MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 1 • 5

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

International Data Supplement
MLE-M1

ACP | Medical Laboratory Evaluation

Total Commitment to Education and Service
Provided by ACP, Inc.

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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 ± the intervals below. An explanation on how to calculate the range of acceptability based upon these limits is also provided in your MLE Program Guide on page 37 under the heading "Acceptable Ranges for Quantitative Results."

Activated Partial Thromboplastin Time	± 15%
CK-MB (U/L)	± 3 SD
Cytomegalovirus	± 2 SD
Fibrinogen	± 20%
International Normalized Ratio (INR)	± 20%
Prothrombin Time	± 15%
Rubella	± 3 SD
Specific Gravity	± 0.010
Toxoplasma	± 2 SD

BLOOD BANK

ABO GROUP

Specimen	Results	Labs	Percent	Performance
BB-1	Group O	135	99.26%	Acceptable
	Group AB	1	0.74%	
BB-2	Group O	135	100%	Acceptable
BB-3	Group A	135	100%	Acceptable
BB-4	Group B	135	99.26%	Acceptable
	Group AB	1	0.74%	
BB-5	Group A	136	100%	Acceptable

RH FACTOR (D TYPE)

Specimen	Results	Labs	Percent	Performance
BB-1	Rh Positive	135	99.26%	Acceptable
	Rh Negative	1	0.74%	
BB-2	Rh Negative	134	99.26%	Acceptable
	Rh Positive	1	0.74%	
BB-3	Rh Negative	135	100%	Acceptable
BB-4	Rh Positive	136	100%	Acceptable
BB-5	Rh Positive	136	100%	Acceptable

UNEXPECTED ANTIBODY DETECTION

Specimen	Results	Labs	Percent	Performance
AB-1	No unexpected antibody detect	93	100%	Acceptable
AB-2	Unexpected antibody detected	93	100%	Acceptable
AB-3	No unexpected antibody detected	92	98.92%	Acceptable
	Unexpected antibody detected	1	1.08%	
AB-4	No unexpected antibody detected	91	97.85%	Acceptable
	Unexpected antibody detected	2	2.15%	
AB-5	Unexpected antibody detected	90	97.83%	Acceptable
	No unexpected antibody detected	2	2.17%	

BLOOD BANK

ANTIBODY IDENTIFICATION

Specimen	*Identification*	*Labs*	*Percent*	*Performance*
AB-1	No antibody detected	42	100%	Acceptable
AB-2	Anti-D	42	100%	Acceptable
AB-3	No antibody detected	42	100%	Acceptable
AB-4	No antibody detected	42	100%	Acceptable
AB-5	Anti-K	42	100%	Acceptable

COMPATIBILITY TESTING

Specimen	*Results*	*Labs*	*Percent*	*Performance*
AB-1	Compatible	95	100%	Acceptable
AB-2	Not Compatible	94	98.95%	Acceptable
	Compatible	1	1.05%	
AB-3	Compatible	93	97.89%	Acceptable
	Not Compatible	2	2.11%	
AB-4	Compatible	94	98.95%	Acceptable
	Not Compatible	1	1.05%	
AB-5	Compatible	92	96.84%	Acceptable
	Not Compatible	3	3.16%	

Coagulation

PROTHROMBIN TIME (seconds)

	Specimen CG-1						Specimen CG-2					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	138	12.04	1.30	10.8	12.1	10.2 - 13.9	139	11.95	1.35	11.3	12.0	10.1 - 13.8
Dade Innovin												
Dade Behring BFT II	5	9.58	0.26	2.7	9.5	8.1 - 11.1	5	9.28	0.43	4.7	9.2	7.8 - 10.7
Sysmex CA-500/600 series	27	10.80	0.44	4.1	10.8	9.1 - 12.5	26	10.55	0.38	3.6	10.5	8.9 - 12.2
All Coagulation Instruments	36	10.58	0.68	6.4	10.7	8.9 - 12.2	36	10.33	0.74	7.2	10.4	8.7 - 11.9
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	5	12.24	0.32	2.6	12.4	10.4 - 14.1	5	12.34	0.23	1.9	12.5	10.4 - 14.2
Diagnostica Stago STart 4/8	11	12.65	0.90	7.1	12.5	10.7 - 14.6	11	12.59	0.76	6.0	12.4	10.7 - 14.5
Human HumaClot Junior	5	12.76	0.17	1.3	12.8	10.8 - 14.7	5	13.24	0.32	2.4	13.2	11.2 - 15.3
RAL Clot-SP	17	13.52	0.57	4.2	13.4	11.4 - 15.6	17	13.26	0.36	2.7	13.2	11.2 - 15.3
All Coagulation Instruments	44	12.92	0.77	6.0	12.8	10.9 - 14.9	44	12.89	0.61	4.7	13.0	10.9 - 14.9
Diagon Dia-PT												
Coalyzer-410	5	12.80	0.55	4.3	13.0	10.8 - 14.8	5	12.28	0.53	4.3	12.2	10.4 - 14.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	11.55	0.29	2.6	11.5	9.8 - 13.3	6	11.72	0.44	3.7	11.7	9.9 - 13.5
IL TEST PT Fibrinogen												
IL ACL, all models	9	11.59	0.23	2.0	11.6	9.8 - 13.4	10	11.54	0.55	4.8	11.5	9.8 - 13.3
IL TEST PT-FIB HS PLUS												
IL ACL, all models	16	13.23	1.10	8.3	13.2	11.2 - 15.3	16	13.21	1.01	7.6	13.2	11.2 - 15.2
IL TEST PT-FIB Recombinant												
IL ACL, all models	7	12.40	0.71	5.8	12.6	10.5 - 14.3	7	12.07	0.99	8.2	12.6	10.2 - 13.9

PROTHROMBIN TIME (seconds)

	Specimen CG-3						Specimen CG-4					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	137	28.96	4.47	15.4	30.0	24.6 - 33.4	132	49.55	9.33	18.8	51.2	42.1 - 57.0
Dade Innovin												
Dade Behring BFT II	5	26.68	2.45	9.2	26.4	22.6 - 30.7	5	47.64	3.88	8.1	48.5	40.4 - 54.8
Sysmex CA-500/600 series	26	25.80	1.44	5.6	25.7	21.9 - 29.7	25	43.54	3.18	7.3	42.9	37.0 - 50.1
All Coagulation Instruments	35	25.87	1.58	6.1	25.8	21.9 - 29.8	34	44.15	3.40	7.7	43.7	37.5 - 50.8
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	5	34.18	1.03	3.0	34.5	29.0 - 39.4	5	62.62	2.00	3.2	63.0	53.2 - 72.1
Diagnostica Stago STart 4/8	11	32.15	1.32	4.1	32.4	27.3 - 37.0	11	56.98	3.29	5.8	57.2	48.4 - 65.6
Human HumaClot Junior	5	31.14	2.45	7.9	30.8	26.4 - 35.9	5	51.86	7.02	13.5	49.6	44.0 - 59.7
RAL Clot-SP	17	32.69	1.22	3.7	32.7	27.7 - 37.6	17	56.29	2.06	3.7	56.6	47.8 - 64.8
All Coagulation Instruments	44	32.21	1.81	5.6	32.5	27.3 - 37.1	41	56.67	4.16	7.3	56.7	48.1 - 65.2
Diagon Dia-PT												
Coalyzer-410	5	29.12	4.14	14.2	29.0	24.7 - 33.5	5	49.50	9.84	19.9	52.2	42.0 - 57.0
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	28.33	3.55	12.5	29.2	24.0 - 32.6	6	49.10	8.21	16.7	50.8	41.7 - 56.5
IL TEST PT Fibrinogen												
IL ACL, all models	10	21.15	3.26	15.4	20.1	17.9 - 24.4	10	32.53	7.56	23.2	30.3	27.6 - 37.5
IL TEST PT-FIB HS PLUS												
IL ACL, all models	14	33.09	1.99	6.0	33.7	28.1 - 38.1	14	55.86	5.42	9.7	57.0	47.4 - 64.3
IL TEST PT-FIB Recombinant												
IL ACL, all models	7	30.87	1.69	5.5	30.6	26.2 - 35.6	7	55.03	5.54	10.1	55.7	46.7 - 63.3

PROTHROMBIN TIME (seconds)

Specimen CG-5

Reagent/Instrument	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
All Method	137	11.84	1.40	11.8	12.1	10.0 - 13.7
Dade Innovin						
Dade Behring BFT II	5	9.08	0.34	3.8	9.1	7.7 - 10.5
Sysmex CA-500/600 series	27	10.48	0.43	4.1	10.4	8.9 - 12.1
All Coagulation Instruments	36	10.21	0.73	7.2	10.4	8.6 - 11.8
Diag Stago STA Neoplastine CI+						
bioMerieux Thrombolyzer Compact X/XR	5	12.26	0.29	2.3	12.3	10.4 - 14.1
Diagnostica Stago STart 4/8	11	12.53	0.68	5.4	12.4	10.6 - 14.5
Human HumaClot Junior	5	13.48	0.73	5.4	13.2	11.4 - 15.6
RAL Clot-SP	17	13.27	0.43	3.2	13.2	11.2 - 15.3
All Coagulation Instruments	43	12.89	0.68	5.3	12.8	10.9 - 14.9
Diagon Dia-PT						
Coalyzer-410	5	12.44	0.67	5.4	12.3	10.5 - 14.4
HemosIL RecombiPlasTin 2G						
IL ACL, all models	6	11.68	0.63	5.4	11.8	9.9 - 13.5
IL TEST PT Fibrinogen						
IL ACL, all models	10	11.10	0.53	4.8	11.0	9.4 - 12.8
IL TEST PT-FIB HS PLUS						
IL ACL, all models	16	12.73	1.26	9.9	12.9	10.8 - 14.7
IL TEST PT-FIB Recombinant						
IL ACL, all models	7	12.10	0.73	6.0	12.3	10.2 - 14.0

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

	Specimen CG-1						Specimen CG-2					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	137	1.00	0.08	8.4	1.0	0.8 - 1.3	138	0.99	0.08	7.7	1.0	0.7 - 1.2
Dade Innovin												
Dade Behring BFT II	5	1.06	0.05	5.2	1.1	0.8 - 1.3	5	1.06	0.05	5.2	1.1	0.8 - 1.3
Sysmex CA-500/600 series	27	1.04	0.06	5.5	1.0	0.8 - 1.3	27	1.02	0.06	5.5	1.0	0.8 - 1.3
All Coagulation Instruments	37	1.05	0.06	5.8	1.1	0.8 - 1.3	37	1.03	0.06	5.9	1.0	0.8 - 1.3
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact												
X/XR	5	0.92	0.08	9.1	0.9	0.7 - 1.2	5	0.96	0.09	9.3	1.0	0.7 - 1.2
Diagnostica Stago STart 4/8	10	0.98	0.08	8.0	1.0	0.7 - 1.2	10	0.96	0.07	7.3	1.0	0.7 - 1.2
RAL Clot-SP	17	1.01	0.07	6.9	1.0	0.8 - 1.3	17	0.99	0.04	4.3	1.0	0.7 - 1.2
All Coagulation Instruments	40	0.99	0.08	8.1	1.0	0.7 - 1.2	39	0.98	0.06	6.4	1.0	0.7 - 1.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	8	1.03	0.12	11.4	1.1	0.8 - 1.3	8	1.05	0.11	10.2	1.1	0.8 - 1.3
IL TEST PT Fibrinogen												
IL ACL, all models	10	1.02	0.06	6.2	1.0	0.8 - 1.3	10	0.98	0.08	8.0	1.0	0.7 - 1.2
IL TEST PT-FIB HS PLUS												
IL ACL, all models	16	0.96	0.10	9.9	1.0	0.7 - 1.2	16	0.96	0.09	9.3	1.0	0.7 - 1.2
IL TEST PT-FIB Recombinant												
IL ACL, all models	7	0.96	0.08	8.2	0.9	0.7 - 1.2	7	0.96	0.05	5.6	1.0	0.7 - 1.2
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	1.04	0.09	8.6	1.0	0.8 - 1.3	5	1.02	0.04	4.4	1.0	0.8 - 1.3

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

	Specimen CG-3						Specimen CG-4					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	136	2.80	0.46	16.3	2.8	2.2 - 3.4	134	5.45	1.52	27.9	5.4	4.3 - 6.6
Dade Innovin												
Dade Behring BFT II	5	2.52	0.22	8.6	2.6	2.0 - 3.1	5	4.14	0.41	9.9	4.3	3.3 - 5.0
Sysmex CA-500/600 series	27	2.44	0.17	6.8	2.4	1.9 - 3.0	25	4.08	0.35	8.6	4.0	3.2 - 4.9
All Coagulation Instruments	37	2.47	0.17	6.8	2.5	1.9 - 3.0	35	4.13	0.37	8.9	4.1	3.3 - 5.0
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact												
X/XR	5	3.56	0.45	12.7	3.8	2.8 - 4.3	5	7.72	1.17	15.1	7.6	6.1 - 9.3
Diagnostica Stago STart 4/8	10	3.29	0.23	6.9	3.2	2.6 - 4.0	10	6.90	0.69	10.0	6.8	5.5 - 8.3
RAL Clot-SP	17	3.26	0.18	5.4	3.3	2.6 - 4.0	17	6.71	0.38	5.7	6.7	5.3 - 8.1
All Coagulation Instruments	39	3.22	0.36	11.2	3.3	2.5 - 3.9	38	6.78	1.01	14.9	6.8	5.4 - 8.2
HemosIL RecombiPlasTin 2G												
IL ACL, all models	8	2.95	0.59	19.9	2.8	2.3 - 3.6	8	5.58	1.59	28.6	5.0	4.4 - 6.7
IL TEST PT Fibrinogen												
IL ACL, all models	10	2.68	0.52	19.3	2.8	2.1 - 3.3	10	5.74	1.24	21.6	6.1	4.5 - 6.9
IL TEST PT-FIB HS PLUS												
IL ACL, all models	15	2.72	0.27	9.8	2.8	2.1 - 3.3	15	4.85	0.87	18.0	5.0	3.8 - 5.9
IL TEST PT-FIB Recombinant												
IL ACL, all models	7	2.69	0.13	5.0	2.7	2.1 - 3.3	7	5.09	0.69	13.6	5.0	4.0 - 6.2
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	3.52	0.24	6.8	3.5	2.8 - 4.3	5	8.26	0.81	9.9	8.2	6.6 - 10.0

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

Specimen CG-5

Reagent/Instrument	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
All Method	136	0.98	0.08	8.2	1.0	0.7 - 1.2
Dade Innovin						
Dade Behring BFT II	5	1.02	0.08	8.2	1.0	0.8 - 1.3
Sysmex CA-500/600 series	27	1.01	0.05	5.3	1.0	0.8 - 1.3
All Coagulation Instruments	36	1.02	0.06	5.8	1.0	0.8 - 1.3
Diag Stago STA Neoplastine CI+ bioMerieux Thrombolyzer Compact X/XR	5	0.92	0.08	9.1	0.9	0.7 - 1.2
Diagnostica Stago STart 4/8	10	0.95	0.07	7.4	0.9	0.7 - 1.2
RAL Clot-SP	17	0.98	0.06	6.5	1.0	0.7 - 1.2
All Coagulation Instruments	40	0.96	0.07	7.3	1.0	0.7 - 1.2
HemosIL RecombiPlasTin 2G						
IL ACL, all models	8	1.04	0.17	16.2	1.1	0.8 - 1.3
IL TEST PT Fibrinogen						
IL ACL, all models	10	0.92	0.04	4.6	0.9	0.7 - 1.2
IL TEST PT-FIB HS PLUS						
IL ACL, all models	16	0.94	0.08	8.6	0.9	0.7 - 1.2
IL TEST PT-FIB Recombinant						
IL ACL, all models	7	0.94	0.08	8.3	0.9	0.7 - 1.2
PH/CMS Thromboplastin-D						
All Coagulation Instruments	5	1.02	0.04	4.4	1.0	0.8 - 1.3

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

	Specimen CG-1						Specimen CG-2					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	80	27.3	2.4	8.8	27	23 - 32	81	29.6	2.7	9.0	29	25 - 35
Dade Actin FSL												
Sysmex CA-500/600 series	13	26.2	0.7	2.6	26	22 - 31	13	27.4	0.7	2.4	27	23 - 32
All Coagulation Instruments	14	26.2	0.7	2.7	26	22 - 31	14	27.4	0.6	2.4	27	23 - 32
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STart 4/8	6	28.3	2.7	9.6	30	24 - 33	6	32.0	2.1	6.6	32	27 - 37
All Coagulation Instruments	13	29.9	1.1	3.7	30	25 - 35	14	32.1	1.8	5.5	32	27 - 37
Diagnostica Stago STA-PTT												
All Coagulation Instruments	5	31.8	3.7	11.6	31	27 - 37	5	33.2	2.9	8.9	33	28 - 39
IL TEST APTT-SP												
IL ACL, all models	30	25.5	1.0	4.0	26	21 - 30	30	28.2	1.4	5.1	28	23 - 33
All Coagulation Instruments	31	25.6	1.2	4.6	26	21 - 30	31	28.3	1.5	5.3	28	24 - 33

	Specimen CG-3						Specimen CG-4					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	79	49.8	6.4	12.9	48	42 - 58	77	72.7	8.9	12.3	71	61 - 84
Dade Actin FSL												
Sysmex CA-500/600 series	13	46.5	2.1	4.5	47	39 - 54	13	66.7	7.9	11.8	68	56 - 77
All Coagulation Instruments	14	46.6	2.1	4.6	47	39 - 54	13	68.8	4.0	5.8	69	58 - 80
Diagnostica Stago STA C.K. Prest												
Diagnostica Stago STart 4/8	6	50.3	3.1	6.1	51	42 - 58	6	75.7	5.5	7.2	74	64 - 88
All Coagulation Instruments	14	49.4	5.1	10.4	52	42 - 57	14	72.9	9.1	12.4	74	61 - 84
Diagnostica Stago STA-PTT												
All Coagulation Instruments	6	48.8	15.9	32.6	50	41 - 57	5	74.2	11.1	14.9	72	63 - 86
IL TEST APTT-SP												
IL ACL, all models	27	47.2	2.0	4.2	47	40 - 55	29	68.9	3.0	4.4	69	58 - 80
All Coagulation Instruments	28	47.2	1.9	4.1	47	40 - 55	30	68.9	3.0	4.3	69	58 - 80

	Specimen CG-5					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	80	29.8	3.5	11.6	29	25 - 35
Dade Actin FSL						
Sysmex CA-500/600 series	13	26.9	1.1	4.1	27	22 - 31
All Coagulation Instruments	14	27.0	1.1	4.1	27	22 - 32
Diagnostica Stago STA C.K. Prest						
Diagnostica Stago STart 4/8	6	32.8	0.8	2.3	33	27 - 38
All Coagulation Instruments	13	32.2	2.2	6.7	32	27 - 38
Diagnostica Stago STA-PTT						
All Coagulation Instruments	5	34.4	3.6	10.6	34	29 - 40
IL TEST APTT-SP						
IL ACL, all models	29	28.2	1.4	4.8	28	23 - 33
All Coagulation Instruments	30	28.3	1.4	5.1	28	24 - 33

FIBRINOGEN (mg/dL)

Specimen CG-1

Reagent/Instrument	Labs	Mean	SD	CV	Median	Range
All Method	35	349.2	39.9	11.4	348	279 - 420
Diagnostica Stago STA Fibrinogen						
All Coagulation Instruments	8	322.9	32.8	10.2	322	258 - 388
IL TEST PT-FIB HS PLUS						
IL ACL, all models	13	358.8	37.3	10.4	356	287 - 431
IL TEST PT-FIB Recombinant						
IL ACL, all models	6	377.7	45.4	12.0	368	302 - 454

Specimen CG-2

Reagent/Instrument	Labs	Mean	SD	CV	Median	Range
All Method	35	556.2	99.9	18.0	570	444 - 668
Diagnostica Stago STA Fibrinogen						
All Coagulation Instruments	8	518.9	111.1	21.4	547	415 - 623
IL TEST PT-FIB HS PLUS						
IL ACL, all models	13	581.5	57.0	9.8	570	465 - 698
IL TEST PT-FIB Recombinant						
IL ACL, all models	6	581.8	98.7	17.0	567	465 - 699

Specimen CG-3

Reagent/Instrument	Labs	Mean	SD	CV	Median	Range
All Method	36	346.5	58.0	16.7	341	277 - 416
Diagnostica Stago STA Fibrinogen						
All Coagulation Instruments	8	299.8	30.9	10.3	302	239 - 360
IL TEST PT-FIB HS PLUS						
IL ACL, all models	13	371.7	34.2	9.2	378	297 - 447
IL TEST PT-FIB Recombinant						
IL ACL, all models	6	365.7	45.0	12.3	361	292 - 439

Specimen CG-4

Reagent/Instrument	Labs	Mean	SD	CV	Median	Range
All Method	32	358.1	58.9	16.4	361	286 - 430
Diagnostica Stago STA Fibrinogen						
All Coagulation Instruments	7	336.7	109.9	32.6	299	269 - 405
IL TEST PT-FIB HS PLUS						
IL ACL, all models	12	396.7	31.5	7.9	397	317 - 477
IL TEST PT-FIB Recombinant						
IL ACL, all models	6	373.0	65.3	17.5	373	298 - 448

Specimen CG-5

Reagent/Instrument	Labs	Mean	SD	CV	Median	Range
All Method	32	541.2	89.1	16.5	546	432 - 650
Diagnostica Stago STA Fibrinogen						
All Coagulation Instruments	5	531.4	54.4	10.2	529	425 - 638
IL TEST PT-FIB HS PLUS						
IL ACL, all models	13	564.2	55.6	9.9	547	451 - 677
IL TEST PT-FIB Recombinant						
IL ACL, all models	6	582.3	100.1	17.2	574	465 - 699

URINALYSIS DIPSTICK–SPECIFIC GRAVITY

Specimen UA-1

Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
All Method	435	1.0192	0.0071	0.7	1.020	1.009 - 1.030
All Refractive Index Methods	11	1.0274	0.0057	0.6	1.029	1.017 - 1.038
All Roche Methods	150	1.0152	0.0070	0.7	1.015	1.005 - 1.026
All Siemens Methods	50	1.0238	0.0035	0.3	1.025	1.013 - 1.034
Arkray Aution Sticks	16	1.0264	0.0049	0.5	1.028	1.016 - 1.037
DIRUI H-100 / H-500 Urine Analyzer	20	1.0230	0.0030	0.3	1.025	1.013 - 1.033
Other Analyzer Method	24	1.0252	0.0074	0.7	1.027	1.015 - 1.036
Roche Chemstrips / Combur	15	1.0120	0.0025	0.3	1.010	1.002 - 1.022
Roche cobas u 411	86	1.0125	0.0027	0.3	1.013	1.002 - 1.023
Roche Urisys	59	1.0195	0.0092	0.9	1.015	1.009 - 1.030
SD UroColor Reagent Strips	29	1.0195	0.0038	0.4	1.020	1.009 - 1.030
Siemens Clinitek Advantus	27	1.0223	0.0033	0.3	1.020	1.012 - 1.033
Siemens Clinitek Status / Status+	11	1.0250	0.0001	0.0	1.025	1.015 - 1.035
UriScan Pro/II	10	1.0217	0.0055	0.5	1.023	1.011 - 1.032
UriScan Reagent Strips	37	1.0222	0.0050	0.5	1.020	1.012 - 1.033

URINALYSIS DIPSTICK–pH

Specimen UA-1

Participant Results

Method	***Labs***	***≤3.5***	***4.0***	***4.5***	***5.0***	***5.5***	***6.0***	***6.5***	***7.0***	***7.5***	***8.0***	***8.5***	***≥9.0***
ALL METHODS	456	-	-	-	-	1	13	34	288	98	21	-	1
Acon Laboratories	5	-	-	-	-	-	-	-	2	2	1	-	-
Analyticon CombiScan 500	1	-	-	-	-	-	1	-	-	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	-	2	-	-	-
Arkray Aution Sticks	17	-	-	-	-	-	-	-	3	12	2	-	-
Arkray PocketChem UA	2	-	-	-	-	-	-	-	-	2	-	-	-
Combi-Screen Test Strips	10	-	-	-	-	-	-	7	3	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	23	-	-	-	-	1	4	6	8	3	-	-	1
DIRUI H-800 Urine Analyzer	5	-	-	-	-	-	1	-	2	2	-	-	-
Erba Mannheim Uro-dipcheck 400e	6	-	-	-	-	-	-	-	5	-	1	-	-
HUMAN Combilyzer	1	-	-	-	-	-	1	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	3	-	-	-	-	-	-	-	-	3	-	-	-
Iris Diagnostics iChem Velocity Strips	7	-	-	-	-	-	-	3	4	-	-	-	-
Other Analyzer Method	25	-	-	-	-	-	1	6	11	7	-	-	-
Other Dipstick Method	9	-	-	-	-	-	2	-	6	1	-	-	-
Plasmatec URIPATH	3	-	-	-	-	-	-	-	2	1	-	-	-
Roche Chemstrip 101	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche Chemstrips / Combur	20	-	-	-	-	-	-	-	15	4	1	-	-
Roche cobas u 411	87	-	-	-	-	-	1	-	85	-	1	-	-
Roche Miditron Junior/II	4	-	-	-	-	-	-	-	3	-	1	-	-
Roche Urilux S	3	-	-	-	-	-	-	-	3	-	-	-	-
Roche Urisys	59	-	-	-	-	-	-	1	46	-	12	-	-
SD UroColor Reagent Strips	32	-	-	-	-	-	-	1	23	6	2	-	-
Siemens Clinitek 50	3	-	-	-	-	-	-	-	-	3	-	-	-
Siemens Clinitek 500	3	-	-	-	-	-	-	-	-	3	-	-	-
Siemens Clinitek Advantus	28	-	-	-	-	-	-	-	5	23	-	-	-
Siemens Clinitek Atlas	6	-	-	-	-	-	-	-	6	-	-	-	-
Siemens Clinitek Status / Status+	11	-	-	-	-	-	-	-	11	-	-	-	-
Siemens Multistix Pro	3	-	-	-	-	-	-	-	-	3	-	-	-
Siemens Reagent Strips	18	-	-	-	-	-	-	-	3	15	-	-	-
Urinometer	5	-	-	-	-	-	-	-	4	1	-	-	-
UriScan Pro/II	9	-	-	-	-	-	-	3	6	-	-	-	-
UriScan Reagent Strips	39	-	-	-	-	-	2	7	26	4	-	-	-
URIT Medical Uritest Analyzers	1	-	-	-	-	-	-	-	1	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-

URINALYSIS DIPSTICK–PROTEIN QUALITATIVE

Specimen UA-1

		Participant Results											
Method	***Labs***	***Negative***	***Trace***	***(1+)***	***(2+)***	***(3+)***	***(4+)***	***10 - 20 mg/dL***	***30 - 70 mg/dL***	***75 mg/dL***	***100 - 200 mg/dL***	***300 - 600 mg/dL***	***>600 or ≥1000 mg/dL***
ALL METHODS	458	5	1	8	65	109	40	1	8	-	66	137	18
Acon Laboratories	5	-	-	-	3	1	-	-	-	-	-	-	1
Analyticon CombiScan 500	2	1	-	-	-	-	-	-	1	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	2	-	-	-	-	-	-	-
Arkray Aution Sticks	17	-	-	-	-	9	1	-	-	-	-	6	1
Arkray PocketChem UA	2	-	-	-	-	-	1	-	-	-	-	1	-
Combi-Screen Test Strips	10	-	1	-	-	-	-	-	1	-	3	5	-
DIRUI H-100 / H-500 Urine Analyzer	24	2	-	2	5	6	-	-	-	-	6	3	-
DIRUI H-800 Urine Analyzer	4	-	-	-	1	2	-	-	-	-	-	1	-
Erba Mannheim Uro-dipcheck 400e	6	-	-	-	2	-	-	-	-	-	2	2	-
HUMAN Combilyzer	1	-	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	3	-	-	-	-	3	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	7	-	-	1	2	-	-	-	2	-	2	-	-
Other Analyzer Method	25	1	-	1	2	8	-	1	-	-	3	7	2
Other Dipstick Method	10	-	-	-	1	5	-	-	-	-	2	2	-
Plasmatec URIPATH	3	-	-	-	3	-	-	-	-	-	-	-	-
Roche Chemstrip 101	1	-	-	-	-	1	-	-	-	-	-	-	-
Roche Chemstrips / Combur	21	-	-	-	4	9	3	-	-	-	3	2	-
Roche cobas u 411	88	1	-	-	1	4	7	-	-	-	20	55	-
Roche Miditron Junior/II	3	-	-	-	-	1	1	-	-	-	-	1	-
Roche Urilux S	4	-	-	-	3	-	1	-	-	-	-	-	-
Roche Urisys	58	-	-	-	-	5	9	-	-	-	15	29	-
SD UroColor Reagent Strips	31	-	-	1	18	4	-	-	-	-	6	2	-
Siemens Clinitek 50	3	-	-	-	-	2	-	-	-	-	-	1	-
Siemens Clinitek 500	3	-	-	-	-	1	1	-	-	-	-	1	-
Siemens Clinitek Advantus	28	-	-	-	-	18	-	-	1	-	-	9	-
Siemens Clinitek Atlas	6	-	-	-	-	4	-	-	-	-	-	2	-
Siemens Clinitek Status / Status+	12	-	-	-	-	8	-	-	-	-	-	4	-
Siemens Multistix Pro	3	-	-	-	1	1	-	-	-	-	1	-	-
Siemens Reagent Strips	17	-	-	1	4	7	2	-	1	-	-	2	-
Urinometer	5	-	-	-	4	-	-	-	-	-	1	-	-
UriScan Pro/II	9	-	-	-	2	-	2	-	-	-	-	-	5
UriScan Reagent Strips	39	-	-	1	6	6	12	-	1	-	2	2	9
URIT Medical Uritest Analyzers	1	-	-	-	-	1	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	1	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-1

Method	Labs	Participant Results: Negative	Trace	(1+)	(2+)	(3+)	(4+)	30 - 100 mg/dL	150 - 300 mg/dL	500 mg/dL	>500 or ≥1000 or ≥2000 mg/dL
ALL METHODS	458	3	1	15	77	60	53	5	45	54	145
Acon Laboratories	6	-	-	2	-	-	3	-	1	-	-
Analyticon CombiScan 500	2	-	-	-	-	-	-	-	-	2	-
Arkray Aution Jet	2	-	-	-	-	1	-	-	-	1	-
Arkray Aution Sticks	17	-	-	-	3	6	-	-	6	2	-
Arkray PocketChem UA	2	-	-	-	1	-	-	-	-	1	-
Combi-Screen Test Strips	10	-	-	-	-	-	-	-	2	3	5
DIRUI H-100 / H-500 Urine Analyzer	24	1	-	-	7	4	-	-	7	5	-
DIRUI H-800 Urine Analyzer	4	-	-	-	3	-	-	-	1	-	-
Erba Mannheim Uro-dipcheck 400e	6	-	-	-	-	2	-	-	4	-	-
HUMAN Combilyzer	1	-	-	-	-	-	-	-	-	-	1
Iris Diagnostics Aution Max AX-4280	3	-	-	-	1	2	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	7	-	-	-	2	-	-	1	4	-	-
Other Analyzer Method	24	-	-	1	2	6	2	1	3	2	7
Other Dipstick Method	9	-	-	-	1	3	1	-	1	2	1
Plasmatec URIPATH	3	-	-	-	2	1	-	-	-	-	-
Roche Chemstrip 101	1	-	-	-	-	-	-	-	-	-	1
Roche Chemstrips / Combur	20	-	-	-	-	-	10	-	-	-	10
Roche cobas u 411	88	1	-	-	-	-	14	-	-	2	71
Roche Miditron Junior/II	4	-	-	-	-	-	1	-	1	-	2
Roche Urilux S	4	-	-	-	1	-	3	-	-	-	-
Roche Urisys	60	-	-	-	-	4	12	2	4	3	35
SD UroColor Reagent Strips	31	-	-	2	12	5	2	-	-	9	1
Siemens Clinitek 50	3	-	-	-	1	1	-	-	-	1	-
Siemens Clinitek 500	3	-	-	-	1	-	-	-	1	1	-
Siemens Clinitek Advantus	27	1	-	2	8	9	-	-	1	3	3
Siemens Clinitek Atlas	6	-	-	-	4	-	-	-	-	1	1
Siemens Clinitek Status / Status+	12	-	-	1	6	-	1	-	2	2	-
Siemens Multistix Pro	3	-	-	-	-	-	-	1	1	1	-
Siemens Reagent Strips	18	-	-	3	5	5	-	-	2	2	1
Urinometer	5	-	-	-	3	-	1	-	1	-	-
UriScan Pro/II	9	-	-	-	-	3	-	-	-	4	2
UriScan Reagent Strips	38	-	-	3	11	8	3	-	3	6	4
URIT Medical Uritest Analyzers	1	-	-	1	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	1	-	-	-	-	-	-

URINALYSIS DIPSTICK–KETONES

Specimen UA-1

		Participant Results													
Method	***Labs***	***Negative***	***Trace***	***Small***	***Moderate***	***Large***	***(1+)***	***(2+)***	***(3+)***	***(4+)***	***5 - 10 mg/dL***	***15 - 20 mg/dL***	***40 - 60 mg/dL***	***80 - 100 mg/dL***	***≥150 mg/dL***
ALL METHODS	456	7	1	-	2	4	28	82	85	35	10	12	52	57	81
Acon Laboratories	6	-	-	-	-	-	1	2	2	-	-	-	1	-	-
Analyticon CombiScan 500	2	-	-	-	-	-	-	-	-	-	-	-	-	2	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	1	1	-	-	-	-	-
Arkray Aution Sticks	17	-	-	-	-	-	-	-	6	4	-	-	1	1	5
Arkray PocketChem UA	2	-	-	-	-	-	-	-	-	1	-	-	-	-	1
Combi-Screen Test Strips	10	-	-	-	-	-	-	2	1	-	-	-	1	5	1
DIRUI H-100 / H-500 Urine Analyzer	24	2	-	-	-	-	2	10	-	-	-	2	8	-	-
DIRUI H-800 Urine Analyzer	3	-	-	-	-	-	-	1	1	-	-	-	-	1	-
Erba Mannheim Uro-dipcheck 400e	6	-	-	-	-	-	2	-	-	-	-	4	-	-	-
HUMAN Combilyzer	1	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Iris Diagnostics Aution Max AX-4280	3	-	-	-	-	-	-	-	1	2	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	7	-	-	-	-	-	1	1	-	-	-	1	2	2	-
Other Analyzer Method	25	-	-	-	-	-	-	4	6	2	2	1	7	1	2
Other Dipstick Method	10	-	-	-	-	-	3	-	4	-	-	-	3	-	-
Plasmatec URIPATH	3	-	-	-	1	-	1	1	-	-	-	-	-	-	-
Roche Chemstrip 101	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Roche Chemstrips / Combur	19	-	-	-	-	-	-	1	11	1	-	-	-	1	5
Roche cobas u 411	88	1	-	-	-	-	-	2	8	11	-	-	-	24	42
Roche Miditron Junior/II	4	-	-	-	-	-	-	1	-	1	-	-	-	-	2
Roche Urilux S	4	-	-	-	-	-	1	-	2	1	-	-	-	-	-
Roche Urisys	58	-	-	-	-	-	-	-	13	7	-	-	2	13	23
SD UroColor Reagent Strips	31	2	1	-	-	-	4	11	4	-	1	1	5	2	-
Siemens Clinitek 50	3	-	-	-	-	-	-	2	-	-	-	-	1	-	-
Siemens Clinitek 500	3	-	-	-	-	-	-	1	-	-	-	-	1	1	-
Siemens Clinitek Advantus	27	-	-	-	1	-	-	17	1	-	-	2	6	-	-
Siemens Clinitek Atlas	6	-	-	-	-	-	-	-	4	-	-	-	-	2	-
Siemens Clinitek Status / Status+	12	-	-	-	-	-	-	3	4	1	-	-	4	-	-
Siemens Multistix Pro	3	-	-	-	-	2	-	-	-	1	-	-	-	-	-
Siemens Reagent Strips	17	1	-	-	-	2	-	2	7	2	-	-	1	2	-
Urinometer	5	-	-	-	-	-	2	3	-	-	-	-	-	-	-
UriScan Pro/II	9	-	-	-	-	-	1	3	2	-	1	-	2	-	-
UriScan Reagent Strips	39	1	-	-	-	-	6	13	6	-	6	1	6	-	-
URIT Medical Uritest Analyzers	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-1

		Participant Results												
Method	***Labs***	***Negative***	***Trace***	***Small***	***Moderate***	***Large***	***(1+)***	***(2+)***	***(3+)***	***(4+)***	***0.5 - 1.0 mg/dL***	***2.0 - 4.0 mg/dL***	***6.0 - 10.0 mg/dL***	***>10.0 mg/dL***
ALL METHODS	447	17	1	-	5	24	3	17	223	47	2	21	87	-
Acon Laboratories	6	-	-	-	-	-	-	-	3	2	-	1	-	-
Analyticon CombiScan 500	2	-	-	-	-	-	-	-	-	1	-	1	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	2	-	-	-	-	-
Arkray Aution Sticks	17	-	-	-	-	-	-	-	9	5	-	1	2	-
Arkray PocketChem UA	2	-	-	-	-	-	-	-	-	2	-	-	-	-
Combi-Screen Test Strips	10	1	-	-	-	-	1	-	1	4	-	3	-	-
DIRUI H-100 / H-500 Urine Analyzer	24	2	-	-	-	-	-	4	11	3	-	-	4	-
DIRUI H-800 Urine Analyzer	3	-	-	-	-	-	-	-	2	-	-	-	1	-
Erba Mannheim Uro-dipcheck 400e	6	-	-	-	-	-	-	-	2	-	-	-	4	-
HUMAN Combilyzer	1	-	-	-	-	-	-	-	-	-	-	-	1	-
Iris Diagnostics Aution Max AX-4280	3	-	-	-	-	-	-	1	1	1	-	-	-	-
Iris Diagnostics iChem Velocity Strips	7	2	-	-	-	-	1	2	-	-	2	-	-	-
Other Analyzer Method	25	2	-	-	-	-	-	-	12	4	-	-	7	-
Other Dipstick Method	10	-	-	-	-	-	-	-	9	-	-	-	1	-
Plasmatec URIPATH	3	-	-	-	1	-	-	-	2	-	-	-	-	-
Roche Chemstrip 101	1	-	-	-	-	-	-	-	1	-	-	-	-	-
Roche Chemstrips / Combur	19	1	-	-	-	1	-	-	14	-	-	-	3	-
Roche cobas u 411	88	1	1	-	1	3	-	2	31	13	-	1	35	-
Roche Miditron Junior/II	4	-	-	-	-	-	-	-	1	-	-	-	3	-
Roche Urilux S	4	-	-	-	-	-	-	-	2	2	-	-	-	-
Roche Urisys	59	-	-	-	-	-	-	2	25	7	-	-	25	-
SD UroColor Reagent Strips	31	3	-	-	1	-	-	-	20	1	-	5	1	-
Siemens Clinitek 50	3	-	-	-	-	2	-	-	1	-	-	-	-	-
Siemens Clinitek 500	3	-	-	-	1	-	-	-	2	-	-	-	-	-
Siemens Clinitek Advantus	28	-	-	-	1	7	1	1	18	-	-	-	-	-
Siemens Clinitek Atlas	6	-	-	-	-	2	-	-	4	-	-	-	-	-
Siemens Clinitek Status / Status+	11	-	-	-	-	4	-	-	7	-	-	-	-	-
Siemens Multistix Pro	3	-	-	-	-	1	-	-	2	-	-	-	-	-
Siemens Reagent Strips	7	1	-	-	-	4	-	-	2	-	-	-	-	-
Urinometer	5	-	-	-	-	-	-	1	4	-	-	-	-	-
UriScan Pro/II	9	1	-	-	-	-	-	-	5	-	-	3	-	-
UriScan Reagent Strips	39	2	-	-	-	-	-	4	25	2	-	6	-	-
URIT Medical Uritest Analyzers	1	-	-	-	-	-	-	-	1	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-1

Participant Results

Method	***Labs***	***Neg or 0.0 - 0.2 mg/dL***	***1.0 or <2.0 mg/dL***	***2.0/3.0 mg/dL***	***4.0 or 4.0/6.0 mg/dL***	***≥8.0 or ≥12.0 mg/dL***
ALL METHODS	443	25	25	26	31	336
Acon Laboratories	6	-	-	1	1	4
Analyticon CombiScan 500	2	-	-	-	-	2
Arkray Aution Jet	2	-	-	-	-	2
Arkray Aution Sticks	16	2	-	-	3	11
Arkray PocketChem UA	2	-	-	-	-	2
Combi-Screen Test Strips	10	1	-	-	-	9
DIRUI H-100 / H-500 Urine Analyzer	23	2	1	-	1	19
DIRUI H-800 Urine Analyzer	3	-	-	1	-	2
Erba Mannheim Uro-dipcheck 400e	6	-	1	2	2	1
HUMAN Combilyzer	1	-	-	-	-	1
Iris Diagnostics Aution Max AX-4280	3	-	-	-	1	2
Iris Diagnostics iChem Velocity Strips	7	-	1	6	-	-
Other Analyzer Method	25	2	3	-	2	18
Other Dipstick Method	10	-	2	1	2	5
Plasmatec URIPATH	3	-	-	1	2	-
Roche Chemstrip 101	1	-	-	-	-	1
Roche Chemstrips / Combur	18	1	-	-	1	16
Roche cobas u 411	88	1	-	2	1	84
Roche Miditron Junior/II	4	-	-	-	-	4
Roche Urilux S	4	1	-	1	2	-
Roche Urisys	59	-	-	1	4	54
SD UroColor Reagent Strips	30	10	11	1	6	2
Siemens Clinitek 50	3	-	-	-	-	3
Siemens Clinitek 500	3	-	-	-	-	3
Siemens Clinitek Advantus	28	-	-	1	-	27
Siemens Clinitek Atlas	6	-	-	3	2	1
Siemens Clinitek Status / Status+	11	-	-	1	-	10
Siemens Multistix Pro	3	-	-	-	-	3
Siemens Reagent Strips	7	-	-	1	-	6
Urinometer	5	2	3	-	-	-
UriScan Pro/II	9	-	-	1	-	8
UriScan Reagent Strips	39	2	1	2	-	34
URIT Medical Uritest Analyzers	1	-	-	-	1	-
URIT Medical Uritest Reagent Strips	1	-	1	-	-	-

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN

Specimen UA-1

		Participant Results																
Method	***Labs***	***Negative***	***Trace***	***Small***	***Moderate***	***Large***	***(1+)***	***(2+)***	***(3+)***	***(4+)***	***(5+)***	***5 - 25 Ery/µL***	***50 - 100 Ery/µL***	***250 Ery/µL***	***±0.03 mg/dL***	***0.06 - 0.10 mg/dL***	***0.2 - 0.5 mg/dL***	***≥ 1.0 mg/dL***
ALL METHODS	455	3	-	-	-	16	3	12	167	34	18	-	4	193	-	-	1	4
Acon Laboratories	6	-	-	-	-	-	-	-	4	2	-	-	-	-	-	-	-	-
Analyticon CombiScan 500	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
Arkray Aution Sticks	17	-	-	-	-	-	-	2	10	-	-	-	-	2	-	-	1	2
Arkray PocketChem UA	2	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
Combi-Screen Test Strips	10	-	-	-	-	-	-	-	3	-	-	-	1	6	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	24	1	-	-	-	-	2	-	14	-	-	-	-	7	-	-	-	-
DIRUI H-800 Urine Analyzer	3	-	-	-	-	-	-	-	3	-	-	-	-	-	-	-	-	-
Erba Mannheim Uro-dipcheck 400e	6	-	-	-	-	-	-	-	2	-	-	-	-	4	-	-	-	-
HUMAN Combilyzer	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	3	-	-	-	-	-	-	1	2	-	-	-	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	7	-	-	-	-	-	-	-	4	-	-	-	-	1	-	-	-	2
Other Analyzer Method	24	-	-	-	-	-	-	2	15	1	-	-	2	4	-	-	-	-
Other Dipstick Method	10	-	-	-	-	-	-	-	6	2	-	-	-	2	-	-	-	-
Plasmatec URIPATH	3	-	-	-	-	1	-	-	2	-	-	-	-	-	-	-	-	-
Roche Chemstrip 101	1	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Roche Chemstrips / Combur	19	-	-	-	-	1	-	-	-	7	2	-	-	9	-	-	-	-
Roche cobas u 411	88	2	-	-	-	2	-	-	-	3	9	-	-	72	-	-	-	-
Roche Miditron Junior/II	4	-	-	-	-	-	-	-	-	1	-	-	1	2	-	-	-	-
Roche Urilux S	4	-	-	-	-	-	-	-	1	2	1	-	-	-	-	-	-	-
Roche Urisys	59	-	-	-	-	-	-	1	-	7	6	-	-	45	-	-	-	-
SD UroColor Reagent Strips	30	-	-	-	-	-	-	-	17	7	-	-	-	6	-	-	-	-
Siemens Clinitek 50	3	-	-	-	-	1	-	-	1	-	-	-	-	1	-	-	-	-
Siemens Clinitek 500	3	-	-	-	-	-	-	-	2	-	-	-	-	1	-	-	-	-
Siemens Clinitek Advantus	28	-	-	-	-	1	-	-	20	-	-	-	-	7	-	-	-	-
Siemens Clinitek Atlas	6	-	-	-	-	-	-	-	4	-	-	-	-	2	-	-	-	-
Siemens Clinitek Status / Status+	12	-	-	-	-	4	-	-	8	-	-	-	-	-	-	-	-	-
Siemens Multistix Pro	3	-	-	-	-	1	-	-	1	-	-	-	-	1	-	-	-	-
Siemens Reagent Strips	17	-	-	-	-	5	-	-	12	-	-	-	-	-	-	-	-	-
Urinometer	5	-	-	-	-	-	-	-	4	1	-	-	-	-	-	-	-	-
UriScan Pro/II	9	-	-	-	-	-	-	-	3	-	-	-	-	6	-	-	-	-
UriScan Reagent Strips	39	-	-	-	-	-	1	5	20	1	-	-	-	12	-	-	-	-
URIT Medical Uritest Analyzers	1	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-1

		Participant Results											
Method	***Labs***	***Negative***	***Trace***	***Small***	***Moderate***	***Large***	***(1+)***	***(2+)***	***(3+)***	***(4+)***	***25 µL***	***75 or 100 µL***	***250 or 500 µL***
ALL METHODS	439	14	5	1	1	17	30	97	103	42	6	16	107
Acon Laboratories	6	-	1	-	-	-	-	2	3	-	-	-	-
Analyticon CombiScan 500	2	-	-	-	-	-	-	-	1	-	1	-	-
Arkray Aution Jet	2	-	-	-	-	-	-	-	-	1	-	-	1
Arkray Aution Sticks	17	-	-	-	-	-	-	-	1	5	-	-	11
Arkray PocketChem UA	2	-	-	-	-	-	-	-	-	-	-	-	2
Combi-Screen Test Strips	10	1	-	-	-	-	1	1	2	1	-	-	4
DIRUI H-100 / H-500 Urine Analyzer	24	1	-	-	-	-	-	9	7	3	-	-	4
DIRUI H-800 Urine Analyzer	3	-	-	-	-	-	-	-	3	-	-	-	-
Erba Mannheim Uro-dipcheck 400e	6	-	-	-	-	-	-	-	2	-	-	-	4
HUMAN Combilyzer	1	-	-	-	-	-	-	-	-	-	1	-	-
Iris Diagnostics Aution Max AX-4280	3	-	-	-	-	-	-	-	1	1	-	-	1
Iris Diagnostics iChem Velocity Strips	7	-	-	-	-	-	-	3	1	-	-	3	-
Other Analyzer Method	25	1	-	-	-	-	1	3	7	3	-	2	8
Other Dipstick Method	9	-	-	-	-	-	-	3	4	-	-	-	2
Plasmatec URIPATH	2	-	-	-	-	-	-	1	1	-	-	-	-
Roche Chemstrip 101	1	-	-	-	-	-	-	1	-	-	-	-	-
Roche Chemstrips / Combur	18	3	2	-	-	2	1	3	3	-	-	1	3
Roche cobas u 411	87	1	-	-	-	4	2	1	30	15	-	-	34
Roche Miditron Junior/II	4	-	-	-	-	-	-	1	-	-	1	-	2
Roche Urilux S	3	-	-	-	-	-	-	2	1	-	-	-	-
Roche Urisys	60	1	-	-	-	1	-	3	18	11	-	1	25
SD UroColor Reagent Strips	29	2	-	-	1	-	10	8	3	1	1	2	1
Siemens Clinitek 50	3	-	-	-	-	1	-	-	1	-	-	-	1
Siemens Clinitek 500	3	-	-	-	-	-	1	2	-	-	-	-	-
Siemens Clinitek Advantus	27	-	-	-	-	1	1	21	-	-	-	2	2
Siemens Clinitek Atlas	6	-	-	-	-	2	-	-	4	-	-	-	-
Siemens Clinitek Status / Status+	11	-	-	-	-	4	-	-	6	1	-	-	-
Siemens Multistix Pro	3	-	-	-	-	-	1	2	-	-	-	-	-
Siemens Reagent Strips	7	-	-	1	-	2	-	2	2	-	-	-	-
Urinometer	5	-	-	-	-	-	2	3	-	-	-	-	-
UriScan Pro/II	9	1	-	-	-	-	1	5	-	-	-	1	1
UriScan Reagent Strips	39	3	1	-	-	-	9	18	1	-	2	4	1
URIT Medical Uritest Analyzers	1	-	-	-	-	-	-	1	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	-	1	-	-	-	-	-

URINALYSIS DIPSTICK–NITRITE

Specimen UA-1

Participant Results

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	445	434	11
Acon Laboratories	7	7	-
Analyticon CombiScan 500	2	2	-
Arkray Aution Jet	2	2	-
Arkray Aution Sticks	16	16	-
Arkray PocketChem UA	2	2	-
Combi-Screen Test Strips	10	9	1
DIRUI H-100 / H-500 Urine Analyzer	24	22	2
DIRUI H-800 Urine Analyzer	3	3	-
Erba Mannheim Uro-dipcheck 400e	6	6	-
HUMAN Combilyzer	1	1	-
Iris Diagnostics Aution Max AX-4280	3	3	-
Iris Diagnostics iChem Velocity Strips	7	7	-
Other Analyzer Method	24	24	-
Other Dipstick Method	10	9	1
Plasmatec URIPATH	3	2	1
Roche Chemstrip 101	1	1	-
Roche Chemstrips / Combur	19	17	2
Roche cobas u 411	88	86	2
Roche Miditron Junior/II	4	3	1
Roche Urilux S	4	4	-
Roche Urisys	58	58	-
SD UroColor Reagent Strips	31	30	1
Siemens Clinitek 50	3	3	-
Siemens Clinitek 500	3	3	-
Siemens Clinitek Advantus	28	28	-
Siemens Clinitek Atlas	5	5	-
Siemens Clinitek Status / Status+	11	11	-
Siemens Multistix Pro	3	3	-
Siemens Reagent Strips	7	7	-
Urinometer	5	5	-
UriScan Pro/II	9	9	-
UriScan Reagent Strips	38	38	-
URIT Medical Uritest Analyzers	1	1	-
URIT Medical Uritest Reagent Strips	1	1	-

URINALYSIS –MICROALBUMIN (dipstick only)

Specimen UA-1

		Participant Results									
Method	***Labs***	***Negative***	***10 mg/L***	***20 mg/L***	***30 mg/L***	***50 mg/L***	***80 mg/L***	***100 mg/L***	***150 mg/L***	***+ (4 - 8 mg/dL)***	***++ (>8 mg/dL)***
ALL METHODS	24	2	1	2	-	1	3	3	9	-	3
Beckman Coulter ICON microAlb	1	-	-	-	-	-	-	1	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	4	-	-	-	-	-	-	1	3	-	-
Other Dipstick Method	2	1	-	-	-	-	-	-	1	-	-
Roche Micral - 1 minute	5	1	-	1	-	-	1	1	-	-	1
Siemens Clinitek Microalbumin	4	-	-	-	-	-	1	-	3	-	-

URINALYSIS –URINE hCG

Specimen UA-1

		Participant Results	
Method	***Labs***	***Positive***	***Negative***
ALL METHODS	114	114	-
Acon Laboratories	13	13	-
Alere Clearview hCG Cassette	1	1	-
Beckman Coulter ICON 25 hCG	1	1	-
bioMerieux VIKIA hCG-D	1	1	-
Biotron 1-Step	12	12	-
Henry Schein One Step	2	2	-
PEP (Lab Supply) HCG	1	1	-
Quidel QuickVue + One-Step	1	1	-
Quidel QuickVue One-Step Combo	21	21	-
Quidel QuickVue One-Step Urine	5	5	-
Stanbio QuStick	1	1	-
Sure-Vue hCG - 25mIU	1	1	-

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen SUS-1	***------Disk Diffusion------***				***------MIC------***				
	Interpretative category data				***Interpretative category data***				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Amikacin	32	25	3	4	8	6	-	2	85.00%
Amoxicillin/Clavulanate	45	6	2	37	42	3	-	39	87.91%
Ampicillin	26	3	-	23	44	3	-	41	91.55%
Ampicillin/Sulbactam	23	10	1	12	39	4	2	33	80.00%[1]
Aztreonam	6	-	-	6	2	2	-	-	Inappropriate drug[2]
Carbenicillin	-	-	-	-	1	1	-	-	Not graded[3]
Cefaclor	11	2	-	9	4	1	-	3	80.00%
Cefamandole	1	1	-	-	1	-	-	1	Not graded[3]
Cefazolin	6	2	-	4	36	4	1	31	83.72%
Cefepime	11	3	1	7	10	4	-	6	80.00%[1]
Cefixime	13	1	-	12	4	1	-	3	Inappropriate drug[2]
Cefoperazone	9	2	1	6	1	-	-	1	80.00%
Cefotaxime	18	3	4	11	11	4	-	7	80.00%[1]
Cefotetan	2	2	-	-	1	-	-	1	Not graded[3]
Cefoxitin	37	2	3	32	40	2	-	38	90.91%
Cefpodoxime	4	-	-	4	2	-	-	2	100.00%
Ceftazidime	19	4	1	14	8	5	-	3	Inappropriate drug[2]
Ceftizoxime	1	-	-	1	1	-	-	1	Not graded[3]
Ceftriaxone	36	5	3	28	12	4	-	8	80.39%
Cefuroxime	30	9	1	20	9	1	-	8	80.00%[1]
Cephalexin	5	1	-	4	4	-	-	4	Inappropriate drug[2]
Cephalothin	10	6	1	3	5	2	-	3	Not graded[4]
Ciprofloxacin	56	9	3	44	133	6	1	126	89.29%
Clarithromycin	1	-	-	1	1	-	1	-	Inappropriate drug[2]
Clindamycin	8	8	-	-	23	22	-	1	Inappropriate drug[2]
Daptomycin	-	-	-	-	50	50	-	-	100.00%
Doxycycline	9	9	-	-	4	4	-	-	100.00%
Ertapenem	4	2	-	2	6	4	-	2	Not graded[4]
Erythromycin	6	-	-	6	20	-	-	20	Inappropriate drug[2]
Fosfomycin	6	6	-	-	15	15	-	-	Inappropriate drug[2]
Gatifloxacin	2	2	-	-	-	-	-	-	Not graded[3]
Gentamicin	49	49	-	-	141	140	1	-	99.49%

[1] This drug is graded by referee consensus.
[2] This is an inappropriate drug for organism and/or source.
[3] This is an ungraded drug due to lack of comparison group.
[4] This is an ungraded drug due to lack of referee group.

ANTIMICROBIAL SUSCEPTIBILIY TESTING (cont'd)

Specimen SUS-1	***------Disk Diffusion------***				***------MIC------***				
	Interpretative category data				***Interpretative category data***				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Imipenem	16	9	-	7	13	1	-	12	80.00%[1]
Kanamycin	2	1	-	1	-	-	-	-	Not graded[3]
Levofloxacin	26	6	3	17	102	4	62	36	92.48%
Linezolid	19	19	-	-	126	126	-	-	100.00%
Lomefloxacin	3	-	1	2	-	-	-	-	Not graded[3]
Meropenem	10	5	2	3	6	3	-	3	Not graded[4]
Methicillin	11	3	-	8	7	-	-	7	83.33%
Minocycline	-	-	-	-	54	54	-	-	Inappropriate drug[2]
Moxifloxacin	15	4	3	8	76	62	4	10	80.00%[1]
Nalidixic Acid	9	2	-	7	1	-	-	1	Inappropriate drug[2]
Netilmicin	5	5	-	-	-	-	-	-	100.00%
Nitrofurantoin	48	47	-	1	120	119	1	-	98.84%
Norfloxacin	25	3	1	21	10	4	-	6	80.00%[1]
Ofloxacin	22	3	1	18	5	-	1	4	82.14%
Oxacillin	45	7	1	37	148	4	-	144	94.00%
Penicillin	38	-	-	38	72	1	-	71	99.12%
Piperacillin	2	-	-	2	1	-	-	1	Inappropriate drug[2]
Piperacillin/Tazobactam	14	2	-	12	1	-	-	1	86.67%
Quinupristin/Dalfopristin	-	-	-	-	45	45	-	-	100.00%
Rifampin	15	14	1	-	115	101	14	-	88.06%
Sulfisoxazole	1	-	-	1	1	1	-	-	Not graded[3]
Teicoplanin	19	18	-	1	63	62	-	1	97.56%
Tetracycline	27	27	-	-	117	116	1	-	99.32%
Ticarcillin	1	-	-	1	-	-	-	-	Not graded[3]
Ticarcillin/Clavulanate	1	-	-	1	1	-	-	1	Not graded[3]
Tigecycline	-	-	-	-	6	6	-	-	Inappropriate drug[2]
Tobramycin	8	7	1	-	3	3	-	-	90.91%
Trimethoprim	-	-	-	-	8	7	-	1	90.00%
Trimethoprim/Sulfamethoxazole	53	53	-	-	164	161	-	3	98.65%
Vancomycin	37	33	2	2	154	148	1	5	94.90%

Organism present in specimen SUS-1: *Staphylococcus aureus* – Methicillin resistant.

PARASITOLOGY (PA Specimens)

Specimen PA-1

Identification	***Labs***	***Percent***	***Performance***
No parasite seen	3	60.00%	Acceptable
Endolimax nana	1	20.00%	
Giardia lamblia	1	20.00%	

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

Specimen PA-2

Identification	***Labs***	***Percent***	***Performance***
Entamoeba coli	2	33.33%	Acceptable
No parasite coli	3	50.00%	
Entamoebia histolytica	1	16.67%	

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

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-3

Identification	***Labs***	***Percent***	***Performance***
Ascaris lumbricoides eggs	16	59.26%	Acceptable
Trichuris trichiura eggs	7	25.93%	Acceptable
Entamoeba histolytica	2	7.41%	
Hymenolepis nana eggs	1	3.70%	
Iodamoeba butschlii	1	3.70%	

Parasites present in specimen PA-3: *Ascaris lumbricoides eggs* and *Trichuris trichiura eggs*.

Specimen PA-4

Identification	***Labs***	***Percent***	***Performance***
Balantidium coli	12	60.00%	Acceptable
No parasite seen	3	15.00%	
Taenia sp. eggs	2	10.00%	
Nonpathogenic Protozoan present	1	5.00%	
Chilomastix mesnili	1	5.00%	
Diphyllobothrium latum	1	5.00%	

Parasite present in specimen PA-4: *Balantidium coli.* (Graded by US consensus)

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-5

Identification	***Labs***	***Percent***	***Performance***
Trypanosoma cruzi	11	78.57%	Acceptable
Trypanosoma sp., NOS	2	14.29%	Acceptable
Plasmodium falciparum	1	7.14%	

Parasite present in specimen PA-5: *Trypanosoma cruzi*.

PARASITOLOGY (FP Specimens)

Specimen FP-1

Identification	***Labs***	***Percent***	***Performance***
No parasite seen	275	91.36%	Acceptable
Ascaris lumbricoides	4	1.33%	
Trichuris trichiura eggs	3	1.00%	
Strongyloides stercoralis larvae	2	0.66%	
Endolimax nana	2	0.66%	
Giardia lamblia	2	0.66%	
Parasite egg seen but no ID	2	0.66%	
Parasite larva seen but no ID	1	0.33%	
Other parasite seen but no ID	1	0.33%	
Nonpath, protoaoan present	1	0.33%	
Hymenolepis diminuta eggs	1	0.33%	
Iodamoeba butschlii	1	0.33%	
Isospora belli oocysts	1	0.33%	
Taenia sp. eggs	1	0.33%	
Protozoan seen but no ID	1	0.33%	
Balantidium coli	1	0.33%	
Diphyllobothrium latum	1	0.33%	
Plasmodium vivax	1	0.33%	

Parasite present in specimen FP-1: No parasite present.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-2

Identification	***Labs***	***Percent***	***Performance***
Taenia sp. eggs	246	62.60%	Acceptable
Giardia lamblia	54	13.74%	Acceptable
Blastocystis hominis	30	7.63%	
Endolimax nana	21	5.34%	
Ascaris lumbricoides eggs	17	4.33%	
No parasite seen	6	1.53%	
Entamoeba histolytica	4	1.02%	
Strongyloides stercoralis larvae	4	1.02%	
Hymenolepis diminuta eggs	3	0.76%	
Enterobius vermicularis eggs	3	0.76%	
Iodamoeba butschlii	2	0.51%	
Entamoeba hartmanni	1	0.25%	
Hymenolepis nana eggs	1	0.25%	
Nonpathogenic protozoan present	1	0.25%	

Parasites present in specimen FP-2: *Taenia sp. eggs* and *Giardia lamblia*. This challenge was graded by 80% referee consensus.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-3

Identification	***Labs***	***Percent***	***Performance***
Hymenolepis nana eggs	256	81.53%	Acceptable
Parasite egg seen but no ID	1	0.32%	Acceptable
Hymenolepis diminuta eggs	34	10.83%	
Ascaris lumbricoides eggs	4	1.27%	
Taenia sp. eggs	4	1.27%	
Endolimax nana	3	0.96%	
Enterobius vermicularis eggs	2	0.64%	
No parasite seen	2	0.64%	
Trichuris trichiura eggs	2	0.64%	
Trichostrongylus sp. eggs	1	0.32%	
Schistosoma mansoni eggs	1	0.32%	
Giardia lamblia	1	0.32%	
Entamoeba histolytica	1	0.32%	
Chilomastix mesnili	1	0.32%	
Diphyllobothrium latum	1	0.32%	

Parasite present in specimen FP-3: *Hymenolepis nana eggs*.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-4

Identification	***Labs***	***Percent***	***Performance***
Ascaris lumbricoides eggs	262	70.24%	Acceptable
Trichuris trichiura eggs	80	21.45%	
No parasite seen	20	5.36%	
Hookworm	4	1.07%	
Hymenolepis nana eggs	2	0.54%	
Entamoeba coli	2	0.54%	
Clonorchis sinensis	1	0.27%	
Taenia sp. eggs	1	0.27%	
Parasite egg seen but no ID	1	0.27%	

Parasite present in specimen FP-4: *Ascaris lumbricoides eggs*. This challenge was graded by 80% referee consensus.

Specimen FP-5

Identification	***Labs***	***Percent***	***Performance***
Plasmodium falciparum	158	53.56%	Acceptable
Plasmodium sp., NOS	52	17.63%	Acceptable
Plasmodium vivax	67	22.71%	
Plasmodium sp., not falciparum	5	1.69%	
Plasmodium malariae	5	1.69%	
Plasmodium ovale	4	1.36%	
No parasite seen	2	0.68%	
Trypanosoma cruzi	1	0.34%	
Babesia sp.	1	0.34%	

Parasite present in specimen FP-5: *Plasmodium falciparum.* This challenge was graded by 80% referee consensus.

Antinuclear Antibody (ANA) - Qualitative

Method	**Specimen AE-1**		**Specimen AE-2**		**Specimen AE-3**	
	Positive	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	1	14	15	-	12	3
BioSystems	-	1	1	-	-	1
Immuno Concepts	-	1	1	-	1	-
INOVA Diagnostics	1	5	6	-	4	2
Kallestad	-	2	2	-	2	-
Zeus	-	1	1	-	1	-

Method	**Specimen AE-4**		**Specimen AE-5**	
	Positive	***Negative***	***Positive***	***Negative***
ALL METHODS	1	14	15	-
BioSystems	-	1	1	-
Immuno Concepts	-	1	1	-
INOVA Diagnostics	1	5	6	-
Kallestad	-	2	2	-
Zeus	-	1	1	-

Specimen AE-3 is graded by 82% referee consensus.

Antinuclear Antibody (ANA)—Quantitative (Titer)

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

Specimen/Method	*8/ 10*	*16/ 20*	*32/ 40*	*64/ 80*	*128/ 160*	*256/ 320*	*512/ 640*	*>640*	*1024/ 1280*	*2048/ 2560*	*≥2560*
Specimen AE-2											
ALL METHODS	-	-	1	-	3	3	3	1	1	-	-
Immuno Concepts	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	3	1	1	1	-	-	-
Kallestad	-	-	-	-	-	-	2	-	-	-	-
Zeus	-	-	-	-	-	1	-	-	-	-	-
Specimen AE-3											
ALL METHODS	-	-	1	3	3	2	1	-	-	-	-
Immuno Concepts	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	1	1	1	1	-	-	-	-
Kallestad	-	-	-	-	1	1	-	-	-	-	-
Zeus	-	-	-	1	-	-	-	-	-	-	-
Specimen AE-5											
ALL METHODS	-	-	1	-	1	4	4	-	2	-	-
Immuno Concepts	-	-	1	-	-	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	1	2	1	-	2	-	-
Kallestad	-	-	-	-	-	1	1	-	-	-	-
Zeus	-	-	-	-	-	1	-	-	-	-	-

Anti-dsDNA

Method	Specimen AE-1 Positive	Specimen AE-1 Negative	Specimen AE-2 Positive	Specimen AE-2 Negative	Specimen AE-3 Positive	Specimen AE-3 Negative
ALL METHODS	-	13	3	10	-	13
BioSystems	-	1	1	-	-	1
INOVA Diagnostics	-	6	2	4	-	6
Zeus	-	1	-	1	-	1

Method	Specimen AE-4 Positive	Specimen AE-4 Negative	Specimen AE-5 Positive	Specimen AE-5 Negative
ALL METHODS	1	12	13	-
BioSystems	-	1	1	-
INOVA Diagnostics	1	5	6	-
Zeus	-	1	1	-

Anti-RNP

Method	Specimen AE-1 Positive	Specimen AE-1 Negative	Specimen AE-2 Positive	Specimen AE-2 Negative	Specimen AE-3 Positive	Specimen AE-3 Negative
ALL METHODS	1	7	8	-	-	8
INOVA Diagnostics	-	6	6	-	-	6

Method	Specimen AE-4 Positive	Specimen AE-4 Negative	Specimen AE-5 Positive	Specimen AE-5 Negative
ALL METHODS	-	8	7	1
INOVA Diagnostics	-	6	5	1

Anti-RNP/Sm

Method	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	Positive	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	1	4	5	-	-	5

Method	Specimen AE-4		Specimen AE-5	
	Positive	*Negative*	*Positive*	*Negative*
ALL METHODS	-	5	5	-

Anti-SSA

Method	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	Positive	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	-	12	12	-	12	-
INOVA Diagnostics	-	6	6	-	6	-

Method	Specimen AE-4		Specimen AE-5	
	Positive	*Negative*	*Positive*	*Negative*
ALL METHODS	-	12	12	-
INOVA Diagnostics	-	6	6	-

Anti-SSB

Method	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	Positive	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	-	12	-	12	-	12
INOVA Diagnostics	-	6	-	6	-	6

Method	Specimen AE-4		Specimen AE-5	
	Positive	*Negative*	*Positive*	*Negative*
ALL METHODS	-	12	-	12
INOVA Diagnostics	-	6	-	6

Anti-SSA/SSB

Method	Specimen AE-1		Specimen AE-2		Specimen AE-3	
	Positive	*Negative*	*Positive*	*Negative*	*Positive*	*Negative*
ALL METHODS	-	1	1	-	1	-

Method	Specimen AE-4		Specimen AE-5	
	Positive	*Negative*	*Positive*	*Negative*
ALL METHODS	-	1	1	-

Anti-Sm

Method	**Specimen AE-1**		**Specimen AE-2**		**Specimen AE-3**	
	Positive	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	12	-	12	-	12
INOVA Diagnostics	-	7	-	7	-	7

Method	**Specimen AE-4**		**Specimen AE-5**	
	Positive	***Negative***	***Positive***	***Negative***
ALL METHODS	-	12	-	12
INOVA Diagnostics	-	7	-	7

Rubella—Qualitative

Method	Specimen RU-1 Positive	Specimen RU-1 Negative	Specimen RU-2 Positive	Specimen RU-2 Negative	Specimen RU-3 Positive	Specimen RU-3 Negative
ALL METHODS	26	-	26	-	-	26
Abbott Architect	9	-	9	-	-	9
bioMerieux Vidas, Mini Vidas	2	-	2	-	-	2
DiaSorin	1	-	1	-	-	1
DPC Immulite 2000	1	-	1	-	-	1
Roche cobas 6000 / c 501	1	-	1	-	-	1
Roche cobas 6000 / e 601	2	-	2	-	-	2
Roche cobas 6000/e601 - IgG	1	-	1	-	-	1
Roche cobas e 411	4	-	4	-	-	4
Siemens ADVIA Centaur - IgG	3	-	3	-	-	3
VITROS ECi	1	-	1	-	-	1

Method	Specimen RU-4 Positive	Specimen RU-4 Negative	Specimen RU-5 Positive	Specimen RU-5 Negative
ALL METHODS	26	-	-	26
Abbott Architect	9	-	-	9
bioMerieux Vidas, Mini Vidas	2	-	-	2
DiaSorin	1	-	-	1
DPC Immulite 2000	1	-	-	1
Roche cobas 6000 / c 501	1	-	-	1
Roche cobas 6000 / e 601	2	-	-	2
Roche cobas 6000/e601 - IgG	1	-	-	1
Roche cobas e 411	4	-	-	4
Siemens ADVIA Centaur - IgG	3	-	-	3
VITROS ECi	1	-	-	1

Rubella—Quantitative (IU/mL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen RU-1						
All Method	34	32.16	14.22	44.2	27.4	0.0 - 74.9
Abbott Architect	13	21.17	1.71	8.1	20.9	16.0 - 26.3
Roche cobas e 411	6	49.73	3.54	7.1	49.4	39.1 - 60.4
Specimen RU-2						
All Method	34	106.43	49.69	46.7	101.5	0.0 - 255.5
Abbott Architect	13	62.64	3.51	5.6	62.1	52.1 - 73.2
Roche cobas e 411	6	165.02	10.81	6.6	167.3	132.5 - 197.5
Specimen RU-3						
All Method	31	0.10	0.14	141.4	0.0	0.0 - 0.6
Abbott Architect	11	0.00	0.01	0.0	0.0	0.0 - 0.1
Roche cobas e 411	6	0.23	0.14	58.6	0.2	0.0 - 0.7
Specimen RU-4						
All Method	34	45.93	21.15	46.1	38.8	0.0 - 109.4
Abbott Architect	13	28.72	1.77	6.2	28.5	23.4 - 34.1
Roche cobas e 411	6	72.48	5.53	7.6	74.1	55.8 - 89.1
Specimen RU-5						
All Method	32	0.12	0.20	164.9	0.0	0.0 - 0.8
Abbott Architect	12	0.00	0.01	0.0	0.0	0.0 - 0.1
Roche cobas e 411	6	0.28	0.23	81.8	0.2	0.0 - 1.0

Syphilis Serology—Qualitative: VDRL Slide

	Specimen SY-1			Specimen SY-2			Specimen SY-3		
Method	***Reactive***	***Weakly Reactive***	***Non-Reactive***	***Reactive***	***Weakly Reactive***	***Non-Reactive***	***Reactive***	***Weakly Reactive***	***Non-Reactive***
ALL METHODS	-	-	28	27	1	-	-	1	27
Acon Laboratories	-	-	1	1	-	-	-	-	1
BioSystems	-	-	1	1	-	-	-	-	1
Omega Diagnostics	-	-	2	2	-	-	-	-	2
Plasmatec	-	-	1	1	-	-	-	-	1
Standard Diagnostics	-	-	1	1	-	-	-	-	1
Wiener Lab	-	-	17	17	-	-	-	-	17

	Specimen SY-4			Specimen SY-5		
Method	***Reactive***	***Weakly Reactive***	***Non-Reactive***	***Reactive***	***Weakly Reactive***	***Non-Reactive***
ALL METHODS	28	-	-	28	-	-
Acon Laboratories	1	-	-	1	-	-
BioSystems	1	-	-	1	-	-
Omega Diagnostics	2	-	-	2	-	-
Plasmatec	1	-	-	1	-	-
Standard Diagnostics	1	-	-	1	-	-
Wiener Lab	17	-	-	17	-	-

Syphilis Serology—Quantitative: VDRL Slide Titer

Specimen/Method	*0 dils*	*1 dil*	*2 dils*	*4 dils*	*8 dils*	*16 dils*	*32 dils*	*>32 dils*
Specimen SY-2								
ALL METHODS	-	-	2	12	5	2	1	-
BioSystems	-	-	-	1	-	-	-	-
Omega Diagnostics	-	-	1	-	-	-	-	-
Plasmatec	-	-	-	1	-	-	-	-
Wiener Lab								
Specimen SY-4								
ALL METHODS	-	-	2	9	7	3	1	-
BioSystems	-	-	-	1	-	-	-	-
Omega Diagnostics	-	-	1	-	-	-	-	-
Plasmatec	-	-	-	1	-	-	-	-
Wiener Lab	-	-	1	7	6	2	1	-
Specimen SY-5								
ALL METHODS	-	-	2	8	6	4	2	-
BioSystems	-	-	-	1	-	-	-	-
Omega Diagnostics	-	-	1	-	-	-	-	-
Plasmatec	-	-	-	-	1	-	-	-
Wiener Lab	-	-	1	7	4	3	2	-

Syphilis Serology—Qualitative: MHA-TP

	Specimen SY-1		Specimen SY-2		Specimen SY-3	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	-	14	14	-	-	14
Abbott Architect	-	4	4	-	-	4
Human	-	2	2	-	-	2
Omega Diagnostics	-	1	1	-	-	1
Serodia	-	1	1	-	-	1
Wiener Lab	-	1	1	-	-	1

	Specimen SY-4		Specimen SY-5	
	Reactive	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	14	-	14	-
Abbott Architect	4	-	4	-
Human	2	-	2	-
Omega Diagnostics	1	-	1	-
Serodia	1	-	1	-
Wiener Lab	1	-	1	-

Syphilis Serology—Qualitative: *Treponema pallidum* Antibodies

	Specimen SY-1		Specimen SY-2		Specimen SY-3	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	-	38	38	-	-	38
Abbott Architect	-	2	2	-	-	2
bioMerieux Vidas, Mini Vidas	-	1	1	-	-	1
Human	-	2	2	-	-	2
Omega Diagnostics	-	4	4	-	-	4
Plasmatec	-	1	1	-	-	1
Roche cobas 6000 / c 501	-	1	1	-	-	1
Serodia	-	16	16	-	-	16
Zeus	-	1	1	-	-	1

	Specimen SY-4		Specimen SY-5	
	Reactive	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	38	-	38	-
Abbott Architect	2	-	2	-
bioMerieux Vidas, Mini Vidas	1	-	1	-
Human	2	-	2	-
Omega Diagnostics	4	-	4	-
Plasmatec	1	-	1	-
Roche cobas 6000 / c 501	1	-	1	-
Serodia	16	-	16	-
Zeus	1	-	1	-

Syphilis Serology—Qualitative: RPR

	Specimen SY-1		Specimen SY-2		Specimen SY-3	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	1	90	90	1	2	89
Abbott Architect	-	1	1	-	-	1
Becton Dickinson	-	2	2	-	-	2
Biokit	-	2	2	-	-	2
bioMerieux	-	3	3	-	-	3
BioSystems	-	12	12	-	-	12
Human	-	11	11	-	-	11
Immunostics Inc.	-	1	1	-	-	1
Omega Diagnostics	1	16	16	1	1	16
Plasmatec	-	10	10	-	-	10
Pulse Scientific	-	1	1	-	-	1
SPINREACT	-	17	17	-	1	16
Standard Diagnostics	-	2	2	-	-	2
Wampole Impact RPR	-	1	1	-	-	1
Wiener Lab	-	1	1	-	-	1

	Specimen SY-4		Specimen SY-5	
	Reactive	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	90	1	90	1
Abbott Architect	1	-	1	-
Becton Dickinson	2	-	2	-
Biokit	2	-	2	-
bioMerieux	3	-	3	-
BioSystems	12	-	12	-
Human	11	-	11	-
Immunostics Inc.	1	-	1	-
Omega Diagnostics	16	1	16	1
Plasmatec	10	-	10	-
Pulse Scientific	1	-	1	-
SPINREACT	17	-	17	-
Standard Diagnostics	2	-	2	-
Wampole Impact RPR	1	-	1	-
Wiener Lab	1	-	1	-

Syphilis Serology—Quantitative: RPR (Titer)

Specimen/Method	***1***	***2***	***4***	***8***	***16***	***32***	***64***	***>64***
Specimen SY-2								
ALL METHODS	1	14	35	9	-	2	1	1
Becton Dickinson	-	-	1	1	-	-	-	-
bioMerieux	-	2	-	-	-	-	-	-
BioSystems	-	2	5	3	-	-	-	-
Human	-	2	4	-	-	1	-	1
Immunostics Inc.	-	1	-	-	-	-	-	-
Omega Diagnostics	1	1	8	2	-	-	-	-
Plasmatec	-	2	4	-	-	-	-	-
SPINREACT	-	3	6	3	-	1	1	-
Wampole Impact RPR	-	-	1	-	-	-	-	-
Wiener Lab								
Specimen SY-4								
ALL METHODS	3	15	24	14	3	-	4	-
Becton Dickinson	-	-	1	1	-	-	-	-
bioMerieux	-	1	1	-	-	-	-	-
BioSystems	-	3	4	3	-	-	-	-
Human	-	2	3	1	-	-	2	-
Immunostics Inc.	-	1	-	-	-	-	-	-
Omega Diagnostics	-	2	4	4	2	-	-	-
Plasmatec	1	1	4	-	-	-	-	-
SPINREACT	1	3	4	3	1	-	2	-
Wampole Impact RPR	-	1	-	-	-	-	-	-
Wiener Lab	-	-	-	1	-	-	-	-

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

Specimen/Method	***1***	***2***	***4***	***8***	***16***	***32***	***64***	***>64***
Specimen SY-5								
ALL METHODS	-	16	25	16	3	2	1	-
Becton Dickinson	-	-	1	1	-	-	-	-
bioMerieux	-	2	-	-	-	-	-	-
BioSystems	-	2	4	4	-	-	-	-
Human	-	1	4	1	1	1	-	-
Immunostics Inc.	-	1	-	-	-	-	-	-
Omega Diagnostics	-	2	6	3	1	-	-	-
Plasmatec	-	2	3	1	-	-	-	-
SPINREACT	-	3	4	4	1	1	1	-
Wampole Impact RPR	-	1	-	-	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-

Viral Markers – Anti-HBc (IgM)

	Specimen VM-1		Specimen VM-2		Specimen VM-3	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	1	74	7	68	4	71
Abbott Architect	-	22	3	19	-	22
Beckman ACCESS / 2 / DxI	-	3	-	3	-	3
bioMerieux	-	5	-	5	-	5
Roche cobas 6000 / e 601	-	13	1	12	1	12
Roche cobas e 411	-	7	1	6	1	6
Roche Elecsys 1010 / 2010	-	2	1	1	1	1
Roche Modular Analytics	-	1	-	1	-	1
Siemens ADVIA Centaur	-	11	-	11	-	11
VITROS 5600	-	2	-	2	-	2
VITROS ECi	-	1	-	1	-	1

	Specimen VM-4		Specimen VM-5	
	Positive	***Negative***	***Positive***	***Negative***
ALL METHODS	8	67	8	67
Abbott Architect	3	19	3	19
Beckman ACCESS / 2 / DxI	-	3	-	3
bioMerieux	-	5	-	5
Roche cobas 6000 / e 601	2	11	2	11
Roche cobas e 411	1	6	1	6
Roche Elecsys 1010 / 2010	1	1	1	1
Roche Modular Analytics	-	1	-	1
Siemens ADVIA Centaur	-	11	-	11
VITROS 5600	-	2	-	2
VITROS ECi	-	1	-	1

Viral Markers – Anti-HBc (Total / IgG)

	Specimen VM-1		Specimen VM-2		Specimen VM-3	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	1	91	90	2	35	57
Abbott Architect	1	34	35	-	-	35
Beckman ACCESS / 2 / DxI	-	2	2	-	2	-
Bio-Rad Evolis	-	1	1	-	-	1
bioMerieux	-	4	3	1	-	4
DiaSorin	-	1	1	-	-	1
Roche cobas 6000 / e 601	-	14	13	1	10	4
Roche cobas e 411	-	8	8	-	8	-
Roche Elecsys 1010 / 2010	-	1	1	-	1	-
Roche Modular Analytics	-	4	4	-	3	1
Siemens ADVIA Centaur	-	11	11	-	7	4
VITROS 5600	-	1	1	-	-	1
VITROS ECi	-	1	1	-	1	-

	Specimen VM-4		Specimen VM-5	
	Positive	***Negative***	***Positive***	***Negative***
ALL METHODS	90	2	90	2
Abbott Architect	35	-	35	-
Beckman ACCESS / 2 / DxI	2	-	2	-
Bio-Rad Evolis	1	-	1	-
bioMerieux	3	1	4	-
DiaSorin	1	-	1	-
Roche cobas 6000 / e 601	13	1	12	2
Roche cobas e 411	8	-	8	-
Roche Elecsys 1010 / 2010	1	-	1	-
Roche Modular Analytics	4	-	4	-
Siemens ADVIA Centaur	11	-	11	-
VITROS 5600	1	-	1	-
VITROS ECi	1	-	1	-

Specimen VM-3 is an ungraded challenge due to less than 80% participant consensus. The vendor assay rate for specimen VM-3 is 0.62.

Viral Markers – Anti-HIV

	Specimen VM-1		Specimen VM-2		Specimen VM-3	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	5	259	-	263	-	263
Abbott Architect	-	70	-	70	-	70
Abbott Architect - Total	-	1	-	1	-	1
Acon Laboratories	-	1	-	1	-	1
Beckman ACCESS / 2 / DxI	-	8	-	7	-	7
Bio-Rad Evolis	-	1	-	1	-	1
bioMerieux	1	14	-	15	-	15
DiaSorin	-	2	-	2	-	2
Human	-	2	-	2	-	2
Roche cobas 6000 / e 601	-	38	-	38	-	38
Roche cobas e 411	3	29	-	32	-	32
Roche Elecsys - Total	-	1	-	1	-	1
Roche Elecsys 1010 / 2010	-	4	-	4	-	4
Roche Modular Analytics	-	7	-	7	-	7
Siemens ADVIA Centaur	1	46	-	47	-	47
Standard Diagnostics	-	3	-	3	-	3
VITROS 5600	-	3	-	3	-	3
VITROS ECi	-	7	-	7	-	7

Viral Markers – Anti-HIV (cont'd)

	Specimen VM-4		Specimen VM-5	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	1	262	258	4
Abbott Architect	-	70	70	-
Abbott Architect - Total	-	1	1	-
Acon Laboratories	-	1	1	-
Beckman ACCESS / 2 / DxI	-	7	7	-
Bio-Rad Evolis	-	1	1	-
bioMerieux	1	14	13	2
DiaSorin	-	2	2	-
Human	-	2	2	-
Roche cobas 6000 / e 601	-	38	37	1
Roche cobas e 411	-	32	32	-
Roche Elecsys - Total	-	1	1	-
Roche Elecsys 1010 / 2010	-	4	4	-
Roche Modular Analytics	-	7	7	-
Siemens ADVIA Centaur	-	47	46	-
Standard Diagnostics	-	3	3	-
VITROS 5600	-	3	3	-
VITROS ECi	-	7	7	-

Viral Markers – Anti-HAV (IgM)

Method	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	Positive	Negative	Positive	Negative	Positive	Negative
ALL METHODS	4	100	8	95	102	1
Abbott Architect	-	29	-	29	29	-
Beckman ACCESS / 2 / DxI	-	3	2	-	2	-
bioMerieux	-	10	-	10	10	-
DiaSorin	1	-	1	-	1	-
Roche cobas 6000 / e 601	1	13	1	13	14	-
Roche cobas e 411	1	8	1	8	9	-
Roche Elecsys 1010 / 2010	-	1	-	1	1	-
Roche Modular Analytics	-	5	-	5	5	-
Siemens ADVIA Centaur	-	16	-	16	16	-
VITROS ECi	-	2	-	2	2	-

Method	Specimen VM-4		Specimen VM-5	
	Positive	Negative	Positive	Negative
ALL METHODS	5	98	6	97
Abbott Architect	-	29	-	29
Beckman ACCESS / 2 / DxI	-	2	-	2
bioMerieux	-	10	-	10
DiaSorin	1	-	1	-
Roche cobas 6000 / e 601	1	13	1	13
Roche cobas e 411	1	8	1	8
Roche Elecsys 1010 / 2010	-	1	-	1
Roche Modular Analytics	-	5	-	5
Siemens ADVIA Centaur	-	16	-	16
VITROS ECi	-	2	-	2

Viral Markers – Anti-HAV (Total/IgG)

Method	Specimen VM-1 Positive	Specimen VM-1 Negative	Specimen VM-2 Positive	Specimen VM-2 Negative	Specimen VM-3 Positive	Specimen VM-3 Negative
ALL METHODS	95	4	95	4	97	2
Abbott Architect	28	-	28	-	28	-
Beckman ACCESS / 2 / DxI	1	-	1	-	1	-
bioMerieux	7	-	7	-	7	-
DiaSorin	1	-	1	-	1	-
Roche cobas 6000 / e 601	12	1	12	1	13	-
Roche cobas e 411	9	-	9	-	9	-
Roche Elecsys 1010 / 2010	2	-	2	-	2	-
Roche Modular Analytics	4	-	4	-	4	-
Siemens ADVIA Centaur	20	-	20	-	20	-
VITROS ECi	2	-	2	-	2	-

Method	Specimen VM-4 Positive	Specimen VM-4 Negative	Specimen VM-5 Positive	Specimen VM-5 Negative
ALL METHODS	96	3	97	2
Abbott Architect	28	-	28	-
Beckman ACCESS / 2 / DxI	1	-	1	-
bioMerieux	7	-	7	-
DiaSorin	1	-	1	-
Roche cobas 6000 / e 601	12	1	12	1
Roche cobas e 411	9	-	9	-
Roche Elecsys 1010 / 2010	2	-	2	-
Roche Modular Analytics	4	-	4	-
Siemens ADVIA Centaur	20	-	20	-
VITROS ECi	2	-	2	-

Viral Markers – HBeAg

	Specimen VM-1		Specimen VM-2		Specimen VM-3	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	66	-	66	-	66
Abbott Architect	-	22	-	22	-	22
bioMerieux	-	3	-	3	-	3
DiaSorin	-	2	-	2	-	2
Roche cobas 6000 / e 601	-	12	-	12	-	12
Roche cobas e 411	-	5	-	5	-	5
Roche Elecsys 1010 / 2010	-	1	-	1	-	1
Roche Modular Analytics	-	4	-	4	-	4
Siemens ADVIA Centaur	-	11	-	11	-	11
VITROS ECi	-	1	-	1	-	1

	Specimen VM-4		Specimen VM-5	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	58	8	1	65
Abbott Architect	21	1	1	21
bioMerieux	1	2	-	3
DiaSorin	2	-	-	2
Roche cobas 6000 / e 601	11	1	-	12
Roche cobas e 411	5	-	-	5
Roche Elecsys 1010 / 2010	1	-	-	1
Roche Modular Analytics	4	-	-	4
Siemens ADVIA Centaur	11	-	-	11
VITROS ECi	-	1	-	1

Viral Markers – Anti-HBs

	Specimen VM-1		Specimen VM-2		Specimen VM-3	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	30	171	3	197	20	180
Abbott Architect	3	50	-	53	2	51
Beckman ACCESS / 2 / DxI	3	1	-	3	1	2
bioMerieux	-	4	1	3	1	3
Roche cobas 6000 / e 601	9	28	1	36	7	30
Roche cobas e 411	8	19	1	26	4	23
Roche Elecsys 1010 / 2010	1	1	-	2	1	1
Roche Modular Analytics	2	5	-	7	1	6
Siemens ADVIA Centaur	-	44	-	44	-	44
VITROS 5600	-	4	-	4	-	4
VITROS ECi	1	3	-	4	1	3

	Specimen VM-4		Specimen VM-5	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	5	195	194	6
Abbott Architect	-	53	53	-
Beckman ACCESS / 2 / DxI	-	3	3	-
bioMerieux	1	3	3	1
Roche cobas 6000 / e 601	2	35	34	3
Roche cobas e 411	1	26	26	1
Roche Elecsys 1010 / 2010	-	2	2	-
Roche Modular Analytics	-	7	7	-
Siemens ADVIA Centaur	-	44	43	1
VITROS 5600	-	4	4	-
VITROS ECi	-	4	4	-

The vendor assay values for specimens VM-1 through VM-5 are: 0.00, 0.21, 0.00, 0.00, and 646.90 mIU/mL, respectively.

Viral Markers – HBsAg

Method	Specimen VM-1 Positive	Specimen VM-1 Negative	Specimen VM-2 Positive	Specimen VM-2 Negative	Specimen VM-3 Positive	Specimen VM-3 Negative
ALL METHODS	1	267	45	222	5	262
Abbott Architect	-	69	1	68	-	69
Abbott Architect - Total	-	1	-	1	-	1
Beckman ACCESS / 2 / DxI	-	9	-	8	-	8
Bio-Rad Evolis	-	1	-	1	-	1
bioMerieux	-	9	1	8	1	8
DiaSorin	-	2	-	2	-	2
Roche cobas 6000 / e 601	1	37	18	20	1	37
Roche cobas e 411	-	35	17	18	3	32
Roche Elecsys - Total	-	1	-	1	-	1
Roche Elecsys 1010 / 2010	-	5	2	3	-	5
Roche Modular Analytics	-	7	4	3	-	7
Siemens ADVIA Centaur	-	49	-	49	-	49
Standard Diagnostics	-	2	-	2	-	2
VITROS 5600	-	4	-	4	-	4
VITROS ECi	-	7	-	7	-	7

Method	Specimen VM-4 Positive	Specimen VM-4 Negative	Specimen VM-5 Positive	Specimen VM-5 Negative
ALL METHODS	265	2	3	264
Abbott Architect	69	-	-	69
Abbott Architect - Total	1	-	-	1
Beckman ACCESS / 2 / DxI	8	-	-	8
Bio-Rad Evolis	1	-	-	1
bioMerieux	8	1	-	9
DiaSorin	2	-	-	2
Roche cobas 6000 / e 601	38	-	1	37
Roche cobas e 411	34	1	-	35
Roche Elecsys - Total	1	-	-	1
Roche Elecsys 1010 / 2010	5	-	-	5
Roche Modular Analytics	7	-	-	7
Siemens ADVIA Centaur	49	-	2	47
Standard Diagnostics	2	-	-	2
VITROS 5600	4	-	-	4
VITROS ECi	7	-	-	7

The vendor assay rate for specimen VM-2 is 0.72.

Viral Markers – Anti-HCV

Method	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	Positive	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	241	1	224	17	235	6
Abbott Architect	68	-	68	-	68	-
Abbott Architect - Total	1	-	1	-	1	-
Beckman ACCESS / 2 / DxI	6	-	5	-	5	-
Bio-Rad Evolis	1	-	1	-	1	-
bioMerieux	9	-	2	7	8	1
DiaSorin	1	-	1	-	1	-
Roche cobas 6000 / e 601	30	-	30	-	30	-
Roche cobas e 411	28	-	28	-	28	-
Roche Elecsys 1010 / 2010	3	-	3	-	3	-
Roche Modular Analytics	7	-	7	-	7	-
Siemens ADVIA Centaur	46	1	46	1	47	-
Standard Diagnostics	3	-	3	-	3	-
VITROS 5600	4	-	4	-	4	-
VITROS ECi	7	-	6	1	6	1

Method	Specimen VM-4		Specimen VM-5	
	Positive	***Negative***	***Positive***	***Negative***
ALL METHODS	39	202	59	182
Abbott Architect	-	68	-	68
Abbott Architect - Total	-	1	-	1
Beckman ACCESS / 2 / DxI	-	5	-	5
Bio-Rad Evolis	-	1	-	1
bioMerieux	-	9	-	9
DiaSorin	-	1	-	1
Roche cobas 6000 / e 601	17	13	24	6
Roche cobas e 411	12	16	24	4
Roche Elecsys 1010 / 2010	1	2	2	1
Roche Modular Analytics	6	1	6	1
Siemens ADVIA Centaur	-	47	-	47
Standard Diagnostics	-	3	-	3
VITROS 5600	-	4	-	4
VITROS ECi	-	7	-	7

Specimens VM-4 and VM-5 are ungraded challenges due to less than 80% participant consensus. The vendor assay rates for specimens VM-4 and VM-5 are 0.01 and 0.03, respectively.

Toxoplasma gondii Antibody (IgG) - Qualitative

	Specimen TOX-1		Specimen TOX-2	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	27	1	28	-
Abbott Architect	10	1	11	-
bioMerieux	3	-	3	-
DiaSorin	1	-	1	-
DPC Immulite 2000	1	-	1	-
Roche cobas 6000 / e 601	2	-	2	-
Roche cobas e 411	5	-	5	-
Roche Elecsys 1010 / 2010	1	-	1	-
Siemens ADVIA Centaur	3	-	3	-

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

Specimen/Method	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
Specimen TOX-1						
All Method	22	332.9	238.4	71.6	255	0 - 810
Abbott Architect	7	100.0	17.7	17.7	105	64 - 136
Roche cobas e 411	5	650.0	0.1	0.0	650	649 - 651
Specimen TOX-2						
All Method	24	152.2	67.4	44.3	124	17 - 288
Abbott Architect	7	93.4	17.5	18.7	99	58 - 129
Roche cobas e 411	5	203.2	65.9	32.4	216	71 - 336

Toxoplasma gondii Antibody (IgM) - Qualitative

	Specimen TOX-1		Specimen TOX-2	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	1	27	28	-
Abbott Architect	1	8	9	-
bioMerieux	-	3	3	-
DiaSorin	-	1	1	-
DPC Immulite 2000	-	1	1	-
Roche cobas 6000 / e 601	-	4	4	-
Roche cobas e 411	-	4	4	-
Roche Elecsys 1010 / 2010	-	1	1	-
Siemens ADVIA Centaur	-	3	3	-

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

Specimen/Method	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
Specimen TOX-1						
All Method	18	0.1	0.3	291.0	0	0 - 1
Abbott Architect	5	0.2	0.4	223.6	0	0 - 2
Specimen TOX-2						
All Method	17	11.4	9.0	79.1	9	0 - 30
Abbott Architect	4	-	-	-	5	0 - 30

Cytomegalovirus (CMV) Antibodies (IgG) - Qualitative

Method	Specimen CMV-1 Positive	Specimen CMV-1 Negative	Specimen CMV-2 Positive	Specimen CMV-2 Negative
ALL METHODS	2	20	20	2
Abbott Architect	1	10	11	-
bioMerieux	-	3	3	-
DiaSorin	-	1	1	-
DPC Immulite 2000	-	1	1	-
Roche cobas 6000 / e 601	-	1	-	1
Roche cobas e 411	1	4	4	1

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

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen CMV-1						
All Method	20	2.6	2.2	86.7	3	0 - 7
Abbott Architect	8	3.5	2.4	70.0	3	0 - 9
Roche cobas e 411	5	1.0	1.7	173.2	0	0 - 5
Specimen CMV-2						
All Method	20	33.3	31.5	94.8	17	0 - 97
Abbott Architect	7	65.7	12.7	19.3	67	40 - 92
Roche cobas e 411	5	2.6	1.5	58.3	3	0 - 6

Cytomegalovirus (CMV) Antibodies (IgM) - Qualitative

Method	Specimen CMV-1 Positive	Specimen CMV-1 Negative	Specimen CMV-2 Positive	Specimen CMV-2 Negative
ALL METHODS	-	20	20	-
Abbott Architect	-	9	9	-
bioMerieux	-	3	3	-
DiaSorin	-	1	1	-
DPC Immulite 2000	-	2	2	-
Roche cobas 6000 / e 601	-	1	1	-
Roche cobas e 411	-	4	4	-

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

Specimen/Method	Labs	Mean	SD	CV	Median	Range
Specimen CMV-1						
All Method	16	0.0	0.1	0.0	0	0 - 1
Abbott Architect	6	0.0	0.1	0.0	0	0 - 1
Specimen CMV-2						
All Method	17	6.4	4.3	66.6	6	0 - 15
Abbott Architect	6	5.5	0.5	10.0	6	4 - 7

CK-MB - Quantitative (U/L)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen CK-1						
All Method	12	20.86	6.57	31.5	17.2	1.1 - 40.6
Roche cobas 6000 / c 501	6	16.97	0.52	3.0	17.1	15.4 - 18.6
Specimen CK-2						
All Method	12	57.18	16.92	29.6	47.1	6.4 - 108.0
Roche cobas 6000 / c 501	6	46.68	1.08	2.3	46.5	43.4 - 50.0
Specimen CK-3						
All Method	14	9.98	3.36	33.6	8.3	0.0 - 20.1
Roche cobas 6000 / c 501	6	7.68	0.52	6.8	7.7	6.1 - 9.3
Specimen CK-4						
All Method	11	35.38	20.03	56.6	27.0	0.0 - 95.5
Roche cobas 6000 / c 501	6	26.75	0.80	3.0	26.8	24.3 - 29.2
Specimen CK-5						
All Method	12	104.16	28.89	27.7	88.1	17.4 - 190.9
Roche cobas 6000 / c 501	6	85.82	2.30	2.7	86.2	78.9 - 92.8

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