

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
MLE-M3**



Total Commitment to Education and Service
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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-11	Group AB	140	98.59%	Acceptable
	Group O	1	0.70%	
	Group B	1	0.70%	
BB-12	Group O	141	99.30%	Acceptable
	Group B	1	0.70%	
BB-13	Group A	142	100%	Acceptable
BB-14	Group B	141	99.30%	Acceptable
	Group AB	1	0.70%	
BB-15	Group A	141	99.30%	Acceptable
	Group AB	1	0.70%	

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Rh Positive	141	99.30%	Acceptable
	Rh Negative	1	0.70%	
BB-12	Rh Positive	140	98.59%	Acceptable
	Rh Negative	2	1.41%	
BB-13	Rh Negative	142	100%	Acceptable
BB-14	Rh Negative	139	97.89%	Acceptable
	Rh Positive	3	2.11%	
BB-15	Rh Positive	140	98.59%	Acceptable
	Rh Negative	2	1.41%	

UNEXPECTED ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	Unexpected antibody detected	93	97.89%	Acceptable
	No unexpected antibody detected	2	2.11%	
AB-12	Unexpected antibody detected	93	97.89%	Acceptable
	No unexpected antibody detected	2	2.11%	
AB-13	No unexpected antibody detected	93	97.89%	Acceptable
	Unexpected antibody detected	2	2.11%	
AB-14	No unexpected antibody detected	93	97.89%	Acceptable
	Unexpected antibody detected	2	2.11%	
AB-15	Unexpected antibody detected	93	97.89%	Acceptable
	No unexpected antibody detected	2	2.11%	

BLOOD BANK

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	Anti-Jk(a)	38	90.48%	Acceptable
	Unable to identify, referred	3	7.14%	Acceptable
	Anti-Jk(b)	1	2.38%	
AB-12	Anti-s	40	95.24%	Acceptable
	Unable to identify, referred	2	4.76%	Acceptable
AB-13	No antibody detected	41	97.62%	Acceptable
	Unable to identify, referred	1	2.38%	
AB-14	No antibody detected	41	97.62%	Acceptable
	Unable to identify, referred	1	2.38%	
AB-15	Anti-D	40	95.24%	Acceptable
	Unable to identify, referred	2	4.76%	Acceptable

COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	Not Compatible	93	93%	Acceptable
	Compatible	1	7%	
AB-12	Not Compatible	96	96%	Acceptable
	Compatible	4	4%	
AB-13	Compatible	99	99%	Acceptable
	Not Compatible	1	1%	
AB-14	Compatible	98	98%	Acceptable
	Not Compatible	2	2%	
AB-15	Not Compatible	96	96%	Acceptable
	Compatible	4	4%	

Coagulation

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<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	127	11.87	1.23	10.4	11.8	10.0 - 13.7	127	13.31	1.07	8.1	13.2	11.3 - 15.4
Dade Innovin												
Dade Behring BFT II	5	9.78	0.53	5.4	9.5	8.3 - 11.3	5	12.10	0.48	4.0	12.0	10.2 - 14.0
Sysmex CA-500/600 series	30	10.78	0.41	3.8	10.8	9.1 - 12.4	29	12.60	0.43	3.4	12.6	10.7 - 14.5
All Coagulation Instruments	38	10.62	0.54	5.1	10.6	9.0 - 12.3	38	12.53	0.49	3.9	12.5	10.6 - 14.5
Diag Stago STA Neoplastine Cl+												
Dagnostica Stago STart 4/8	6	12.40	0.37	3.0	12.5	10.5 - 14.3	6	13.13	0.33	2.5	13.1	11.1 - 15.2
RAL Clot-SP	16	13.10	0.39	2.9	13.0	11.1 - 15.1	16	14.10	0.35	2.5	14.1	11.9 - 16.3
All Coagulation Instruments	32	12.81	0.47	3.7	12.8	10.8 - 14.8	32	13.80	0.53	3.8	13.9	11.7 - 15.9
Diagon Dia-PT												
Coalyzer-410	6	15.30	2.43	15.9	15.4	13.0 - 17.6	5	14.18	1.84	13.0	14.2	12.0 - 16.4
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	11.32	0.31	2.7	11.3	9.6 - 13.1	6	11.75	0.14	1.2	11.8	9.9 - 13.6
All Coagulation Instruments	7	11.54	0.66	5.7	11.3	9.8 - 13.3	7	12.03	0.75	6.2	11.8	10.2 - 13.9
IL TEST PT Fibrinogen												
IL ACL, all models	12	11.65	0.29	2.5	11.6	9.9 - 13.4	12	13.28	0.44	3.3	13.2	11.2 - 15.3
IL TEST PT-FIB HS PLUS												
IL ACL, all models	10	13.62	0.87	6.4	13.5	11.5 - 15.7	10	14.93	0.47	3.2	14.9	12.6 - 17.2
IL TEST PT-FIB Recombinant												
IL ACL, all models	12	12.23	0.77	6.3	12.1	10.3 - 14.1	12	14.33	1.00	6.9	14.4	12.1 - 16.5
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	11.42	0.61	5.3	11.6	9.7 - 13.2	5	12.46	1.06	8.5	12.3	10.5 - 14.4

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-13						Specimen CG-14					
	<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	28.26	4.53	16.0	29.0	24.0 - 32.6	128	48.15	9.41	19.5	49.7	40.9 - 55.4
Dade Innovin												
Dade Behring BFT II	5	28.00	1.00	3.6	27.6	23.8 - 32.2	5	51.08	1.95	3.8	50.8	43.4 - 58.8
Sysmex CA-500/600 series	30	25.77	1.24	4.8	25.8	21.9 - 29.7	29	44.34	3.09	7.0	44.2	37.6 - 51.0
All Coagulation Instruments	39	26.24	1.60	6.1	26.0	22.3 - 30.2	38	45.60	4.03	8.8	44.9	38.7 - 52.5
Diag Stago STA Neoplastine CI+												
Diagnostica Stago STart 4/8	6	31.90	1.65	5.2	32.4	27.1 - 36.7	6	58.00	2.07	3.6	57.7	49.3 - 66.7
RAL Clot-SP	16	31.14	1.33	4.3	30.9	26.4 - 35.9	16	53.44	2.62	4.9	53.5	45.4 - 61.5
All Coagulation Instruments	32	31.44	1.63	5.2	31.4	26.7 - 36.2	32	55.14	4.33	7.9	54.7	46.8 - 63.5
Diagon Dia-PT												
Coalyzer-410	5	32.98	5.72	17.3	30.2	28.0 - 38.0	5	45.56	4.89	10.7	46.7	38.7 - 52.4
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	30.07	1.52	5.0	29.8	25.5 - 34.6	6	52.77	3.44	6.5	51.6	44.8 - 60.7
All Coagulation Instruments	7	29.93	1.43	4.8	29.7	25.4 - 34.5	7	52.33	3.35	6.4	51.5	44.4 - 60.2
IL TEST PT Fibrinogen												
IL ACL, all models	12	20.12	0.67	3.3	20.0	17.0 - 23.2	12	29.91	1.04	3.5	29.8	25.4 - 34.4
IL TEST PT-FIB HS PLUS												
IL ACL, all models	10	32.24	3.33	10.3	33.0	27.4 - 37.1	10	56.58	7.00	12.4	57.9	48.0 - 65.1
IL TEST PT-FIB Recombinant												
IL ACL, all models	12	31.42	2.31	7.4	31.4	26.7 - 36.2	12	53.62	5.48	10.2	54.3	45.5 - 61.7
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	20.48	0.80	3.9	20.5	17.4 - 23.6	5	31.36	1.96	6.2	31.1	26.6 - 36.1

PROTHROMBIN TIME (seconds)

Specimen CG-15						
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	127	11.57	1.32	11.4	11.4	9.8 - 13.4
Dade Innovin						
Dade Behring BFT II	5	9.18	0.24	2.6	9.1	7.8 - 10.6
Sysmex CA-500/600 series	29	10.40	0.30	2.9	10.4	8.8 - 12.0
All Coagulation Instruments	39	10.23	0.56	5.5	10.3	8.6 - 11.8
Diag Stago STA Neoplastine CI+						
Diagnostica Stago STart 4/8	6	12.17	0.41	3.4	12.4	10.3 - 14.0
RAL Clot-SP	16	13.02	0.38	2.9	13.0	11.0 - 15.0
All Coagulation Instruments	32	12.72	0.54	4.3	12.8	10.8 - 14.7
Diagon Dia-PT						
Coalyzer-410	6	14.60	2.08	14.2	14.3	12.4 - 16.8
HemosIL RecombiPlasTin 2G						
IL ACL, all models	6	11.65	0.34	2.9	11.6	9.9 - 13.4
All Coagulation Instruments	7	11.89	0.70	5.9	11.7	10.1 - 13.7
IL TEST PT Fibrinogen						
IL ACL, all models	12	11.18	0.37	3.4	11.1	9.4 - 12.9
IL TEST PT-FIB HS PLUS						
IL ACL, all models	10	13.04	1.07	8.2	12.9	11.0 - 15.0
IL TEST PT-FIB Recombinant						
IL ACL, all models	12	11.68	1.70	14.5	11.1	9.9 - 13.5
PH/CMS Thromboplastin-D						
All Coagulation Instruments	5	11.24	0.72	6.4	11.1	9.5 - 13.0

PROTHROMBIN TIME-INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<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	126	1.03	0.08	7.4	1.0	0.8 - 1.3	125	1.18	0.12	9.8	1.2	0.9 - 1.5
Dade Innovin												
Dade Behring BFT II	5	1.10	0.00	0.0	1.1	0.8 - 1.4	5	1.28	0.04	3.5	1.3	1.0 - 1.6
Sysmex CA-500/600 series	29	1.04	0.06	6.0	1.0	0.8 - 1.3	28	1.21	0.04	3.7	1.2	0.9 - 1.5
All Coagulation Instruments	39	1.05	0.06	5.7	1.1	0.8 - 1.3	37	1.22	0.05	4.0	1.2	0.9 - 1.5
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact												
X/XR	5	0.98	0.04	4.6	1.0	0.7 - 1.2	5	1.14	0.05	4.8	1.1	0.9 - 1.4
Diagnostica Stago STart 4/8	6	0.98	0.12	11.9	1.0	0.7 - 1.2	6	1.08	0.13	12.3	1.0	0.8 - 1.3
RAL Clot-SP	16	0.99	0.06	5.8	1.0	0.7 - 1.2	16	1.08	0.05	5.0	1.1	0.8 - 1.3
All Coagulation Instruments	30	0.99	0.07	7.0	1.0	0.7 - 1.2	30	1.09	0.08	7.2	1.1	0.8 - 1.4
Diagon Dia-PT												
Coalyzer-410	6	1.25	0.21	16.6	1.3	1.0 - 1.5	6	1.27	0.21	16.3	1.2	1.0 - 1.6
HemosIL RecombiPlasTin 2G												
IL ACL, all models	7	1.01	0.04	3.7	1.0	0.8 - 1.3	7	1.07	0.05	4.6	1.1	0.8 - 1.3
All Coagulation Instruments	8	1.03	0.05	4.5	1.0	0.8 - 1.3	8	1.09	0.06	5.9	1.1	0.8 - 1.4
IL TEST PT Fibrinogen												
IL ACL, all models	12	1.04	0.07	6.4	1.1	0.8 - 1.3	12	1.33	0.09	6.7	1.3	1.0 - 1.6
IL TEST PT-FIB HS PLUS												
IL ACL, all models	11	1.05	0.10	9.9	1.0	0.8 - 1.3	11	1.17	0.06	5.5	1.2	0.9 - 1.5
IL TEST PT-FIB Recombinant												
IL ACL, all models	12	1.01	0.10	9.9	1.0	0.8 - 1.3	12	1.18	0.15	12.6	1.1	0.9 - 1.5
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	1.04	0.11	11.0	1.0	0.8 - 1.3	5	1.32	0.23	17.3	1.3	1.0 - 1.6

PROTHROMBIN TIME-INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-13						Specimen CG-14					
	<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	2.82	0.44	15.6	2.8	2.2 - 3.4	123	5.30	1.27	23.9	5.1	4.2 - 6.4
Dade Innovin												
Dade Behring BFT II	5	2.58	0.16	6.4	2.6	2.0 - 3.1	5	4.28	0.22	5.1	4.4	3.4 - 5.2
Sysmex CA-500/600 series	29	2.42	0.14	5.7	2.4	1.9 - 3.0	27	4.14	0.25	6.0	4.1	3.3 - 5.0
All Coagulation Instruments	38	2.47	0.16	6.5	2.5	1.9 - 3.0	37	4.18	0.32	7.6	4.3	3.3 - 5.1
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact												
X/XR	5	3.54	0.30	8.4	3.5	2.8 - 4.3	5	7.82	0.78	10.0	7.7	6.2 - 9.4
Diagnostica Stago STart 4/8	6	3.47	0.53	15.3	3.3	2.7 - 4.2	6	7.62	1.14	15.0	7.2	6.0 - 9.2
RAL Clot-SP	16	3.01	0.16	5.3	3.0	2.4 - 3.7	16	6.13	0.28	4.6	6.2	4.9 - 7.4
All Coagulation Instruments	29	3.14	0.33	10.5	3.1	2.5 - 3.8	30	6.68	1.15	17.3	6.4	5.3 - 8.1
Diagon Dia-PT												
Coalyzer-410	6	3.15	0.66	20.8	3.2	2.5 - 3.8	5	4.34	0.69	15.9	4.2	3.4 - 5.3
HemosIL RecombiPlasTin 2G												
IL ACL, all models	7	2.80	0.20	7.1	2.8	2.2 - 3.4	7	4.91	0.40	8.1	4.8	3.9 - 5.9
All Coagulation Instruments	8	2.70	0.34	12.5	2.8	2.1 - 3.3	8	4.86	0.40	8.1	4.8	3.8 - 5.9
IL TEST PT Fibrinogen												
IL ACL, all models	12	2.88	0.19	6.7	2.9	2.3 - 3.5	12	5.91	0.52	8.8	6.2	4.7 - 7.1
IL TEST PT-FIB HS PLUS												
IL ACL, all models	11	2.74	0.41	15.0	2.8	2.1 - 3.3	10	5.23	0.77	14.7	5.5	4.1 - 6.3
IL TEST PT-FIB Recombinant												
IL ACL, all models	12	2.73	0.27	10.0	2.7	2.1 - 3.3	12	4.85	0.59	12.2	4.8	3.8 - 5.9
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	3.76	0.30	7.9	3.9	3.0 - 4.6	5	9.36	0.56	6.0	9.1	7.4 - 11.3

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

Specimen CG-15						
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	127	0.99	0.09	8.9	1.0	0.7 - 1.2
Dade Innovin						
Dade Behring BFT II	5	1.04	0.05	5.3	1.0	0.8 - 1.3
Sysmex CA-500/600 series	29	1.00	0.04	3.8	1.0	0.8 - 1.2
All Coagulation Instruments	38	1.01	0.05	4.6	1.0	0.8 - 1.3
Diag Stago STA Neoplastine CI+						
bioMerieux Thrombolyzer Compact						
X/XR	5	0.98	0.04	4.6	1.0	0.7 - 1.2
Diagnostica Stago STart 4/8	6	0.95	0.14	14.5	0.9	0.7 - 1.2
RAL Clot-SP	16	0.97	0.07	7.3	1.0	0.7 - 1.2
All Coagulation Instruments	30	0.97	0.08	8.2	1.0	0.7 - 1.2
Diagon Dia-PT						
Coalyzer-410	6	1.17	0.21	17.7	1.2	0.9 - 1.5
HemosIL RecombiPlasTin 2G						
IL ACL, all models	7	1.09	0.04	3.5	1.1	0.8 - 1.4
All Coagulation Instruments	8	1.10	0.05	4.9	1.1	0.8 - 1.4
IL TEST PT Fibrinogen						
IL ACL, all models	12	0.96	0.07	7.0	1.0	0.7 - 1.2
IL TEST PT-FIB HS PLUS						
IL ACL, all models	11	1.02	0.12	11.5	1.0	0.8 - 1.3
IL TEST PT-FIB Recombinant						
IL ACL, all models	12	0.93	0.12	13.1	0.9	0.7 - 1.2
PH/CMS Thromboplastin-D						
All Coagulation Instruments	5	1.00	0.07	7.1	1.0	0.8 - 1.2

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

Specimen CG-11							Specimen CG-12					
<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	72	27.3	2.3	8.6	26	23 - 32	71	35.4	5.1	14.4	35	30 - 41
Dade Actin FSL												
Sysmex CA-500/600 series	17	26.0	0.8	3.0	26	22 - 30	17	28.6	0.6	2.2	29	24 - 33
All Coagulation Instruments	19	26.3	1.2	4.6	26	22 - 31	18	28.7	0.8	2.9	29	24 - 34
Diagnostica Stago STA C.K. Prest												
All Coagulation Instruments	9	30.0	0.9	2.9	30	25 - 35	9	40.1	2.6	6.5	39	34 - 47
IL TEST APTT-SP												
IL ACL, all models	29	26.0	1.4	5.3	26	22 - 30	28	34.9	1.5	4.2	35	29 - 41
All Coagulation Instruments	31	26.1	1.5	5.7	26	22 - 31	29	35.0	1.5	4.4	35	29 - 41
All Method	72	27.3	2.3	8.6	26	23 - 32	71	35.4	5.1	14.4	35	30 - 41
Specimen CG-13							Specimen CG-14					
<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	67	49.5	5.2	10.5	48	42 - 57	66	72.6	8.1	11.2	70	61 - 84
Dade Actin FSL												
Sysmex CA-500/600 series	17	46.2	2.2	4.7	46	39 - 54	17	68.7	3.6	5.3	69	58 - 80
All Coagulation Instruments	18	46.3	2.1	4.6	46	39 - 54	18	68.8	3.5	5.1	70	58 - 80
Diagnostica Stago STA C.K. Prest												
All Coagulation Instruments	9	51.6	3.9	7.6	52	43 - 60	9	76.2	6.9	9.0	76	64 - 88
IL TEST APTT-SP												
IL ACL, all models	27	47.4	2.2	4.5	47	40 - 55	27	68.7	3.3	4.8	68	58 - 79
All Coagulation Instruments	29	47.5	2.2	4.6	48	40 - 55	28	68.8	3.3	4.8	69	58 - 80
Specimen CG-15												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	72	29.4	2.7	9.2	29	25 - 34						
Dade Actin FSL												
Sysmex CA-500/600 series	17	27.0	0.9	3.2	27	22 - 32						
All Coagulation Instruments	19	27.4	1.4	5.1	27	23 - 32						
Diagnostica Stago STA C.K. Prest												
All Coagulation Instruments	9	31.4	2.9	9.1	32	26 - 37						
IL TEST APTT-SP												
IL ACL, all models	29	28.8	1.6	5.4	28	24 - 34						
All Coagulation Instruments	30	28.9	1.5	5.4	28	24 - 34						

FIBRINOGEN (mg/dL)

Specimen CG-11							Specimen CG-12					
<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	27	349.9	53.7	15.3	346	279 - 420	25	150.4	26.2	17.4	154	120 - 181
Diagnostica Stago STA Fibrinogen												
All Coagulation Instruments	5	346.4	11.4	3.3	344	277 - 416	5	137.0	34.6	25.2	153	109 - 165
IL TEST PT-FIB HS PLUS												
IL ACL, all models	6	349.0	19.2	5.5	351	279 - 419	7	155.0	16.4	10.5	155	124 - 186
IL TEST PT-FIB Recombinant												
IL ACL, all models	10	384.0	57.1	14.9	374	307 - 461	7	163.9	18.4	11.2	165	131 - 197
Specimen CG-13							Specimen CG-14					
<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	27	330.5	52.2	15.8	324	264 - 397	27	338.4	73.6	21.8	337	270 - 407
Diagnostica Stago STA Fibrinogen												
All Coagulation Instruments	5	305.2	19.3	6.3	308	244 - 367	5	301.2	18.5	6.2	303	240 - 362
IL TEST PT-FIB HS PLUS												
IL ACL, all models	8	354.1	42.4	12.0	362	283 - 425	7	377.0	56.6	15.0	372	301 - 453
IL TEST PT-FIB Recombinant												
IL ACL, all models	8	361.4	46.8	12.9	354	289 - 434	9	387.2	43.7	11.3	381	309 - 465
Specimen CG-15												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	27	530.2	107.2	20.2	575	424 - 637						
Diagnostica Stago STA Fibrinogen												
All Coagulation Instruments	5	610.0	54.6	8.9	595	488 - 732						
IL TEST PT-FIB HS PLUS												
IL ACL, all models	7	518.0	53.0	10.2	518	414 - 622						
IL TEST PT-FIB Recombinant												
IL ACL, all models	9	574.6	57.2	10.0	583	459 - 690						

URINALYSIS DIPSTICK–SPECIFIC GRAVITY

Specimen UA-3

<u>Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	441	1.0187	0.0067	0.7	1.020	1.008 - 1.029
All Bayer Instruments	54	1.0216	0.0039	0.4	1.020	1.011 - 1.032
All Refractive Index Methods	12	1.0269	0.0041	0.4	1.029	1.016 - 1.037
All Roche Instruments	148	1.0163	0.0072	0.7	1.015	1.006 - 1.027
Arkray Aution Sticks	15	1.0274	0.0043	0.4	1.029	1.017 - 1.038
Bayer Clinitek Advantus	24	1.0202	0.0023	0.2	1.020	1.010 - 1.031
Bayer Clinitek Status / Status+ DIRUI H-100 / H-500 Urine Analyzer	13	1.0223	0.0033	0.3	1.020	1.012 - 1.033
Other Analyzer Method	22	1.0209	0.0030	0.3	1.020	1.010 - 1.031
Roche Chemstrips / Combur	19	1.0222	0.0075	0.7	1.025	1.012 - 1.033
Roche cobas u 411	19	1.0124	0.0026	0.3	1.010	1.002 - 1.023
Roche cobas u 411	77	1.0129	0.0026	0.3	1.015	1.002 - 1.023
Roche Urisys	61	1.0207	0.0087	0.8	1.015	1.010 - 1.031
SD UroColor Reagent Strips	21	1.0179	0.0046	0.5	1.015	1.007 - 1.028
UriScan Pro/II	13	1.0206	0.0055	0.5	1.020	1.010 - 1.031
UriScan Reagent Strips	41	1.0200	0.0045	0.4	1.020	1.010 - 1.030

URINALYSIS DIPSTICK–pH

Specimen UA-3

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	460	-	-	-	-	-	4	41	221	127	66	-	1
Acon Laboratories	8	-	-	-	-	-	-	-	4	4	-	-	-
Analyticon CombiScan 500	1	-	-	-	-	-	1	-	-	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	-	2	-	-	-
Arkray Aution Sticks	16	-	-	-	-	-	-	-	1	14	1	-	-
Arkray PocketChem UA	2	-	-	-	-	-	-	-	-	2	-	-	-
Bayer Clinitek 50	6	-	-	-	-	-	-	-	-	6	-	-	-
Bayer Clinitek 500	5	-	-	-	-	-	-	-	-	5	-	-	-
Bayer Clinitek Advantus	24	-	-	-	-	-	-	-	-	24	-	-	-
Bayer Clinitek Atlas	6	-	-	-	-	-	-	-	4	2	-	-	-
Bayer Clinitek Status / Status+	13	-	-	-	-	-	-	-	12	1	-	-	-
Bayer Multistix Pro	7	-	-	-	-	-	-	-	1	6	-	-	-
Bayer Reagent Strips	20	-	-	-	-	-	-	-	1	18	1	-	-
Combi-Screen Test Strips	8	-	-	-	-	-	1	6	1	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	24	-	-	-	-	-	1	12	9	2	-	-	-
DIRUI H-800 Urine Analyzer	4	-	-	-	-	-	-	-	-	4	-	-	-
Erba Mannheim Uro-dipcheck 400e	6	-	-	-	-	-	-	-	3	-	3	-	-
HUMAN COMBINA Test Strips	1	-	-	-	-	-	-	1	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	4	-	-	-	-	-	-	-	-	4	-	-	-
Iris Diagnostics iChem Velocity Strips	8	-	-	-	-	-	-	2	6	-	-	-	-
Other Analyzer Method	23	-	-	-	-	-	1	8	5	6	3	-	-
Other Dipstick Method	8	-	-	-	-	-	-	-	6	2	-	-	-
Plasmatec URIPATH	2	-	-	-	-	-	-	-	1	1	-	-	-
Roche Chemstrip 101	3	-	-	-	-	-	-	-	3	-	-	-	-
Roche Chemstrips / Combur	23	-	-	-	-	-	-	-	13	4	6	-	-
Roche cobas u 411	78	-	-	-	-	-	-	-	55	-	22	-	1
Roche Miditron Junior/II	6	-	-	-	-	-	-	-	2	-	4	-	-
Roche Urilux S	3	-	-	-	-	-	-	-	3	-	-	-	-
Roche Urisys	62	-	-	-	-	-	-	1	36	1	24	-	-
SD UroColor Reagent Strips	22	-	-	-	-	-	-	-	13	9	-	-	-
Urinometer	2	-	-	-	-	-	-	-	-	1	1	-	-
UriScan Pro/II	12	-	-	-	-	-	-	6	6	-	-	-	-
UriScan Reagent Strips	42	-	-	-	-	-	-	5	31	5	1	-	-
URIT Medical Uritest Analyzers	3	-	-	-	-	-	-	-	3	-	-	-	-

URINALYSIS DIPSTICK-PROTEIN QUALITATIVE

Specimen UA-3

<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	462	5	1	12	114	234	34	62
Acon Laboratories	8	-	-	1	3	2	1	1
Analyticon CombiScan 500	2	2	-	-	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	2	-	-
Arkray Aution Sticks	16	-	-	-	-	11	4	1
Arkray PocketChem UA	2	-	-	-	-	1	-	1
Bayer Clinitek 50	6	-	-	-	-	3	3	-
Bayer Clinitek 500	5	-	-	-	-	3	1	1
Bayer Clinitek Advantus	24	-	-	-	-	16	7	1
Bayer Clinitek Atlas	6	-	-	-	-	3	3	-
Bayer Clinitek Status / Status+	14	-	-	-	-	12	2	-
Bayer Multistix Pro	7	-	-	-	3	1	2	1
Bayer Reagent Strips	19	-	-	-	4	14	1	-
Combi-Screen Test Strips	8	1	-	-	3	4	-	-
DIRUI H-100 / H-500 Urine Analyzer	24	-	-	2	10	9	2	1
DIRUI H-800 Urine Analyzer	4	-	-	1	1	1	1	-
Erba Mannheim Uro-dipcheck 400e	6	-	-	-	5	1	-	-
HUMAN Combilyzer	1	1	-	-	-	-	-	-
HUMAN COMBINA Test Strips	1	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	4	-	-	-	-	2	2	-
Iris Diagnostics iChem Velocity Strips	8	-	-	-	7	1	-	-
Other Analyzer Method	23	-	-	-	6	9	-	8
Other Dipstick Method	8	-	-	1	4	3	-	-
Plasmatec URIPATH	2	-	-	1	1	-	-	-
Roche Chemstrip 101	3	-	-	-	2	1	-	-
Roche Chemstrips / Combur	23	-	-	-	5	17	-	1
Roche cobas u 411	79	1	1	-	18	54	1	4
Roche Miditron Junior/II	6	-	-	-	-	4	-	2
Roche Urilux S	3	-	-	-	2	1	-	-
Roche Urisys	61	-	-	-	12	42	4	3
SD UroColor Reagent Strips	22	-	-	2	16	2	-	2
Urinometer	2	-	-	-	2	-	-	-
UriScan Pro/II	12	-	-	-	-	1	-	11
UriScan Reagent Strips	42	-	-	1	8	9	-	24
URIT Medical Uritest Analyzers	3	-	-	-	-	3	-	-

URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-3

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>300 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	465	2	10	9	105	3	147	159	27	3
Acon Laboratories	8	-	-	-	5	-	2	1	-	-
Analyticon CombiScan 500	2	-	-	-	1	-	1	-	-	-
Arkray Aution Jet	2	-	-	-	1	-	1	-	-	-
Arkray Aution Sticks	16	-	-	-	6	1	9	-	-	-
Arkray PocketChem UA	2	-	-	-	-	-	2	-	-	-
Bayer Clinitek 50	6	-	-	-	2	-	2	-	1	1
Bayer Clinitek 500	5	-	-	-	3	-	2	-	-	-
Bayer Clinitek Advantus	24	-	1	1	6	-	16	-	-	-
Bayer Clinitek Atlas	6	-	-	-	1	-	5	-	-	-
Bayer Clinitek Status / Status+	14	-	-	1	7	-	6	-	-	-
Bayer Multistix Pro	7	-	-	-	5	-	2	-	-	-
Bayer Reagent Strips	20	-	-	-	9	-	10	1	-	-
Combi-Screen Test Strips	8	-	-	-	-	-	4	3	1	-
DIRUI H-100 / H-500 Urine Analyzer	24	-	3	2	15	-	1	3	-	-
DIRUI H-800 Urine Analyzer	5	-	-	1	3	-	1	-	-	-
Erba Mannheim Uro-dipcheck 400e	6	-	-	-	3	2	1	-	-	-
HUMAN Combilyzer	1	-	-	-	-	-	-	1	-	-
HUMAN COMBINA Test Strips	1	-	-	-	1	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	4	-	-	-	1	-	3	-	-	-
Iris Diagnostics iChem Velocity Strips	8	-	1	1	2	-	3	-	1	-
Other Analyzer Method	23	-	1	1	3	-	9	6	3	-
Other Dipstick Method	8	-	-	-	5	-	1	1	1	-
Plasmatec URIPATH	2	-	-	-	-	-	1	-	1	-
Roche Chemstrip 101	3	-	-	-	-	-	1	2	-	-
Roche Chemstrips / Combur	23	-	-	-	1	-	3	18	1	-
Roche cobas u 411	80	2	1	-	1	-	-	70	6	-
Roche Miditron Junior/II	6	-	-	-	-	-	-	3	2	1
Roche Urilux S	3	-	-	-	-	-	-	3	-	-
Roche Urisys	62	-	-	-	7	-	6	41	8	-
SD UroColor Reagent Strips	22	-	1	1	3	-	16	-	-	1
Urinometer	2	-	-	-	-	-	2	-	-	-
UriScan Pro/II	12	-	-	-	2	-	6	3	1	-
UriScan Reagent Strips	41	-	-	1	7	-	29	3	1	-
URIT Medical Uritest Analyzers	3	-	1	-	2	-	-	-	-	-

URINALYSIS DIPSTICK–KETONES

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace (5 mg/dL)</u>	<u>Small (1+, 15 mg/dL)</u>	<u>Moderate (2+, 40 mg/dL)</u>	<u>Large (3+, 80 mg/dL)</u>	<u>150 mg/dL</u>	<u>≥ 160 mg/dL</u>
ALL METHODS	464	5	1	8	112	150	162	26
Acon Laboratories	8	-	-	-	3	3	1	1
Analyticon CombiScan 500	2	-	-	-	-	1	1	-
Arkray Aution Jet	2	-	-	-	-	2	-	-
Arkray Aution Sticks	16	1	-	-	-	7	5	3
Arkray PocketChem UA	2	-	-	-	-	-	2	-
Bayer Clinitek 50	6	-	-	-	1	5	-	-
Bayer Clinitek 500	5	-	-	-	2	1	-	2
Bayer Clinitek Advantus	24	-	-	-	11	13	-	-
Bayer Clinitek Atlas	6	-	-	-	1	5	-	-
Bayer Clinitek Status / Status+	14	-	-	-	3	6	2	3
Bayer Multistix Pro	7	-	-	-	2	5	-	-
Bayer Reagent Strips	19	-	-	-	3	14	-	2
Combi-Screen Test Strips	8	1	-	-	-	3	-	4
DIRUI H-100 / H-500 Urine Analyzer	24	-	-	-	21	2	-	1
DIRUI H-800 Urine Analyzer	4	-	-	-	1	3	-	-
Erba Mannheim Uro-dipcheck 400e	6	-	-	-	6	-	-	-
HUMAN Combilyzer	1	-	-	-	-	-	1	-
HUMAN COMBINA Test Strips	1	-	-	-	-	-	-	1
Iris Diagnostics Aution Max AX-4280	4	-	-	-	-	1	3	-
Iris Diagnostics iChem Velocity Strips	8	-	-	-	1	6	1	-
Other Analyzer Method	24	-	-	1	6	9	6	2
Other Dipstick Method	8	1	-	-	2	2	2	1
Plasmatec URIPATH	2	-	-	-	2	-	-	-
Roche Chemstrip 101	3	-	-	-	1	2	-	-
Roche Chemstrips / Combur	22	-	-	-	2	13	7	-
Roche cobas u 411	80	1	-	2	-	2	73	2
Roche Miditron Junior/II	6	-	-	-	-	-	6	-
Roche Urilux S	3	-	-	-	-	2	1	-
Roche Urisys	62	-	-	-	1	6	51	4
SD UroColor Reagent Strips	22	1	-	-	12	9	-	-
Urinometer	2	-	-	-	1	1	-	-
UriScan Pro/II	12	-	1	-	5	6	-	-
UriScan Reagent Strips	42	-	-	2	21	19	-	-
URIT Medical Uritest Analyzers	3	-	-	2	1	-	-	-

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-3

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	454	20	7	44	383
Acon Laboratories	8	-	-	1	7
Analyticon CombiScan 500	2	-	-	1	1
Arkray Aution Jet	2	-	-	-	2
Arkray Aution Sticks	16	-	-	1	15
Arkray PocketChem UA	2	-	-	-	2
Bayer Clinitek 50	6	-	-	-	6
Bayer Clinitek 500	5	-	1	1	3
Bayer Clinitek Advantus	24	6	-	8	10
Bayer Clinitek Atlas	6	1	-	-	5
Bayer Clinitek Status / Status+	13	-	-	-	13
Bayer Multistix Pro	7	-	-	-	7
Bayer Reagent Strips	9	-	1	-	8
Combi-Screen Test Strips	8	1	-	3	4
DIRUI H-100 / H-500 Urine Analyzer	23	-	-	1	22
DIRUI H-800 Urine Analyzer	4	-	-	-	4
Erba Mannheim Uro-dipcheck 400e	6	-	-	-	6
HUMAN Combilyzer	1	-	-	-	1
HUMAN COMBINA Test Strips	1	-	-	-	1
Iris Diagnostics Aution Max AX-4280	4	-	-	1	3
Iris Diagnostics iChem Velocity Strips	8	5	1	1	1
Other Analyzer Method	24	1	-	1	22
Other Dipstick Method	8	-	-	2	6
Plasmatec URIPATH	2	1	-	-	1
Roche Chemstrip 101	3	-	-	-	3
Roche Chemstrips / Combur	22	1	-	-	21
Roche cobas u 411	81	2	3	10	66
Roche Miditron Junior/II	6	-	1	-	5
Roche Urilux S	3	-	-	-	3
Roche Urisys	63	-	-	8	55
SD UroColor Reagent Strips	22	2	-	3	17
Urinometer	2	-	-	1	1
UriScan Pro/II	12	-	-	-	12
UriScan Reagent Strips	42	-	-	1	41
URIT Medical Uritest Analyzers	3	-	-	-	3

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-3

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>3.0 mg/dL</u>	<u>4.0 mg/dL</u>	<u>6.0 mg/dL</u>	<u>>8.0 mg/dL</u>
ALL METHODS	451	18	10	16	2	40	1	364
Acon Laboratories	8	-	-	-	-	3	-	5
Analyticon CombiScan 500	2	-	-	-	-	-	-	2
Arkray Aution Jet	2	-	-	-	-	-	-	2
Arkray Aution Sticks	16	-	-	1	-	1	-	14
Arkray PocketChem UA	2	-	-	-	-	-	-	2
Bayer Clinitek 50	6	-	-	-	-	-	-	6
Bayer Clinitek 500	5	-	-	-	-	-	-	5
Bayer Clinitek Advantus	24	-	-	-	-	-	-	24
Bayer Clinitek Atlas	6	-	-	1	-	4	-	1
Bayer Clinitek Status / Status+	13	-	-	-	-	-	-	13
Bayer Multistix Pro	7	-	-	-	-	-	-	7
Bayer Reagent Strips	9	-	-	-	-	1	-	8
Combi-Screen Test Strips	8	1	-	-	-	-	-	7
DIRUI H-100 / H-500 Urine Analyzer	23	-	-	2	-	4	-	17
DIRUI H-800 Urine Analyzer	4	-	-	-	-	3	-	1
Erba Mannheim Uro-dipcheck 400e	6	-	1	1	2	1	1	-
HUMAN Combilyzer	1	-	-	-	-	-	-	1
HUMAN COMBINA Test Strips	1	-	-	-	-	-	-	1
Iris Diagnostics Aution Max AX-4280	4	-	-	-	-	-	-	4
Iris Diagnostics iChem Velocity Strips	8	1	-	4	-	3	-	-
Other Analyzer Method	23	-	2	1	-	2	-	18
Other Dipstick Method	8	-	1	1	-	1	-	5
Plasmatec URIPATH	2	-	-	1	-	1	-	-
Roche Chemstrip 101	3	-	-	-	-	2	-	1
Roche Chemstrips / Combur	22	-	-	1	-	4	-	17
Roche cobas u 411	80	2	-	-	-	2	-	76
Roche Mditron Junior/II	6	-	-	-	-	1	-	5
Roche Urilux S	3	-	-	-	-	-	-	3
Roche Urisys	62	-	-	-	-	3	-	59
SD UroColor Reagent Strips	21	11	4	1	-	3	-	2
Urinometer	2	1	-	1	-	-	-	-
UriScan Pro/II	12	-	-	-	-	-	-	12
UriScan Reagent Strips	42	1	1	1	-	-	-	39
URIT Medical Uritest Analyzers	3	-	-	-	-	1	-	2

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN

Specimen UA-3

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	461	2	-	4	25	430
Acon Laboratories	8	-	-	-	1	7
Analyticon CombiScan 500	1	-	-	-	-	1
Arkray Aution Jet	2	-	-	-	1	1
Arkray Aution Sticks	16	1	-	-	4	11
Arkray PocketChem UA	2	-	-	-	1	1
Bayer Clinitek 50	6	-	-	-	-	6
Bayer Clinitek 500	5	-	-	-	-	5
Bayer Clinitek Advantus	24	-	-	-	-	24
Bayer Clinitek Atlas	6	-	-	-	-	6
Bayer Clinitek Status / Status+	14	-	-	-	-	14
Bayer Multistix Pro	7	-	-	-	1	6
Bayer Reagent Strips	19	-	-	-	1	18
Combi-Screen Test Strips	8	1	-	-	-	7
DIRUI H-100 / H-500 Urine Analyzer	23	-	-	-	-	23
DIRUI H-800 Urine Analyzer	4	-	-	-	-	4
Erba Mannheim Uro-dipcheck 400e	6	-	-	-	-	6
HUMAN Combilyzer	1	-	-	-	-	1
HUMAN COMBINA Test Strips	1	-	-	-	-	1
Iris Diagnostics Aution Max AX-4280	4	-	-	-	1	3
Iris Diagnostics iChem Velocity Strips	8	-	-	-	2	6
Other Analyzer Method	24	-	-	-	3	21
Other Dipstick Method	8	-	-	1	1	6
Plasmatec URIPATH	2	-	-	-	-	2
Roche Chemstrip 101	3	-	-	-	1	2
Roche Chemstrips / Combur	22	-	-	-	-	22
Roche cobas u 411	78	-	-	-	1	77
Roche Miditron Junior/II	6	-	-	-	-	6
Roche Urilux S	3	-	-	-	-	3
Roche Urisys	63	-	-	-	1	62
SD UroColor Reagent Strips	22	-	-	-	1	21
Urinometer	2	-	-	1	-	1
UriScan Pro/II	12	-	-	-	-	12
UriScan Reagent Strips	42	-	-	2	3	37
URIT Medical Uritest Analyzers	3	-	-	-	2	1

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-3

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	444	59	29	72	181	103
Acon Laboratories	8	-	-	2	3	3
Analyticon CombiScan 500	2	2	-	-	-	-
Arkray Aution Jet	2	-	-	-	2	-
Arkray Aution Sticks	16	-	-	-	6	10
Arkray PocketChem UA	2	-	-	-	-	2
Bayer Clinitek 50	6	-	-	-	-	6
Bayer Clinitek 500	5	1	-	-	3	1
Bayer Clinitek Advantus	24	-	-	2	22	-
Bayer Clinitek Atlas	6	-	-	-	1	5
Bayer Clinitek Status / Status+	13	-	-	-	-	13
Bayer Multistix Pro	7	-	2	3	-	2
Bayer Reagent Strips	8	-	1	2	4	1
Combi-Screen Test Strips	8	4	-	4	-	-
DIRUI H-100 / H-500 Urine Analyzer	23	-	-	2	16	5
DIRUI H-800 Urine Analyzer	4	-	-	-	-	4
Erba Mannheim Uro-dipcheck 400e	6	-	-	-	1	5
HUMAN Combilyzer	1	1	-	-	-	-
HUMAN COMBINA Test Strips	1	-	-	-	1	-
Iris Diagnostics Aution Max AX-4280	4	-	-	-	3	1
Iris Diagnostics iChem Velocity Strips	8	6	1	1	-	-
Other Analyzer Method	22	1	-	2	10	9
Other Dipstick Method	8	1	-	2	3	2
Plasmatec URIPATH	1	-	1	-	-	-
Roche Chemstrip 101	3	1	2	-	-	-
Roche Chemstrips / Combur	21	6	8	2	3	2
Roche cobas u 411	77	3	2	10	47	15
Roche Miditron Junior/II	6	-	-	-	6	-
Roche Mini UA	1	-	-	-	1	-
Roche Urilux S	4	2	1	-	1	-
Roche Urisys	62	2	-	6	40	14
SD UroColor Reagent Strips	22	12	2	5	3	-
Urinometer	2	1	-	1	-	-
UriScan Pro/II	12	2	2	7	1	-
UriScan Reagent Strips	41	10	5	20	4	2
URIT Medical Uritest Analyzers	3	1	2	-	-	-

URINALYSIS DIPSTICK–NITRITE

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	450	441	9
Acon Laboratories	8	8	-
Analyticon CombiScan 500	2	2	-
Arkray Aution Sticks	2	2	-
Arkray PocketChem UA	15	15	-
Bayer Clinitek 10 / 100	2	2	-
Bayer Clinitek 50	6	6	-
Bayer Clinitek 500	5	5	-
Bayer Clinitek Advantus	24	24	-
Bayer Clinitek Atlas	6	6	-
Bayer Clinitek Status / Status+	13	13	-
Bayer Multistix Pro	7	7	-
Bayer Reagent Strips	9	9	-
Combi-Screen Test Strips	8	7	1
CYBOW Urine Reagent Strips	24	24	-
DIRUI H-100 / H-500 Urine Analyzer	4	4	-
DIRUI H-800 Urine Analyzer	6	6	-
Erba Mannheim Uro-dipcheck 400e	1	1	-
HUMAN Combilyzer	1	1	-
Iris Diagnostics Aution Max AX-4280	4	4	-
Iris Diagnostics iChem 100	8	8	-
Iris Diagnostics iChem Velocity Strips	24	24	-
Iris Diagnostics vChem Urine Strips	8	7	1
Other Analyzer Method	2	1	1
Other Dipstick Method	3	3	-
Plasmatec URIPATH	22	22	-
Roche Chemstrips / Combur	77	75	2
Roche cobas u 411	6	6	-
Roche Mditron Junior/II	3	3	-
Roche Urilux S	62	62	-
Roche Urisys	23	21	2
SD UroColor Reagent Strips	2	2	-
Urinometer	12	12	-
UriScan Pro/II	42	41	1
UriScan Reagent Strips	3	3	-

URINALYSIS –MICROALBUMIN (dipstick only)

Specimen UA-3

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	41	4	1	-	2	7	12	15
Bayer Clinitek Microalbumin	10	-	-	-	-	6	-	4
DIRUI H-100 / H-500 Urine Analyzer	3	-	-	-	-	-	-	3
HUMAN COMBINA Test Strips	2	-	-	-	1	-	-	1
Roche Micral - 1 minute	6	2	1	-	-	-	2	1
URIT Medical Uritest Analyzers	1	-	-	-	-	-	1	-

URINALYSIS –URINE hCG

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	112	112	-
Acon Laboratories	15	15	-
ASI ProPhase Combo S/U	1	1	-
Beckman Coulter ICON 25 hCG	2	2	-
Biotron 1-Step	12	12	-
Henry Schein One Step	3	3	-
Inverness Clearview hCG Cassette	1	1	-
Quidel QuickVue + One-Step	2	2	-
Quidel QuickVue One-Step Combo	24	24	-
Quidel QuickVue One-Step Urine	8	8	-
Stanbio QuStick	1	1	-
Sure-Vue hCG - 25mIU	2	2	-

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Specimen SUS-11

<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	30	29	-	1	121	119	-	2	98.10%
Amoxicillin/Clavulanate	50	32	4	14	57	50	3	4	76.15% ¹
Ampicillin	35	1	1	33	133	1	1	131	97.71%
Ampicillin/Sulbactam	23	16	2	5	106	6	27	73	60.14%
Aztreonam	14	13	-	1	51	48	1	2	94.12%
Cefaclor	5	5	-	-	1	1	-	-	100.00%
Cefazolin	5	5	-	-	72	68	2	2	93.83%
Cefepime	17	17	-	-	124	121	-	3	97.28%
Cefixime	22	22	-	-	3	3	-	-	100.00%
Cefoperazone	8	8	-	-	1	1	-	-	100.00%
Cefotaxime	21	21	-	-	83	80	-	3	96.33%
Cefotetan	-	-	-	-	3	3	-	-	Not graded ²
Cefoxitin	7	7	-	-	73	71	-	2	97.59%
Cefpodoxime	5	5	-	-	3	3	-	-	100.00%
Ceftazidime	32	31	-	1	118	114	1	3	96.18%
Ceftizoxime	2	2	-	-	2	2	-	-	Not graded ²
Ceftriaxone	53	52	-	1	124	120	-	4	97.28%
Cefuroxime	35	33	1	1	80	76	-	4	94.17%
Cephalexin	8	6	-	2	3	3	-	-	83.33%
Cephalothin	22	13	4	5	51	41	7	3	74.36%
Ciprofloxacin	57	57	-	-	161	159	-	2	99.13%
Doxycycline	3	2	1	-	1	-	1	-	60.00%
Ertapenem	9	9	-	-	120	120	-	-	100.00%
Fosfomycin	5	5	-	-	16	16	-	-	100.00%
Gatifloxacin	1	1	-	-	2	2	-	-	Not graded ²
Gentamicin	40	38	-	2	147	145	1	1	97.94%
Imipenem	27	27	-	-	74	72	-	2	98.04%
Kanamycin	2	2	-	-	1	1	-	-	Not graded ²
Levofloxacin	22	22	-	-	40	40	-	-	100.00%
Linezolid	3	-	-	3	-	-	-	-	Inappropriate drug ³

¹ This challenge is 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

<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>	
Lomefloxacin	2	2	-	-	1	1	-	-	Not graded ²
Meropenem	20	19	-	1	105	105	-	-	99.24%
Moxifloxacin	11	11	-	-	2	2	-	-	Inappropriate drug
Nalidixic Acid	19	18	-	1	10	10	-	-	96.67%
Netilmicin	5	5	-	-	2	2	-	-	100.00%
Nitrofurantoin	53	52	1	-	122	118	3	1	97.24%
Norfloxacin	30	30	-	-	42	42	-	-	100.00%
Ofloxacin	20	20	-	-	3	3	-	-	100.00%
Oxacillin	2	-	-	2	-	-	-	-	Inappropriate drug
Penicillin	4	-	-	4	-	-	-	-	Inappropriate drug
Piperacillin	1	1	-	-	32	2	3	27	80.56%
Piperacillin/Tazobactam	18	18	-	-	81	78	1	2	97.09%
Quinupristin/Dalfopristin	-	-	-	-	1	1	-	-	Inappropriate drug
Rifampin	2	-	-	2	-	-	-	-	Inappropriate drug
Sulfisoxazole	1	1	-	-	1	1	-	-	Not graded ²
Teicoplanin	-	-	-	-	1	1	-	-	Inappropriate drug
Tetracycline	4	4	-	-	7	7	-	-	100.00%
Ticarcillin	-	-	-	-	2	2	-	-	Not graded ²
Ticarcillin/Clavulanate	1	1	-	-	2	1	1	-	Not graded ²
Tigecycline	-	-	-	-	5	5	-	-	Inappropriate drug
Tobramycin	5	5	-	-	44	44	-	-	100.00%
Trimethoprim	2	2	-	-	5	5	-	-	100.00%
Trimethoprim/Sulfamethoxazole	49	48	-	1	151	149	-	2	98.56%
Vancomycin	3	-	-	3	1	1	-	-	Not graded ⁴

Organism present in specimen SUS-11: *Escherichia coli*.

⁴ This is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY (PA Specimens)

Specimen PA-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	1	50.00%	Acceptable
No parasite seen	1	50.00%	Unacceptable

Parasite present in specimen PA-11: *Giardia lamblia*. (Graded by US consensus)

Specimen PA-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	1	50.00%	Acceptable
Entamoeba histolytica	1	50.00%	Unacceptable

Parasite present in specimen PA-12: No parasite seen. (Graded by US consensus)

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	12	100%	Acceptable

Parasite present in specimen PA-13: *Hookworm*.

Specimen PA-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. Eggs	12	100%	Acceptable

Parasites present in specimen PA-14: *Taenia sp. eggs*.

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Trypanosoma sp., NOS	4	40%	Not graded
Trypanosoma brucei	2	20%	
Trypanosoma cruzi	4	40%	

Parasite present in specimen PA-15: Trypanosoma brucei. This is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY (FP Specimens)

Specimen FP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Clonorchis sinensis	94	31.13%	Acceptable
Parasite egg seen but no ID	1	0.33%	Acceptable
No parasite seen	167	55.30%	
Taenia sp. Eggs	10	3.31%	
Fasciola hepatica eggs	5	1.66%	
Giardia lamblia	4	1.32%	
Trichuris trichiura eggs	3	0.99%	
Enterobius vermicularis eggs	2	0.66%	
Paragonimus westermani eggs	2	0.66%	
Entamoeba histolytica	2	0.66%	
Ascaris lumbricoides eggs	2	0.66%	
Blastocystis hominis	2	0.66%	
Dientamoeba fragilis	1	0.33%	
Entamoeba hartmanni	1	0.33%	
Sarcocystis sp. Oocysts	1	0.33%	
Schistosoma sp. Eggs, NOS	1	0.33%	
Strongyloides stercoralis larvae	1	0.33%	
Nonpath. Protozoan present	1	0.33%	
Hymenolepis diminuta eggs	1	0.33%	
Hymenolepis nana eggs	1	0.33%	

Parasite present in specimen FP-11: *Clonorchis sinensis*. This challenge was graded by 82% referee consensus.

PARASITOLOGY (FP Specimens)

Specimen FP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis larvae	263	87.38%	Acceptable
Parasite larva seen but no ID	4	1.33%	Acceptable
No parasite seen	18	5.98%	
Hookworm	5	1.66%	
Endolimax nana	4	1.33%	
Giardia lamblia	2	0.66%	
Hymenolepis nana eggs	1	0.33%	
Entamoeba coli	1	0.33%	
Entamoeba hartmanni	1	0.33%	
Fasciola hepatica eggs	1	0.33%	
Chilomastix mesnili	1	0.33%	

Parasite present in specimen FP-12: *Strongyloides stercoralis* larvae.

Specimen FP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hymenolepis nana eggs	247	80.19%	Acceptable
Hymenolepis diminuta eggs	20	6.49%	
Taenia sp. Eggs	16	5.19%	
No parasite seen	10	3.25%	
Endolimax nana	5	1.62%	
Entamoeda coli	2	0.65%	
Schistosoma japonicum eggs	2	0.65%	
Strongyloides steroralis larvae	2	0.65%	
Ascaris lumbricoides eggs	1	0.32%	
Iodamoeba butschili	1	0.32%	
Paragonimus westermani eggs	1	0.32%	

Parasite present in specimen FP-13: *Hymenolepis nana* eggs.

PARASITOLOGY (FP Specimens)

Specimen FP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba coli	258	52.76%	Acceptable
Giardia lamblia	186	38.04%	
Entamoeba histolytica	18	3.68%	Acceptable
Blastocystis hominis	8	1.64%	
Trichuris trichiura eggs	7	1.43%	
No parasite seen	3	0.61%	
Taenia sp. eggs	2	0.41%	
Chilomastix mesnili	2	0.41%	
Endolimax nana	2	0.41%	
Ascaris lumbricoides eggs	2	0.41%	
Trichostrongylus sp. Eggs	1	0.20%	

Parasites present in specimen FP-14: *Entamoeba coli* and *Giardia lamblia*.

Specimen FP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	243	87.73%	Acceptable
Plasmodium vivax	8	2.89%	
Plasmodium sp., NOS	6	2.17%	
Babesia sp.	5	1.81%	
Leishmania sp.	4	1.44%	
Plasmodium falciparum	3	1.08%	
Plasmodium ovale	3	1.08%	
Plasmodium malariae	1	0.36%	
Plasmodium sp., not falciparum	1	0.36%	
Pneumocystis carinii	1	0.36%	
Toxoplasma gondii	1	0.36%	
Other parasite seen but no ID	1	0.36%	

Parasite present in specimen FP-15: No parasite present.

Antinuclear Antibody (ANA) - Qualitative

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

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	2	-	13
BioSystems	1	-	-	1
Immuno Concepts	1	-	-	1
INOVA Diagnostics	3	-	-	3
Kallestad	2	-	-	2
Zeus	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>
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Specimen AE-11

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

Specimen AE-13

ALL METHODS	-	-	1	-	-	4	1	-	3	-	-
Immuno Concepts	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	2	1	-	-	-	-
Kallestad	-	-	-	-	-	-	-	-	1	-	-
Zeus	-	-	-	-	-	1	-	-	-	-	-

Specimen AE-15

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

Anti-dsDNA

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	-	-	9	-	9
BioSystems	1	-	-	1	-	1
INOVA Diagnostics	4	-	-	4	-	4
Zeus	1	-	-	1	-	1

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	9	-	9
BioSystems	-	1	-	1
INOVA Diagnostics	-	4	-	4
Zeus	-	1	-	1

Anti-RNP

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7	7	-
INOVA Diagnostics	-	5	-	5	5	-

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7
INOVA Diagnostics	-	5	-	5

Anti-RNP/Sm

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<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-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	-	2

Anti-SSA

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	-	-	9	9	-
INOVA Diagnostics	5	-	-	5	5	-

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	9	-	9
INOVA Diagnostics	-	5	-	5

Anti-SSB

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	7	-	9	-	9
INOVA Diagnostics	1	4	-	5	-	5

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	9	-	9
INOVA Diagnostics	-	5	-	5

Specimen AE-11 is an ungraded challenge due to less than 80% participant consensus.

Anti-SSA/SSB

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	-	-	1	1	-

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	1	-	1

Anti-Sm

<u>Method</u>	Specimen AE-11		Specimen AE-12		Specimen AE-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	9	-	9	7	2
INOVA Diagnostics	-	6	-	6	6	-

Specimen AE-13 is an ungraded challenge due to less than 80% participant consensus.

<u>Method</u>	Specimen AE-14		Specimen AE-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	9	-	9
INOVA Diagnostics	-	6	-	6

Rubella—Qualitative

<u>Method</u>	Specimen RU-11		Specimen RU-12		Specimen RU-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	22	1	22	1	-	23
Abbott Architect	7	-	7	-	-	7
bioMerieux Vidas, Mini Vidas	2	-	2	-	-	2
DiaSorin	1	-	1	-	-	1
DPC Immulite 2000	3	-	3	-	-	3
Roche cobas 6000 / e 601	2	-	2	-	-	2
Roche cobas 6000/e601 - IgG	-	1	-	1	-	1
Roche cobas e 411	3	-	3	-	-	3
Roche Modular Analytics	3	-	3	-	-	3
VITROS ECI	1	-	1	-	-	1

<u>Method</u>	Specimen RU-14		Specimen RU-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	22	1	-	23
Abbott Architect	7	-	-	7
bioMerieux Vidas, Mini Vidas	2	-	-	2
DiaSorin	1	-	-	1
DPC Immulite 2000	3	-	-	3
Roche cobas 6000 / e 601	2	-	-	2
Roche cobas 6000/e601 - IgG	-	1	-	1
Roche cobas e 411	3	-	-	3
Roche Modular Analytics	3	-	-	3
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-11						
All Method	33	37.72	13.74	36.4	37.0	0.0 - 79.0
Abbott Architect	8	24.38	1.12	4.6	24.3	21.0 - 27.8
Roche cobas e 411	6	51.80	7.65	14.8	54.6	28.8 - 74.8
Specimen RU-12						
All Method	35	118.00	47.54	40.3	118.0	0.0 - 260.7
Abbott Architect	8	68.75	4.87	7.1	66.7	54.1 - 83.4
Roche cobas e 411	6	160.90	20.94	13.0	164.1	98.0 - 223.8
Specimen RU-13						
All Method	35	0.70	1.57	224.9	0.2	0.0 - 5.4
Abbott Architect	8	0.00	0.00	0.0	0.0	0.0 - 0.0
Roche cobas e 411	6	0.22	0.10	45.4	0.2	0.0 - 0.6
Specimen RU-14						
All Method	33	39.27	14.32	36.5	39.0	0.0 - 82.3
Abbott Architect	8	24.21	1.46	6.0	23.8	19.8 - 28.6
Roche cobas e 411	6	52.33	7.05	13.5	54.5	31.1 - 73.5
Specimen RU-15						
All Method	35	0.69	1.57	226.9	0.1	0.0 - 5.4
Abbott Architect	8	0.00	0.00	0.0	0.0	0.0 - 0.0
Roche cobas e 411	6	0.20	0.11	54.8	0.2	0.0 - 0.6

Syphilis Serology—Qualitative: VDRL Slide

<u>Method</u>	Specimen SY-11			Specimen SY-12			Specimen SY-13		
	<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	27	-	-	-	-	27	27	-	-
Abbott Architect	1	-	-	-	-	1	1	-	-
Acon Laboratories	1	-	-	-	-	1	1	-	-
BioSystems	1	-	-	-	-	1	1	-	-
Omega Diagnostics	1	-	-	-	-	1	1	-	-
Plasmatec	2	-	-	-	-	2	2	-	-
Standard Diagnostics	1	-	-	-	-	1	1	-	-
Wiener Lab	15	-	-	-	-	15	15	-	-

<u>Method</u>	Specimen SY-14			Specimen SY-15		
	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>	<u>Reactive</u>	<u>Weakly Reactive</u>	<u>Non- Reactive</u>
ALL METHODS	-	-	27	-	-	27
Abbott Architect	-	-	1	-	-	1
Acon Laboratories	-	-	1	-	-	1
BioSystems	-	-	1	-	-	1
Omega Diagnostics	-	-	1	-	-	1
Plasmatec	-	-	2	-	-	2
Standard Diagnostics	-	-	1	-	-	1
Wiener Lab	-	-	15	-	-	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>
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Specimen SY-11

ALL METHODS	-	1	8	8	1	-	-	-
BioSystems	-	-	-	-	1	-	-	-
Plasmatec	-	-	1	-	-	-	-	-
Wiener Lab	-	1	5	8	-	-	-	-

Specimen SY-13

ALL METHODS	1	1	8	6	1	1	-	-
BioSystems	-	-	-	-	-	1	-	-
Plasmatec	-	-	1	-	-	-	-	-
Wiener Lab	1	1	5	6	1	-	-	-

Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	14	-	-	14	14	-
Abbott Architect	3	-	-	3	3	-
bioMerieux	1	-	-	1	1	-
Human	2	-	-	2	2	-
Omega Diagnostics	2	-	-	2	2	-
Serodia	1	-	-	1	1	-

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

Syphilis Serology—Qualitative: *Treponema pallidum* Antibodies

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	45	-	-	43	45	-
Abbott Architect	5	-	-	4	5	-
bioMerieux	1	-	-	1	1	-
bioMerieux Vidas, Mini Vidas	1	-	-	1	1	-
Human	2	-	-	2	2	-
Omega Diagnostics	4	-	-	4	4	-
Plasmatec	2	-	-	2	2	-
Serodia	14	-	-	13	14	-
SPINREACT	2	-	-	2	2	-
Zeus	1	-	-	1	1	-

	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	43	1	42
Abbott Architect	-	4	-	4
bioMerieux	-	1	-	1
bioMerieux Vidas, Mini Vidas	-	1	-	1
Human	-	2	-	2
Omega Diagnostics	-	4	-	4
Plasmatec	-	2	-	2
Serodia	-	13	-	13
SPINREACT	-	2	-	2
Zeus	-	1	-	1

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	98	-	-	98	98	-
Acon Laboratories	2	-	-	2	2	-
ASI	1	-	-	1	1	-
Becton Dickinson	3	-	-	3	3	-
Biokit	1	-	-	1	1	-
bioMerieux	4	-	-	4	4	-
BioSystems	11	-	-	11	11	-
Human	11	-	-	11	11	-
Immunostics Inc.	1	-	-	1	1	-
Omega Diagnostics	18	-	-	18	18	-
Plasmatec	10	-	-	10	10	-
Pulse Scientific	2	-	-	2	2	-
SPINREACT	19	-	-	19	19	-
Standard Diagnostics	1	-	-	1	1	-
Wampole Impact RPR	1	-	-	1	1	-

	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	98	-	98
Acon Laboratories	-	2	-	2
ASI	-	1	-	1
Becton Dickinson	-	3	-	3
Biokit	-	1	-	1
bioMerieux	-	4	-	4
BioSystems	-	11	-	11
Human	-	11	-	11
Immunostics Inc.	-	1	-	1
Omega Diagnostics	-	18	-	18
Plasmatec	-	10	-	10
Pulse Scientific	-	2	-	2
SPINREACT	-	19	-	19
Standard Diagnostics	-	1	-	1
Wampole Impact RPR	-	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>
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Specimen SY-11

ALL METHODS	6	32	15	6	1	2	-	-
Becton Dickinson	-	-	1	1	-	-	-	-
bioMerieux	-	3	-	-	-	-	-	-
BioSystems	-	5	2	2	-	-	-	-
Human	1	4	1	1	-	1	-	-
Immunostics Inc.	-	1	-	-	-	-	-	-
Omega Diagnostics	1	8	3	-	-	-	-	-
Plasmatec	3	2	2	-	-	-	-	-
Pulse Scientific	-	-	-	-	-	1	-	-
SPINREACT	1	7	4	2	1	-	-	-

Specimen SY-13

ALL METHODS	5	31	15	7	2	2	-	-
Becton Dickinson	-	1	-	-	1	-	-	-
bioMerieux	-	2	1	-	-	-	-	-
BioSystems	-	3	2	3	1	-	-	-
Human	-	5	2	-	-	1	-	-
Immunostics Inc.	-	1	-	-	-	-	-	-
Omega Diagnostics	-	7	5	-	-	-	-	-
Plasmatec	2	3	2	-	-	-	-	-
Pulse Scientific	-	-	-	-	-	1	-	-
SPINREACT	2	7	2	4	-	-	-	-

Viral Markers – Anti-HBc

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	89	19	107	1	107	1
Abbott Architect	5	-	5	-	5	-
Abbott Architect - IgG	7	-	7	-	7	-
Abbott Architect - IgM	1	2	3	-	3	-
Abbott Architect - Total	22	-	22	-	22	-
Bayer ADVIA Centaur	1	2	3	-	3	-
Bayer ADVIA Centaur - IgG	2	-	2	-	2	-
Bayer ADVIA Centaur - IgM	-	4	4	-	4	-
Bayer ADVIA Centaur - Total	9	-	9	-	9	-
Beckman ACCESS / 2 / DxI	2	-	2	-	2	-
Bio-Rad Evolis	1	-	1	-	1	-
bioMerieux Vidas - IgG	1	-	1	-	1	-
bioMerieux Vidas - IgM	-	1	1	-	1	-
bioMerieux Vidas - Total	3	-	3	-	3	-
DiaSorin - Total	1	-	1	-	1	-
Other Total Method	3	-	3	-	3	-
Roche cobas 6000 / e 601	6	-	6	-	6	-
Roche cobas 6000/e601 - IgG	3	-	3	-	3	-
Roche cobas 6000/e601 - IgM	1	-	1	-	1	-
Roche cobas e 411 - IgG	6	-	6	-	6	-
Roche cobas e 411 - IgM	-	3	3	-	3	-
Roche Elecsys - IgM	-	2	2	-	2	-
Roche Elecsys - Total	4	-	4	-	4	-
Roche Elecsys 1010 / 2010	2	-	2	-	2	-
Roche Modular Analytics	5	-	5	-	5	-
VITROS ECI - IgG	1	-	1	-	1	-
VITROS ECI - IgM	-	2	2	-	2	-
VITROS ECI - Total	1	-	1	-	1	-

Viral Markers – Anti-HBc (cont'd)

	Specimen VM-14		Specimen VM-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	104	7	100
Abbott Architect	-	5	2	3
Abbott Architect - IgG	-	7	1	6
Abbott Architect - IgM	-	3	-	3
Abbott Architect - Total	-	22	1	21
Bayer ADVIA Centaur	-	3	-	3
Bayer ADVIA Centaur - IgG	-	2	-	2
Bayer ADVIA Centaur - IgM	-	4	-	4
Bayer ADVIA Centaur - Total	-	9	-	9
Beckman ACCESS / 2 / DxI	1	1	1	1
Bio-Rad Evolis	-	1	-	1
bioMerieux Vidas - IgG	-	1	-	1
bioMerieux Vidas - IgM	-	1	-	1
bioMerieux Vidas - Total	-	3	-	3
DiaSorin - Total	-	1	-	1
Other Total Method	-	3	-	2
Roche cobas 6000 / e 601	-	6	-	6
Roche cobas 6000/e601 - IgG	-	3	-	3
Roche cobas 6000/e601 - IgM	-	1	-	1
Roche cobas e 411 - IgG	1	5	-	6
Roche cobas e 411 - IgM	-	3	-	3
Roche Elecsys - IgM	-	2	-	2
Roche Elecsys - Total	-	4	-	4
Roche Elecsys 1010 / 2010	-	2	-	2
Roche Modular Analytics	-	5	-	5
VITROS ECI - IgG	1	-	1	-
VITROS ECI - IgM	-	2	-	2
VITROS ECI - Total	-	1	-	1

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	255	2	256	1	257	-
Abbott Architect	30	-	30	-	30	-
Abbott Architect - IgG	2	-	2	-	2	-
Abbott Architect - Total	35	-	35	-	35	-
Abbott AxSYM - Total	1	-	1	-	1	-
Acon Laboratories	1	-	1	-	1	-
Bayer ADVIA Centaur	35	-	35	-	35	-
Bayer ADVIA Centaur - IgM	1	-	1	-	1	-
Bayer ADVIA Centaur - Total	12	-	12	-	12	-
Beckman ACCESS / 2 / DxI	4	-	4	-	4	-
Beckman ACCESS / 2 / DxI - Total	3	-	3	-	3	-
Bio-Rad Evolis	1	-	1	-	1	-
bioMerieux	1	-	1	-	1	-
bioMerieux Vidas - Total	12	-	12	-	12	-
bioMerieux Vidas, Mini Vidas	3	1	3	1	4	-
DiaSorin - Total	1	-	1	-	1	-
Human	1	-	1	-	1	-
Other Total Method	6	-	6	-	6	-
Roche cobas 6000 / e 601	20	-	20	-	20	-
Roche cobas 6000/e601 - IgG	2	-	2	-	2	-
Roche cobas e 411	21	-	21	-	21	-
Roche cobas e 411 - Total	3	-	3	-	3	-
Roche Elecsys - Total	13	-	13	-	13	-
Roche Elecsys 1010 / 2010	5	-	5	-	5	-
Roche Modular Analytics	14	-	14	-	14	-
Standard Diagnostics	4	-	4	-	4	-
VITROS 5600	1	-	1	-	1	-
VITROS ECI	5	-	5	-	5	-
VITROS ECI - Total	5	-	5	-	5	-

Viral Markers – Anti-HIV (cont'd)

<u>Method</u>	Specimen VM-14		Specimen VM-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	21	235	21	235
Abbott Architect	-	30	-	30
Abbott Architect - IgG	-	2	-	2
Abbott Architect - Total	-	35	-	35
Abbott AxSYM - Total	-	1	-	1
Acon Laboratories	-	1	-	1
Bayer ADVIA Centaur	5	29	4	30
Bayer ADVIA Centaur - IgM	-	1	-	1
Bayer ADVIA Centaur - Total	2	10	2	10
Beckman ACCESS / 2 / DxI	-	4	-	4
Beckman ACCESS / 2 / DxI - Total	-	3	-	3
Bio-Rad Evolis	-	1	-	1
bioMerieux	-	1	-	1
bioMerieux Vidas - Total	2	10	1	11
bioMerieux Vidas, Mini Vidas	1	3	1	3
DiaSorin - Total	1	-	1	-
Human	-	1	-	1
Other Total Method	-	6	-	6
Roche cobas 6000 / e 601	-	20	1	19
Roche cobas 6000/e601 - IgG	-	2	-	2
Roche cobas e 411	-	21	-	21
Roche cobas e 411 - Total	-	3	-	3
Roche Elecsys - Total	-	13	-	13
Roche Elecsys 1010 / 2010	-	5	-	5
Roche Modular Analytics	-	14	-	14
Standard Diagnostics	-	4	-	4
VITROS 5600	-	1	-	1
VITROS ECI	3	2	3	2
VITROS ECI - Total	5	-	5	-

Viral Markers – HAV

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	86	45	87	45	84	47
Abbott Architect	1	-	1	-	1	-
Abbott Architect - IgG	19	-	19	-	19	-
Abbott Architect - IgM	-	8	-	8	-	8
Abbott Architect - Total	2	-	2	-	2	-
Abbott AxSYM - IgM	-	1	-	1	-	1
Bayer ADVIA Centaur	4	2	4	2	4	2
Bayer ADVIA Centaur - IgG	1	-	1	-	1	-
Bayer ADVIA Centaur - IgM	-	6	-	7	-	7
Bayer ADVIA Centaur - Total	18	-	18	-	18	-
Beckman ACCESS / 2 / DxI	1	-	1	-	1	-
bioMerieux Vidas - IgM	1	3	1	3	1	2
bioMerieux Vidas - Total	6	-	6	-	6	-
Other IgG Method	-	1	-	1	-	1
Roche cobas 6000 / e 601	10	-	10	-	10	-
Roche cobas 6000/e601 - IgG	-	1	-	1	-	1
Roche cobas 6000/e601 - IgM	-	6	-	6	-	6
Roche cobas e 411 - IgG	1	-	1	-	1	-
Roche cobas e 411 - IgM	-	6	-	6	-	6
Roche cobas e 411 - Total	5	-	5	-	5	-
Roche Elecsys - IgG	2	-	2	-	2	-
Roche Elecsys - IgM	-	8	-	8	-	8
Roche Elecsys - Total	3	-	3	-	3	-
Roche Modular Analytics	6	-	6	-	6	-
VITROS ECI - IgM	-	2	-	2	-	2
VITROS ECI - Total	1	-	1	-	-	1

Viral Markers – HAV (cont'd)

<u>Method</u>	Specimen VM-14		Specimen VM-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	126	5	24	107
Abbott Architect	1	-	1	-
Abbott Architect - IgG	19	-	19	-
Abbott Architect - IgM	7	1	-	8
Abbott Architect - Total	2	-	2	-
Abbott AxSYM - IgM	1	-	-	1
Bayer ADVIA Centaur	6	-	-	6
Bayer ADVIA Centaur - IgG	1	-	-	1
Bayer ADVIA Centaur - IgM	6	1	-	7
Bayer ADVIA Centaur - Total	18	-	-	18
Beckman ACCESS / 2 / DxI	1	-	-	1
bioMerieux Vidas - IgM	3	-	-	3
bioMerieux Vidas - Total	6	-	-	6
Other IgG Method	-	1	-	1
Roche cobas 6000 / e 601	10	-	1	9
Roche cobas 6000/e601 - IgG	1	-	-	1
Roche cobas 6000/e601 - IgM	6	-	-	6
Roche cobas e 411 - IgG	1	-	-	1
Roche cobas e 411 - IgM	6	-	-	6
Roche cobas e 411 - Total	5	-	-	5
Roche Elecsys - IgG	2	-	-	2
Roche Elecsys - IgM	7	1	1	7
Roche Elecsys - Total	3	-	-	3
Roche Modular Analytics	6	-	-	6
VITROS ECI - IgM	2	-	-	2
VITROS ECI - Total	-	1	-	1

Viral Markers – HBeAg

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	72	5	67	72	-
Abbott Architect	-	13	-	13	13	-
Abbott Architect - IgG	-	1	-	1	1	-
Abbott Architect - Total	-	6	-	6	6	-
Bayer ADVIA Centaur	-	10	3	7	10	-
Bayer ADVIA Centaur - IgG	-	1	-	1	1	-
Bayer ADVIA Centaur - Total	-	3	1	2	3	-
bioMerieux	-	1	-	1	1	-
bioMerieux Vidas - Total	-	1	-	1	1	-
bioMerieux Vidas, Mini Vidas	-	2	-	2	2	-
DiaSorin - Total	-	1	-	1	1	-
Other Total Method	-	3	-	3	3	-
Roche cobas 6000 / e 601	-	6	-	6	6	-
Roche cobas 6000/e601 - IgG	-	2	-	2	2	-
Roche cobas e 411	-	5	-	5	5	-
Roche Elecsys - Total	-	3	-	3	3	-
Roche Modular Analytics	-	5	-	5	5	-
VITROS ECI	-	2	-	2	2	-
VITROS ECI - Total	-	1	-	1	1	-

Viral Markers – HBeAg (cont'd)

<u>Method</u>	Specimen VM-14		Specimen VM-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	70	-	72
Abbott Architect	-	13	-	13
Abbott Architect - IgG	-	1	-	1
Abbott Architect - Total	-	6	-	6
Bayer ADVIA Centaur	2	8	-	10
Bayer ADVIA Centaur - IgG	-	1	-	1
Bayer ADVIA Centaur - Total	-	3	-	3
bioMerieux	-	1	-	1
bioMerieux Vidas - Total	-	1	-	1
bioMerieux Vidas, Mini Vidas	-	2	-	2
DiaSorin - Total	-	1	-	1
Other Total Method	-	3	-	3
Roche cobas 6000 / e 601	-	6	-	6
Roche cobas 6000/e601 - IgG	-	2	-	2
Roche cobas e 411	-	5	-	5
Roche Elecsys - Total	-	3	-	3
Roche Modular Analytics	-	5	-	5
VITROS ECI	-	2	-	2
VITROS ECI - Total	-	1	-	1

Viral Markers – HBsAb

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	185	6	185	4	187
Abbott Architect	-	24	-	24	-	24
Abbott Architect - IgG	-	3	-	3	-	3
Abbott Architect - Total	-	17	-	17	-	17
Abbott AxSYM - Total	-	1	-	1	-	1
Bayer ADVIA Centaur	-	36	-	36	-	36
Bayer ADVIA Centaur - IgG	-	2	-	2	-	2
Bayer ADVIA Centaur - IgM	-	1	-	1	-	1
Bayer ADVIA Centaur - Total	-	8	-	8	-	8
Beckman ACCESS / 2 / Dxl	-	2	-	2	-	2
bioMerieux Vidas - Total	-	5	-	5	-	5
Other Total Method	2	2	1	3	-	4
Roche cobas 6000 / e 601	1	17	2	16	1	17
Roche cobas 6000/e601 - IgG	-	3	-	3	-	3
Roche cobas e 411	2	23	2	23	2	23
Roche Elecsys - IgG	-	1	-	1	-	1
Roche Elecsys - Total	-	8	-	8	-	8
Roche Elecsys 1010 / 2010	-	3	-	3	-	3
Roche Modular Analytics	-	13	-	13	-	13
VITROS 5600	-	2	-	2	-	2
VITROS ECI	-	2	-	2	-	2
VITROS ECI - Total	-	5	-	5	-	5

Viral Markers – HBsAb (cont'd)

<u>Method</u>	Specimen VM-14		Specimen VM-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	187	3	187	4
Abbott Architect	24	-	24	-
Abbott Architect - IgG	3	-	3	-
Abbott Architect - Total	17	-	17	-
Abbott AxSYM - Total	1	-	1	-
Bayer ADVIA Centaur	36	-	36	-
Bayer ADVIA Centaur - IgG	2	-	2	-
Bayer ADVIA Centaur - IgM	1	-	1	-
Bayer ADVIA Centaur - Total	8	-	8	-
Beckman ACCESS / 2 / DxI	2	-	2	-
bioMerieux Vidas - Total	5	-	5	-
Other Total Method	3	1	3	1
Roche cobas 6000 / e 601	18	-	18	-
Roche cobas 6000/e601 - IgG	3	-	3	-
Roche cobas e 411	24	1	24	1
Roche Elecsys - IgG	1	-	1	-
Roche Elecsys - Total	7	-	8	-
Roche Elecsys 1010 / 2010	3	-	3	-
Roche Modular Analytics	13	-	13	-
VITROS 5600	2	-	2	-
VITROS ECI	2	-	1	1
VITROS ECI - Total	5	-	5	-

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	259	261	1	262	-
Abbott Architect	-	38	38	-	38	-
Abbott Architect - IgG	-	1	1	-	1	-
Abbott Architect - IgM	1	-	1	-	1	-
Abbott Architect - Total	-	30	30	-	30	-
Acon Laboratories	-	3	3	-	3	-
Bayer ADVIA Centaur	-	39	39	-	39	-
Bayer ADVIA Centaur - IgM	-	2	2	-	2	-
Bayer ADVIA Centaur - Total	-	8	8	-	8	-
Beckman ACCESS / 2 / DxI	-	6	6	-	6	-
Bio-Rad Evolis	-	1	1	-	1	-
bioMerieux Vidas - IgG	-	1	1	-	1	-
bioMerieux Vidas - Total	-	7	7	-	7	-
bioMerieux Vidas, Mini Vidas	-	3	3	-	3	-
DiaSorin - Total	-	1	1	-	1	-
Human	-	2	2	-	2	-
Other Total Method	-	6	6	-	6	-
Roche cobas 6000 / e 601	-	22	22	-	22	-
Roche cobas 6000/e601 - IgG	-	2	2	-	2	-
Roche cobas e 411	2	27	28	1	29	-
Roche cobas e 411 - Total	-	3	3	-	3	-
Roche Elecsys - IgG	-	1	1	-	1	-
Roche Elecsys - Total	-	13	13	-	13	-
Roche Elecsys 1010 / 2010	-	4	4	-	4	-
Roche Modular Analytics	-	13	13	-	13	-
Standard Diagnostics	-	2	2	-	2	-
VITROS 5600	-	2	2	-	2	-
VITROS ECI	-	5	5	-	5	-
VITROS ECI - Total	-	5	5	-	5	-

Viral Markers – HBsAg (cont'd)

<u>Method</u>	Specimen VM-14		Specimen VM-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	15	247	9	253
Abbott Architect	2	36	2	36
Abbott Architect - IgG	-	1	-	1
Abbott Architect - IgM	-	1	-	1
Abbott Architect - Total	-	30	-	30
Acon Laboratories	-	3	-	3
Bayer ADVIA Centaur	1	38	1	38
Bayer ADVIA Centaur - IgM	-	2	-	2
Bayer ADVIA Centaur - Total	-	8	1	7
Beckman ACCESS / 2 / DxI	1	5	1	5
Bio-Rad Evolis	-	1	-	1
bioMerieux Vidas - IgG	-	1	-	1
bioMerieux Vidas - Total	2	5	1	6
bioMerieux Vidas, Mini Vidas	1	2	1	2
DiaSorin - Total	-	1	-	1
Human	-	2	-	2
Other Total Method	-	6	-	6
Roche cobas 6000 / e 601	1	21	1	21
Roche cobas 6000/e601 - IgG	-	2	-	2
Roche cobas e 411	1	28	-	29
Roche cobas e 411 - Total	-	3	-	3
Roche Elecsys - IgG	-	1	-	1
Roche Elecsys - Total	1	12	1	12
Roche Elecsys 1010 / 2010	-	4	-	4
Roche Modular Analytics	2	11	-	13
Standard Diagnostics	-	2	-	2
VITROS 5600	-	2	-	2
VITROS ECI	1	4	-	5
VITROS ECI - Total	-	5	-	5

Viral Markers – HCV

<u>Method</u>	Specimen VM-11		Specimen VM-12		Specimen VM-13	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	230	4	7	227	18	216
Abbott Architect	27	-	-	27	-	27
Abbott Architect - IgG	4	-	-	4	-	4
Abbott Architect - Total	33	-	-	33	-	33
Abbott AxSYM - Total	1	-	-	1	-	1
Acon Laboratories	4	-	-	4	-	4
Bayer ADVIA Centaur	33	2	3	32	-	35
Bayer ADVIA Centaur - IgG	3	-	-	3	-	3
Bayer ADVIA Centaur - IgM	1	-	1	-	-	1
Bayer ADVIA Centaur - Total	8	-	1	7	-	8
Beckman ACCESS / 2 / DxI	2	-	-	2	-	2
Beckman ACCESS / 2 / DxI - Total	1	-	-	1	-	1
Bio-Rad Evolis	1	-	-	1	-	1
bioMerieux Vidas - IgG	1	-	-	1	1	-
bioMerieux Vidas - Total	4	-	-	4	4	-
bioMerieux Vidas, Mini Vidas	4	-	-	4	2	2
DiaSorin - IgG	1	-	-	1	-	1
Other IgG Method	1	-	-	1	-	1
Other Total Method	6	-	-	6	-	6
Roche cobas 6000 / e 601	21	-	-	21	-	21
Roche cobas 6000/e601 - IgG	1	1	-	2	-	2
Roche cobas e 411	24	1	1	24	-	25
Roche Elecsys - Total	8	-	-	8	-	8
Roche Elecsys 1010 / 2010	3	-	-	3	-	3
Roche Modular Analytics	9	-	-	9	-	9
Standard Diagnostics	3	-	-	3	-	3
VITROS 5600	2	-	-	2	1	1
VITROS ECI	4	-	1	3	2	2
VITROS ECI - Total	6	-	-	6	6	-

Viral Markers – HCV (cont'd)

<u>Method</u>	<u>Specimen VM-14</u>		<u>Specimen VM-15</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	233	-	233
Abbott Architect	-	27	-	27
Abbott Architect - IgG	-	4	-	4
Abbott Architect - Total	-	33	-	33
Abbott AxSYM - Total	1	-	-	1
Acon Laboratories	-	4	-	4
Bayer ADVIA Centaur	-	35	-	35
Bayer ADVIA Centaur - IgG	-	3	-	3
Bayer ADVIA Centaur - IgM	-	1	-	1
Bayer ADVIA Centaur - Total	-	8	-	8
Beckman ACCESS / 2 / Dxl	-	2	-	2
Beckman ACCESS / 2 / Dxl - Total	-	1	-	1
Bio-Rad Evolis	-	1	-	1
bioMerieux Vidas - IgG	-	1	-	1
bioMerieux Vidas - Total	-	4	-	4
bioMerieux Vidas, Mini Vidas	-	4	-	3
DiaSorin - IgG	-	1	-	1
Other IgG Method	-	1	-	1
Other Total Method	-	6	-	6
Roche cobas 6000 / e 601	-	21	-	21
Roche cobas 6000/e601 - IgG	-	2	-	2
Roche cobas e 411	-	25	-	25
Roche Elecsys - Total	-	8	-	8
Roche Elecsys 1010 / 2010	-	3	-	3
Roche Modular Analytics	-	9	-	9
Standard Diagnostics	-	3	-	3
VITROS 5600	-	2	-	2
VITROS ECi	-	4	-	4
VITROS ECi - Total	-	6	-	6

Toxoplasma gondii Antibody

<u>Method</u>	Specimen TOX-5		Specimen TOX-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	26	-	1	25
Abbott Architect - IgG	7	-	-	7
Abbott Architect - IgM	2	-	-	2
Bayer ADVIA Centaur	1	-	1	-
Beckman ACCESS / 2 / DxI - IgM	1	-	-	1
bioMerieux Vidas - IgG	3	-	-	3
DiaSorin	1	-	-	1
DPC Immulite 2000	1	-	-	1
Other IgG Method	2	-	-	2
Other IgM method	1	-	-	1
Roche cobas 6000/e601 - IgG	1	-	-	1
Roche cobas 6000/e601 - IgM	1	-	-	1
Roche cobas e 411 - IgG	1	-	-	1
Roche cobas e 411 - IgM	2	-	-	2
Roche Elecsys - IgG	1	-	-	1
Roche Elecsys - IgM	1	-	-	1

Cytomegalovirus (CMV) Antibodies

<u>Method</u>	Specimen CMV-5		Specimen CMV-6	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	14	14	7
Abbott Architect - IgG	1	6	6	1
Abbott Architect - IgM	2	-	-	2
Beckman ACCESS / 2 / DxI - IgM	1	-	-	1
bioMerieux Vidas - IgG	-	2	2	-
DiaSorin	-	1	1	-
DPC Immulite 2000	-	1	1	-
Other IgG Method	-	2	2	-
Roche cobas 6000/e601 - IgG	-	1	1	-
Roche cobas 6000/e601 - IgM	1	-	-	1
Roche cobas e 411 - IgM	2	1	1	2

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-5

All Method	22	157.5	150.5	95.5	101	0 - 459
All IgG Methods	13	177.0	135.9	76.8	115	0 - 449
All IgM Methods	5	12.8	13.8	107.6	5	0 - 41
Abbott Architect - IgG	6	84.2	16.0	19.0	79	52 - 117

Specimen TOX-6

All Method	23	0.9	1.5	174.4	0	0 - 4
All IgG Methods	13	0.3	0.6	204.9	0	0 - 2
All IgM Methods	6	0.3	0.5	154.9	0	0 - 2
Abbott Architect - IgG	6	0.3	0.5	154.9	0	0 - 2

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-5

All Method	20	1.6	1.6	100.2	2	0 - 5
All IgG Methods	13	1.5	1.7	113.9	1	0 - 5
Roche cobas e 411 - IgG	5	0.4	0.9	223.6	0	0 - 3

Specimen CMV-6

All Method	19	167.1	177.0	105.9	82	0 - 522
All IgG Methods	12	258.1	162.8	63.1	217	0 - 584
Roche cobas e 411 - IgG	4	-	-	-	432	0 - 584

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-11						
All Method	6	79.65	1.78	2.2	79.7	74.2 - 85.1
All Method	5	79.98	1.78	2.2	80.2	74.6 - 85.4
Specimen CK-12						
All Method	6	6.72	0.46	6.9	6.8	5.3 - 8.2
All Method	5	6.58	0.36	5.4	6.7	5.5 - 7.7
Specimen CK-13						
All Method	6	43.72	1.09	2.5	43.6	40.4 - 47.0
All Method	5	44.00	0.94	2.1	44.0	41.1 - 46.9
Specimen CK-14						
All Method	6	15.72	0.35	2.3	15.9	14.6 - 16.8
All Method	5	15.66	0.36	2.3	15.8	14.5 - 16.8
Specimen CK-15						
All Method	6	25.32	0.69	2.7	25.4	23.2 - 27.4
All Method	5	25.36	0.77	3.0	25.6	23.0 - 27.7

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