

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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



Total Commitment to Education and Service
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**International Data Supplement
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	$\pm 15\%$
CK-MB (U/L)	± 3 SD
Cytomegalovirus	± 2 SD
Fibrinogen	$\pm 20\%$
International Normalized Ratio (INR)	$\pm 20\%$
Prothrombin Time	$\pm 15\%$
Rubella	± 3 SD
Specific Gravity	± 0.010
Toxoplasma	± 2 SD

**BLOOD BANK
ABO GROUP**

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-1	Group O	95	98.96%	Acceptable
	Group B	1	1.04%	
BB-2	Group A	96	100%	Acceptable
BB-3	Group AB	96	100%	Acceptable
BB-4	Group A	95	98.96%	Acceptable
	Group B	1	1.04%	
BB-5	Group B	93	96.88%	Acceptable
	Group AB	1	1.04%	
	Group O	1	1.04%	
	Group A	1	1.04%	

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-1	Rh Positive	95	98.96%	Acceptable
	Rh Negative	1	1.04%	
BB-2	Rh Positive	95	98.96%	Acceptable
	Rh Negative	1	1.04%	
BB-3	Rh Negative	96	100%	Acceptable
BB-4	Rh Negative	95	98.96%	Acceptable
	Rh Positive	1	1.04%	
BB-5	Rh Negative	95	98.96%	Acceptable
	Rh Positive	1	1.04%	

ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	No unexpected antibody detected	58	98.31%	Acceptable
	Unexpected antibody detected	1	1.69%	
AB-2	Unexpected antibody detected	59	100%	Acceptable
AB-3	Unexpected antibody detected	57	96.61%	Acceptable
	No expected antibody detected	2	3.39%	
AB-4	No expected antibody detected	59	100%	Acceptable
AB-5	Unexpected antibody detected	57	96.61%	Acceptable
	No expected antibody detected	2	3.39%	

BLOOD BANK

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	No antibody detected	32	100%	Acceptable
AB-2	Anti-E	32	84.21%	Acceptable
	Anti-Jk(b)	2	5.26%	
	Anti-Le(B)	2	5.26%	
	Anti-S	2	5.26%	
AB-3	Anti-Jk(a)	32	88.89%	Acceptable
	Anti-k	2	5.56%	
	Anti-Lu(b)	2	5.56%	
AB-4	No antibody detected	32	100%	Acceptable
AB-5	Anti-K	32	88.89%	Acceptable
	Anti-Le(a)	2	5.56%	
	Anti-C	2	5.56%	

Specimens AB-2, AB-3 and AB-5 were graded by 100 referee consensus.

COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-1	Compatible	61	100%	Acceptable
AB-2	Not Compatible	59	96.72%	Acceptable
	Compatible	2	3.28%	
AB-3	Not Compatible	58	95.08%	Acceptable
	Compatible	3	4.92%	
AB-4	Compatible	61	100%	Acceptable
AB-5	Compatible	59	96.72%	Acceptable
	Not Compatible	2	3.28%	

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	131	11.91	1.20	10.1	11.7	10.1 - 13.7	129	14.46	1.36	9.4	14.2	12.2 - 16.7
Dade Innovin												
Dade Behring BFT II	5	9.92	0.43	4.4	9.9	8.4 - 11.5	5	13.14	0.59	4.5	13.2	11.1 - 15.2
Sysmex CA-500/540/560	26	11.06	0.38	3.5	11.0	9.4 - 12.8	25	13.76	0.44	3.2	13.7	11.6 - 15.9
All Coagulation Instruments	37	10.81	0.59	5.4	10.9	9.1 - 12.5	35	13.63	0.49	3.6	13.6	11.5 - 15.7
Diag Stago STA Neoplastine CI+												
RAL Clot-SP	10	12.90	0.24	1.9	13.0	10.9 - 14.9	10	15.46	0.27	1.7	15.5	13.1 - 17.8
All Coagulation Instruments	19	12.81	0.45	3.5	12.7	10.8 - 14.8	19	15.28	0.55	3.6	15.3	12.9 - 17.6
HUMAN HemoStat Thromboplastin - SI												
All Coagulation Instruments	5	13.02	1.25	9.6	12.7	11.0 - 15.0	5	15.38	1.26	8.2	14.9	13.0 - 17.7
IL TEST PT Fibrinogen												
IL ACL, all models	18	11.76	0.49	4.2	11.7	9.9 - 13.6	18	13.92	0.63	4.5	14.0	11.8 - 16.1
IL TEST PT-FIB HS PLUS												
IL ACL, all models	14	13.11	1.06	8.1	13.4	11.1 - 15.1	14	16.20	0.87	5.4	16.2	13.7 - 18.7
IL TEST PT-FIB Recombinant												
IL ACL, all models	11	11.63	1.17	10.0	11.4	9.8 - 13.4	11	15.15	1.60	10.5	15.5	12.8 - 17.5
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	11.44	0.44	3.8	11.5	9.7 - 13.2	5	13.26	0.86	6.5	13.0	11.2 - 15.3

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	132	29.60	5.57	18.8	29.4	25.1 - 34.1	126	47.14	11.22	23.8	45.8	40.0 - 54.3
Dade Innovin												
Dade Behring BFT II	5	28.78	0.80	2.8	28.7	24.4 - 33.1	5	46.14	1.84	4.0	46.0	39.2 - 53.1
Sysmex CA-500/540/560	26	27.88	1.41	5.0	27.9	23.6 - 32.1	26	43.12	2.67	6.2	42.9	36.6 - 49.6
All Coagulation Instruments	37	28.15	1.37	4.9	28.1	23.9 - 32.4	37	43.85	2.93	6.7	43.9	37.2 - 50.5
Diag Stago STA Neoplastine CI+												
RAL Clot-SP	10	32.90	0.88	2.7	33.2	27.9 - 37.9	10	56.68	3.01	5.3	57.2	48.1 - 65.2
All Coagulation Instruments	19	33.79	1.86	5.5	33.4	28.7 - 38.9	18	58.57	4.42	7.6	57.9	49.7 - 67.4
HUMAN HemoStat Thromboplastin - SI												
All Coagulation Instruments	5	34.30	8.72	25.4	35.8	29.1 - 39.5	4	-	-	-	65.9	56.3 - 76.4
IL TEST PT Fibrinogen												
IL ACL, all models	18	21.70	1.41	6.5	21.7	18.4 - 25.0	18	31.36	2.35	7.5	31.5	26.6 - 36.1
IL TEST PT-FIB HS PLUS												
IL ACL, all models	14	35.64	2.41	6.8	35.9	30.2 - 41.0	14	58.02	5.70	9.8	60.0	49.3 - 66.8
IL TEST PT-FIB Recombinant												
IL ACL, all models	11	33.20	2.78	8.4	32.6	28.2 - 38.2	9	50.10	4.37	8.7	50.0	42.5 - 57.7
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	21.94	1.23	5.6	22.3	18.6 - 25.3	5	32.76	2.59	7.9	32.5	27.8 - 37.7

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	130	11.96	1.33	11.1	11.6	10.1 - 13.8
Dade Innovin						
Dade Behring BFT II	5	9.92	0.69	7.0	9.5	8.4 - 11.5
Sysmex CA-500/540/560	26	11.00	0.31	2.8	11.0	9.3 - 12.7
All Coagulation Instruments	37	10.78	0.59	5.4	10.9	9.1 - 12.4
Diag Stago STA Neoplastine CI+						
RAL Clot-SP	10	13.37	0.37	2.8	13.4	11.3 - 15.4
All Coagulation Instruments	19	13.21	0.58	4.4	13.2	11.2 - 15.2
HUMAN HemoStat Thromboplastin - SI						
All Coagulation Instruments	5	13.18	1.68	12.7	12.5	11.2 - 15.2
IL TEST PT Fibrinogen						
IL ACL, all models	18	11.80	0.43	3.6	11.7	10.0 - 13.6
IL TEST PT-FIB HS PLUS						
IL ACL, all models	14	13.05	1.30	10.0	13.5	11.0 - 15.1
IL TEST PT-FIB Recombinant						
IL ACL, all models	10	11.03	0.93	8.5	10.8	9.3 - 12.7
PH/CMS Thromboplastin-D						
All Coagulation Instruments	5	11.52	0.48	4.2	11.4	9.7 - 13.3

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	128	1.01	0.08	8.1	1.0	0.8 - 1.3	129	1.28	0.13	10.4	1.3	1.0 - 1.6
Dade Innovin												
Dade Behring BFT II	5	1.08	0.04	4.1	1.1	0.8 - 1.3	5	1.36	0.05	4.0	1.4	1.0 - 1.7
Sysmex CA-500/540/560	26	1.06	0.06	5.4	1.1	0.8 - 1.3	25	1.34	0.06	4.8	1.3	1.0 - 1.7
All Coagulation Instruments	37	1.06	0.05	5.1	1.1	0.8 - 1.3	36	1.34	0.06	4.8	1.3	1.0 - 1.7
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact												
X/XR	5	1.02	0.08	8.2	1.0	0.8 - 1.3	5	1.26	0.11	9.0	1.3	1.0 - 1.6
RAL Clot-SP	10	0.98	0.04	4.3	1.0	0.7 - 1.2	10	1.22	0.04	3.5	1.2	0.9 - 1.5
All Coagulation Instruments	20	1.00	0.08	7.6	1.0	0.7 - 1.2	19	1.23	0.07	5.3	1.2	0.9 - 1.5
HemosIL RecombiPlasTin 2G												
All Coagulation Instruments	5	0.94	0.05	5.8	0.9	0.7 - 1.2	5	1.14	0.09	7.8	1.2	0.9 - 1.4
IL TEST PT Fibrinogen												
IL ACL, all models	18	0.96	0.05	5.2	1.0	0.7 - 1.2	18	1.32	0.09	6.6	1.3	1.0 - 1.6
IL TEST PT-FIB HS PLUS												
IL ACL, all models	14	0.95	0.09	9.9	1.0	0.7 - 1.2	14	1.21	0.15	12.5	1.2	0.9 - 1.5
IL TEST PT-FIB Recombinant												
IL ACL, all models	10	1.01	0.12	11.9	1.0	0.8 - 1.3	10	1.34	0.12	8.8	1.4	1.0 - 1.7
PH/CMS Thromboplastin-D												
All Coagulation Instruments	6	1.07	0.08	7.7	1.1	0.8 - 1.3	6	1.37	0.12	8.9	1.4	1.0 - 1.7
TriniCLOT PT Excel												
All Coagulation Instruments	5	1.00	0.07	7.1	1.0	0.8 - 1.2	5	1.24	0.15	12.2	1.3	0.9 - 1.5

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	129	2.92	0.39	13.2	2.9	2.3 - 3.6	124	5.12	1.16	22.6	4.6	4.0 - 6.2
Dade Innovin												
Dade Behring BFT II	5	2.76	0.22	7.9	2.9	2.2 - 3.4	5	4.18	0.41	9.9	4.3	3.3 - 5.1
Sysmex CA-500/540/560	26	2.71	0.14	5.1	2.7	2.1 - 3.3	26	4.23	0.25	5.9	4.3	3.3 - 5.1
All Coagulation Instruments	37	2.73	0.15	5.5	2.7	2.1 - 3.3	37	4.22	0.26	6.1	4.3	3.3 - 5.1
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact												
X/XR	5	3.84	0.25	6.5	3.7	3.0 - 4.7	5	8.06	0.68	8.5	7.7	6.4 - 9.7
RAL Clot-SP	10	3.24	0.11	3.3	3.2	2.5 - 3.9	10	6.54	0.46	7.0	6.5	5.2 - 7.9
All Coagulation Instruments	19	3.38	0.33	9.7	3.3	2.7 - 4.1	18	6.92	0.91	13.2	6.8	5.5 - 8.4
HemosIL RecombiPlasTin 2G												
All Coagulation Instruments	5	2.76	0.30	10.7	2.8	2.2 - 3.4	5	4.68	0.67	14.4	4.6	3.7 - 5.7
IL TEST PT Fibrinogen												
IL ACL, all models	18	2.91	0.19	6.4	2.9	2.3 - 3.5	18	5.59	0.50	8.9	5.6	4.4 - 6.8
IL TEST PT-FIB HS PLUS												
IL ACL, all models	14	2.86	0.38	13.1	3.0	2.2 - 3.5	14	4.74	0.86	18.3	4.8	3.7 - 5.7
IL TEST PT-FIB Recombinant												
IL ACL, all models	10	2.94	0.17	5.8	3.0	2.3 - 3.6	9	4.63	0.55	11.8	4.4	3.7 - 5.6
PH/CMS Thromboplastin-D												
All Coagulation Instruments	6	3.63	0.19	5.1	3.6	2.9 - 4.4	6	7.75	1.02	13.2	7.4	6.2 - 9.3
TriniCLOT PT Excel												
All Coagulation Instruments	5	2.58	0.23	8.8	2.6	2.0 - 3.1	5	4.66	0.90	19.3	4.8	3.7 - 5.6

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	5	1.08	0.04	4.1	1.1	0.8 - 1.3
Dade Innovin	26	1.07	0.05	4.6	1.1	0.8 - 1.3
Dade Behring BFT II	37	1.06	0.05	4.5	1.1	0.8 - 1.3
Sysmex CA-500/540/560						
All Coagulation Instruments	5	1.02	0.04	4.4	1.0	0.8 - 1.3
Diag Stago STA Neoplastine CI+	10	1.02	0.04	4.1	1.0	0.8 - 1.3
bioMerieux Thrombolyzer Compact						
X/XR	19	1.02	0.04	3.7	1.0	0.8 - 1.3
RAL Clot-SP						
All Coagulation Instruments	5	1.00	0.10	10.0	1.0	0.8 - 1.2
HemosIL RecombiPlasTin 2G						
All Coagulation Instruments	18	0.98	0.04	4.4	1.0	0.7 - 1.2
IL TEST PT Fibrinogen						
IL ACL, all models	14	0.94	0.09	9.0	1.0	0.7 - 1.2
IL TEST PT-FIB HS PLUS						
IL ACL, all models	10	1.29	1.03	79.5	1.0	1.0 - 1.6
IL TEST PT-FIB Recombinant						
IL ACL, all models	6	1.07	0.05	4.8	1.1	0.8 - 1.3
PH/CMS Thromboplastin-D						
All Coagulation Instruments	5	0.96	0.11	11.9	1.0	0.7 - 1.2
TriniCLOT PT Excel	5	1.08	0.04	4.1	1.1	0.8 - 1.3
All Coagulation Instruments	26	1.07	0.05	4.6	1.1	0.8 - 1.3

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

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	77	28.5	2.5	8.9	28	24 - 33	78	37.3	4.6	12.4	38	31 - 43	
Dade Actin FSL													
Sysmex CA-500/540/560	17	27.6	0.9	3.2	27	23 - 32	17	31.8	1.5	4.6	32	27 - 37	
All Coagulation Instruments	20	27.7	1.0	3.6	28	23 - 32	21	32.6	2.4	7.4	32	27 - 38	
Diagnostica Stago STA C.K. Prest													
All Coagulation Instruments	6	32.3	1.6	5.1	33	27 - 38	6	43.8	2.1	4.9	44	37 - 51	
IL TEST APTT-SP													
IL ACL, all models	27	28.0	1.0	3.6	28	23 - 33	28	38.9	2.0	5.2	39	33 - 45	
All Coagulation Instruments	30	28.3	1.4	4.8	28	24 - 33	30	38.9	2.1	5.5	39	33 - 45	
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	76	51.9	5.1	9.8	51	44 - 60	76	75.0	10.6	14.1	74	63 - 87	
Dade Actin FSL													
Sysmex CA-500/540/560	16	52.1	1.2	2.3	52	44 - 60	18	74.5	3.9	5.2	75	63 - 86	
All Coagulation Instruments	19	52.6	1.9	3.7	52	44 - 61	19	75.4	2.8	3.7	75	64 - 87	
Diagnostica Stago STA C.K. Prest													
All Coagulation Instruments	6	55.7	3.7	6.6	57	47 - 65	6	82.5	5.7	6.9	84	70 - 95	
IL TEST APTT-SP	76	51.9	5.1	9.8	51	44 - 60	76	75.0	10.6	14.1	74	63 - 87	
IL ACL, all models													
All Coagulation Instruments	16	52.1	1.2	2.3	52	44 - 60	18	74.5	3.9	5.2	75	63 - 86	
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	77	30.7	2.5	8.2	30	26 - 36							
Dade Actin FSL													
Sysmex CA-500/540/560	18	29.1	1.4	4.8	29	24 - 34							
All Coagulation Instruments	21	29.4	1.6	5.3	30	24 - 34							
Diagnostica Stago STA C.K. Prest													
All Coagulation Instruments	6	33.7	1.5	4.5	34	28 - 39							
IL TEST APTT-SP													
IL ACL, all models	28	30.5	1.5	4.9	31	25 - 36							
All Coagulation Instruments	30	30.5	1.5	4.8	31	25 - 36							

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	36	318.5	36.6	11.5	326	254 - 383	32	140.5	22.3	15.9	142	112 - 169
Diagnostica Stago STA Fibrinogen												
bioMerieux Thrombolyzer Compact												
X/XR	5	295.8	30.4	10.3	300	236 - 355	4	-	-	-	142	119 - 179
All Coagulation Instruments	6	308.7	41.7	13.5	300	246 - 371	5	149.0	20.7	13.9	147	119 - 179
IL TEST PT-FIB HS PLUS												
IL ACL, all models	11	329.9	25.6	7.8	333	263 - 396	10	150.6	17.1	11.3	147	120 - 181
IL TEST PT-FIB Recombinant												
IL ACL, all models	11	331.1	36.6	11.1	336	264 - 398	9	138.2	21.0	15.2	142	110 - 166
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	35	329.0	54.6	16.6	324	263 - 395	35	324.5	53.4	16.4	320	259 - 390
Diagnostica Stago STA Fibrinogen												
bioMerieux Thrombolyzer Compact												
X/XR	5	276.4	30.2	10.9	284	221 - 332	5	285.8	35.0	12.3	288	228 - 343
All Coagulation Instruments	6	292.0	46.8	16.0	290	233 - 351	6	290.8	33.7	11.6	294	232 - 349
IL TEST PT-FIB HS PLUS												
IL ACL, all models	11	348.9	37.9	10.8	352	279 - 419	11	353.6	35.2	10.0	353	282 - 425
IL TEST PT-FIB Recombinant												
IL ACL, all models	11	349.3	46.2	13.2	338	279 - 420	10	340.3	55.0	16.2	341	272 - 409
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	37	454.0	61.6	13.6	456	363 - 545						
Diagnostica Stago STA Fibrinogen												
bioMerieux Thrombolyzer Compact												
X/XR	5	410.4	71.1	17.3	449	328 - 493						
All Coagulation Instruments	6	418.8	66.9	16.0	454	335 - 503						
IL TEST PT-FIB HS PLUS												
IL ACL, all models	11	448.0	35.1	7.8	447	358 - 538						
IL TEST PT-FIB Recombinant												
IL ACL, all models	11	468.3	73.1	15.6	497	374 - 562						

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	373	1.0121	0.0065	0.6	1.010	1.002 - 1.023
All Bayer Instruments	37	1.0119	0.0047	0.5	1.010	1.001 - 1.022
All Roche Instruments	133	1.0139	0.0054	0.5	1.015	1.003 - 1.024
Arkray Aution Sticks	13	1.0180	0.0051	0.5	1.020	1.008 - 1.028
Bayer Clinitek Advantus	18	1.0094	0.0015	0.2	1.010	0.999 - 1.020
DIRUI H-800 Urine Analyzer	11	1.0158	0.0074	0.7	1.020	1.005 - 1.026
Erba Mannheim Uro-dipcheck 400e	13	1.0014	0.0022	0.2	1.000	0.991 - 1.012
Other Analyzer Method	14	1.0124	0.0068	0.7	1.010	1.002 - 1.023
Roche Chemstrips / Combur	22	1.0050	0.0027	0.3	1.005	0.995 - 1.015
Roche cobas u 411	68	1.0125	0.0036	0.4	1.013	1.002 - 1.023
Roche Mditron Junior/II	11	1.0136	0.0039	0.4	1.015	1.003 - 1.024
Roche Urisys	50	1.0165	0.0061	0.6	1.015	1.006 - 1.027
SD UroColor Reagent Strips	13	1.0062	0.0021	0.2	1.005	0.996 - 1.017
UriScan Reagent Strips	55	1.0133	0.0048	0.5	1.015	1.003 - 1.024

URINALYSIS DIPSTICK–pH

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>3.5 or less</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	1	3	173	118	95
Acon Laboratories	1	-	-	-	-	-	-	-	-	-	-	-	1
Arkray Aution Jet	2	-	-	-	-	-	-	-	-	-	1	1	-
Arkray Aution Sticks	13	-	-	-	-	-	-	-	-	-	7	6	-
Arkray PocketChem UA	2	-	-	-	-	-	-	-	-	-	1	1	-
Bayer Clinitek 50	3	-	-	-	-	-	-	-	-	-	-	3	-
Bayer Clinitek 500	5	-	-	-	-	-	-	-	-	-	-	5	-
Bayer Clinitek Advantus	18	-	-	-	-	-	-	-	-	-	1	15	2
Bayer Clinitek Atlas	4	-	-	-	-	-	-	-	-	-	2	2	-
Bayer Clinitek Status / Status+	8	-	-	-	-	-	-	-	-	-	-	6	2
Bayer Multistix Pro	4	-	-	-	-	-	-	-	-	-	2	2	-
Bayer Reagent Strips	19	-	-	-	-	-	-	-	-	1	1	17	-
Combi-Screen Test Strips	1	-	-	-	-	-	-	-	-	-	1	-	-
DIRUI H-100 / H-500 Urine Analyzer	3	-	-	-	-	-	-	1	-	-	1	1	-
DIRUI H-800 Urine Analyzer	11	-	-	-	-	-	-	-	-	-	1	10	-
Erba Mannheim Uro-dipcheck 400e	13	-	-	-	-	-	-	-	-	-	4	1	8
HUMAN Combilyzer	1	-	-	-	-	-	-	-	-	-	1	-	-
HUMAN COMBINA Test Strips	2	-	-	-	-	-	-	-	-	-	2	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	-	-	-	1	-
Iris Diagnostics iChem 100	1	-	-	-	-	-	-	-	-	-	-	1	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	-	-	-	-	-	-	-	1
Other Analyzer Method	16	-	-	-	-	-	-	-	-	-	9	7	-
Other Dipstick Method	5	-	-	-	-	-	-	-	-	-	-	2	3
Roche Chemstrip 101	3	-	-	-	-	-	-	-	-	-	2	1	-
Roche Chemstrips / Combur	25	-	-	-	-	-	-	-	-	-	14	4	7
Roche cobas u 411	68	-	-	-	-	-	-	-	-	1	51	-	16
Roche Miditron Junior/II	11	-	-	-	-	-	-	-	-	-	4	-	7
Roche Mini UA	1	-	-	-	-	-	-	-	-	-	-	-	1
Roche SuperUA/ChemstripUA	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche Urilux S	2	-	-	-	-	-	-	-	-	-	-	-	2
Roche Urisys	53	-	-	-	-	-	-	-	-	-	21	3	29
SD UroColor Reagent Strips	13	-	-	-	-	-	-	-	-	-	5	5	3
TECO URS Strips	1	-	-	-	-	-	-	-	-	-	-	1	-
THME UDC-2020	1	-	-	-	-	-	-	-	-	-	-	1	-
Urinometer	2	-	-	-	-	-	-	-	-	-	1	1	-
UriScan Pro/II	4	-	-	-	-	-	-	-	-	-	3	-	1
UriScan Reagent Strips	54	-	-	-	-	-	-	-	-	1	35	14	4
URIT Medical Uritest Analyzers	4	-	-	-	-	-	-	-	-	-	2	1	1
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	-	-	-	-	-	-	1

URINALYSIS DIPSTICK–PROTEIN QUALITATIVE

Specimen UA-1

<u>Method</u>	<u>Labs</u>	<i>Participant Results</i>						
		<u>Negative</u>	<u>Trace</u>	<u>30mg/dL (1+)</u>	<u>100 mg/dL (2+)</u>	<u>300-500mg/dL (3+)</u>	<u>>300mg/dl</u>	<u>≥1000mg/dL (4+)</u>
ALL METHODS	389	23	40	210	114	1	-	1
Acon Laboratories	1	-	-	1	-	-	-	-
Arkray Aution Jet	2	-	-	2	-	-	-	-
Arkray Aution Sticks	12	-	-	12	-	-	-	-
Arkray PocketChem UA	2	-	-	2	-	-	-	-
Bayer Albumstix	1	-	-	1	-	-	-	-
Bayer Clinitek 50	3	-	-	-	3	-	-	-
Bayer Clinitek 500	5	-	-	5	-	-	-	-
Bayer Clinitek Advantus	18	-	-	13	5	-	-	-
Bayer Clinitek Atlas	4	-	-	2	2	-	-	-
Bayer Clinitek Status / Status+	9	-	-	1	8	-	-	-
Bayer Multistix Pro	4	1	-	3	-	-	-	-
Bayer Reagent Strips	18	-	-	12	6	-	-	-
Bayer Uristix	1	-	-	-	1	-	-	-
Combi-Screen Test Strips	1	-	-	-	1	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	3	1	-	-	2	-	-	-
DIRUI H-800 Urine Analyzer	11	-	-	6	5	-	-	-
Erba Mannheim Uro-dipcheck 400e	13	1	-	9	3	-	-	-
HUMAN Combilyzer	2	-	-	2	-	-	-	-
HUMAN COMBINA Test Strips	1	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	1	-	-	-	-
Iris Diagnostics iChem 100	1	-	1	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	-	-	1	-	-	-	-
Other Analyzer Method	16	2	2	11	1	-	-	-
Other Dipstick Method	5	-	-	2	3	-	-	-
Roche Chemstrip 101	3	-	-	3	-	-	-	-
Roche Chemstrips / Combur	25	-	3	19	3	-	-	-
Roche cobas u 411	68	4	3	16	45	-	-	-
Roche Miditron Junior/II	10	-	-	7	3	-	-	-
Roche Mini UA	1	-	-	-	1	-	-	-
Roche SuperUA/ChemstripUA	1	-	1	-	-	-	-	-
Roche Urilux S	2	-	-	2	-	-	-	-
Roche Urisys	50	4	4	26	15	-	-	1
SD UroColor Reagent Strips	13	3	5	4	1	-	-	-
Sulfosalicylic Acid	1	-	-	1	-	-	-	-
TECO URS Strips	1	-	-	1	-	-	-	-
THME UDC-2020	1	-	-	1	-	-	-	-
Urinometer	2	-	-	2	-	-	-	-
UriScan Pro/II	4	-	2	2	-	-	-	-
UriScan Reagent Strips	54	6	17	28	3	-	-	-
URIT Medical Uritest Analyzers	4	-	1	2	1	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	1	-	-	-	-

URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>50-100 mg/dL (Trace)</u>	<u>150 mg/dL</u>	<u>250 mg/dL</u>	<u>500 mg/dL</u>	<u>1000 mg/dL</u>	<u>>1000 mg/dL</u>	<u>≥2000 mg/dL</u>
ALL METHODS	392	4	13	7	72	104	150	34	8
Acon Laboratories	1	-	-	-	1	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	-	2	-	-
Arkray Aution Sticks	13	-	-	2	-	7	3	1	-
Arkray PocketChem UA	2	-	-	-	-	2	-	-	-
Bayer Clinitek 50	3	-	-	-	-	2	1	-	-
Bayer Clinitek 500	5	-	1	-	1	3	-	-	-
Bayer Clinitek Advantus	18	-	-	-	2	14	2	-	-
Bayer Clinitek Atlas	4	-	1	-	1	2	-	-	-
Bayer Clinitek Status / Status+	9	-	-	1	8	-	-	-	-
Bayer Multistix Pro	4	-	-	-	1	2	1	-	-
Bayer Reagent Strips	19	-	-	1	11	7	-	-	-
Combi-Screen Test Strips	1	-	-	-	-	1	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	3	1	-	-	1	1	-	-	-
DIRUI H-800 Urine Analyzer	11	1	-	-	-	8	-	2	-
Erba Mannheim Uro-dipcheck 400e	13	-	1	1	10	1	-	-	-
HUMAN Combilyzer	1	-	-	-	-	-	1	-	-
HUMAN COMBINA Test Strips	2	-	-	-	-	-	2	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1	-
Iris Diagnostics iChem 100	1	-	-	1	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	-	-	1	-
Other Analyzer Method	16	-	3	-	8	1	2	2	-
Other Dipstick Method	5	1	-	-	2	2	-	-	-
Roche Chemstrip 101	3	-	1	-	-	-	1	1	-
Roche Chemstrips / Combur	25	-	1	-	1	1	15	7	-
Roche cobas u 411	67	-	2	-	1	1	60	3	-
Roche Mditron Junior/II	11	-	-	1	1	1	7	1	-
Roche Mini UA	1	-	-	-	-	-	1	-	-
Roche SuperUA/ChemstripUA	1	-	-	-	-	-	1	-	-
Roche Urilux S	2	-	-	-	-	-	1	1	-
Roche Urisys	54	-	-	-	3	6	35	10	-
SD UroColor Reagent Strips	13	-	-	-	2	11	-	-	-
TECO URS Strips	1	-	-	-	1	-	-	-	-
THME UDC-2020	1	1	-	-	-	-	-	-	-
Urinometer	2	-	-	-	-	-	2	-	-
UriScan Pro/II	4	-	-	-	-	1	3	-	-
UriScan Reagent Strips	53	-	1	-	5	27	9	3	8
URIT Medical Uritest Analyzers	4	-	-	-	4	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	1	-	-	-	-

URINALYSIS DIPSTICK–KETONES

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u> <u>(5 mg/dL)</u>	<u>Small</u> <u>(1+, 15</u> <u>mg/dL)</u>	<u>Moderate</u> <u>(2+, 40</u> <u>mg/dL)</u>	<u>Large</u> <u>(3+, 80</u> <u>mg/dL)</u>	<u>150 mg/dL</u>	<u>≥ 160 mg/dL</u>
ALL METHODS	392	4	-	2	15	170	143	58
Acon Laboratories	1	-	-	-	-	-	1	-
Arkray Aution Jet	2	-	-	-	-	-	-	2
Arkray Aution Sticks	13	-	-	-	-	2	8	3
Arkray PocketChem UA	2	1	-	-	-	1	-	-
Bayer Clinitek 50	3	-	-	-	-	3	-	-
Bayer Clinitek 500	5	-	-	-	-	4	-	1
Bayer Clinitek Advantus	18	-	-	-	-	18	-	-
Bayer Clinitek Atlas	5	-	-	-	-	2	1	2
Bayer Clinitek Status / Status+	9	-	-	-	-	-	-	9
Bayer Multistix Pro	4	-	-	-	-	2	-	2
Bayer Reagent Strips	18	-	-	-	-	4	-	14
Combi-Screen Test Strips	1	-	-	-	1	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	3	1	-	-	-	2	-	-
DIRUI H-800 Urine Analyzer	10	-	-	-	-	10	-	-
Erba Mannheim Uro-dipcheck 400e	13	-	-	-	-	3	9	1
HUMAN Combilyzer	1	-	-	-	-	-	1	-
HUMAN COMBINA Test Strips	2	-	-	-	-	1	-	1
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	1
Iris Diagnostics iChem 100	1	-	-	-	-	-	1	-
Iris Diagnostics vChem Urine Strips	1	-	-	-	-	1	-	-
Other Analyzer Method	17	1	-	-	-	11	2	3
Other Dipstick Method	6	-	-	-	-	4	-	2
Roche Chemstrip 101	3	-	-	-	1	2	-	-
Roche Chemstrips / Combur	25	-	-	-	1	15	8	1
Roche cobas u 411	67	-	-	1	-	8	54	4
Roche Miditron Junior/II	11	-	-	1	-	2	8	-
Roche Mini UA	1	-	-	-	-	-	1	-
Roche SuperUA/ChemstripUA	1	-	-	-	-	1	-	-
Roche Urilux S	2	-	-	-	-	1	1	-
Roche Urisys	54	1	-	-	1	7	41	4
SD UroColor Reagent Strips	13	-	-	-	3	8	1	1
TECO URS Strips	1	-	-	-	-	1	-	-
THME UDC-2020	1	-	-	-	-	1	-	-
Urinometer	2	-	-	-	2	-	-	-
UriScan Pro/II	4	-	-	-	-	4	-	-
UriScan Reagent Strips	54	-	-	-	5	42	3	4
URIT Medical Uritest Analyzers	4	-	-	-	-	2	2	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	1	-	-

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Small (1+)</u>	<u>Moderate (2+)</u>	<u>Large (3+)</u>
ALL METHODS	379	378	1	-	-
Acon Laboratories	1	1	-	-	-
Arkray Aution Jet	2	2	-	-	-
Arkray Aution Sticks	13	12	1	-	-
Arkray PocketChem UA	2	2	-	-	-
Bayer Clinitek 50	3	3	-	-	-
Bayer Clinitek 500	5	5	-	-	-
Bayer Clinitek Advantus	18	18	-	-	-
Bayer Clinitek Atlas	5	5	-	-	-
Bayer Clinitek Status / Status+	8	8	-	-	-
Bayer Multistix Pro	4	4	-	-	-
Bayer Reagent Strips	8	8	-	-	-
Combi-Screen Test Strips	1	1	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	3	3	-	-	-
DIRUI H-800 Urine Analyzer	11	11	-	-	-
Erba Mannheim Uro-dipcheck 400e	13	13	-	-	-
HUMAN Combilyzer	1	1	-	-	-
HUMAN COMBINA Test Strips	2	2	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-
Iris Diagnostics iChem 100	1	1	-	-	-
Iris Diagnostics vChem Urine Strips	1	1	-	-	-
Other Analyzer Method	16	16	-	-	-
Other Dipstick Method	6	6	-	-	-
Roche Chemstrip 101	3	3	-	-	-
Roche Chemstrips / Combur	25	25	-	-	-
Roche cobas u 411	67	67	-	-	-
Roche Miditron Junior/II	10	10	-	-	-
Roche Mini UA	1	1	-	-	-
Roche SuperUA/ChemstripUA	1	1	-	-	-
Roche Urilux S	2	2	-	-	-
Roche Urisys	53	53	-	-	-
SD UroColor Reagent Strips	13	13	-	-	-
TECO URS Strips	1	1	-	-	-
THME UDC-2020	1	1	-	-	-
Urinometer	2	2	-	-	-
UriScan Pro/II	4	4	-	-	-
UriScan Reagent Strips	54	54	-	-	-
URIT Medical Uritest Analyzers	4	4	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>0.2/Normal mg/dL</u>	<u>1.0 mg/dL</u>	<u>2.0 mg/dL</u>	<u>4.0 mg/dL</u>	<u>>8.0 mg/dL</u>
ALL METHODS	380	374	1	4	1	-
Acon Laboratories	1	1	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-
Arkray Aution Sticks	13	13	-	-	-	-
Arkray PocketChem UA	2	2	-	-	-	-
Bayer Clinitek 50	3	3	-	-	-	-
Bayer Clinitek 500	5	5	-	-	-	-
Bayer Clinitek Advantus	18	17	-	1	-	-
Bayer Clinitek Atlas	5	4	-	-	1	-
Bayer Clinitek Status / Status+	8	8	-	-	-	-
Bayer Multistix Pro	4	4	-	-	-	-
Bayer Reagent Strips	8	8	-	-	-	-
Combi-Screen Test Strips	1	1	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	3	3	-	-	-	-
DIRUI H-800 Urine Analyzer	11	10	-	1	-	-
Erba Mannheim Uro-dipcheck 400e	13	13	-	-	-	-
HUMAN Combilyzer	1	1	-	-	-	-
HUMAN COMBINA Test Strips	2	2	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-
Iris Diagnostics iChem 100	1	1	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	1	-	-	-	-
Other Analyzer Method	16	15	1	-	-	-
Other Dipstick Method	6	6	-	-	-	-
Roche Chemstrip 101	3	3	-	-	-	-
Roche Chemstrips / Combur	25	23	-	2	-	-
Roche cobas u 411	67	67	-	-	-	-
Roche Miditron Junior/II	11	11	-	-	-	-
Roche Mini UA	1	1	-	-	-	-
Roche SuperUA/ChemstripUA	1	1	-	-	-	-
Roche Urilux S	2	2	-	-	-	-
Roche Urisys	53	53	-	-	-	-
SD UroColor Reagent Strips	13	13	-	-	-	-
TECO URS Strips	1	1	-	-	-	-
THME UDC-2020	1	1	-	-	-	-
Urinometer	2	2	-	-	-	-
UriScan Pro/II	4	4	-	-	-	-
UriScan Reagent Strips	54	54	-	-	-	-
URIT Medical Uritest Analyzers	4	4	-	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small (1+)</u>	<u>Moderate (2+)</u>	<u>Large (3+)</u>
ALL METHODS	391	4	5	34	119	229
Acon Laboratories	1	-	-	-	1	-
Arkray Aution Jet	2	-	-	2	-	-
Arkray Aution Sticks	13	-	-	8	4	1
Arkray PocketChem UA	2	-	1	-	1	-
Bayer Clinitek 50	3	-	-	-	3	-
Bayer Clinitek 500	5	-	-	-	4	1
Bayer Clinitek Advantus	18	-	-	-	10	8
Bayer Clinitek Atlas	5	-	-	-	4	1
Bayer Clinitek Status / Status+	9	-	-	-	8	1
Bayer Multistix Pro	4	-	-	-	2	2
Bayer Reagent Strips	17	-	-	1	6	10
Behring Reagent Strips	1	-	-	-	-	1
Combi-Screen Test Strips	1	-	-	1	-	-
DIRUI H-100 / H-500 Urine Analyzer	3	1	-	-	-	2
DIRUI H-800 Urine Analyzer	11	-	-	-	-	11
Erba Mannheim Uro-dipcheck 400e	13	-	-	1	10	2
HUMAN Combilyzer	1	-	-	-	-	1
HUMAN COMBINA Test Strips	2	-	1	-	-	1
Iris Diagnostics Aution Max AX-4280	1	-	1	-	-	-
Iris Diagnostics iChem 100	1	-	-	1	-	-
Iris Diagnostics vChem Urine Strips	1	-	1	-	-	-
Other Analyzer Method	16	-	-	4	4	8
Other Dipstick Method	6	1	-	1	1	3
Roche Chemstrip 101	3	-	-	1	-	2
Roche Chemstrips / Combur	25	2	-	-	6	17
Roche cobas u 411	67	-	-	-	2	65
Roche Mditron Junior/II	11	-	-	-	1	10
Roche Mini UA	1	-	-	-	-	1
Roche SuperUA/ChemstripUA	1	-	-	-	1	-
Roche Urilux S	2	-	-	-	-	2
Roche Urisys	53	-	-	-	4	49
SD UroColor Reagent Strips	12	-	-	-	2	10
TECO URS Strips	1	-	-	-	1	-
THME UDC-2020	1	-	-	-	1	-
Urinometer	2	-	-	1	1	-
UriScan Pro/II	4	-	-	-	2	2
UriScan Reagent Strips	54	-	1	9	34	10
URIT Medical Uritest Analyzers	4	-	-	3	1	-
URIT Medical Uritest Reagent Strips	2	-	-	1	-	1

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small (1+)</u>	<u>Moderate (2+)</u>	<u>Large (3+)</u>
ALL METHODS	375	372	1	2	-	-
Acon Laboratories	1	1	-	-	-	-
Arkray Aution Jet	2	2	-	-	-	-
Arkray Aution Sticks	13	13	-	-	-	-
Arkray PocketChem UA	2	2	-	-	-	-
Bayer Clinitek 50	3	3	-	-	-	-
Bayer Clinitek 500	5	5	-	-	-	-
Bayer Clinitek Advantus	18	18	-	-	-	-
Bayer Clinitek Atlas	5	5	-	-	-	-
Bayer Clinitek Status / Status+	8	8	-	-	-	-
Bayer Multistix Pro	4	4	-	-	-	-
Bayer Reagent Strips	8	8	-	-	-	-
Combi-Screen Test Strips	1	1	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	3	3	-	-	-	-
DIRUI H-800 Urine Analyzer	11	11	-	-	-	-
Erba Mannheim Uro-dipcheck 400e	13	13	-	-	-	-
HUMAN Combilyzer	1	1	-	-	-	-
HUMAN COMBINA Test Strips	2	2	-	-	-	-
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-
Iris Diagnostics iChem 100	1	1	-	-	-	-
Iris Diagnostics vChem Urine Strips	1	1	-	-	-	-
Other Analyzer Method	16	16	-	-	-	-
Other Dipstick Method	6	6	-	-	-	-
Roche Chemstrip 101	3	3	-	-	-	-
Roche Chemstrips / Combur	24	24	-	-	-	-
Roche cobas u 411	67	66	-	1	-	-
Roche Mditron Junior/II	10	10	-	-	-	-
Roche Mini UA	1	1	-	-	-	-
Roche SuperUA/ChemstripUA	1	1	-	-	-	-
Roche Urilux S	1	1	-	-	-	-
Roche Urisys	53	52	-	1	-	-
SD UroColor Reagent Strips	13	13	-	-	-	-
TECO URS Strips	1	1	-	-	-	-
THME UDC-2020	1	1	-	-	-	-
Urinometer	2	2	-	-	-	-
UriScan Pro/II	4	4	-	-	-	-
UriScan Reagent Strips	54	54	-	-	-	-
URIT Medical Uritest Analyzers	4	4	-	-	-	-
URIT Medical Uritest Reagent Strips	2	2	-	-	-	-

URINALYSIS DIPSTICK–NITRITE

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	379	1	378
Acon Laboratories	1	-	1
Arkray Aution Jet	2	-	2
Arkray Aution Sticks	13	-	13
Arkray PocketChem UA	2	-	2
Bayer Clinitek 50	3	-	3
Bayer Clinitek 500	5	-	5
Bayer Clinitek Advantus	18	-	18
Bayer Clinitek Atlas	5	-	5
Bayer Clinitek Status / Status+	8	-	8
Bayer Multistix Pro	4	-	4
Bayer Reagent Strips	8	-	8
Combi-Screen Test Strips	1	-	1
DIRUI H-100 / H-500 Urine Analyzer	3	-	3
DIRUI H-800 Urine Analyzer	11	-	11
Erba Mannheim Uro-dipcheck 400e	13	-	13
HUMAN Combilyzer	1	-	1
HUMAN COMBINA Test Strips	2	-	2
Iris Diagnostics Aution Max AX-4280	1	-	1
Iris Diagnostics iChem 100	1	-	1
Iris Diagnostics vChem Urine Strips	1	-	1
Other Analyzer Method	16	-	16
Other Dipstick Method	6	-	6
Roche Chemstrip 101	3	-	3
Roche Chemstrips / Combur	24	-	24
Roche cobas u 411	69	1	68
Roche Miditron Junior/II	10	-	10
Roche Mini UA	1	-	1
Roche SuperUA/ChemstripUA	1	-	1
Roche Urilux S	2	-	2
Roche Urisys	53	-	53
SD UroColor Reagent Strips	12	-	12
TECO URS Strips	1	-	1
THME UDC-2020	1	-	1
Urinometer	2	-	2
UriScan Pro/II	4	-	4
UriScan Reagent Strips	54	-	54
URIT Medical Uritest Analyzers	4	-	4
URIT Medical Uritest Reagent Strips	1	-	1

URINALYSIS –MICROALBUMIN (dipstick only)

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>10 mg/L(Pos)</u>	<u>20/30 mg/L</u>	<u>50 mg/L (+)</u>	<u>80 mg/L</u>	<u>100 mg/L (++)</u>	<u>150 mg/L</u>
ALL METHODS	21	1	-	3	2	2	4	9
Bayer Clinitek Microalbumin	6	-	-	-	-	-	-	6
DCL ImmunoDip	1	-	-	-	-	-	-	1
HUMAN COMBINA Test Strips	1	-	-	-	-	1	-	-
Roche Micral - 1 minute	6	1	-	-	2	-	2	1
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	1	-

URINALYSIS –URINE hCG

Specimen UA-1

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	114	1	113
Acon Laboratories	18	-	18
Biotron 1-Step	11	-	11
Genzyme OSOM hCG Combo Test	1	-	1
Henry Schein One Step	2	-	2
Inverness Clearview hCG Cassette	1	-	1
Inverness Clearview25 hCG Combo	1	-	1
PEP (Lab Supply) HCG	1	-	1
Quidel QuickVue + One-Step	4	-	4
Quidel QuickVue One-Step Combo	26	-	26
Quidel QuickVue One-Step Urine	8	-	8
Stanbio QuStick	1	-	1
Sure-Vue hCG - 25mIU	1	-	1

ANTIMICROBIAL SUSCEPTIBILITY 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	34	32	1	1	97	97	-	-	98.59%
Amoxicillin/Clavulanate	46	41	2	3	39	37	1	1	92.55%
Ampicillin	38	33	-	5	94	90	-	4	93.84%
Ampicillin/Sulbactam	22	22	-	-	83	81	-	2	98.25%
Aztreonam	8	8	-	-	36	34	-	2	95.65%
Carbenicillin	2	2	-	-	-	-	-	-	Not graded ¹
Cefaclor	6	6	-	-	1	1	-	-	100.00%
Cefazolin	7	6	-	1	40	34	1	5	85.42%
Cefepime	17	17	-	-	83	80	1	2	97.27%
Cefixime	15	15	-	-	16	15	-	1	97.06%
Cefoperazone	3	3	-	-	-	-	-	-	Not graded ¹
Cefotaxime	15	15	-	-	53	51	-	2	97.37%
Cefotetan	-	-	-	-	4	4	-	-	Not graded ¹
Cefoxitin	8	7	1	-	69	69	-	-	98.78%
Cefpodoxime	4	4	-	-	1	1	-	-	100.00%
Ceftazidime	24	24	-	-	82	80	-	2	98.26%
Ceftizoxime	1	1	-	-	2	2	-	-	100.00%
Ceftriaxone	47	46	1	-	75	72	-	3	96.97%
Cefuroxime	33	33	-	-	47	47	-	-	100.00%
Cephalexin	7	6	1	-	3	3	-	-	90.00%
Cephalothin	28	25	2	1	57	56	-	1	95.74%
Ciprofloxacin	59	59	-	-	110	110	-	-	100.00%
Daptomycin	1	1	-	-	-	-	-	-	Inappropriate drug ²
Doxycycline	8	-	-	8	1	-	-	1	100.00%
Ertapenem	5	5	-	-	51	51	-	-	100.00%
Fosfomycin	2	2	-	-	1	1	-	-	Inappropriate drug ²
Gatifloxacin	-	-	-	-	1	1	-	-	Not graded ¹
Gentamicin	33	31	1	1	91	91	-	-	98.53%
Imipenem	25	25	-	-	31	23	-	8	84.75%
Kanamycin	2	1	-	1	2	2	-	-	Not graded ¹

¹ This is an ungraded challenge due to lack of comparison group.

² This is an inappropriate drug of the organism and/or source.

ANTIMICROBIAL SUSCEPTIBILITY TESTING (cont'd)
Specimen SUS-1

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>
	<u>Interpretative category data</u>				<u>Interpretative category data</u>				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Levofloxacin	15	15	-	-	12	12	-	-	100.00%
Linezolid	1	-	-	1	-	-	-	-	Inappropriate drug ²
Lomefloxacin	1	1	-	-	-	-	-	-	Not graded ¹
Meropenem	14	14	-	-	52	52	-	-	100.00%
Methicillin	1	1	-	-	-	-	-	-	Inappropriate drug ²
Moxifloxacin	6	6	-	-	-	-	-	-	Inappropriate drug ²
Nalidixic Acid	18	14	3	1	10	10	-	-	87.10%
Netilmicin	9	9	-	-	2	2	-	-	100.00%
Nitrofurantoin	37	4	3	30	74	1	1	72	92.62%
Norfloxacin	24	24	-	-	40	40	-	-	100.00%
Ofloxacin	17	17	-	-	2	2	-	-	100.00%
Oxacillin	3	-	1	2	1	-	-	1	Inappropriate drug ²
Penicillin	4	-	-	4	-	-	-	-	Inappropriate drug ²
Piperacillin	3	3	-	-	15	14	-	1	94.44%
Piperacillin/Tazobactam	15	15	-	-	44	42	-	2	96.92%
Rifampin	2	-	-	2	-	-	-	-	Inappropriate drug ²
Sulfisoxazole	-	-	-	-	1	1	-	-	Not graded ¹
Teicoplanin	-	-	-	-	1	-	-	1	Inappropriate drug ²
Tetracycline	6	-	-	6	7	1	-	6	92.31%
Ticarcillin	-	-	-	-	1	1	-	-	Not graded ¹
Ticarcillin/Clavulanate	-	-	-	-	5	5	-	-	100.00%
Tobramycin	4	4	-	-	28	27	1	-	97.06%
Trimethoprim	3	3	-	-	5	5	-	-	100.00%
Trimethoprim/Sulfamethoxazole	44	41	2	1	93	93	-	-	98.01%
Vancomycin	5	1	-	4	1	-	-	1	Inappropriate drug ²

Organism present in specimen SUS-1: *Proteus mirabilis*.

PARASITOLOGY (PA Specimens)

Specimen PA-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	5	55.56%	Not graded
Entamoeba histolytica	2	22.22%	
Iodamoeba butschlii	1	11.11%	
Blastocystis hominis	1	11.11%	

Parasite present in specimen PA-1: *Dientamoeba fragilis*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	3	33.33%	Acceptable
Giardia lamblia	3	33.33%	
Other parasite seen but no ID	1	11.11%	
Cryptosporidium sp., oocysts	1	11.11%	
Endolimax nana	1	11.11%	

Parasite present in specimen PA-2: No parasite seen. (Graded by US consensus)

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. eggs	32	78.05%	Acceptable
Ascaris lumbricoides eggs	4	9.76%	
No parasite seen	2	4.88%	
Blastocystis hominis	1	2.44%	
Entamoeba histolytica	1	2.44%	
Strongyloides stercoralis larvae	1	2.44%	

Parasite present in specimen PA-3: *Taenia sp. eggs*. (Graded by US Consensus)

Specimen PA-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis larvae	36	90.00%	Acceptable
Parasite larva seen but no ID	1	2.50%	Acceptable
Hookworm	2	5.00%	
Taenia sp. eggs	1	2.50%	

Parasite present in specimen PA-4: *Strongyloides stercoralis larvae*.

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Microfilaria – Loa loa	10	26.32%	Not graded
Microfilaria, NOS	4	10.53%	
No parasite seen	8	21.05%	
Microfilaria – Mansonella ozzardi	6	15.79%	
Microfilaria – Onchocerca volvulus	4	10.53%	
Microfilaria – Brugia species	2	5.26%	
Microfilaria – Wuchereria bancrofti	2	5.26%	
Plasmodium sp., NOS	1	2.63%	
Babesia sp.	1	2.63%	

Parasite present in specimen PA-5: *Microfilaria-Loa loa*. This 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>
Clonorchis sinensis	87	36.55%	Not graded
No parasite seen	107	44.96%	
Taenia sp. eggs	9	3.78%	
Giardia lamblia	7	2.94%	
Fasciola hepatica eggs	6	2.52%	
Trichuris trichiura eggs	4	1.68%	
Ascaris lumbricoides eggs	3	1.26%	
Enterobius vermicularis eggs	2	0.84%	
Endolimax nana	2	0.84%	
Entamoeba coli	2	0.84%	
Isospora belli oocysts	2	0.84%	

Parasite present in specimen FP-1: *Clonorchis sinensis*. This is an ungraded challenge due to less than 80% referee consensus.

Technical note: The specimen manufacturer's certificate of analysis showed only three parasites per coverslip. Direct wet mounts are normally examined at low power (100X) and high dry power (400X). It is recommended that testing personnel scan the entire coverslip using the low power (10X) objective, then examine at least one-third of the coverslip area using the high dry (40X) objective, even if nothing suspicious was seen on low power.

Clonorchis sinensis is a liver fluke acquired by ingestion of undercooked fish. *Clonorchis* eggs are oval, thick shelled, yellowish brown, and operculated. They measure 27-35 µm long by 12-19 µm wide.

Reference:

Garcia, L.S., Bullock-Iacullo, S., Palmer, J., Shimizu, R.Y. "Diagnosis of Parasitic Infections: Collection, Processing, and Examination of Specimens." *Manual of Clinical Microbiology*. 6th ed. Ed. P.R. Murray. Washington, D.C.: ASM Press, 1995. 1146,1147, 1237.

PARASITOLOGY (FP Specimens)

Specimen FP-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Diphyllobothrium latum	172	69.92%	Acceptable
Parasite egg seen but no ID	5	2.03%	Acceptable
Hookworm	15	6.10%	
Fasciola hepatica eggs	12	4.88%	
No parasite seen	9	3.66%	
Endolimax nana	9	3.66%	
Paragonimus westermani eggs	6	2.44%	
Ascaris lumbricoides eggs	4	1.63%	
Blastocystis hominis	4	1.63%	
Strongyloides stercoralis larvae	2	0.81%	
Entamoeba histolytica	2	0.81%	

Parasite present in specimen FP-2: *Diphyllobothrium latum*. This challenge was graded by 87% referee consensus.

PARASITOLOGY (FP Specimens)

Specimen FP-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba histolytica	160	40.20%	Acceptable
Entamoeba coli	137	34.42%	Acceptable
Endolimax nana	66	16.58%	
Blastocystis hominis	14	3.52%	
Entamoeba hartmanni	9	2.26%	
No parasite seen	6	1.51%	
Iodamoeba butschlii	2	0.50%	
Ascaris lumbricoides eggs	2	0.50%	

Parasites present in specimen FP-3: *Entamoeba histolytica* and *Entamoeba coli*. This challenge was graded by 90% referee consensus.

PARASITOLOGY (FP Specimens)

Specimen FP-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	207	82.47%	Acceptable
Trichuris trichiura eggs	1	0.40%	Acceptable
Parasite seen but no ID	1	0.40%	Acceptable
No parasite seen	10	3.98%	
Entamoeba coli	10	3.98%	
Endolimax nana	5	1.99%	
Schistosoma mansoni eggs	4	1.59%	
Taenia sp. eggs	3	1.20%	
Blastocystis hominis	2	0.80%	
Entamoeba histolytica	2	0.80%	

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

Specimen FP-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	183	83.18%	Acceptable
Plasmodium sp., NOS	13	5.91%	
Plasmodium falciparum	8	3.64%	
Babesia sp.	5	2.27%	
Leishmania sp.	4	1.82%	
Microfilaria, NOS	2	0.91%	
Toxoplasma gondii	2	0.91%	

Parasite present in specimen FP-5: No parasite seen.

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	9	1	-	10	-	10
Immuno Concepts	1	-	-	1	-	1
INOVA Diagnostics	2	1	-	3	-	3
Wampole	1	-	-	1	-	1
Wampole Impact	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	9	1	10	-
Immuno Concepts	1	-	1	-
INOVA Diagnostics	2	1	3	-
Wampole	1	-	1	-
Wampole Impact	1	-	1	-

Antinuclear Antibody (ANA)—Quantitative (Titer)

This portion is not evaluated. Titers reported are as follows:

<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>
Specimen AE-1											
ALL METHODS	-	-	-	1	1	2	2	-	-	-	-
INOVA Diagnostics	-	-	-	-	1	1	-	-	-	-	-
Wampole	-	-	-	-	-	-	1	-	-	-	-
Wampole Impact	-	-	-	1	-	-	-	-	-	-	-
Specimen AE-4											
ALL METHODS	-	-	-	-	-	-	4	-	1	-	1
INOVA Diagnostics	-	-	-	-	-	-	2	-	-	-	-
Wampole	-	-	-	-	-	-	-	-	1	-	-
Wampole Impact	-	-	-	-	-	-	-	-	-	-	1
Specimen AE-5											
ALL METHODS	-	-	-	-	1	-	1	-	1	3	1
INOVA Diagnostics	-	-	-	-	1	-	-	-	-	1	1
Wampole	-	-	-	-	-	-	-	-	-	1	-
Wampole Impact	-	-	-	-	-	-	-	-	-	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	-	5	1	4	1	4
Diamedix	-	1	-	1	-	1
INOVA Diagnostics	-	2	1	1	1	1
Wampole Impact	-	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	4	1	1	4
Diamedix	1	-	-	1
INOVA Diagnostics	2	-	1	1
Wampole Impact	-	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	6	-	-	6	-	6
INOVA Diagnostics	4	-	-	4	-	4
Other Method Specified	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	1	5	6	-
INOVA Diagnostics	1	3	4	-
Other Method Specified	-	2	2	-

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	14	-	-	14	-	14
Diamedix	5	-	-	5	-	5
GenBio ImmunoDOT Panel 1	1	-	-	1	-	1
INOVA Diagnostics	1	-	-	1	-	1
Theratest	5	-	-	5	-	5
Wampole	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	-	14	12	1
Diamedix	-	5	4	-
GenBio ImmunoDOT Panel 1	-	1	1	-
INOVA Diagnostics	-	1	-	1
Theratest	-	5	5	-
Wampole	-	1	1	-

Anti-SSA

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

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	-	6	-
Diamedix	1	-	1	-
INOVA Diagnostics	3	-	3	-

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	-	6	-	6	-	6
Diamedix	-	1	-	1	-	1
INOVA Diagnostics	-	3	-	3	-	3

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	-	6	-
Diamedix	1	-	1	-
INOVA Diagnostics	3	-	3	-

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
INOVA Diagnostics	1	-	-	1	-	1

<u>Method</u>	Specimen AE-4		Specimen AE-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	-	2	-
INOVA Diagnostics	1	-	1	-

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	6	-	-	6	-	6
Diamedix	1	-	-	1	-	1
INOVA Diagnostics	4	-	-	4	-	4

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

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	14	1	14	1	-	15
Abbott Architect	2	-	2	-	-	2
Bayer ADVIA Centaur	1	-	1	-	-	1
bioMerieux Vidas, Mini Vidas	3	-	3	-	-	3
DiaSorin	1	-	1	-	-	1
DPC Immulite 2000	2	-	2	-	-	2
Roche cobas 6000 / e 601	1	-	1	-	-	1
Roche cobas e 411	1	-	1	-	-	1
Roche Modular Analytics	1	-	1	-	-	1
VITROS ECI	2	1	2	1	-	3

<u>Method</u>	Specimen RU-4		Specimen RU-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	1	-	15
Abbott Architect	2	-	-	2
Bayer ADVIA Centaur	1	-	-	1
bioMerieux Vidas, Mini Vidas	3	-	-	3
Roche cobas 6000 / c 501	1	-	-	1
Roche cobas 6000 / e 601	2	-	-	2
Roche cobas e 411	1	-	-	1
Roche Elecsys 1010 / 2010	1	-	-	1
Roche Modular Analytics	1	-	-	1
VITROS ECI	2	1	-	3

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-1						
All Method	26	37.98	16.98	44.7	32.6	0.0 - 89.0
Abbott Architect	5	21.18	2.98	14.1	22.4	12.2 - 30.2
bioMerieux Vidas, Mini Vidas	5	32.00	4.24	13.3	32.0	19.2 - 44.8
Specimen RU-2						
All Method	28	130.44	55.08	42.2	116.5	0.0 - 295.7
Abbott Architect	5	73.56	12.01	16.3	72.3	37.5 - 109.6
bioMerieux Vidas, Mini Vidas	5	115.60	10.29	8.9	115.0	84.7 - 146.5
Specimen RU-3						
All Method	28	0.76	1.60	209.7	0.1	0.0 - 5.6
Abbott Architect	5	0.00	0.00	0.0	0.0	0.0 - 0.0
bioMerieux Vidas, Mini Vidas	5	0.00	0.00	0.0	0.0	0.0 - 0.0
Specimen RU-4						
All Method	26	38.52	16.82	43.7	33.5	0.0 - 89.0
Abbott Architect	5	21.50	3.57	16.6	22.5	10.7 - 32.3
bioMerieux Vidas, Mini Vidas	5	34.60	2.88	8.3	34.0	25.9 - 43.3
Specimen RU-5						
All Method	28	0.77	1.60	208.6	0.1	0.0 - 5.6
Abbott Architect	5	0.00	0.00	0.0	0.0	0.0 - 0.0
bioMerieux Vidas, Mini Vidas	5	0.00	0.00	0.0	0.0	0.0 - 0.0

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	26	2	1	-	-	29	26	1	2
Abbott Architect	1	-	-	-	-	1	1	-	-
Acon Laboratories	1	-	-	-	-	1	1	-	-
bioMerieux	1	-	-	-	-	1	1	-	-
BioSystems	2	-	-	-	-	2	2	-	-
Standard Diagnostics	2	-	-	-	-	2	2	-	-
Wiener Lab	14	2	1	-	-	17	14	1	2

<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	-	-	29	-	-	29
Abbott Architect	-	-	1	-	-	1
Acon Laboratories	-	-	1	-	-	1
bioMerieux	-	-	1	-	-	1
BioSystems	-	-	2	-	-	2
Standard Diagnostics	-	-	2	-	-	2
Wiener Lab	-	-	17	-	-	17

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>
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Specimen SY-1

ALL METHODS	2	6	7	7	-	-	-	-
bioMerieux	-	1	-	-	-	-	-	-
BioSystems	-	-	2	-	-	-	-	-
Wiener Lab	1	4	4	7	-	-	-	-

Specimen SY-3

ALL METHODS	2	5	9	4	1	-	-	-
bioMerieux	-	1	-	-	-	-	-	-
BioSystems	-	-	2	-	-	-	-	-
Wiener Lab	1	3	6	4	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	13	-	-	13	13	-
Abbott Architect	2	-	-	2	2	-
Biokit	1	-	-	1	1	-
bioMerieux	1	-	-	1	1	-
Human	1	-	-	1	1	-
Omega Diagnostics	1	-	-	1	1	-
Serodia	2	-	-	2	2	-
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	-	13	-	13
Abbott Architect	-	2	-	2
Biokit	-	1	-	1
bioMerieux	-	1	-	1
Human	-	1	-	1
Omega Diagnostics	-	1	-	1
Serodia	-	2	-	2
Wiener Lab	-	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	21	-	-	21	21	-
Abbott Architect	2	-	-	2	2	-
Human	1	-	-	1	1	-
Omega Diagnostics	1	-	-	1	1	-
Plasmatec	1	-	-	1	1	-
Serodia	8	-	-	8	8	-
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	-	21	-	21
Abbott Architect	-	2	-	2
Human	-	1	-	1
Omega Diagnostics	-	1	-	1
Plasmatec	-	1	-	1
Serodia	-	8	-	8
SPINREACT	-	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	69	2	1	70	70	1
ASI	2	-	-	2	2	-
Becton Dickinson	5	-	-	5	5	-
bioMerieux	4	-	-	4	4	-
BioSystems	9	-	-	9	9	-
Human	11	-	-	11	11	-
Omega Diagnostics	10	-	-	10	10	-
Plasmatec	6	-	-	6	6	-
SPINREACT	9	-	-	9	9	-
Standard Diagnostics	1	-	-	1	1	-
Wampole Impact RPR	3	-	-	3	3	-

	Specimen SY-4		Specimen SY-5	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	71	1	70
ASI	-	2	-	2
Becton Dickinson	-	5	-	5
bioMerieux	-	4	-	4
BioSystems	-	9	-	9
Human	-	11	1	10
Omega Diagnostics	-	10	-	10
Plasmatec	-	6	-	6
SPINREACT	-	9	-	9
Standard Diagnostics	-	1	-	1
Wampole Impact RPR	-	3	-	3

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>
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Specimen SY-1

ALL METHODS	11	25	4	-	-	4	1	-
Becton Dickinson	-	2	-	-	-	-	-	-
bioMerieux	-	3	-	-	-	-	-	-
BioSystems	4	4	-	-	-	-	-	-
Human	1	4	1	-	-	1	1	-
Omega Diagnostics	2	2	2	-	-	-	-	-
Plasmatec	-	4	-	-	-	1	-	-
SPINREACT	2	4	-	-	-	2	-	-

Specimen SY-3

ALL METHODS	9	25	4	2	2	2	1	-
Becton Dickinson	-	2	-	-	-	-	-	-
bioMerieux	-	3	-	-	-	-	-	-
BioSystems	4	3	1	-	-	-	-	-
Human	-	5	1	-	1	1	-	-
Omega Diagnostics	2	1	2	1	-	-	-	-
Plasmatec	-	4	-	-	-	1	-	-
SPINREACT	1	5	-	-	1	-	1	-

Viral Markers – Anti-HBc

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	89	4	3	90	2	91
Abbott Architect	4	-	-	4	-	4
Abbott Architect - IgG	2	-	-	2	-	2
Abbott Architect - IgM	2	-	-	2	-	2
Abbott Architect - Total	20	-	1	19	-	20
Abbott AxSYM - Total	5	-	-	5	-	5
Bayer ADVIA Centaur - IgG	2	-	-	2	-	2
Bayer ADVIA Centaur - Total	6	-	-	6	-	6
Bio-Rad Evolis	1	1	-	2	-	2
bioMerieux Vidas - Total	5	-	-	5	-	5
Other Total Method	3	-	-	3	-	3
Roche cobas 6000 / e 601	9	2	1	10	1	10
Roche cobas e 411 - IgG	2	-	-	2	-	2
Roche cobas e 411 - IgM	1	-	1	-	1	-
Roche Elecsys - IgG	6	-	-	6	-	6
Roche Elecsys - IgM	2	-	-	2	-	2
Roche Elecsys - Total	4	-	-	4	-	4
Roche Elecsys 1010 / 2010	1	-	-	1	-	1
Roche Modular Analytics	4	-	-	4	-	4
VITROS ECI - IgG	2	-	-	2	-	2
VITROS ECI - IgM	4	1	-	5	-	5
VITROS ECI - Total	2	-	-	2	-	2

Viral Markers – Anti-HBc (cont'd)

	Specimen VM-4		Specimen VM-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	90	91	2
Abbott Architect	-	4	4	-
Abbott Architect - IgG	-	2	2	-
Abbott Architect - IgM	-	2	2	-
Abbott Architect - Total	2	18	20	-
Abbott AxSYM - Total	-	5	5	-
Bayer ADVIA Centaur - IgG	-	2	2	-
Bayer ADVIA Centaur - Total	-	6	6	-
Bio-Rad Evolis	-	2	1	1
bioMerieux Vidas - Total	-	5	5	-
Other Total Method	-	3	3	-
Roche cobas 6000 / e 601	1	10	10	1
Roche cobas e 411 - IgG	-	2	2	-
Roche cobas e 411 - IgM	-	1	1	-
Roche Elecsys - IgG	-	6	6	-
Roche Elecsys - IgM	-	2	2	-
Roche Elecsys - Total	-	4	4	-
Roche Elecsys 1010 / 2010	-	1	1	-
Roche Modular Analytics	-	4	4	-
VITROS ECI - IgG	-	2	2	-
VITROS ECI - IgM	-	5	5	-
VITROS ECI - Total	-	2	2	-

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	198	7	194	3	198
Abbott Architect	-	25	1	24	1	24
Abbott Architect - IgG	-	1	-	1	-	1
Abbott Architect - Total	-	25	-	25	-	25
Abbott AxSYM - Total	-	4	-	4	-	4
Bayer ADVIA Centaur	-	7	1	6	-	7
Bayer ADVIA Centaur - Total	-	9	-	9	-	9
Beckman ACCESS / 2 / DxI	-	1	-	1	-	1
Bio-Rad Evolis	-	2	-	2	-	2
bioMerieux Vidas - Total	-	8	-	8	-	8
bioMerieux Vidas, Mini Vidas	-	2	-	2	-	2
Other IgG Method	-	2	-	2	-	2
Other Total Method	1	6	1	6	-	7
Roche cobas 6000 / e 601	-	23	1	22	-	23
Roche cobas e 411	-	13	-	13	-	13
Roche Elecsys - Total	1	22	2	21	-	23
Roche Elecsys 1010 / 2010	-	7	-	7	-	7
Roche Modular Analytics	1	11	-	12	-	12
Standard Diagnostics	-	1	-	1	-	1
VITROS ECI	-	8	-	8	-	8
VITROS ECI - IgG	-	2	-	2	-	2
VITROS ECI - Total	-	9	1	8	2	7

Viral Markers – Anti-HIV (cont'd)

<u>Method</u>	Specimen VM-4		Specimen VM-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	200	1	5	196
Abbott Architect	25	-	-	25
Abbott Architect - IgG	1	-	-	1
Abbott Architect - Total	25	-	1	24
Abbott AxSYM - Total	4	-	-	4
Bayer ADVIA Centaur	7	-	-	7
Bayer ADVIA Centaur - Total	9	-	-	9
Beckman ACCESS / 2 / DxI	1	-	-	1
Bio-Rad Evolis	2	-	-	2
bioMerieux Vidas - Total	8	-	-	8
bioMerieux Vidas, Mini Vidas	2	-	-	2
Other IgG Method	2	-	-	2
Other Total Method	7	-	2	5
Roche cobas 6000 / e 601	22	1	1	22
Roche cobas e 411	13	-	-	13
Roche Elecsys - Total	23	-	-	23
Roche Elecsys 1010 / 2010	7	-	-	7
Roche Modular Analytics	12	-	-	12
Standard Diagnostics	1	-	-	1
VITROS ECI	8	-	-	8
VITROS ECI - IgG	2	-	-	2
VITROS ECI - Total	9	-	1	8

Viral Markers – HAV

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	70	30	72	28	99	1
Abbott Architect - IgG	15	-	15	-	15	-
Abbott Architect - IgM	-	5	-	5	5	-
Abbott Architect - Total	2	1	2	1	3	-
Abbott AxSYM - IgG	1	-	1	-	1	-
Abbott AxSYM - IgM	-	1	-	1	1	-
Abbott AxSYM - Total	-	1	-	1	1	-
Bayer ADVIA Centaur	2	-	2	-	2	-
Bayer ADVIA Centaur - IgG	1	-	1	-	1	-
Bayer ADVIA Centaur - Total	9	1	9	1	10	-
bioMerieux Vidas - IgG	1	-	1	-	1	-
bioMerieux Vidas - IgM	-	3	-	3	3	-
bioMerieux Vidas - Total	5	-	5	-	5	-
Other IgG Method	1	-	1	-	1	-
Other Total Method	1	1	2	-	2	-
Roche cobas 6000 / e 601	5	1	5	1	6	-
Roche cobas 6000/e601 - IgM	-	5	-	5	5	-
Roche cobas e 411 - IgG	1	-	1	-	1	-
Roche cobas e 411 - Total	4	-	4	-	4	-
Roche Elecsys - IgG	8	-	8	-	8	-
Roche Elecsys - IgM	-	3	-	3	3	-
Roche Elecsys - Total	6	-	6	-	6	-
Roche Modular Analytics	4	1	4	1	5	-
VITROS ECI - IgG	-	1	-	1	-	1
VITROS ECI - IgM	-	5	-	5	5	-
VITROS ECI - Total	2	-	2	-	2	-

Viral Markers – HAV (cont'd)

<u>Method</u>	<u>Specimen VM-4</u>		<u>Specimen VM-5</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	70	30	70	30
Abbott Architect - IgG	15	-	15	-
Abbott Architect - IgM	-	5	-	5
Abbott Architect - Total	2	1	2	1
Abbott AxSYM - IgG	1	-	1	-
Abbott AxSYM - IgM	-	1	-	1
Abbott AxSYM - Total	-	1	-	1
Bayer ADVIA Centaur	2	-	2	-
Bayer ADVIA Centaur - IgG	1	-	1	-
Bayer ADVIA Centaur - Total	9	1	9	1
bioMerieux Vidas - IgG	1	-	1	-
bioMerieux Vidas - IgM	-	3	-	3
bioMerieux Vidas - Total	5	-	5	-
Other IgG Method	1	-	1	-
Other Total Method	1	1	1	1
Roche cobas 6000 / e 601	5	1	5	1
Roche cobas 6000/e601 - IgM	-	5	-	5
Roche cobas e 411 - IgG	1	-	1	-
Roche cobas e 411 - Total	4	-	4	-
Roche Elecsys - IgG	8	-	8	-
Roche Elecsys - IgM	-	3	-	3
Roche Elecsys - Total	6	-	6	-
Roche Modular Analytics	4	1	4	1
VITROS ECI - IgG	-	1	-	1
VITROS ECI - IgM	-	5	-	5
VITROS ECI - Total	2	-	2	-

Viral Markers – HBeAg

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	57	2	54	5	1	58
Abbott Architect	7	-	7	-	-	7
Abbott Architect - IgG	1	-	1	-	-	1
Abbott Architect - Total	10	-	10	-	1	9
Abbott AxSYM	1	-	1	-	-	1
Bayer ADVIA Centaur	2	-	2	-	-	2
Bayer ADVIA Centaur - IgG	1	-	1	-	-	1
Bayer ADVIA Centaur - Total	3	-	3	-	-	3
bioMerieux Vidas - Total	1	-	-	1	-	1
bioMerieux Vidas, Mini Vidas	3	-	2	1	-	3
DiaSorin - Total	1	-	1	-	-	1
Other IgG Method	1	-	1	-	-	1
Roche cobas 6000 / e 601	8	-	8	-	-	8
Roche cobas e 411	1	1	1	1	-	2
Roche Elecsys - Total	2	1	3	-	-	3
Roche Modular Analytics	6	-	6	-	-	6
VITROS ECI	4	-	4	-	-	4
VITROS ECI - IgG	1	-	1	-	-	1
VITROS ECI - Total	1	-	1	-	-	1

Viral Markers – HBeAg (cont'd)

<u>Method</u>	Specimen VM-4		Specimen VM-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	59	58	1
Abbott Architect	-	7	7	-
Abbott Architect - IgG	-	1	1	-
Abbott Architect - Total	-	10	10	-
Abbott AxSYM	-	1	1	-
Bayer ADVIA Centaur	-	2	2	-
Bayer ADVIA Centaur - IgG	-	1	1	-
Bayer ADVIA Centaur - Total	-	3	3	-
bioMerieux Vidas - Total	-	1	1	-
bioMerieux Vidas, Mini Vidas	-	3	3	-
DiaSorin - Total	-	1	1	-
Other IgG Method	-	1	1	-
Roche cobas 6000 / e 601	-	8	8	-
Roche cobas e 411	-	2	1	1
Roche Elecsys - Total	-	3	3	-
Roche Modular Analytics	-	6	6	-
VITROS ECI	-	4	4	-
VITROS ECI - IgG	-	1	1	-
VITROS ECI - Total	-	1	1	-

Viral Markers – HBsAb

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	145	12	137	142	7
Abbott Architect	-	16	-	16	15	1
Abbott Architect - IgG	-	1	-	1	1	-
Abbott Architect - Total	-	19	-	19	19	-
Abbott AxSYM - Total	-	1	-	1	1	-
Bayer ADVIA Centaur	-	5	-	5	5	-
Bayer ADVIA Centaur - IgG	-	3	-	3	3	-
Bayer ADVIA Centaur - Total	-	8	-	8	8	-
Beckman ACCESS / 2 / DxI	-	1	-	1	1	-
bioMerieux Vidas - IgG	-	1	-	1	1	-
bioMerieux Vidas - Total	-	5	1	4	5	-
Other IgG Method	-	1	1	-	1	-
Other Total Method	-	3	-	3	3	-
Roche cobas 6000 / e 601	1	16	2	15	17	-
Roche cobas 6000/e601 - IgG	-	1	-	1	1	-
Roche cobas e 411	1	9	1	9	9	1
Roche Elecsys - IgG	-	1	-	1	1	-
Roche Elecsys - Total	-	13	2	11	13	-
Roche Elecsys 1010 / 2010	-	5	-	5	5	-
Roche Modular Analytics	1	15	2	14	15	1
VITROS ECI	-	6	1	5	6	-
VITROS ECI - IgG	-	1	-	1	1	-
VITROS ECI - Total	-	10	-	10	8	2

Viral Markers – HBsAb (cont'd)

<u>Method</u>	Specimen VM-4		Specimen VM-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	143	6	4	145
Abbott Architect	15	1	-	16
Abbott Architect - IgG	1	-	-	1
Abbott Architect - Total	19	-	-	19
Abbott AxSYM - Total	1	-	-	1
Bayer ADVIA Centaur	5	-	-	5
Bayer ADVIA Centaur - IgG	3	-	-	3
Bayer ADVIA Centaur - Total	8	-	-	8
Beckman ACCESS / 2 / DxI	1	-	-	1
bioMerieux Vidas - IgG	1	-	-	1
bioMerieux Vidas - Total	5	-	-	5
Other IgG Method	1	-	-	1
Other Total Method	3	-	-	3
Roche cobas 6000 / e 601	17	-	1	16
Roche cobas 6000/e601 - IgG	1	-	-	1
Roche cobas e 411	9	1	1	9
Roche Elecsys - IgG	1	-	-	1
Roche Elecsys - Total	13	-	-	13
Roche Elecsys 1010 / 2010	5	-	-	5
Roche Modular Analytics	15	1	1	15
VITROS ECI	6	-	-	6
VITROS ECI - IgG	1	-	-	1
VITROS ECI - Total	8	2	-	10

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	195	2	185	12	15	182
Abbott Architect	26	-	26	-	2	24
Abbott Architect - IgG	1	-	1	-	-	1
Abbott Architect - Total	22	-	22	-	1	21
Abbott AxSYM	1	-	1	-	-	1
Abbott AxSYM - Total	3	-	3	-	1	2
Bayer ADVIA Centaur	9	-	9	-	-	9
Bayer ADVIA Centaur - IgG	1	-	1	-	-	1
Bayer ADVIA Centaur - IgM	1	-	1	-	-	1
Bayer ADVIA Centaur - Total	7	-	7	-	1	6
Beckman ACCESS / 2 / DxI	1	-	1	-	-	1
Bio-Rad Evolis	2	-	2	-	-	2
bioMerieux Vidas - Total	5	-	4	1	-	5
bioMerieux Vidas, Mini Vidas	3	-	3	-	-	3
Other IgG Method	2	-	2	-	-	2
Other Total Method	7	-	4	3	-	7
Roche cobas 6000 / e 601	22	1	22	1	3	20
Roche cobas e 411	14	-	14	-	-	14
Roche Elecsys - Total	21	-	20	1	4	17
Roche Elecsys 1010 / 2010	7	-	7	-	-	7
Roche Modular Analytics	13	-	13	-	2	11
Standard Diagnostics	1	-	-	1	-	1
VITROS ECI	9	-	9	-	-	9
VITROS ECI - Total	8	1	8	1	1	8

Viral Markers – HBsAg (cont'd)

<u>Method</u>	Specimen VM-4		Specimen VM-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	183	194	3
Abbott Architect	4	22	26	-
Abbott Architect - IgG	-	1	1	-
Abbott Architect - Total	2	20	21	1
Abbott AxSYM	-	1	1	-
Abbott AxSYM - Total	1	2	3	-
Bayer ADVIA Centaur	-	9	9	-
Bayer ADVIA Centaur - IgG	-	1	1	-
Bayer ADVIA Centaur - IgM	-	1	1	-
Bayer ADVIA Centaur - Total	1	6	7	-
Beckman ACCESS / 2 / DxI	-	1	1	-
Bio-Rad Evolis	-	2	2	-
bioMerieux Vidas - Total	-	5	5	-
bioMerieux Vidas, Mini Vidas	-	3	3	-
Other IgG Method	-	2	2	-
Other Total Method	1	6	7	-
Roche cobas 6000 / e 601	2	21	22	1
Roche cobas e 411	-	14	14	-
Roche Elecsys - Total	2	19	21	-
Roche Elecsys 1010 / 2010	-	7	7	-
Roche Modular Analytics	-	13	13	-
Standard Diagnostics	-	1	1	-
VITROS ECI	-	9	9	-
VITROS ECI - Total	1	8	8	1

Viral Markers – HCV

<u>Method</u>	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	174	4	2	176	2	176
Abbott Architect	22	-	2	20	-	22
Abbott Architect - IgG	3	-	-	3	-	3
Abbott Architect - Total	26	-	-	26	-	26
Abbott AxSYM	1	-	-	1	-	1
Abbott AxSYM - Total	4	-	-	4	1	3
Acon Laboratories	1	-	-	1	-	1
Bayer ADVIA Centaur	8	-	-	8	-	8
Bayer ADVIA Centaur - IgG	3	-	-	3	-	3
Bayer ADVIA Centaur - Total	8	-	-	8	-	8
Beckman ACCESS / 2 / DxI	1	-	-	1	-	1
Bio-Rad Evolis	4	-	-	4	-	4
bioMerieux Vidas - Total	1	-	-	1	-	1
Other IgG Method	3	1	-	4	-	4
Other Total Method	5	-	-	5	-	5
Roche cobas 6000 / e 601	13	1	-	14	-	14
Roche cobas e 411	7	-	-	7	-	7
Roche Elecsys - Total	15	-	-	15	-	15
Roche Elecsys 1010 / 2010	2	-	-	2	-	2
Roche Modular Analytics	13	-	-	13	-	13
Standard Diagnostics	1	-	-	1	-	1
VITROS ECI	6	-	-	6	-	6
VITROS ECI - IgG	3	-	-	3	-	3
VITROS ECI - Total	11	1	-	12	-	12

Viral Markers – HCV (cont'd)

<u>Method</u>	Specimen VM-4		Specimen VM-5	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	177	2	176
Abbott Architect	-	22	-	22
Abbott Architect - IgG	-	3	-	3
Abbott Architect - Total	-	26	1	25
Abbott AxSYM	-	1	-	1
Abbott AxSYM - Total	1	3	1	3
Acon Laboratories	-	1	-	1
Bayer ADVIA Centaur	-	8	-	8
Bayer ADVIA Centaur - IgG	-	3	-	3
Bayer ADVIA Centaur - Total	-	8	-	8
Beckman ACCESS / 2 / DxI	-	1	-	1
Bio-Rad Evolis	-	4	-	4
bioMerieux Vidas - Total	-	1	-	1
Other IgG Method	-	4	-	4
Other Total Method	-	5	-	5
Roche cobas 6000 / e 601	-	14	-	14
Roche cobas e 411	-	7	-	7
Roche Elecsys - Total	-	15	-	15
Roche Elecsys 1010 / 2010	-	2	-	2
Roche Modular Analytics	-	13	-	13
Standard Diagnostics	-	1	-	1
VITROS ECI	-	6	-	6
VITROS ECI - IgG	-	3	-	3
VITROS ECI - Total	-	12	-	12

Toxoplasma gondii Antibody

<u>Method</u>	Specimen TOX-1		Specimen TOX-2	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	-	14	-
Abbott Architect - IgG	3	-	3	-
Abbott Architect - IgM	1	-	1	-
Bayer ADVIA Centaur - IgG	1	-	1	-
bioMerieux Vidas - IgG	4	-	4	-
Other IgG Method	1	-	1	-
Roche cobas 6000/e601 - IgG	1	-	1	-
Roche cobas e 411 - IgG	1	-	1	-
Roche Elecsys - IgM	1	-	1	-
VITROS ECI - IgM	1	-	1	-

Cytomegalovirus (CMV) Antibodies

<u>Method</u>	Specimen CMV-1		Specimen CMV-2	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	3	10	-
Abbott Architect - IgG	2	-	2	-
Abbott Architect - IgM	-	1	1	-
Abbott AxSYM - IgG	1	-	1	-
bioMerieux Vidas - IgG	3	-	3	-
Other IgG Method	1	-	1	-
Roche Elecsys - IgM	-	1	1	-
VITROS ECI - IgM	-	1	1	-

Toxoplasma gondii Antibody —Quantitative (IU/mL)

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

All Method	18	158.7	135.1	85.1	124	0 - 429
Abbott Architect - IgG	5	122.4	8.0	6.5	123	106 - 139

Specimen TOX-2

All Method	18	172.2	100.0	58.1	157	0 - 373
Abbott Architect - IgG	5	138.0	9.4	6.8	139	119 - 157

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

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

All Method	12	97.1	72.5	74.7	88	0 - 243
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Specimen CMV-2

All Method	12	25.4	18.5	72.9	21	0 - 63
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CK-MB - Quantitative (U/L)

<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 CK-1						
All Method	5	74.58	5.68	7.6	71.7	57.5 - 91.7
Specimen CK-2						
All Method	5	14.10	1.46	10.3	14.1	9.7 - 18.5
Specimen CK-3						
All Method	5	40.16	2.97	7.4	39.5	31.2 - 49.1
Specimen CK-4						
All Method	5	23.02	2.04	8.9	22.9	16.9 - 29.2
Specimen CK-5						
All Method	5	6.14	1.00	16.3	6.0	3.1 - 9.2

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