-	11	-	-

Viral Markers – Anti-HAV (IgM)

Specimen VM-1				Specimen VM-2			Specimen VM-3		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	89	-	-	89	-	-	89	-
Abbott Architect	-	30	-	-	30	-	-	30	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-	-	1	-
bioMerieux Vidas, Mini	-	9	-	-	9	-	-	9	-
Roche cobas 6000 / e 601	-	14	-	-	14	-	-	14	-
Roche cobas e 411	-	6	-	-	6	-	-	6	-
Roche Modular Analytics	-	3	-	-	3	-	-	3	-
Siemens ADVIA Centaur	-	15	-	-	15	-	-	15	-
Standard Diagnostics	-	1	-	-	1	-	-	1	-
VITROS 3600/4600/5600	-	1	-	-	1	-	-	1	-
VITROS ECI	-	4	-	-	4	-	-	4	-

Specimen VM-4				Specimen VM-5		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	88	-	-	89	-
Abbott Architect	-	30	-	-	30	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-
bioMerieux Vidas, Mini	-	9	-	-	9	-
Roche cobas 6000 / e 601	-	14	-	-	14	-
Roche cobas e 411	-	6	-	-	6	-
Roche Modular Analytics	-	3	-	-	3	-
Siemens ADVIA Centaur	-	15	-	-	15	-
Standard Diagnostics	-	1	-	-	1	-
VITROS 3600/4600/5600	-	1	-	-	1	-
VITROS ECI	-	4	-	-	4	-

Viral Markers – Anti-HAV (Total/IgG)

	Specimen VM-1			Specimen VM-2			Specimen VM-3		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	46	30	1	2	75	-	1	76	-
Abbott Architect	10	17	1	-	28	-	-	28	-
Beckman ACCESS / 2 / Dxl	-	1	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	5	1	-	-	6	-	-	6	-
Roche cobas 6000 / e 601	11	-	-	1	10	-	-	11	-
Roche cobas e 411	7	2	-	1	8	-	-	9	-
Roche Elecsys 1010 / 2010	1	-	-	-	1	-	-	1	-
Roche Modular Analytics	2	-	-	-	2	-	-	2	-
Siemens ADVIA Centaur	9	4	-	-	13	-	-	13	-
Standard Diagnostics	-	1	-	-	1	-	-	1	-
VITROS ECI	-	1	-	-	1	-	-	1	-

	Specimen VM-4			Specimen VM-5		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	76	1	-	76	1	-
Abbott Architect	28	-	-	28	-	-
Beckman ACCESS / 2 / Dxl	1	-	-	1	-	-
bioMerieux Vidas, Mini Vidas	6	-	-	6	-	-
Roche cobas 6000 / e 601	11	-	-	11	-	-
Roche cobas e 411	9	-	-	9	-	-
Roche Elecsys 1010 / 2010	1	-	-	1	-	-
Roche Modular Analytics	2	-	-	2	-	-
Siemens ADVIA Centaur	13	-	-	13	-	-
Standard Diagnostics	-	1	-	-	1	-
VITROS ECI	1	-	-	1	-	-

Viral Markers – HBeAg

	Specimen VM-1			Specimen VM-2			Specimen VM-3		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	59	-	-	-	59	-	-	59	-
Abbott Architect	23	-	-	-	23	-	-	23	-
bioMerieux Vidas, Mini									
Vidas	4	-	-	-	4	-	-	4	-
DiaSorin	2	-	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	11	-	-	-	11	-	-	11	-
Roche cobas e 411	4	-	-	-	4	-	-	4	-
Roche Modular Analytics	2	-	-	-	2	-	-	2	-
Siemens ADVIA Centaur	8	-	-	-	8	-	-	8	-
VITROS ECI	1	-	-	-	1	-	-	1	-

	Specimen VM-4			Specimen VM-5		
<u>Method</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	59	-	1	58	-
Abbott Architect	-	23	-	1	22	-
bioMerieux Vidas, Mini						
Vidas	-	4	-	-	4	-
DiaSorin	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	11	-	-	11	-
Roche cobas e 411	-	4	-	-	4	-
Roche Modular Analytics	-	2	-	-	2	-
Siemens ADVIA Centaur	-	8	-	-	8	-
VITROS ECI	-	1	-	-	1	-

Viral Markers – Anti-HBs

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	4	154	-	5	153	-	156	1	1
Abbott Architect	-	51	-	-	51	-	50	-	1
Beckman ACCESS / 2 / Dxl	-	2	-	-	2	-	2	-	-
bioMerieux Vidas, Mini									
Vidas	-	6	-	-	6	-	6	-	-
Roche cobas 6000 / e 601	-	32	-	-	32	-	32	-	-
Roche cobas e 411	2	15	-	3	14	-	17	-	-
Roche Elecsys 1010 / 2010	-	1	-	-	1	-	1	-	-
Roche Modular Analytics	-	4	-	-	4	-	4	-	-
Siemens ADVIA Centaur	1	25	-	1	25	-	26	-	-
VITROS 3600/4600/5600	-	4	-	-	4	-	4	-	-
VITROS ECI	-	6	-	-	6	-	6	-	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	155	3	-	156	2	-
Abbott Architect	51	-	-	51	-	-
Beckman ACCESS / 2 / Dxl	2	-	-	2	-	-
bioMerieux Vidas, Mini						
Vidas	6	-	-	6	-	-
Roche cobas 6000 / e 601	31	1	-	32	-	-
Roche cobas e 411	17	-	-	17	-	-
Roche Elecsys 1010 / 2010	1	-	-	1	-	-
Roche Modular Analytics	4	-	-	4	-	-
Siemens ADVIA Centaur	25	1	-	25	1	-
VITROS 3600/4600/5600	4	-	-	4	-	-
VITROS ECI	6	-	-	6	-	-

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	216	4	-	197	19	3	5	214	1
Abbott Architect	63	1	-	62	1	1	1	63	-
Beckman ACCESS / 2 / Dxl	6	-	-	4	1	-	-	6	-
Bio-Rad Evolis	-	1	-	1	-	-	-	1	-
bioMerieux Vidas, Mini Vidas	10	-	-	10	-	-	-	10	-
DiaSorin	1	-	-	1	-	-	-	1	-
Human	2	-	-	1	1	-	-	2	-
Roche cobas 6000 / e 601	35	-	-	35	-	-	2	33	-
Roche cobas e 411	22	-	-	22	-	-	1	20	1
Roche Elecsys 1010 / 2010	2	-	-	2	-	-	-	2	-
Roche Modular Analytics	5	-	-	5	-	-	-	5	-
Siemens ADVIA Centaur	29	1	-	27	1	2	1	29	-
Siemens Immulite/1000	1	-	-	1	-	-	-	1	-
Standard Diagnostics	1	-	-	-	1	-	-	1	-
VITROS 3600/4600/5600	3	-	-	3	-	-	-	3	-
VITROS ECI	12	-	-	11	1	-	-	12	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	3	217	-	1	218	1
Abbott Architect	-	64	-	-	64	-
Beckman ACCESS / 2 / Dxl	-	6	-	-	6	-
Bio-Rad Evolis	1	-	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	10	-	-	10	-
DiaSorin	-	1	-	-	1	-
Human	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	35	-	-	35	-
Roche cobas e 411	1	21	-	-	21	1
Roche Elecsys 1010 / 2010	-	2	-	-	2	-
Roche Modular Analytics	-	5	-	-	5	-
Siemens ADVIA Centaur	1	29	-	1	29	-
Siemens Immulite/1000	-	1	-	-	1	-
Standard Diagnostics	-	1	-	-	1	-
VITROS 3600/4600/5600	-	3	-	-	3	-

VITROS ECI - 12 - | - 12 -

Viral Markers – Anti-HCV

<u>Method</u>	Specimen VM-1			Specimen VM-2			Specimen VM-3		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	195	-	70	122	2	192	3	-
Abbott Architect	-	62	-	8	54	-	62	-	-
Beckman ACCESS / 2 / Dxl	-	3	-	-	2	-	3	-	-
Bio-Rad Evolis	-	1	-	-	1	-	-	1	-
bioMerieux Vidas, Mini Vidas	-	6	-	1	5	-	6	-	-
DiaSorin	-	1	-	-	1	-	1	-	-
Human	-	1	-	1	-	-	1	-	-
Roche cobas 6000 / e 601	-	29	-	29	-	-	29	-	-
Roche cobas e 411	-	19	-	18	1	-	18	1	-
Roche Elecsys 1010 / 2010	-	2	-	2	-	-	2	-	-
Roche Modular Analytics	-	4	-	4	-	-	4	-	-
Siemens ADVIA Centaur	-	28	-	2	24	2	28	-	-
Standard Diagnostics	-	3	-	-	3	-	3	-	-
VITROS 3600/4600/5600	-	3	-	-	3	-	3	-	-
VITROS ECI	-	11	-	1	10	-	11	-	-

<u>Method</u>	Specimen VM-4			Specimen VM-5		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	194	-	1	194	-
Abbott Architect	-	62	-	-	62	-
Beckman ACCESS / 2 / Dxl	-	3	-	-	3	-
Bio-Rad Evolis	-	1	-	1	-	-
bioMerieux Vidas, Mini Vidas	-	6	-	-	6	-
DiaSorin	-	1	-	-	1	-
Human	-	1	-	-	1	-
Roche cobas 6000 / e 601	-	29	-	-	29	-
Roche cobas e 411	1	18	-	-	19	-
Roche Elecsys 1010 / 2010	-	2	-	-	2	-
Roche Modular Analytics	-	4	-	-	4	-
Siemens ADVIA Centaur	-	28	-	-	28	-
Standard Diagnostics	-	3	-	-	3	-
VITROS 3600/4600/5600	-	3	-	-	3	-
VITROS ECI	-	11	-	-	11	-

Toxoplasma gondii Antibody (IgG) - Qualitative

<u>Method</u>	Specimen TOX-1		Specimen TOX-2	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	-	18	-
Abbott Architect	9	-	9	-
Beckman ACCESS / 2 / Dxl	2	-	2	-
bioMerieux Vidas, Mini Vidas	1	-	1	-
Roche cobas 6000 / e 601	2	-	2	-
Roche cobas e 411	1	-	1	-
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-1						
All Method	20	39.005	49.372	126.6	8.50	0.00 - 137.75
Abbott Architect	9	4.444	0.503	11.3	4.50	3.43 - 5.45
Roche cobas 6000 / e 601	4	114.275	9.430	8.3	117.15	95.41 - 133.14
Specimen TOX-2						
All Method	20	187.965	163.383	86.9	85.30	0.00 - 514.74
Abbott Architect	10	71.410	16.860	23.6	76.05	37.68 - 105.14
Roche cobas 6000 / e 601	4	448.975	58.845	13.1	458.95	331.28 - 566.67

Toxoplasma gondii Antibody (IgM) - Qualitative

<u>Method</u>	Specimen TOX-1		Specimen TOX-2	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	19	19	-
Abbott Architect	-	8	8	-
Beckman ACCESS / 2 / Dxl	-	2	2	-
bioMerieux Vidas, Mini Vidas	-	1	1	-
Roche cobas 6000 / e 601	-	4	4	-
Roche cobas e 411	-	1	1	-
Siemens Immulite 2000	-	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-1						
All Method	19	0.148	0.062	41.9	0.15	0.02 - 0.28
Abbott Architect	9	0.120	0.035	29.2	0.12	0.05 - 0.19
Roche cobas 6000 / e 601	3	0.207	0.049	23.9	0.23	0.10 - 0.31
Specimen TOX-2						
All Method	18	9.209	8.042	87.3	4.81	0.00 - 25.30
Abbott Architect	9	4.364	0.553	12.7	4.33	3.25 - 5.48
Roche cobas 6000 / e 601	3	14.543	0.396	2.7	14.33	13.75 - 15.34

Cytomegalovirus (CMV) Antibodies (IgG) - Qualitative

<u>Method</u>	<u>Specimen CMV-1</u>		<u>Specimen CMV-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	4	16	-
Abbott Architect	9	-	9	-
Beckman ACCESS / 2 / Dxl	-	1	1	-
bioMerieux Vidas, Mini Vidas	-	1	1	-
Roche cobas 6000 / e 601	-	1	1	-
Roche cobas e 411	-	1	1	-
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-1						
All Method	18	8.140	6.753	83.0	10.15	0.00 - 21.65
Abbott Architect	9	13.922	3.368	24.2	13.40	7.18 - 20.66
Specimen CMV-2						
All Method	18	38.499	17.001	44.2	41.85	4.49 - 72.50
Abbott Architect	9	42.378	8.124	19.2	43.50	26.12 - 58.63

Cytomegalovirus (CMV) Antibodies (IgM) - Qualitative

<u>Method</u>	<u>Specimen CMV-1</u>		<u>Specimen CMV-2</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	3	-	17
Abbott Architect	8	-	-	8
Beckman ACCESS / 2 / Dxl	1	-	-	1
bioMerieux Vidas, Mini Vidas	1	-	-	1
Roche cobas 6000 / e 601	-	2	-	2
Roche cobas e 411	-	1	-	1
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-1						
All Method	16	2.559	1.307	51.1	3.15	0.00 - 5.18
Abbott Architect	8	3.349	0.517	15.5	3.26	2.31 - 4.39
Specimen CMV-2						
All Method	16	0.143	0.058	40.6	0.16	0.02 - 0.26
Abbott Architect	8	0.164	0.032	19.8	0.17	0.09 - 0.23

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-1						
All Method	12	8.82	3.40	38.5	7.4	0.0 - 19.1
Roche cobas 6000 / c 501	5	7.22	0.15	2.1	7.2	6.7 - 7.7
Specimen CK-2						
All Method	12	31.72	10.04	31.7	27.2	1.5 - 61.9
Roche cobas 6000 / c 501	5	27.00	0.60	2.2	26.9	25.1 - 28.9
Specimen CK-3						
All Method	12	19.98	6.94	34.7	16.9	0.0 - 40.8
Roche cobas 6000 / c 501	5	16.68	0.33	2.0	16.8	15.6 - 17.7
Specimen CK-4						
All Method	12	99.96	29.47	29.5	85.5	11.5 - 188.4
Roche cobas 6000 / c 501	5	85.10	1.70	2.0	85.5	80.0 - 90.2
Specimen CK-5						
All Method	12	54.58	17.07	31.3	46.5	3.3 - 105.9
Roche cobas 6000 / c 501	5	46.14	0.83	1.8	46.4	43.6 - 48.7

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