

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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



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**International Data Supplement
MLE-M3**

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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)	$\pm 3 \text{ SD}$
Cytomegalovirus	$\pm 2 \text{ SD}$
Fibrinogen	$\pm 20\%$
International Normalized Ratio (INR)	$\pm 20\%$
Prothrombin Time	$\pm 15\%$
Rubella	$\pm 3 \text{ SD}$
Specific Gravity	± 0.010
Toxoplasma	$\pm 2 \text{ SD}$

BLOOD BANK

ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Group AB	106	100%	Acceptable
BB-12	Group A	106	100%	Acceptable
BB-13	Group A	105	99.06%	Acceptable
	Group B	1	0.94%	
BB-14	Group B	105	99.06%	Acceptable
	Group A	1	0.94%	
BB-15	Group O	106	100%	Acceptable

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Rh Positive	106	100%	Acceptable
BB-12	Rh Negative	105	99.06%	Acceptable
	Rh Positive	1	0.94%	
BB-13	Rh Positive	105	99.06%	Acceptable
	Rh Negative	1	0.94%	
BB-14	Rh Negative	105	99.06%	Acceptable
	Rh Positive	1	0.94%	
BB-15	Rh Positive	104	98.11%	Acceptable
	Rh Negative	2	1.89%	

ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	No expected antibody detected	72	100%	Acceptable
AB-12	No expected antibody detected	72	100%	Acceptable
AB-13	Unexpected antibody detected	67	93.06%	Acceptable
	No expected antibody detected	5	6.94%	
AB-14	Unexpected antibody detected	72	100%	Acceptable
AB-15	Unexpected antibody detected	69	95.83%	Acceptable
	No expected antibody detected	3	4.17%	

Specimen AB-13 is graded by 100% referee consensus.

BLOOD BANK

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	No antibody detected	37	100%	Acceptable
AB-12	No antibody detected	37	100%	Acceptable
AB-13	Anti-Fy _a	37	100%	Acceptable
AB-14	Anti-c	37	100%	Acceptable
AB-15	Anti-M	37	100%	Acceptable

COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	Compatible	74	97.37%	Acceptable
	Not Compatible	2	2.63%	
AB-12	Compatible	74	97.37%	Acceptable
	Not Compatible	2	2.63%	
AB-13	Compatible	74	97.37%	Acceptable
	Not Compatible	2	2.63%	
AB-14	Not Compatible	74	97.37%	Acceptable
	Compatible	2	2.63%	
AB-15	Not Compatible	74	97.37%	Acceptable
	Compatible	2	2.63%	

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	134	28.23	5.24	18.6	28.1	23.9 - 32.5	132	47.63	10.69	22.4	48.1	40.4 - 54.8
Dade Innovin												
Dade Behring BFT II	5	26.92	0.54	2.0	27.0	22.8 - 31.0	5	49.52	1.48	3.0	48.9	42.0 - 57.0
Other Instrument Specified	5	26.04	0.93	3.6	25.8	22.1 - 30.0	5	44.98	1.42	3.2	44.9	38.2 - 51.8
Sysmex CA-500/540/560	25	25.89	1.25	4.8	25.6	22.0 - 29.8	24	42.92	2.69	6.3	42.7	36.4 - 49.4
All Coagulation Instruments	38	26.08	1.23	4.7	25.9	22.1 - 30.0	38	44.61	3.67	8.2	44.4	37.9 - 51.3
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	6	36.08	2.02	5.6	35.5	30.6 - 41.5	6	63.23	3.89	6.2	63.1	53.7 - 72.8
RAL Clot-SP	10	31.00	1.10	3.5	31.1	26.3 - 35.7	10	53.53	2.18	4.1	53.6	45.5 - 61.6
All Coagulation Instruments	24	32.54	2.61	8.0	32.0	27.6 - 37.5	23	56.75	4.98	8.8	55.3	48.2 - 65.3
Diagon Dia-PT												
Coalyzer-410	5	27.32	4.11	15.0	28.3	23.2 - 31.5	5	52.94	6.32	11.9	48.7	44.9 - 60.9
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	28.20	2.56	9.1	27.6	23.9 - 32.5	5	48.42	3.35	6.9	46.5	41.1 - 55.7
IL TEST PT Fibrinogen												
IL ACL, all models	15	20.49	1.13	5.5	20.4	17.4 - 23.6	15	30.05	1.82	6.1	30.0	25.5 - 34.6
IL TEST PT-FIB HS PLUS												
IL ACL, all models	12	35.90	2.94	8.2	36.4	30.5 - 41.3	12	60.70	5.66	9.3	61.0	51.5 - 69.9
IL TEST PT-FIB Recombinant												
IL ACL, all models	11	30.65	2.60	8.5	30.9	26.0 - 35.3	11	51.96	5.52	10.6	50.4	44.1 - 59.8
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	20.20	1.71	8.5	20.2	17.1 - 23.3	5	30.46	3.37	11.1	29.0	25.8 - 35.1

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	134	11.77	1.15	9.8	11.6	10.0 - 13.6	134	11.59	1.26	10.8	11.4	9.8 - 13.4
Dade Innovin												
Dade Behring BFT II	5	10.00	0.39	3.9	9.9	8.5 - 11.5	5	9.38	0.34	3.6	9.5	7.9 - 10.8
Other Instrument Specified	5	10.40	0.84	8.0	10.6	8.8 - 12.0	5	10.24	0.91	8.9	10.6	8.7 - 11.8
Sysmex CA-500/540/560	25	10.79	0.25	2.4	10.8	9.1 - 12.5	24	10.58	0.31	2.9	10.6	8.9 - 12.2
All Coagulation Instruments	37	10.64	0.42	3.9	10.7	9.0 - 12.3	38	10.40	0.66	6.4	10.5	8.8 - 12.0
Diag Stago STA Neoplastine CI+												
bioMerieux Thrombolyzer Compact X/XR	6	12.43	0.55	4.4	12.3	10.5 - 14.3	6	12.38	0.51	4.1	12.3	10.5 - 14.3
RAL Clot-SP	10	13.04	0.42	3.3	13.0	11.0 - 15.0	10	13.02	0.40	3.1	13.0	11.0 - 15.0
All Coagulation Instruments	24	12.70	0.52	4.1	12.7	10.7 - 14.7	24	12.76	0.50	3.9	12.8	10.8 - 14.7
Diagon Dia-PT												
Coalyzer-410	5	13.44	0.61	4.5	13.1	11.4 - 15.5	5	13.30	0.79	5.9	13.1	11.3 - 15.3
HemosIL RecombiPlasTin 2G												
IL ACL, all models	5	10.60	0.74	7.0	10.7	9.0 - 12.2	5	10.82	0.66	6.1	10.7	9.1 - 12.5
IL TEST PT Fibrinogen												
IL ACL, all models	15	11.59	0.42	3.6	11.6	9.8 - 13.4	15	11.33	0.44	3.8	11.3	9.6 - 13.1
IL TEST PT-FIB HS PLUS												
IL ACL, all models	12	13.25	0.80	6.1	13.4	11.2 - 15.3	12	12.98	1.16	9.0	13.2	11.0 - 15.0
IL TEST PT-FIB Recombinant												
IL ACL, all models	11	11.74	0.82	7.0	11.4	9.9 - 13.5	11	10.96	0.81	7.4	10.8	9.3 - 12.7
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	11.26	0.93	8.3	11.3	9.5 - 13.0	5	11.04	0.97	8.7	11.4	9.3 - 12.7

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	132	14.41	1.35	9.4	14.2	12.2 - 16.6
Dade Innovin						
Dade Behring BFT II	5	13.46	0.40	3.0	13.2	11.4 - 15.5
Other Instrument Specified	4	-	-	-	13.4	11.3 - 15.4
Sysmex CA-500/540/560	25	13.42	0.39	2.9	13.4	11.4 - 15.5
All Coagulation Instruments	37	13.34	0.48	3.6	13.3	11.3 - 15.4
Diag Stago STA Neoplastine CI+						
bioMerieux Thrombolyzer Compact X/XR	6	15.28	0.70	4.6	15.3	12.9 - 17.6
RAL Clot-SP	10	15.53	0.49	3.2	15.6	13.2 - 17.9
All Coagulation Instruments	24	15.30	0.53	3.5	15.3	13.0 - 17.6
Diagon Dia-PT						
Coalyzer-410	5	16.04	1.12	7.0	15.8	13.6 - 18.5
HemosIL RecombiPlasTin 2G						
IL ACL, all models	5	13.38	1.42	10.6	13.5	11.3 - 15.4
IL TEST PT Fibrinogen						
IL ACL, all models	15	13.73	0.59	4.3	13.6	11.6 - 15.8
IL TEST PT-FIB HS PLUS						
IL ACL, all models	12	16.45	0.96	5.8	16.3	13.9 - 19.0
IL TEST PT-FIB Recombinant						
IL ACL, all models	11	15.57	1.39	8.9	15.3	13.2 - 18.0
PH/CMS Thromboplastin-D						
All Coagulation Instruments	5	13.04	1.22	9.4	12.8	11.0 - 15.0

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	134	2.79	0.43	15.5	2.7	2.2 - 3.4	133	5.22	1.25	24.0	4.8	4.1 - 6.3
Dade Innovin												
Dade Behring BFT II	5	2.52	0.18	7.1	2.5	2.0 - 3.1	5	4.26	0.30	7.0	4.4	3.4 - 5.2
Other Instrument Specified	5	2.52	0.11	4.3	2.5	2.0 - 3.1	5	4.30	0.20	4.7	4.2	3.4 - 5.2
Sysmex CA-500/540/560	25	2.49	0.15	6.1	2.5	1.9 - 3.0	25	4.15	0.34	8.2	4.2	3.3 - 5.0
All Coagulation Instruments	39	2.51	0.15	6.0	2.5	2.0 - 3.1	39	4.21	0.32	7.6	4.2	3.3 - 5.1
Diag Stago STA Neoplastine CI+ bioMerieux Thrombolyzer Compact												
X/XR	6	3.72	0.21	5.7	3.8	2.9 - 4.5	6	7.62	0.84	11.0	7.7	6.0 - 9.2
RAL Clot-SP	10	2.94	0.13	4.3	3.0	2.3 - 3.6	10	5.92	0.32	5.4	5.9	4.7 - 7.2
All Coagulation Instruments	23	3.23	0.43	13.3	3.1	2.5 - 3.9	22	6.58	1.09	16.6	6.3	5.2 - 7.9
Diagon Dia-PT												
Coalyzer-410	5	2.28	0.50	22.0	2.5	1.8 - 2.8	5	4.72	0.89	18.9	4.9	3.7 - 5.7
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	2.62	0.21	8.2	2.6	2.0 - 3.2	6	4.55	0.34	7.6	4.6	3.6 - 5.5
IL TEST PT Fibrinogen												
IL ACL, all models	15	3.00	0.38	12.5	3.0	2.4 - 3.6	15	6.09	0.90	14.8	6.2	4.8 - 7.4
IL TEST PT-FIB HS PLUS												
IL ACL, all models	12	2.92	0.31	10.5	2.9	2.3 - 3.6	12	5.18	0.70	13.4	5.1	4.1 - 6.3
IL TEST PT-FIB Recombinant												
IL ACL, all models	12	2.70	0.29	10.6	2.7	2.1 - 3.3	12	4.63	0.61	13.2	4.5	3.7 - 5.6
PH/CMS Thromboplastin-D												
All Coagulation Instruments	6	3.32	0.37	11.0	3.4	2.6 - 4.0	6	7.65	0.59	7.7	7.8	6.1 - 9.2

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	132	1.00	0.07	7.2	1.0	0.8 - 1.3	132	0.98	0.08	7.9	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	1.04	0.05	5.3	1.0	0.8 - 1.3
Other Instrument Specified	5	1.02	0.04	4.4	1.0	0.8 - 1.3	5	1.02	0.04	4.4	1.0	0.8 - 1.3
Sysmex CA-500/540/560	25	1.03	0.05	4.6	1.0	0.8 - 1.3	25	1.02	0.06	5.5	1.0	0.8 - 1.3
All Coagulation Instruments	39	1.04	0.05	4.7	1.0	0.8 - 1.3	39	1.02	0.05	5.1	1.0	0.8 - 1.3
Diag Stago STA Neoplastine CI+ bioMerieux Thrombolyzer Compact												
X/XR	6	0.97	0.05	5.3	1.0	0.7 - 1.2	6	0.95	0.05	5.8	1.0	0.7 - 1.2
RAL Clot-SP	10	0.98	0.06	6.5	1.0	0.7 - 1.2	10	0.99	0.03	3.2	1.0	0.7 - 1.2
All Coagulation Instruments	23	0.97	0.06	6.4	1.0	0.7 - 1.2	23	0.98	0.05	5.0	1.0	0.7 - 1.2
Diagon Dia-PT												
Coalyzer-410	5	1.02	0.08	8.2	1.0	0.8 - 1.3	5	1.04	0.09	8.6	1.1	0.8 - 1.3
HemosIL RecombiPlasTin 2G												
IL ACL, all models	6	1.00	0.06	6.3	1.0	0.8 - 1.2	6	1.02	0.04	4.0	1.0	0.8 - 1.3
IL TEST PT Fibrinogen												
IL ACL, all models	15	1.05	0.12	11.3	1.0	0.8 - 1.3	15	1.03	0.19	18.9	1.0	0.8 - 1.3
IL TEST PT-FIB HS PLUS												
IL ACL, all models	12	0.94	0.11	11.5	1.0	0.7 - 1.2	12	0.93	0.10	10.4	1.0	0.7 - 1.2
IL TEST PT-FIB Recombinant												
IL ACL, all models	12	1.01	0.11	10.7	1.0	0.8 - 1.3	12	0.95	0.10	10.5	1.0	0.7 - 1.2
PH/CMS Thromboplastin-D												
All Coagulation Instruments	6	1.00	0.06	6.3	1.0	0.8 - 1.2	6	0.98	0.08	7.7	1.0	0.7 - 1.2

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	130	1.28	0.12	9.6	1.3	1.0 - 1.6
Dade Innovin						
Dade Behring BFT II	5	1.38	0.08	6.1	1.4	1.1 - 1.7
Other Instrument Specified	4	-	-	-	1.4	1.0 - 1.6
Sysmex CA-500/540/560	25	1.28	0.06	4.5	1.3	1.0 - 1.6
All Coagulation Instruments	38	1.30	0.07	5.4	1.3	1.0 - 1.6
Diag Stago STA Neoplastine CI+						
bioMerieux Thrombolyzer Compact						
X/XR	6	1.23	0.08	6.6	1.3	0.9 - 1.5
RAL Clot-SP	10	1.22	0.06	5.2	1.2	0.9 - 1.5
All Coagulation Instruments	22	1.23	0.07	5.7	1.2	0.9 - 1.5
Diagon Dia-PT						
Coalyzer-410	5	1.24	0.15	12.2	1.3	0.9 - 1.5
HemosIL RecombiPlasTin 2G						
IL ACL, all models	6	1.22	0.08	6.2	1.2	0.9 - 1.5
IL TEST PT Fibrinogen						
IL ACL, all models	15	1.44	0.19	13.1	1.4	1.1 - 1.8
IL TEST PT-FIB HS PLUS						
IL ACL, all models	12	1.19	0.17	14.1	1.2	0.9 - 1.5
IL TEST PT-FIB Recombinant						
IL ACL, all models	12	1.37	0.16	11.4	1.3	1.0 - 1.7
PH/CMS Thromboplastin-D						
All Coagulation Instruments	6	1.33	0.14	10.2	1.3	1.0 - 1.6

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	81	53.5	11.9	22.3	49	45 - 62	80	79.3	19.3	24.3	74	67 - 92
Dade Actin FSL												
Sysmex CA-500/540/560	16	47.8	2.9	6.1	49	40 - 55	16	72.8	5.2	7.1	74	61 - 84
All Coagulation Instruments	19	48.4	3.2	6.5	49	41 - 56	19	72.8	4.9	6.7	74	61 - 84
Diagnostica Stago STA C.K. Prest												
All Coagulation Instruments	7	54.0	2.9	5.3	54	45 - 63	7	80.6	3.6	4.4	80	68 - 93
Diagon Dia-PTT												
Coalyzer-410	5	106.6	10.4	9.7	112	90 - 123	5	208.0	22.0	10.6	200	176 - 240
IL TEST APTT-SP												
IL ACL, all models	28	46.8	3.1	6.6	47	39 - 54	29	69.3	4.8	6.9	69	58 - 80
All Coagulation Instruments	30	46.8	3.0	6.4	47	39 - 54	30	69.4	4.7	6.8	69	58 - 80
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	83	27.5	2.3	8.2	27	23 - 32	82	29.2	2.4	8.3	28	24 - 34
Dade Actin FSL												
Sysmex CA-500/540/560	16	26.6	1.2	4.3	26	22 - 31	16	27.8	0.8	3.0	28	23 - 32
All Coagulation Instruments	21	26.7	1.4	5.1	26	22 - 31	20	28.0	1.2	4.4	28	23 - 33
Diagnostica Stago STA C.K. Prest												
All Coagulation Instruments	7	30.1	1.5	4.9	30	25 - 35	7	31.9	1.2	3.8	32	27 - 37
Diagon Dia-PTT												
Coalyzer-410	5	31.8	2.4	7.5	33	27 - 37	5	32.2	2.7	8.3	32	27 - 38
IL TEST APTT-SP												
IL ACL, all models	28	26.6	1.4	5.2	26	22 - 31	29	28.5	2.0	7.1	28	24 - 33
All Coagulation Instruments	30	26.7	1.4	5.3	26	22 - 31	31	28.6	2.0	7.0	28	24 - 33
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	83	37.4	5.0	13.3	39	31 - 44						
Dade Actin FSL												
Sysmex CA-500/540/560	16	30.3	1.7	5.6	31	25 - 35						
All Coagulation Instruments	20	30.4	1.7	5.5	31	25 - 35						
Diagnostica Stago STA C.K. Prest												
All Coagulation Instruments	7	42.3	2.1	5.1	41	35 - 49						
Diagon Dia-PTT												
Coalyzer-410	5	41.4	4.7	11.3	42	35 - 48						
IL TEST APTT-SP												
IL ACL, all models	29	39.4	1.5	3.8	40	33 - 46						
All Coagulation Instruments	31	39.5	1.5	3.9	40	33 - 46						

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	39	317.2	51.2	16.1	323	253 - 381	39	312.3	53.7	17.2	314	249 - 375
Diagnostica Stago STA Fibrinogen												
bioMerieux Thrombolyzer Compact												
X/XR	5	298.8	64.2	21.5	282	239 - 359	4	-	-	-	267	237 - 356
All Coagulation Instruments	8	304.8	55.0	18.1	293	243 - 366	8	296.4	39.3	13.2	313	237 - 356
IL TEST PT-FIB HS PLUS												
IL ACL, all models	9	356.7	24.3	6.8	363	285 - 429	9	357.0	34.6	9.7	366	285 - 429
IL TEST PT-FIB Recombinant												
IL ACL, all models	13	331.2	43.4	13.1	336	264 - 398	13	327.9	52.1	15.9	322	262 - 394
All Coagulation Instruments	14	333.2	42.4	12.7	337	266 - 400	14	327.6	50.1	15.3	323	262 - 394
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	38	337.9	36.2	10.7	340	270 - 406	38	554.0	68.9	12.4	560	443 - 665
Diagnostica Stago STA Fibrinogen												
bioMerieux Thrombolyzer Compact												
X/XR	4	-	-	-	314	274 - 413	5	614.2	144.6	23.5	568	491 - 738
All Coagulation Instruments	7	343.7	49.1	14.3	347	274 - 413	9	624.7	104.1	16.7	615	499 - 750
IL TEST PT-FIB HS PLUS												
IL ACL, all models	9	354.2	33.5	9.4	369	283 - 426	9	557.1	31.2	5.6	552	445 - 669
IL TEST PT-FIB Recombinant												
IL ACL, all models	13	345.5	22.8	6.6	343	276 - 415	13	552.0	34.6	6.3	556	441 - 663
All Coagulation Instruments	14	345.0	21.9	6.4	342	276 - 414	14	552.5	33.3	6.0	558	442 - 663
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	36	137.9	21.5	15.6	138	110 - 166						
Diagnostica Stago STA Fibrinogen												
bioMerieux Thrombolyzer Compact												
X/XR	5	141.6	14.4	10.1	140	113 - 170						
All Coagulation Instruments	9	137.4	14.1	10.2	139	109 - 165						
IL TEST PT-FIB HS PLUS												
IL ACL, all models	9	137.6	32.1	23.3	150	110 - 166						
IL TEST PT-FIB Recombinant												
IL ACL, all models	11	132.4	18.6	14.1	135	105 - 159						
All Coagulation Instruments	12	134.6	19.3	14.4	139	107 - 162						

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	405	1.0168	0.0047	0.5	1.015	1.006 - 1.027
All Bayer Instruments	53	1.0161	0.0042	0.4	1.015	1.006 - 1.027
All Refractive Index Methods	11	1.0209	0.0023	0.2	1.021	1.010 - 1.031
All Roche Instruments	143	1.0149	0.0037	0.4	1.015	1.004 - 1.025
Arkray Aution Sticks	13	1.0233	0.0052	0.5	1.020	1.013 - 1.034
Bayer Clinitek Advantus	19	1.0147	0.0031	0.3	1.015	1.004 - 1.025
Bayer Clinitek Status / Status+	15	1.0180	0.0025	0.2	1.020	1.008 - 1.028
DIRUI H-100 / H-500 Urine Analyzer	17	1.0155	0.0038	0.4	1.015	1.005 - 1.026
Erba Mannheim Uro-dipcheck 400e	13	1.0138	0.0050	0.5	1.015	1.003 - 1.024
Other Analyzer Method	15	1.0201	0.0049	0.5	1.020	1.010 - 1.031
Roche Chemstrips / Combur	18	1.0128	0.0026	0.3	1.015	1.002 - 1.023
Roche cobas u 411	77	1.0140	0.0022	0.2	1.015	1.003 - 1.024
Roche Urisys	59	1.0166	0.0050	0.5	1.015	1.006 - 1.027
SD UroColor Reagent Strips	14	1.0207	0.0034	0.3	1.020	1.010 - 1.031
UriScan Reagent Strips	42	1.0213	0.0043	0.4	1.020	1.011 - 1.032

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	427	1	-	-	2	7	96	230	88	1	2	-	-
Acon Laboratories	4	-	-	-	-	-	-	4	-	-	-	-	-
Analyticon CombiScan 500	2	-	-	-	-	-	2	-	-	-	-	-	-
Arkray Aution Sticks	13	-	-	-	-	1	1	10	1	-	-	-	-
Arkray PocketChem UA	1	-	-	-	-	-	-	1	-	-	-	-	-
Bayer Clinitek 10 / 100	1	-	-	-	-	-	-	1	-	-	-	-	-
Bayer Clinitek 50	9	-	-	-	-	1	1	7	-	-	-	-	-
Bayer Clinitek 500	4	-	-	-	-	-	-	3	1	-	-	-	-
Bayer Clinitek Advantus	19	-	-	-	-	-	3	16	-	-	-	-	-
Bayer Clinitek Atlas	5	-	-	-	-	-	-	5	-	-	-	-	-
Bayer Clinitek Status / Status+	15	-	-	-	-	-	1	9	5	-	-	-	-
Bayer Multistix Pro	5	-	-	-	-	-	1	1	3	-	-	-	-
Bayer Reagent Strips	20	-	-	-	-	-	2	14	3	1	-	-	-
Combi-Screen Test Strips	5	-	-	-	-	-	2	1	2	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	19	-	-	-	-	1	14	2	1	-	1	-	-
DIRUI H-800 Urine Analyzer	8	-	-	-	-	-	1	6	1	-	-	-	-
Erba Mannheim Uro-dipcheck 400e	13	-	-	-	1	-	6	5	-	-	1	-	-
HUMAN Combilyzer	2	-	-	-	-	-	2	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	3	-	-	-	-	-	1	2	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	5	-	-	-	-	-	-	5	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	2	-	-	-	-	-	-	2	-	-	-	-	-
Other Analyzer Method	14	-	-	-	-	-	4	9	1	-	-	-	-
Other Dipstick Method	8	-	-	-	-	-	4	3	1	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	1	-	-	-	-	-	-
Roche Chemstrip 101	2	-	-	-	-	-	2	-	-	-	-	-	-
Roche Chemstrips / Combur	25	1	-	-	-	-	10	5	9	-	-	-	-
Roche cobas u 411	77	-	-	-	-	-	2	41	34	-	-	-	-
Roche Miditron Junior/II	6	-	-	-	-	-	-	6	-	-	-	-	-
Roche Urilux S	3	-	-	-	-	-	2	1	-	-	-	-	-
Roche Urisys	60	-	-	-	-	-	2	35	23	-	-	-	-
SD UroColor Reagent Strips	13	-	-	-	-	-	4	9	-	-	-	-	-
Urinometer	2	-	-	-	-	-	-	2	-	-	-	-	-
UriScan Pro/II	10	-	-	-	-	1	5	4	-	-	-	-	-
UriScan Reagent Strips	41	-	-	-	1	3	22	13	2	-	-	-	-
URIT Medical Uritest Analyzers	3	-	-	-	-	-	-	3	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	-	1	-	-	-	-	-

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	429	414	2	2	5	3	-	3
Acon Laboratories	4	3	-	-	1	-	-	-
Analyticon CombiScan 500	2	2	-	-	-	-	-	-
Arkray Aution Sticks	12	12	-	-	-	-	-	-
Arkray PocketChem UA	1	1	-	-	-	-	-	-
Bayer Albumstix	1	1	-	-	-	-	-	-
Bayer Clinitek 10 / 100	1	1	-	-	-	-	-	-
Bayer Clinitek 50	9	9	-	-	-	-	-	-
Bayer Clinitek 500	4	4	-	-	-	-	-	-
Bayer Clinitek Advantus	19	19	-	-	-	-	-	-
Bayer Clinitek Atlas	5	5	-	-	-	-	-	-
Bayer Clinitek Status / Status+	16	16	-	-	-	-	-	-
Bayer Multistix Pro	5	5	-	-	-	-	-	-
Bayer Reagent Strips	19	19	-	-	-	-	-	-
Combi-Screen Test Strips	6	5	1	-	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	19	18	-	1	-	-	-	-
DIRUI H-800 Urine Analyzer	8	7	-	-	-	1	-	-
Erba Mannheim Uro-dipcheck 400e	13	11	-	1	1	-	-	-
HUMAN Combilyzer	2	2	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	3	3	-	-	-	-	-	-
Iris Diagnostics iChem Velocity Strips	5	5	-	-	-	-	-	-
Iris Diagnostics vChem Urine Strips	2	2	-	-	-	-	-	-
Other Analyzer Method	14	13	-	-	1	-	-	-
Other Dipstick Method	9	9	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-
Roche Chemstrip 101	2	2	-	-	-	-	-	-
Roche Chemstrips / Combur	25	24	-	-	-	1	-	-
Roche cobas u 411	77	75	-	-	1	1	-	-
Roche Miditron Junior/II	6	6	-	-	-	-	-	-
Roche Urilux S	3	2	-	-	-	-	-	1
Roche Urisys	60	59	-	-	-	-	-	1
SD UroColor Reagent Strips	13	13	-	-	-	-	-	-
TECO URS Strips	1	1	-	-	-	-	-	-
Urinometer	2	2	-	-	-	-	-	-
UriScan Pro/II	10	9	-	-	-	-	-	1
UriScan Reagent Strips	41	39	1	-	1	-	-	-
URIT Medical Uritest Analyzers	3	3	-	-	-	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-	-	-

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>500 mg/dL</u>	<u>1000 mg/dL</u>	<u>>1000 mg/dL</u>	<u>≥2000 mg/dL</u>
ALL METHODS	429	4	6	8	71	111	192	31	6
Acon Laboratories	4	-	-	1	1	2	-	-	-
Analyticon CombiScan 500	2	-	-	-	-	1	-	1	-
Arkray Aution Sticks	13	-	-	-	1	5	5	-	2
Arkray PocketChem UA	1	-	-	-	-	-	-	1	-
Bayer Clinitek 10 / 100	1	-	-	-	-	-	1	-	-
Bayer Clinitek 50	9	-	-	-	3	5	1	-	-
Bayer Clinitek 500	4	-	1	-	2	1	-	-	-
Bayer Clinitek Advantus	19	-	1	1	2	14	-	1	-
Bayer Clinitek Atlas	5	-	-	-	-	2	3	-	-
Bayer Clinitek Status / Status+	16	-	-	-	9	6	1	-	-
Bayer Multistix Pro	5	-	-	-	-	2	2	1	-
Bayer Reagent Strips	20	-	-	1	11	8	-	-	-
Combi-Screen Test Strips	6	-	-	-	1	1	3	1	-
DIRUI H-100 / H-500 Urine Analyzer	19	-	1	2	9	4	3	-	-
DIRUI H-800 Urine Analyzer	8	-	-	-	-	6	-	1	1
Erba Mannheim Uro-dipcheck 400e	13	-	-	-	12	-	1	-	-
HUMAN Combilyzer	2	-	1	-	-	1	-	-	-
Iris Diagnostics Aution Max AX-4280	3	-	-	-	-	-	1	1	1
Iris Diagnostics iChem Velocity Strips	5	-	-	-	-	4	1	-	-
Iris Diagnostics vChem Urine Strips	2	-	-	-	-	1	-	1	-
Other Analyzer Method	14	1	-	-	3	2	5	3	-
Other Dipstick Method	8	-	1	-	3	2	1	1	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-
Roche Chemstrip 101	2	-	-	-	-	2	-	-	-
Roche Chemstrips / Combur	25	-	-	-	1	2	15	7	-
Roche cobas u 411	77	-	1	-	3	-	72	1	-
Roche Mditron Junior/II	6	-	-	-	-	-	5	1	-
Roche Urilux S	3	-	-	-	-	-	2	1	-
Roche Urisys	60	-	-	1	1	2	49	7	-
SD UroColor Reagent Strips	13	-	-	2	-	8	3	-	-
TECO URS Strips	1	-	-	-	1	-	-	-	-
Urinometer	2	-	-	-	-	2	-	-	-
UriScan Pro/II	10	-	-	-	-	6	2	1	1
UriScan Reagent Strips	40	1	-	-	6	18	13	1	1
URIT Medical Uritest Analyzers	3	-	-	-	1	2	-	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	-	1	-	-

URINALYSIS DIPSTICK–KETONES

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u> <u>(5 mg/dL)</u>	<u>Small</u> <u>(1+, 15</u> <u>mg/dL)</u>	<u>Moderate</u> <u>(2+, 40</u> <u>mg/dL)</u>	<u>Large</u> <u>(3+, 80</u> <u>mg/dL)</u>	<u>150 mg/dL</u>	<u>≥ 160 mg/dL</u>
ALL METHODS	428	1	-	5	26	171	165	60
Acon Laboratories	4	-	-	-	2	-	-	2
Analyticon CombiScan 500	2	-	-	-	-	1	-	1
Arkray Aution Sticks	13	-	-	-	-	2	6	5
Arkray PocketChem UA	1	-	-	-	-	-	-	1
Bayer Clinitek 10 / 100	1	-	-	-	-	-	-	1
Bayer Clinitek 2000	1	-	-	-	-	1	-	-
Bayer Clinitek 50	8	-	-	-	-	7	-	1
Bayer Clinitek 500	4	-	-	1	-	3	-	-
Bayer Clinitek Advantus	19	-	-	1	-	18	-	-
Bayer Clinitek Atlas	5	-	-	-	-	2	1	2
Bayer Clinitek Status / Status+	16	-	-	-	-	3	2	11
Bayer Multistix Pro	5	-	-	-	-	2	-	3
Bayer Reagent Strips	19	-	-	-	-	4	-	15
Combi-Screen Test Strips	6	-	-	-	1	2	-	3
DIRUI H-100 / H-500 Urine Analyzer	19	-	-	-	2	16	-	1
DIRUI H-800 Urine Analyzer	8	-	-	-	2	6	-	-
Erba Mannheim Uro-dipcheck 400e	13	-	-	-	-	5	8	-
HUMAN Combilyzer	2	-	-	1	-	1	-	-
Iris Diagnostics Aution Max AX-4280	3	-	-	-	-	1	2	-
Iris Diagnostics iChem Velocity Strips	5	-	-	-	-	3	2	-
Iris Diagnostics vChem Urine Strips	2	-	-	-	-	1	1	-
Other Analyzer Method	14	-	-	1	-	7	3	3
Other Dipstick Method	8	-	-	-	1	1	2	4
Plasmatec URIPATH	1	-	-	-	-	1	-	-
Roche Chemstrip 101	2	-	-	-	-	2	-	-
Roche Chemstrips / Combur	24	-	-	-	1	16	6	1
Roche cobas u 411	76	-	-	1	-	7	67	1
Roche Miditron Junior/II	7	-	-	-	-	-	7	-
Roche Urilux S	3	-	-	-	-	1	2	-
Roche Urisys	60	1	-	-	1	6	50	2
SD UroColor Reagent Strips	13	-	-	-	6	7	-	-
TECO URS Strips	1	-	-	-	-	1	-	-
Urinometer	2	-	-	-	2	-	-	-
UriScan Pro/II	10	-	-	-	2	8	-	-
UriScan Reagent Strips	41	-	-	-	4	31	4	2
URIT Medical Uritest Analyzers	3	-	-	-	1	2	-	-
URIT Medical Uritest Reagent Strips	1	-	-	-	-	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	417	411	1	-	5
Acon Laboratories	4	3	-	-	1
Analyticon CombiScan 500	2	2	-	-	-
Arkray Aution Sticks	13	13	-	-	-
Arkray PocketChem UA	1	1	-	-	-
Bayer Clinitek 10 / 100	1	1	-	-	-
Bayer Clinitek 50	9	9	-	-	-
Bayer Clinitek 500	4	4	-	-	-
Bayer Clinitek Advantus	19	19	-	-	-
Bayer Clinitek Atlas	5	5	-	-	-
Bayer Clinitek Status / Status+	15	15	-	-	-
Bayer Multistix Pro	5	5	-	-	-
Bayer Reagent Strips	9	9	-	-	-
Combi-Screen Test Strips	6	6	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	19	19	-	-	-
DIRUI H-800 Urine Analyzer	8	7	-	-	1
Erba Mannheim Uro-dipcheck 400e	13	13	-	-	-
HUMAN Combilyzer	2	2	-	-	-
Iris Diagnostics Aution Max AX-4280	3	3	-	-	-
Iris Diagnostics iChem Velocity Strips	5	5	-	-	-
Iris Diagnostics vChem Urine Strips	2	2	-	-	-
Other Analyzer Method	14	13	1	-	-
Other Dipstick Method	8	8	-	-	-
Plasmatec URIPATH	1	1	-	-	-
Roche Chemstrip 101	2	2	-	-	-
Roche Chemstrips / Combur	24	24	-	-	-
Roche cobas u 411	77	75	-	-	2
Roche Miditron Junior/II	6	6	-	-	-
Roche Urilux S	3	3	-	-	-
Roche Urisys	60	60	-	-	-
SD UroColor Reagent Strips	13	13	-	-	-
TECO URS Strips	1	1	-	-	-
Urinometer	2	2	-	-	-
UriScan Pro/II	10	9	-	-	1
UriScan Reagent Strips	41	41	-	-	-
URIT Medical Uritest Analyzers	3	3	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-

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>4.0 mg/dL</u>	<u>>8.0 mg/dL</u>
ALL METHODS	416	406	2	3	2	3
Acon Laboratories	4	3	-	-	-	1
Analyticon CombiScan 500	2	2	-	-	-	-
Arkray Aution Sticks	13	13	-	-	-	-
Arkray PocketChem UA	1	1	-	-	-	-
Bayer Clinitek 10 / 100	1	1	-	-	-	-
Bayer Clinitek 50	9	9	-	-	-	-
Bayer Clinitek 500	4	4	-	-	-	-
Bayer Clinitek Advantus	19	18	-	1	-	-
Bayer Clinitek Atlas	5	5	-	-	-	-
Bayer Clinitek Status / Status+	15	14	-	-	1	-
Bayer Multistix Pro	5	5	-	-	-	-
Bayer Reagent Strips	9	9	-	-	-	-
Combi-Screen Test Strips	6	6	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	19	18	-	1	-	-
DIRUI H-800 Urine Analyzer	8	7	-	1	-	-
Erba Mannheim Uro-dipcheck 400e	13	13	-	-	-	-
HUMAN Combilyzer	2	2	-	-	-	-
Iris Diagnostics Aution Max AX-4280	3	3	-	-	-	-
Iris Diagnostics iChem Velocity Strips	5	5	-	-	-	-
Iris Diagnostics vChem Urine Strips	2	2	-	-	-	-
Other Analyzer Method	14	13	1	-	-	-
Other Dipstick Method	8	8	-	-	-	-
Roche Chemstrip 101	2	2	-	-	-	-
Roche Chemstrips / Combur	24	24	-	-	-	-
Roche cobas u 411	76	74	-	-	1	1
Roche Mditron Junior/II	7	7	-	-	-	-
Roche Urilux S	3	3	-	-	-	-
Roche Urisys	60	59	1	-	-	-
SD UroColor Reagent Strips	13	13	-	-	-	-
TECO URS Strips	1	1	-	-	-	-
Urinometer	2	2	-	-	-	-
UriScan Pro/II	10	9	-	-	-	1
UriScan Reagent Strips	41	41	-	-	-	-
URIT Medical Uritest Analyzers	3	3	-	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-

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	425	410	6	4	2	3
Acon Laboratories	4	3	-	-	-	1
Analyticon CombiScan 500	1	1	-	-	-	-
Arkray Aution Sticks	13	13	-	-	-	-
Arkray PocketChem UA	1	1	-	-	-	-
Bayer Clinitek 10 / 100	1	1	-	-	-	-
Bayer Clinitek 50	9	8	1	-	-	-
Bayer Clinitek 500	4	4	-	-	-	-
Bayer Clinitek Advantus	19	19	-	-	-	-
Bayer Clinitek Atlas	5	5	-	-	-	-
Bayer Clinitek Status / Status+	16	16	-	-	-	-
Bayer Multistix Pro	5	3	2	-	-	-
Bayer Reagent Strips	19	19	-	-	-	-
Combi-Screen Test Strips	6	6	-	-	-	-
DIRUI H-100 / H-500 Urine Analyzer	19	17	1	-	1	-
DIRUI H-800 Urine Analyzer	8	7	-	-	-	1
Erba Mannheim Uro-dipcheck 400e	13	12	-	1	-	-
HUMAN Combilyzer	2	2	-	-	-	-
Iris Diagnostics Aution Max AX-4280	3	3	-	-	-	-
Iris Diagnostics iChem Velocity Strips	5	5	-	-	-	-
Iris Diagnostics vChem Urine Strips	2	2	-	-	-	-
Other Analyzer Method	14	13	-	-	1	-
Other Dipstick Method	8	8	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-
Roche Chemstrip 101	2	2	-	-	-	-
Roche Chemstrips / Combur	24	24	-	-	-	-
Roche cobas u 411	76	73	1	1	-	1
Roche Mditron Junior/II	7	7	-	-	-	-
Roche Urilux S	3	3	-	-	-	-
Roche Urisys	59	57	1	1	-	-
SD UroColor Reagent Strips	12	12	-	-	-	-
TECO URS Strips	1	1	-	-	-	-
Urinometer	2	2	-	-	-	-
UriScan Pro/II	9	8	-	1	-	-
UriScan Reagent Strips	41	41	-	-	-	-
URIT Medical Uritest Analyzers	3	3	-	-	-	-
URIT Medical Uritest Reagent Strips	2	2	-	-	-	-

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	413	9	2	10	100	292
Acon Laboratories	4	-	-	-	4	-
Analyticon CombiScan 500	2	-	-	-	-	2
Arkray Aution Sticks	13	-	-	-	-	13
Arkray PocketChem UA	1	-	-	-	-	1
Bayer Clinitek 10 / 100	1	-	-	-	-	1
Bayer Clinitek 50	9	-	-	1	4	4
Bayer Clinitek 500	4	-	-	-	4	-
Bayer Clinitek Advantus	19	-	-	-	15	4
Bayer Clinitek Atlas	5	-	-	-	-	5
Bayer Clinitek Status / Status+	15	-	1	4	6	4
Bayer Multistix Pro	5	-	-	-	5	-
Bayer Reagent Strips	9	1	-	-	8	-
Combi-Screen Test Strips	5	-	-	-	-	5
DIRUI H-100 / H-500 Urine Analyzer	19	1	-	1	7	10
DIRUI H-800 Urine Analyzer	8	-	-	-	4	4
Erba Mannheim Uro-dipcheck 400e	12	1	-	-	-	11
HUMAN Combilyzer	2	-	-	-	-	2
Iris Diagnostics Aution Max AX-4280	3	-	-	1	-	2
Iris Diagnostics iChem Velocity Strips	5	-	-	-	-	5
Iris Diagnostics vChem Urine Strips	2	-	-	-	-	2
Other Analyzer Method	13	-	-	-	3	10
Other Dipstick Method	8	-	-	-	2	6
Roche Chemstrip 101	2	-	-	-	2	-
Roche Chemstrips / Combur	23	3	-	-	6	14
Roche cobas u 411	76	1	-	-	2	73
Roche Mditron Junior/II	6	-	-	1	-	5
Roche SuperUA/ChemstripUA	1	-	-	-	-	1
Roche Urilux S	3	-	-	-	-	3
Roche Urisys	60	-	-	-	2	58
SD UroColor Reagent Strips	14	1	-	-	7	6
TECO URS Strips	1	-	-	-	1	-
Urinometer	2	-	-	-	2	-
UriScan Pro/II	10	-	-	1	3	6
UriScan Reagent Strips	41	1	-	1	11	28
URIT Medical Uritest Analyzers	3	-	-	-	-	3
URIT Medical Uritest Reagent Strips	1	-	-	-	-	1

URINALYSIS DIPSTICK–NITRITE

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	415	411	4
Acon Laboratories	4	4	-
Analyticon CombiScan 500	2	2	-
Arkray Aution Sticks	13	13	-
Arkray PocketChem UA	1	1	-
Bayer Clinitek 10 / 100	1	1	-
Bayer Clinitek 50	9	9	-
Bayer Clinitek 500	4	4	-
Bayer Clinitek Advantus	19	19	-
Bayer Clinitek Atlas	5	5	-
Bayer Clinitek Status / Status+	15	15	-
Bayer Multistix Pro	5	5	-
Bayer Reagent Strips	9	9	-
Combi-Screen Test Strips	6	6	-
DIRUI H-100 / H-500 Urine Analyzer	19	18	1
DIRUI H-800 Urine Analyzer	8	8	-
Erba Mannheim Uro-dipcheck 400e	13	12	1
HUMAN Combilyzer	2	2	-
Iris Diagnostics Aution Max AX-4280	3	3	-
Iris Diagnostics iChem Velocity Strips	5	5	-
Iris Diagnostics vChem Urine Strips	2	2	-
Other Analyzer Method	14	14	-
Other Dipstick Method	8	8	-
Roche Chemstrip 101	2	2	-
Roche Chemstrips / Combur	24	24	-
Roche cobas u 411	76	76	-
Roche Miditron Junior/II	6	6	-
Roche Urilux S	3	3	-
Roche Urisys	60	60	-
SD UroColor Reagent Strips	13	13	-
TECO URS Strips	1	1	-
Urinometer	2	2	-
UriScan Pro/II	10	10	-
UriScan Reagent Strips	41	39	2
URIT Medical Uritest Analyzers	3	3	-
URIT Medical Uritest Reagent Strips	1	1	-

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	26	14	10	2	-	-	-	-
Bayer Clinitek Microalbumin	10	1	9	-	-	-	-	-
HUMAN Combilyzer	2	1	1	-	-	-	-	-
HUMAN COMBINA Test Strips	1	1	-	-	-	-	-	-
Other Dipstick Method	1	-	-	1	-	-	-	-
Roche cobas u 411	1	1	-	-	-	-	-	-
Roche Micral - 1 minute	6	6	-	-	-	-	-	-

URINALYSIS –URINE hCG

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	116	-	116
Acon Laboratories	19	-	19
Biotron 1-Step	12	-	12
Henry Schein One Step	2	-	2
Innovacon hCG One Step	1	-	1
PEP (Lab Supply) HCG	1	-	1
Quidel QuickVue + One-Step	3	-	3
Quidel QuickVue One-Step Combo	31	-	31
Quidel QuickVue One-Step Urine	6	-	6
Sekisui OSOM hCG Combo Test	1	-	1
Stanbio QuStick	1	-	1
Sure-Vue hCG - 25mIU	1	-	1
Veda lab	1	-	1

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	31	30	1	-	126	126	-	-	99.39%
Amoxicillin/Clavulanate	44	11	9	24	38	5	-	33	80.00% ¹
Ampicillin	31	14	1	16	54	1	3	50	90.00% ¹
Ampicillin/Sulbactam	20	18	-	2	39	19	-	20	80.00% ¹
Aztreonam	8	8	-	-	41	37	1	3	92.00%
Carbenicillin	-	-	-	-	1	1	-	-	Not graded ²
Cefaclor	3	2	1	-	1	-	-	1	Not graded ²
Cefamandole	1	1	-	-	-	-	-	-	Not graded ²
Cefazolin	5	1	-	4	47	-	-	47	98.08%
Cefepime	16	16	-	-	115	115	-	-	100.00%
Cefixime	16	16	-	-	10	5	-	5	80.77%
Cefoperazone	2	2	-	-	2	2	-	-	Not graded ²
Cefotaxime	16	16	-	-	58	56	-	2	97.47%
Cefotetan	-	-	-	-	6	6	-	-	100.00%
Cefoxitin	5	-	-	5	67	5	1	61	92.21%
Cefpodoxime	1	1	-	-	3	1	1	1	Not graded ²
Ceftazidime	23	22	-	1	102	99	1	2	96.95%
Ceftizoxime	1	1	-	-	-	-	-	-	Not graded ²
Ceftriaxone	50	49	-	1	98	95	-	3	97.40%
Cefuroxime	31	30	-	1	45	38	1	6	88.89%
Cephalexin	3	1	1	1	1	-	-	1	Not graded ²
Cephalothin	25	2	4	19	47	2	1	44	88.61%
Ciprofloxacin	59	58	-	1	143	142	-	1	99.05%
Doripenem	1	1	-	-	6	6	-	-	100.00%
Doxycycline	5	5	-	-	-	-	-	-	100.00%
Ertapenem	9	9	-	-	93	93	-	-	100.00%
Fosfomycin	3	3	-	-	9	9	-	-	Inappropriate drug ³
Gatifloxacin	-	-	-	-	2	2	-	-	Not graded ²
Gentamicin	34	33	1	-	130	129	1	-	98.84%
Imipenem	20	20	-	-	53	53	-	-	100.00%

¹ This drug was graded by referee consensus.

² This drug is ungraded due to lack of comparison group.

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

ANTIMICROBIAL SUSCEPTIBILITY TESTING (cont'd)

Specimen SUS-11

<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>	
Kanamycin	1	1	-	-	1	1	-	-	Not graded ²
Levofloxacin	15	15	-	-	36	36	-	-	100.00%
Linezolid	2	-	-	2	2	2	-	-	Inappropriate drug ³
Lomefloxacin	2	2	-	-	1	1	-	-	Not graded ²
Meropenem	18	18	-	-	86	86	-	-	100.00%
Minocycline	1	1	-	-	1	1	-	-	Not graded ²
Moxifloxacin	8	8	-	-	3	3	-	-	Inappropriate drug ³
Nalidixic Acid	20	20	-	-	9	9	-	-	100.00%
Netilmicin	8	8	-	-	3	3	-	-	100.00%
Nitrofurantoin	47	46	-	1	113	112	-	1	98.80%
Norfloxacin	24	24	-	-	45	45	-	-	100.00%
Ofloxacin	18	18	-	-	3	3	-	-	100.00%
Oxacillin	2	-	-	2	-	-	-	-	Inappropriate drug ³
Penicillin	4	-	-	4	-	-	-	-	Inappropriate drug ³
Piperacillin	2	2	-	-	27	24	3	-	90.00%
Piperacillin/Tazobactam	16	16	-	-	73	73	-	-	100.00%
Quinupristin/Dalfopristin	-	-	-	-	1	-	-	1	Inappropriate drug ³
Rifampin	1	-	-	1	-	-	-	-	Inappropriate drug ³
Sulfisoxazole	-	-	-	-	2	2	-	-	Not graded ²
Teicoplanin	-	-	-	-	1	1	-	-	Inappropriate drug ³
Tetracycline	9	8	-	1	12	12	-	-	95.24%
Ticarcillin/Clavulanate	1	1	-	-	5	5	-	-	100.00%
Tigecycline	-	-	-	-	8	8	-	-	Inappropriate drug ³
Tobramycin	5	5	-	-	38	38	-	-	100.00%
Trimethoprim	1	1	-	-	2	2	-	-	Not graded ²
Trimethoprim/Sulfamethoxazole	48	47	-	1	135	132	-	3	97.93%
Vancomycin	3	1	-	2	1	1	-	-	Inappropriate drug ³

Organism present in specimen SUS-11: *Citrobacter freundii*.

PARASITOLOGY (PA Specimens)

Specimen PA-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	8	80.00%	Acceptable
Cryptosporidium sp., oocysts	2	20.00%	

Parasite present in specimen PA-11: No parasite seen.

Specimen PA-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	8	80.00%	Acceptable
Cryptosporidium sp., oocysts	1	10.00%	
No parasite seen	1	10.00%	

Parasite present in specimen PA-12: *Giardia lamblia*.

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	10	83.33%	Acceptable
Paragonimus westermani eggs	1	8.33%	
Trichuris trichiura eggs	1	8.33%	

Parasite present in specimen PA-13: *Ascaris lumbricoides* eggs.

Specimen PA-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Clonorchis sinensis	5	41.67%	Not graded
Taenia sp. eggs	3	25.00%	
No parasite seen	3	25.00%	
Fasciola hepatica eggs	1	8.33%	

Parasite present in specimen PA-14: *Clonorchis sinensis*. This is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium falciparum	7	70.00%	Acceptable
Plasmodium ovale	1	10.00%	Acceptable
Plasmodium sp., NOS	1	10.00%	Acceptable
Trichuris trichiura eggs	1	10.00%	

Parasites present in specimen PA-15: *Plasmodium falciparum* and *Plasmodium ovale*.

PARASITOLOGY (FP Specimens)

Specimen FP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	242	92.72%	Acceptable
Endolimax nana	5	1.92%	
Fasciola hepatica eggs	2	0.77%	
Clonorchis sinensis	2	0.77%	

Parasite present in specimen FP-11: No parasite seen.

Specimen FP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Schistosoma haematobium eggs	201	76.72%	Acceptable
Schistosoma sp. eggs, NOS	15	5.73%	Acceptable
No parasite seen	27	10.31%	
Fasciola hepatica eggs	5	1.91%	
Schistosoma mansoni eggs	4	1.53%	
Schistosoma japonicum eggs	3	1.15%	
Diphyllbothrium latum	3	1.15%	

Parasite present in specimen FP-12: *Schistosoma haematobium* eggs.

PARASITOLOGY (FP Specimens)

Specimen FP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Paragonimus westermani eggs	181	68.05%	Acceptable
Other parasite seen but no ID	2	0.75%	Acceptable
Fasciola hepatica eggs	37	13.91%	
Diphyllbothrium latum	20	7.52%	
No parasite seen	10	3.76%	
Endolimax nana	3	1.13%	
Trichuris trichiura eggs	3	1.13%	
Hookworm	3	1.13%	
Ascaris lumbricoides eggs	3	1.13%	
Entamoeba histolytica	2	0.75%	

Parasite present in specimen FP-13: *Paragonimus westermani* eggs. This challenge was graded by 80% referee consensus.

PARASITOLOGY (FP Specimens)

Specimen FP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. eggs	221	81.85%	Acceptable
Blastocystis hominis	15	5.56%	
No parasite seen	11	4.07%	
Ascaris lumbricoides eggs	6	2.22%	
Hymenolepis nana eggs	5	1.85%	
Endolimax nana	5	1.85%	
Hymenolepis diminuta eggs	4	1.48%	

Parasite present in specimen FP-14: *Taenia sp. eggs*.

Specimen FP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Microfilaria-Loa Loa	53	21.20%	Acceptable
Microfilaria, NOS	72	28.80%	Acceptable
No parasite seen	80	32.00%	
Microfilaria-Onchocerca volvulus	20	8.00%	
Microfilaria-Wuchereria bancrofti	5	2.00%	
Microfilaria-Mansonella ozzardi	4	1.60%	
Microfilaria-Mansonella perstans	4	1.60%	
Microfilaria, unsheathed, NOS	3	1.20%	
Microfilaria-Brugia species	2	0.80%	
Plasmodium sp., NOS	2	0.80%	
Plasmodium falciparum	2	0.80%	

Parasite present in specimen FP-15: *Microfilaria-Loa Loa*. This challenge was graded by 90% referee consensus.

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	9	5	4	10	-	14
Immuno Concepts	-	1	-	1	-	1
INOVA Diagnostics	3	2	2	3	-	5
Kallestad	2	-	1	1	-	2
Wampole Impact	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	-	14	14	-
Immuno Concepts	-	1	1	-
INOVA Diagnostics	-	5	5	-
Kallestad	-	2	2	-
Wampole Impact	-	1	1	-

Antinuclear Antibody (ANA)—Quantitative (Titer)

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

<u>Specimen/Method</u>	<u>8/ 10</u>	<u>16/ 20</u>	<u>32/ 40</u>	<u>64/ 80</u>	<u>128/ 160</u>	<u>256/ 320</u>	<u>512/ 640</u>	<u>>640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
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Specimen AE-11

ALL METHODS	1	-	1	2	2	1	-	-	-	-	-
INOVA Diagnostics	-	-	-	1	-	1	-	-	-	-	-
Kallestad	-	-	-	1	1	-	-	-	-	-	-
Wampole Impact	-	-	1	-	-	-	-	-	-	-	-

Specimen AE-12

ALL METHODS	1	-	-	2	1	-	-	-	-	-	-
INOVA Diagnostics	-	-	-	-	1	-	-	-	-	-	-
Kallestad	-	-	-	1	-	-	-	-	-	-	-
Wampole Impact	-	-	-	-	-	-	-	-	-	-	-

Specimen AE-15

ALL METHODS	-	-	-	-	1	4	2	-	3	-	-
INOVA Diagnostics	-	-	-	-	-	3	-	-	1	-	-
Kallestad	-	-	-	-	-	-	1	-	1	-	-
Wampole Impact	-	-	-	-	-	-	-	-	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	-	7	-	7	-	7
Diamedix	-	1	-	1	-	1
INOVA Diagnostics	-	3	-	3	-	3
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	-	7	7	-
Diamedix	-	1	1	-
INOVA Diagnostics	-	3	3	-
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	6	-	-	6	-	6
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	-	6	1	5
INOVA Diagnostics	-	5	1	4

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
Diamedix	-	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	-	2	-	2
Diamedix	-	1	-	1

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	8	1	-	9	-	9
Diamedix	-	1	-	1	-	1
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	-
Diamedix	-	1	1	-
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	7	2	-	9	-	9
Diamedix	-	1	-	1	-	1
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	-
Diamedix	-	1	1	-
INOVA Diagnostics	-	5	5	-

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
GenBio ImmunoDOT Panel 1	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	-
GenBio ImmunoDOT Panel 1	-	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	-	9
Diamedix	-	1	-	1	-	1
INOVA Diagnostics	-	6	-	6	-	6

<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
Diamedix	-	1	-	1
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	1	24	22	3	21	4
Abbott Architect	-	5	4	1	4	1
Bayer ADVIA Centaur	1	3	3	1	3	1
Bayer ADVIA Centaur - IgG	-	1	1	-	1	-
bioMerieux Vidas, Mini Vidas	-	2	2	-	2	-
DiaSorin	-	1	1	-	1	-
DPC Immulite 2000	-	2	2	-	2	-
Roche cobas 6000 / e 601	-	2	2	-	2	-
Roche cobas e 411	-	2	2	-	1	1
Roche Modular Analytics	-	2	2	-	2	-
VITROS ECI	-	3	2	1	2	1
VITROS ECI - IgG	-	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	3	-	25
Abbott Architect	4	1	-	5
Bayer ADVIA Centaur	3	1	-	4
Bayer ADVIA Centaur - IgG	1	-	-	1
bioMerieux Vidas, Mini Vidas	2	-	-	2
DiaSorin	1	-	-	1
DPC Immulite 2000	2	-	-	2
Roche cobas 6000 / e 601	2	-	-	2
Roche cobas e 411	2	-	-	2
Roche Modular Analytics	2	-	-	2
VITROS ECI	2	1	-	3
VITROS ECI - IgG	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	31	0.81	1.68	207.0	0.1	0.0 - 5.9
Abbott Architect	8	0.03	0.05	185.2	0.0	0.0 - 0.2
Specimen RU-12						
All Method	31	67.76	47.56	70.2	50.7	0.0 - 210.5
Abbott Architect	8	32.89	14.52	44.2	34.6	0.0 - 76.5
Specimen RU-13						
All Method	31	44.85	36.77	82.0	28.9	0.0 - 155.2
Abbott Architect	8	18.76	8.44	45.0	19.9	0.0 - 44.1
Specimen RU-14						
All Method	31	109.15	71.09	65.1	92.8	0.0 - 322.5
Abbott Architect	8	58.85	25.68	43.6	62.8	0.0 - 135.9
Specimen RU-15						
All Method	30	1.00	1.86	185.1	0.2	0.0 - 6.6
Abbott Architect	8	0.00	0.00	0.0	0.0	0.0 - 0.0

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	-	1	26	26	-	1
Abbott Architect	-	-	1	-	-	1	1	-	-
Acon Laboratories	-	-	2	-	-	2	2	-	-
bioMerieux	-	-	2	-	-	2	2	-	-
bioMerieux Vidas, Mini Vidas	-	-	1	-	-	1	1	-	-
Omega Diagnostics	-	-	1	-	-	1	1	-	-
SPINREACT	-	-	2	-	1	1	2	-	-
Standard Diagnostics	-	-	1	-	-	1	1	-	-
Wiener Lab	-	-	15	-	-	15	14	-	1

<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	22	2	3	25	-	2
Abbott Architect	1	-	-	1	-	-
Acon Laboratories	1	-	1	1	-	1
bioMerieux	2	-	-	2	-	-
bioMerieux Vidas, Mini Vidas	1	-	-	1	-	-
Omega Diagnostics	1	-	-	1	-	-
SPINREACT	1	1	-	2	-	-
Standard Diagnostics	1	-	-	1	-	-
Wiener Lab	12	1	2	14	-	1

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-13

ALL METHODS	2	2	11	3	-	-	1	-
bioMerieux	1	-	1	-	-	-	-	-
bioMerieux Vidas, Mini Vidas	-	-	1	-	-	-	-	-
Omega Diagnostics	-	-	-	-	-	-	1	-
Wiener Lab	1	2	7	3	-	-	-	-

Specimen SY-14

ALL METHODS	6	5	4	2	-	1	-	-
bioMerieux	1	-	1	-	-	-	-	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	-	-	-	-
Omega Diagnostics	-	-	-	-	-	1	-	-
Wiener Lab	4	4	2	2	-	-	-	-

Specimen SY-15

ALL METHODS	1	2	11	3	2	-	-	-
bioMerieux	1	-	1	-	-	-	-	-
bioMerieux Vidas, Mini Vidas	-	-	1	-	-	-	-	-
Omega Diagnostics	-	-	-	1	-	-	-	-
Wiener Lab	-	2	7	2	2	-	-	-

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	1	15	-	16	14	2
Abbott Architect	-	2	-	2	2	-
bioMerieux	-	2	-	2	2	-
Human	-	3	-	3	2	1
Omega Diagnostics	-	2	-	2	2	-
Serodia	-	3	-	3	3	-
SPINREACT	1	1	-	2	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	2	15	1
Abbott Architect	2	-	2	-
bioMerieux	2	-	2	-
Human	2	1	2	1
Omega Diagnostics	2	-	2	-
Serodia	3	-	3	-
SPINREACT	2	-	2	-

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	-	31	-	31	31	-
Abbott Architect	-	3	-	3	3	-
bioMerieux	-	1	-	1	1	-
bioMerieux Vidas, Mini Vidas	-	1	-	1	1	-
Human	-	2	-	2	2	-
Omega Diagnostics	-	2	-	2	2	-
Plasmatec	-	1	-	1	1	-
Roche cobas 6000 / c 501	-	1	-	1	1	-
Serodia	-	8	-	8	8	-
SPINREACT	-	1	-	1	1	-
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	31	-	31	-
Abbott Architect	3	-	3	-
bioMerieux	1	-	1	-
bioMerieux Vidas, Mini Vidas	1	-	1	-
Human	2	-	2	-
Omega Diagnostics	2	-	2	-
Plasmatec	1	-	1	-
Roche cobas 6000 / c 501	1	-	1	-
Serodia	8	-	8	-
SPINREACT	1	-	1	-
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	2	79	1	81	78	4
ASI	-	2	-	2	2	-
Becton Dickinson	-	3	-	3	3	-
bioMerieux	-	5	-	5	4	1
BioSystems	-	10	-	10	10	-
Fisher HealthCare Sure-Vue	-	1	-	1	1	-
Human	-	10	-	10	9	1
Immunostics Inc.	-	1	-	1	1	-
Omega Diagnostics	-	11	-	11	11	-
Plasmatec	-	8	-	8	8	-
SPINREACT	1	15	1	15	15	1
Wampole Impact RPR	-	3	-	3	3	-

	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	72	10	78	4
ASI	2	-	2	-
Becton Dickinson	2	1	3	-
bioMerieux	4	1	4	1
BioSystems	10	-	10	-
Fisher HealthCare Sure-Vue	-	1	1	-
Human	9	1	9	1
Immunostics Inc.	1	-	1	-
Omega Diagnostics	11	-	11	-
Plasmatec	5	3	8	-
SPINREACT	16	-	16	-
Wampole Impact RPR	3	-	3	-

Syphilis Serology—Quantitative: RPR (Titer)

<u>Specimen/Method</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>
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Specimen SY-13

ALL METHODS	14	29	5	1	1	-	1	-
Becton Dickinson	-	1	1	-	-	-	-	-
bioMerieux	2	1	-	-	-	-	-	-
BioSystems	2	6	-	-	-	-	-	-
Human	2	3	1	-	-	-	-	-
Immunostics Inc.	-	-	-	-	1	-	-	-
Omega Diagnostics	2	3	1	-	-	-	1	-
Plasmatec	2	5	-	-	-	-	-	-
SPINREACT	2	9	1	1	-	-	-	-

Specimen SY-14

ALL METHODS	30	13	2	1	-	1	-	1
Becton Dickinson	-	2	-	-	-	-	-	-
bioMerieux	2	1	-	-	-	-	-	-
BioSystems	6	2	-	-	-	-	-	-
Human	3	2	1	-	-	-	-	-
Immunostics Inc.	-	-	-	1	-	-	-	-
Omega Diagnostics	3	3	-	-	-	-	-	1
Plasmatec	4	1	-	-	-	-	-	-
SPINREACT	9	2	1	-	-	1	-	-

Specimen SY-15

ALL METHODS	17	28	4	1	-	-	-	1
Becton Dickinson	-	1	1	-	-	-	-	-
bioMerieux	2	1	-	-	-	-	-	-
BioSystems	4	4	-	-	-	-	-	-
Human	2	4	-	-	-	-	-	-
Immunostics Inc.	-	1	-	-	-	-	-	-
Omega Diagnostics	4	2	-	-	-	-	-	1
Plasmatec	1	6	-	-	-	-	-	-
SPINREACT	2	8	2	1	-	-	-	-

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	77	19	94	2	8	88
Abbott Architect	6	1	7	-	2	5
Abbott Architect - IgG	5	-	5	-	-	5
Abbott Architect - IgM	-	2	2	-	-	2
Abbott Architect - Total	19	-	19	-	1	18
Abbott AxSYM - Total	2	-	2	-	1	1
Bayer ADVIA Centaur	2	-	1	1	-	2
Bayer ADVIA Centaur - IgG	1	-	1	-	-	1
Bayer ADVIA Centaur - Total	4	3	7	-	-	7
Bio-Rad Evolis	-	1	1	-	-	1
bioMerieux Vidas - IgG	-	1	1	-	-	1
bioMerieux Vidas - Total	2	1	3	-	-	3
bioMerieux Vidas, Mini Vidas	-	1	1	-	-	1
Other Total Method	4	1	5	-	1	4
Roche cobas 6000 / e 601	7	-	7	-	-	7
Roche cobas e 411 - IgG	3	-	3	-	2	1
Roche Elecsys - IgG	5	-	5	-	-	5
Roche Elecsys - IgM	-	2	2	-	-	2
Roche Elecsys - Total	5	-	5	-	-	5
Roche Elecsys 1010 / 2010	2	-	2	-	-	2
Roche Modular Analytics	2	-	2	-	-	2
VITROS ECI	1	-	1	-	-	1
VITROS ECI - IgG	1	-	1	-	-	1
VITROS ECI - IgM	1	4	5	-	-	5
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	89	7	91	5
Abbott Architect	7	-	7	-
Abbott Architect - IgG	5	-	5	-
Abbott Architect - IgM	2	-	2	-
Abbott Architect - Total	19	-	19	-
Abbott AxSYM - Total	2	-	2	-
Bayer ADVIA Centaur	-	2	2	-
Bayer ADVIA Centaur - IgG	1	-	1	-
Bayer ADVIA Centaur - Total	7	-	7	-
Bio-Rad Evolis	1	-	1	-
bioMerieux Vidas - IgG	1	-	1	-
bioMerieux Vidas - Total	2	1	2	1
bioMerieux Vidas, Mini Vidas	1	-	1	-
Other Total Method	5	-	4	1
Roche cobas 6000 / e 601	7	-	7	-
Roche cobas e 411 - IgG	3	-	3	-
Roche Elecsys - IgG	5	-	5	-
Roche Elecsys - IgM	-	2	-	2
Roche Elecsys - Total	5	-	5	-
Roche Elecsys 1010 / 2010	2	-	2	-
Roche Modular Analytics	2	-	2	-
VITROS ECI	1	-	1	-
VITROS ECI - IgG	1	-	1	-
VITROS ECI - IgM	3	2	4	1
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	16	201	212	5	217	-
Abbott Architect	1	28	29	-	29	-
Abbott Architect - IgG	1	1	1	1	2	-
Abbott Architect - Total	-	28	28	-	28	-
Abbott AxSYM - Total	-	1	1	-	1	-
Bayer ADVIA Centaur	1	13	14	-	14	-
Bayer ADVIA Centaur - Total	-	9	9	-	9	-
Beckman ACCESS / 2 / DxI	-	1	1	-	1	-
Bio-Rad Evolis	-	1	1	-	1	-
bioMerieux	-	1	1	-	1	-
bioMerieux Vidas - IgG	-	2	2	-	2	-
bioMerieux Vidas - Total	-	8	7	1	8	-
bioMerieux Vidas, Mini Vidas	-	4	4	-	4	-
Human	-	1	1	-	1	-
Other IgG Method	-	1	1	-	1	-
Other Total Method	-	8	7	1	8	-
Roche cobas 6000 / e 601	-	19	19	-	19	-
Roche cobas e 411	-	19	19	-	19	-
Roche Elecsys - Total	-	24	24	-	24	-
Roche Elecsys 1010 / 2010	-	6	6	-	6	-
Roche Modular Analytics	-	10	10	-	10	-
Standard Diagnostics	-	2	1	1	2	-
VITROS 5600	1	-	1	-	1	-
VITROS ECI	5	2	7	-	7	-
VITROS ECI - IgG	-	1	1	-	1	-
VITROS ECI - Total	6	-	6	-	6	-

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	212	5	213	4
Abbott Architect	29	-	29	-
Abbott Architect - IgG	1	1	2	-
Abbott Architect - Total	28	-	28	-
Abbott AxSYM - Total	1	-	1	-
Bayer ADVIA Centaur	14	-	14	-
Bayer ADVIA Centaur - Total	9	-	9	-
Beckman ACCESS / 2 / DxI	1	-	1	-
Bio-Rad Evolis	1	-	1	-
bioMerieux	1	-	1	-
bioMerieux Vidas - IgG	2	-	2	-
bioMerieux Vidas - Total	7	1	7	1
bioMerieux Vidas, Mini Vidas	4	-	4	-
Human	1	-	1	-
Other IgG Method	1	-	1	-
Other Total Method	7	1	7	1
Roche cobas 6000 / e 601	19	-	19	-
Roche cobas e 411	19	-	19	-
Roche Elecsys - Total	24	-	24	-
Roche Elecsys 1010 / 2010	6	-	6	-
Roche Modular Analytics	10	-	10	-
Standard Diagnostics	1	1	1	1
VITROS 5600	1	-	1	-
VITROS ECI	7	-	7	-
VITROS ECI - IgG	1	-	1	-
VITROS ECI - Total	6	-	6	-

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	17	100	83	34	81	36
Abbott Architect - IgG	16	2	17	1	17	1
Abbott Architect - IgM	-	5	-	5	-	5
Abbott Architect - Total	1	1	2	-	2	-
Abbott AxSYM - IgG	-	1	1	-	1	-
Abbott AxSYM - IgM	-	1	-	1	-	1
Bayer ADVIA Centaur	-	2	2	-	2	-
Bayer ADVIA Centaur - IgG	-	1	1	-	1	-
Bayer ADVIA Centaur - IgM	-	4	1	3	1	3
Bayer ADVIA Centaur - Total	-	12	12	-	12	-
bioMerieux Vidas - IgG	-	2	-	2	-	2
bioMerieux Vidas - IgM	-	3	-	3	-	3
bioMerieux Vidas - Total	-	5	5	-	5	-
Other IgG Method	-	2	2	-	1	1
Other IgM method	-	3	-	3	-	3
Other Total Method	-	2	1	1	1	1
Roche cobas 6000 / e 601	-	7	7	-	7	-
Roche cobas 6000/e601 - IgM	-	3	-	3	-	3
Roche cobas e 411 - IgG	-	2	2	-	2	-
Roche cobas e 411 - Total	-	4	4	-	4	-
Roche Elecsys - IgG	-	8	8	-	8	-
Roche Elecsys - IgM	-	11	1	10	-	11
Roche Elecsys - Total	-	4	4	-	4	-
Roche Modular Analytics	-	5	5	-	5	-
VITROS ECI	-	1	1	-	1	-
VITROS ECI - IgG	-	1	1	-	1	-
VITROS ECI - IgM	-	3	1	2	1	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	117	-	82	35
Abbott Architect - IgG	18	-	17	1
Abbott Architect - IgM	5	-	-	5
Abbott Architect - Total	2	-	2	-
Abbott AxSYM - IgG	1	-	1	-
Abbott AxSYM - IgM	1	-	-	1
Bayer ADVIA Centaur	2	-	2	-
Bayer ADVIA Centaur - IgG	1	-	1	-
Bayer ADVIA Centaur - IgM	4	-	1	3
Bayer ADVIA Centaur - Total	12	-	12	-
bioMerieux Vidas - IgG	2	-	-	2
bioMerieux Vidas - IgM	3	-	-	3
bioMerieux Vidas - Total	5	-	5	-
Other IgG Method	2	-	2	-
Other IgM method	3	-	-	3
Other Total Method	2	-	1	1
Roche cobas 6000 / e 601	7	-	7	-
Roche cobas 6000/e601 - IgM	3	-	-	3
Roche cobas e 411 - IgG	2	-	2	-
Roche cobas e 411 - Total	4	-	4	-
Roche Elecsys - IgG	8	-	8	-
Roche Elecsys - IgM	11	-	-	11
Roche Elecsys - Total	4	-	4	-
Roche Modular Analytics	5	-	5	-
VITROS ECI	1	-	1	-
VITROS ECI - IgG	1	-	1	-
VITROS ECI - IgM	3	-	1	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	1	60	60	1	2	59
Abbott Architect	-	9	9	-	-	9
Abbott Architect - IgG	-	1	1	-	-	1
Abbott Architect - Total	-	8	8	-	-	8
Abbott AxSYM	-	2	2	-	-	2
Bayer ADVIA Centaur	-	4	4	-	1	3
Bayer ADVIA Centaur - IgG	-	1	1	-	-	1
Bayer ADVIA Centaur - Total	1	3	4	-	-	4
bioMerieux Vidas - Total	-	1	1	-	-	1
bioMerieux Vidas, Mini Vidas	-	1	1	-	-	1
DiaSorin - Total	-	1	1	-	-	1
Other IgG Method	-	1	1	-	-	1
Other Total Method	-	2	2	-	-	2
Roche cobas 6000 / e 601	-	5	5	-	-	5
Roche cobas e 411	-	2	2	-	-	2
Roche Elecsys - Total	-	4	4	-	1	3
Roche Modular Analytics	-	5	5	-	-	5
VITROS ECI	-	4	4	-	-	4
VITROS ECI - IgG	-	1	1	-	-	1
VITROS ECI - Total	-	1	1	-	-	1

Viral Markers – HBeAg (cont'd)

<u>Method</u>	Specimen VM-14		Specimen VM-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	58	2	58	2
Abbott Architect	9	-	9	-
Abbott Architect - IgG	1	-	1	-
Abbott Architect - Total	8	-	8	-
Abbott AxSYM	2	-	2	-
Bayer ADVIA Centaur	4	-	4	-
Bayer ADVIA Centaur - IgG	1	-	1	-
Bayer ADVIA Centaur - Total	4	-	4	-
bioMerieux Vidas - Total	1	-	1	-
bioMerieux Vidas, Mini Vidas	1	-	1	-
DiaSorin - Total	1	-	1	-
Other IgG Method	1	-	1	-
Other Total Method	1	1	1	1
Roche cobas 6000 / e 601	5	-	5	-
Roche cobas e 411	2	-	2	-
Roche Elecsys - Total	4	-	4	-
Roche Modular Analytics	4	-	4	-
VITROS ECI	4	-	4	-
VITROS ECI - IgG	1	-	1	-
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	158	3	3	158	9	152
Abbott Architect	16	-	-	16	-	16
Abbott Architect - IgG	3	-	-	3	-	3
Abbott Architect - Total	19	-	-	19	-	19
Abbott AxSYM	1	-	-	1	-	1
Abbott AxSYM - Total	1	-	-	1	-	1
Bayer ADVIA Centaur	12	2	2	12	1	13
Bayer ADVIA Centaur - IgG	1	-	-	1	-	1
Bayer ADVIA Centaur - Total	9	-	-	9	-	9
bioMerieux Vidas - IgG	2	-	-	2	-	2
bioMerieux Vidas - Total	4	-	-	4	-	4
Other IgG Method	1	-	-	1	-	1
Other Total Method	5	-	-	5	-	5
Roche cobas 6000 / e 601	19	-	-	19	2	17
Roche cobas 6000/e601 - IgG	1	-	-	1	-	1
Roche cobas e 411	14	-	-	14	1	13
Roche Elecsys - IgG	1	-	-	1	-	1
Roche Elecsys - Total	12	-	-	12	1	11
Roche Elecsys 1010 / 2010	5	-	-	5	-	5
Roche Modular Analytics	13	-	-	13	2	11
VITROS 5600	1	-	-	1	-	1
VITROS ECI	5	-	-	5	-	5
VITROS ECI - IgG	1	-	-	1	-	1
VITROS ECI - Total	6	-	-	6	1	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	3	158	2	159
Abbott Architect	-	16	-	16
Abbott Architect - IgG	-	3	-	3
Abbott Architect - Total	-	19	-	19
Abbott AxSYM	-	1	-	1
Abbott AxSYM - Total	-	1	-	1
Bayer ADVIA Centaur	1	13	1	13
Bayer ADVIA Centaur - IgG	-	1	-	1
Bayer ADVIA Centaur - Total	-	9	-	9
bioMerieux Vidas - IgG	-	2	-	2
bioMerieux Vidas - Total	-	4	-	4
Other IgG Method	-	1	-	1
Other Total Method	-	5	-	5
Roche cobas 6000 / e 601	-	19	-	19
Roche cobas 6000/e601 - IgG	-	1	-	1
Roche cobas e 411	-	14	-	14
Roche Elecsys - IgG	-	1	-	1
Roche Elecsys - Total	-	12	-	12
Roche Elecsys 1010 / 2010	-	5	-	5
Roche Modular Analytics	1	12	-	13
VITROS 5600	-	1	-	1
VITROS ECI	-	5	-	5
VITROS ECI - IgG	-	1	-	1
VITROS ECI - Total	-	6	-	6

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	4	215	217	2	205	14
Abbott Architect	-	29	29	-	29	-
Abbott Architect - IgM	-	1	1	-	1	-
Abbott Architect - Total	-	27	27	-	26	1
Abbott AxSYM	-	1	1	-	1	-
Bayer ADVIA Centaur	1	16	16	1	16	1
Bayer ADVIA Centaur - IgM	-	1	1	-	1	-
Bayer ADVIA Centaur - Total	-	6	6	-	6	-
Beckman ACCESS / 2 / Dxl	-	1	1	-	1	-
Bio-Rad Evolis	-	1	1	-	1	-
bioMerieux	-	1	1	-	1	-
bioMerieux Vidas - IgG	-	1	1	-	1	-
bioMerieux Vidas - Total	-	4	4	-	3	1
bioMerieux Vidas, Mini Vidas	-	6	6	-	6	-
Human	-	1	1	-	1	-
Other IgG Method	-	1	1	-	1	-
Other Total Method	-	8	8	-	4	4
Roche cobas 6000 / e 601	1	20	21	-	21	-
Roche cobas e 411	-	25	25	-	25	-
Roche Elecsys - Total	1	21	22	-	21	1
Roche Elecsys 1010 / 2010	-	5	5	-	5	-
Roche Modular Analytics	-	12	12	-	12	-
Standard Diagnostics	-	1	1	-	-	1
VITROS 5600	-	1	1	-	1	-
VITROS ECI	-	6	6	-	6	-
VITROS ECI - IgG	-	1	1	-	1	-
VITROS ECI - Total	-	6	6	-	6	-

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	216	3	217	2
Abbott Architect	29	-	29	-
Abbott Architect - IgM	1	-	1	-
Abbott Architect - Total	26	1	27	-
Abbott AxSYM	1	-	1	-
Bayer ADVIA Centaur	16	1	16	1
Bayer ADVIA Centaur - IgM	1	-	1	-
Bayer ADVIA Centaur - Total	6	-	6	-
Beckman ACCESS / 2 / DxI	1	-	1	-
Bio-Rad Evolis	1	-	1	-
bioMerieux	1	-	1	-
bioMerieux Vidas - IgG	1	-	1	-
bioMerieux Vidas - Total	4	-	4	-
bioMerieux Vidas, Mini Vidas	6	-	6	-
Human	1	-	1	-
Other IgG Method	1	-	1	-
Other Total Method	8	-	8	-
Roche cobas 6000 / e 601	21	-	21	-
Roche cobas e 411	25	-	25	-
Roche Elecsys - Total	22	-	22	-
Roche Elecsys 1010 / 2010	5	-	5	-
Roche Modular Analytics	12	-	12	-
Standard Diagnostics	1	-	1	-
VITROS 5600	1	-	1	-
VITROS ECI	6	-	6	-
VITROS ECI - IgG	1	-	1	-
VITROS ECI - Total	6	-	6	-

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	195	2	19	178	2	195
Abbott Architect	23	-	-	23	-	23
Abbott Architect - IgG	3	-	-	3	-	3
Abbott Architect - Total	30	1	-	31	-	31
Abbott AxSYM - Total	1	-	-	1	-	1
Acon Laboratories	1	-	-	1	-	1
Bayer ADVIA Centaur	16	-	-	16	1	15
Bayer ADVIA Centaur - IgG	2	-	-	2	-	2
Bayer ADVIA Centaur - Total	8	-	-	8	-	8
Beckman ACCESS / 2 / DxI	1	-	-	1	-	1
Bio-Rad Evolis	1	-	-	1	-	1
bioMerieux	1	-	-	1	-	1
bioMerieux Vidas - Total	1	-	1	-	-	1
bioMerieux Vidas, Mini Vidas	3	-	2	1	-	3
Other IgG Method	4	1	1	4	-	5
Other Total Method	9	-	1	8	-	9
Roche cobas 6000 / e 601	15	-	-	15	-	15
Roche cobas e 411	16	-	-	16	-	16
Roche Elecsys - Total	14	-	-	14	-	14
Roche Elecsys 1010 / 2010	3	-	-	3	-	3
Roche Modular Analytics	11	-	-	11	-	11
Standard Diagnostics	1	-	-	1	-	1
VITROS 5600	1	-	1	-	-	1
VITROS ECI	5	-	3	2	-	5
VITROS ECI - IgG	2	-	2	-	-	2
VITROS ECI - Total	8	-	7	1	1	7

Viral Markers – HCV (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	19	178	194	3
Abbott Architect	-	23	23	-
Abbott Architect - IgG	-	3	3	-
Abbott Architect - Total	1	30	31	-
Abbott AxSYM - Total	-	1	1	-
Acon Laboratories	-	1	1	-
Bayer ADVIA Centaur	-	16	16	-
Bayer ADVIA Centaur - IgG	-	2	2	-
Bayer ADVIA Centaur - Total	-	8	8	-
Beckman ACCESS / 2 / DxI	-	1	1	-
Bio-Rad Evolis	-	1	1	-
bioMerieux	-	1	1	-
bioMerieux Vidas - Total	1	-	1	-
bioMerieux Vidas, Mini Vidas	2	1	3	-
Other IgG Method	-	5	4	1
Other Total Method	1	8	8	1
Roche cobas 6000 / e 601	-	15	14	1
Roche cobas e 411	-	16	16	-
Roche Elecsys - Total	-	14	14	-
Roche Elecsys 1010 / 2010	-	3	3	-
Roche Modular Analytics	-	11	11	-
Standard Diagnostics	-	1	1	-
VITROS 5600	1	-	1	-
VITROS ECI	4	1	5	-
VITROS ECI - IgG	2	-	2	-
VITROS ECI - Total	7	1	8	-

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	23	1	24	-
Abbott Architect - IgG	4	-	4	-
Abbott Architect - IgM	2	1	3	-
Bayer ADVIA Centaur - IgG	4	-	4	-
bioMerieux Vidas - IgG	3	-	3	-
DPC Immulite 2000	1	-	1	-
Other IgG Method	1	-	1	-
Roche cobas 6000/e601 - IgG	2	-	2	-
Roche cobas 6000/e601 - IgM	1	-	1	-
Roche cobas e 411 - IgG	1	-	1	-
Roche cobas e 411 - IgM	1	-	1	-
Roche Elecsys - IgM	1	-	1	-
VITROS ECI - IgG	1	-	1	-
VITROS ECI - 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	10	10	7
Abbott Architect - IgG	-	2	2	-
Abbott Architect - IgM	4	-	-	4
Abbott AxSYM - IgG	-	1	1	-
bioMerieux Vidas - IgG	-	2	2	-
DPC Immulite 2000	-	1	1	-
Other IgG Method	-	2	2	-
Roche cobas 6000/e601 - IgG	-	1	1	-
Roche cobas e 411 - IgM	1	-	-	1
Roche Elecsys - IgM	1	-	-	1
VITROS ECI - IgG	-	1	1	-
VITROS ECI - IgM	1	-	-	1

Toxoplasma gondii Antibody —Quantitative (IU/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
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Specimen TOX-5

All Method	22	307.0	226.8	73.9	225	0 - 761
Abbott Architect - IgG	9	196.3	58.7	29.9	200	78 - 314

Specimen TOX-6

All Method	23	251.5	185.9	73.9	206	0 - 624
Abbott Architect - IgG	9	207.0	170.1	82.2	150	0 - 548

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	15	2.3	1.4	62.0	3	0 - 6
Abbott Architect - IgG	7	8.0	12.8	160.1	3	0 - 34

Specimen CMV-6

All Method	15	31.5	17.4	55.4	32	0 - 67
Abbott Architect - IgG	7	82.8	121.9	147.2	36	0 - 327

CK-MB - Quantitative (U/L)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen CK-11						
All Method	5	39.62	1.06	2.7	39.8	36.4 - 42.9
Specimen CK-12						
All Method	5	6.86	0.36	5.2	6.9	5.7 - 8.0
Specimen CK-13						
All Method	5	72.28	2.32	3.2	73.6	65.3 - 79.3
Specimen CK-14						
All Method	5	22.98	0.70	3.0	23.2	20.8 - 25.1
Specimen CK-15						
All Method	5	14.42	0.61	4.2	14.2	12.6 - 16.3

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