

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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



Total Commitment to Education and Service
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**International Data Supplement
MLE – M3**

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2011 Evaluation Criteria

The evaluation criteria used in the 2011 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 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.

Blood Bank	95% Consensus
Antimicrobial Susceptibility Testing	80% 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 pages 39-40 under the heading "Acceptable Ranges for Quantitative Results."

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

BLOOD BANK

ABO GROUP

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-11	Group B	113	99.12%	Acceptable
	Group AB	1	0.88%	
BB-12	Group O	113	99.12%	Acceptable
	Group B	1	0.88%	
BB-13	Group A	114	100%	Acceptable
BB-14	Group B	113	99.12%	Acceptable
	Group O	1	0.88%	
BB-15	GroupAB	114	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	114	100%	Acceptable
BB-12	Rh Negative	114	100%	Acceptable
BB-13	Rh Negative	113	99.12%	Acceptable
	Rh Positive	1	0.88%	
BB-14	Rh Negative	114	100%	Acceptable
BB-15	Rh Positive	114	100%	Acceptable

ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	Unexpected antibody detected	78	95.12%	Acceptable
	No unexpected antibody detected	4	4.88%	
AB-12	No unexpected antibody detected	82	100%	Acceptable
AB-13	No unexpected antibody detected	81	98.78%	Acceptable
	Unexpected antibody detected	1	1.22%	
AB-14	Unexpected antibody detected	81	98.78%	Acceptable
	No unexpected antibody detected	1	1.22%	
AB-15	Unexpected antibody detected	82	100%	Acceptable

BLOOD BANK

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	Anti-K	31	96.88%	Acceptable
	Unable to identify, referred	1	3.13%	Acceptable
AB-12	No antibody detected	31	96.88%	Acceptable
	Anti-Lu(a)	1	3.13%	
AB-13	No antibody detected	31	96.88%	Acceptable
	Anti-Lu(a)	1	3.13%	
AB-14	Anti-c	32	100%	Acceptable
AB-15	Anti-S	30	93.75%	Acceptable
	Unable to identify, referred	1	3.13%	Acceptable
	Anti-Le(b)	1	3.13%	

COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-11	Compatible	84	97.67%	Acceptable
	Not Compatible	2	2.33%	
AB-12	Compatible	85	98.84%	Acceptable
	Not Compatible	1	1.16%	
AB-13	Compatible	85	98.84%	Acceptable
	Not Compatible	1	1.16%	
AB-14	Not Compatible	85	98.84%	Acceptable
	Compatible	1	1.16%	
AB-15	Not Compatible	83	96.51%	Acceptable
	Compatible	3	3.49%	

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	162	11.90	1.08	9.1	11.7	10.1 - 13.7	161	15.05	1.55	10.3	14.6	12.7 - 17.4
Dade Innovin												
Sysmex CA-500/560	28	11.13	0.19	1.7	11.1	9.4 - 12.8	27	13.96	0.23	1.6	13.9	11.8 - 16.1
All Coagulation Instruments	31	11.11	0.23	2.1	11.1	9.4 - 12.8	32	13.93	0.33	2.3	13.9	11.8 - 16.1
Dade Thromborel S												
Sysmex CA-500/560	12	10.79	0.87	8.1	10.5	9.1 - 12.5	11	13.87	1.20	8.6	13.6	11.7 - 16.0
All Coagulation Instruments	13	10.82	0.84	7.8	10.5	9.1 - 12.5	12	13.93	1.16	8.3	13.7	11.8 - 16.1
Diag Stago STA Neoplastine CI+												
RAL Clot-SP	11	13.37	0.34	2.5	13.3	11.3 - 15.4	11	16.74	0.34	2.0	16.7	14.2 - 19.3
All Coagulation Instruments	15	13.31	0.53	4.0	13.3	11.3 - 15.4	14	16.68	0.41	2.4	16.7	14.1 - 19.2
HUMAN HemoStat Thromboplastin - SI												
bioMerieux Thrombolyzer Compact X/XR	8	12.41	0.56	4.5	12.8	10.5 - 14.3	8	15.59	0.75	4.8	15.7	13.2 - 18.0
All Coagulation Instruments	12	12.55	1.02	8.1	12.4	10.6 - 14.5	12	15.61	0.99	6.4	15.7	13.2 - 18.0
IL TEST PT Fibrinogen												
IL ACL, all models	23	11.76	0.42	3.6	11.8	9.9 - 13.6	23	14.80	0.56	3.8	14.8	12.5 - 17.1
IL TEST PT-FIB HS PLUS												
IL ACL, all models	26	13.21	0.39	3.0	13.2	11.2 - 15.2	26	16.88	0.51	3.0	16.9	14.3 - 19.5
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	10.82	0.42	3.9	10.7	9.1 - 12.5	5	13.58	0.70	5.2	13.3	11.5 - 15.7
TriniCLOT PT Excel												
OTC Coag-A-Mate XM	10	11.11	0.34	3.0	11.0	9.4 - 12.8	10	13.45	0.31	2.3	13.4	11.4 - 15.5
All Coagulation Instruments	16	11.40	0.63	5.5	11.2	9.6 - 13.2	15	13.59	0.39	2.8	13.6	11.5 - 15.7

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	162	30.10	6.80	22.6	28.8	25.5 - 34.7	162	43.03	11.99	27.9	40.5	36.5 - 49.5
Dade Innovin												
Sysmex CA-500/560	28	27.86	1.09	3.9	28.0	23.6 - 32.1	27	39.27	1.50	3.8	39.4	33.3 - 45.2
All Coagulation Instruments	32	27.78	1.18	4.3	27.9	23.6 - 32.0	32	39.17	2.11	5.4	39.4	33.2 - 45.1
Dade Thromborel S												
Sysmex CA-500/560	12	36.20	7.55	20.9	33.8	30.7 - 41.7	12	50.35	6.48	12.9	49.7	42.7 - 58.0
All Coagulation Instruments	13	36.12	7.24	20.0	33.8	30.7 - 41.6	13	51.86	8.25	15.9	49.7	44.0 - 59.7
Diag Stago STA Neoplastine CI+												
RAL Clot-SP	11	37.03	1.03	2.8	36.8	31.4 - 42.6	11	55.52	2.02	3.6	54.8	47.1 - 63.9
All Coagulation Instruments	15	37.08	1.80	4.9	36.7	31.5 - 42.7	14	55.54	3.11	5.6	54.8	47.2 - 63.9
HUMAN HemoStat Thromboplastin - SI												
bioMerieux Thrombolyzer Compact X/XR	8	38.90	2.76	7.1	38.7	33.0 - 44.8	7	62.04	5.33	8.6	61.8	52.7 - 71.4
All Coagulation Instruments	12	37.68	5.63	15.0	38.7	32.0 - 43.4	11	59.11	11.23	19.0	61.8	50.2 - 68.0
IL TEST PT Fibrinogen												
IL ACL, all models	23	22.36	1.01	4.5	22.3	19.0 - 25.8	23	29.69	1.57	5.3	29.3	25.2 - 34.2
IL TEST PT-FIB HS PLUS												
IL ACL, all models	25	37.56	1.26	3.4	37.7	31.9 - 43.2	26	54.99	2.96	5.4	55.7	46.7 - 63.3
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	21.52	0.54	2.5	21.4	18.2 - 24.8	5	29.02	0.88	3.0	29.0	24.6 - 33.4
TriniCLOT PT Excel												
OTC Coag-A-Mate XM	10	21.35	0.80	3.7	21.3	18.1 - 24.6	10	28.10	1.23	4.4	28.2	23.8 - 32.4
All Coagulation Instruments	16	21.53	0.77	3.6	21.6	18.3 - 24.8	16	27.99	1.30	4.6	28.1	23.7 - 32.2

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	160	12.32	1.29	10.5	11.9	10.4 - 14.2
Dade Innovin						
Sysmex CA-500/560	27	11.22	0.38	3.4	11.2	9.5 - 13.0
All Coagulation Instruments	31	11.17	0.46	4.1	11.2	9.4 - 12.9
Dade Thromborel S						
Sysmex CA-500/560	10	12.22	1.22	10.0	11.8	10.3 - 14.1
All Coagulation Instruments	11	12.25	1.16	9.5	11.8	10.4 - 14.1
Diag Stago STA Neoplastine CI+						
RAL Clot-SP	11	13.67	0.38	2.8	13.6	11.6 - 15.8
All Coagulation Instruments	15	13.73	0.59	4.3	13.6	11.6 - 15.8
HUMAN HemoStat Thromboplastin - SI						
bioMerieux Thrombolyzer Compact X/XR	8	13.50	0.53	3.9	13.5	11.4 - 15.6
All Coagulation Instruments	12	13.63	1.20	8.8	13.7	11.5 - 15.7
IL TEST PT Fibrinogen						
IL ACL, all models	23	11.74	0.37	3.2	11.8	9.9 - 13.6
IL TEST PT-FIB HS PLUS						
IL ACL, all models	26	13.68	0.35	2.5	13.7	11.6 - 15.8
PH/CMS Thromboplastin-D						
All Coagulation Instruments	5	10.74	0.54	5.0	10.7	9.1 - 12.4
TriniCLOT PT Excel						
OTC Coag-A-Mate XM	10	11.00	0.16	1.5	11.0	9.3 - 12.7
All Coagulation Instruments	16	11.25	0.59	5.3	11.0	9.5 - 13.0

PROTHROMBIN TIME-INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-11						Specimen CG-12					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	159	0.99	0.09	9.1	1.0	0.7 - 1.3	158	1.32	0.13	10.0	1.3	0.9 - 1.8
Dade Innovin												
Sysmex CA-500/560	29	1.09	0.04	4.1	1.1	0.9 - 1.3	28	1.36	0.05	3.6	1.4	1.2 - 1.6
All Coagulation Instruments	32	1.09	0.04	3.9	1.1	0.9 - 1.3	32	1.36	0.06	4.1	1.4	1.1 - 1.6
Dade Thromborel S												
Sysmex CA-500/560	11	0.94	0.09	9.9	0.9	0.6 - 1.3	10	1.17	0.14	12.1	1.1	0.7 - 1.6
All Coagulation Instruments	13	0.94	0.10	11.1	0.9	0.6 - 1.3	12	1.18	0.14	11.5	1.1	0.7 - 1.6
Diag Stago STA Neoplastine CI+												
RAL Clot-SP	11	1.02	0.06	5.9	1.0	0.8 - 1.2	11	1.35	0.05	3.9	1.3	1.1 - 1.6
All Coagulation Instruments	15	1.02	0.09	8.4	1.0	0.7 - 1.3	14	1.34	0.06	4.7	1.3	1.1 - 1.6
HUMAN HemoStat Thromboplastin - SI												
bioMerieux Thrombolyzer Compact												
X/XR	8	0.89	0.10	11.2	0.9	0.5 - 1.2	8	1.20	0.13	10.9	1.3	0.8 - 1.6
All Coagulation Instruments	10	0.92	0.11	12.3	0.9	0.5 - 1.3	10	1.25	0.16	12.6	1.3	0.7 - 1.8
IL TEST PT Fibrinogen												
IL ACL, all models	23	0.97	0.05	5.6	1.0	0.8 - 1.2	23	1.47	0.10	6.7	1.5	1.1 - 1.8
IL TEST PT-FIB HS PLUS												
IL ACL, all models	26	0.91	0.08	8.8	0.9	0.6 - 1.2	26	1.22	0.11	8.7	1.2	0.9 - 1.6
PH/CMS Thromboplastin-D												
All Coagulation Instruments	6	1.00	0.00	0.0	1.0	1.0 - 1.0	6	1.47	0.14	9.3	1.5	1.0 - 1.9
TriniCLOT PT Excel												
OTC Coag-A-Mate XM	10	0.97	0.05	5.0	1.0	0.8 - 1.2	10	1.30	0.07	5.1	1.3	1.1 - 1.5
All Coagulation Instruments	16	0.98	0.07	6.7	1.0	0.7 - 1.2	16	1.32	0.08	5.7	1.3	1.0 - 1.6

PROTHROMBIN TIME-INTERNATIONAL NORMALIZED RATIO (INR)

<u>Reagent/Instrument</u>	Specimen CG-13						Specimen CG-14					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	157	3.03	0.39	12.8	3.0	1.8 - 4.2	156	4.72	0.89	18.9	4.7	2.0 - 7.4
Dade Innovin												
Sysmex CA-500/560	28	2.74	0.13	4.9	2.8	2.3 - 3.2	28	3.89	0.20	5.2	3.9	3.2 - 4.5
All Coagulation Instruments	32	2.73	0.15	5.4	2.8	2.2 - 3.2	32	3.89	0.24	6.3	3.9	3.1 - 4.7
Dade Thromborel S												
Sysmex CA-500/560	11	3.02	0.64	21.1	2.8	1.1 - 5.0	11	4.17	0.62	14.9	4.1	2.3 - 6.1
All Coagulation Instruments	13	2.98	0.59	19.8	2.8	1.2 - 4.8	12	3.83	1.34	35.1	4.1	0.0 - 7.9
Diag Stago STA Neoplastine CI+												
RAL Clot-SP	11	3.47	0.18	5.2	3.5	2.9 - 4.1	11	5.85	0.27	4.7	5.8	5.0 - 6.7
All Coagulation Instruments	14	3.46	0.26	7.6	3.5	2.6 - 4.3	15	5.55	0.85	15.3	5.8	3.0 - 8.2
HUMAN HemoStat Thromboplastin - SI												
bioMerieux Thrombolyzer Compact												
X/XR	8	3.66	0.60	16.4	3.9	1.8 - 5.5	7	6.40	1.36	21.3	6.9	2.3 - 10.5
All Coagulation Instruments	10	3.63	0.59	16.1	3.9	1.8 - 5.4	9	6.27	1.31	20.9	6.8	2.3 - 10.2
IL TEST PT Fibrinogen												
IL ACL, all models	23	3.03	0.18	5.9	3.0	2.4 - 3.6	23	4.97	0.37	7.4	5.0	3.8 - 6.1
IL TEST PT-FIB HS PLUS												
IL ACL, all models	26	3.08	0.33	10.6	3.2	2.0 - 4.1	26	4.83	0.55	11.4	5.0	3.1 - 6.5
PH/CMS Thromboplastin-D												
All Coagulation Instruments	5	3.46	0.30	8.6	3.5	2.5 - 4.4	5	6.16	0.54	8.7	6.1	4.5 - 7.8
TriniCLOT PT Excel												
OTC Coag-A-Mate XM	10	2.91	0.27	9.2	2.9	2.1 - 3.8	10	4.61	0.43	9.3	4.8	3.3 - 5.9
All Coagulation Instruments	16	2.88	0.26	9.1	2.9	2.0 - 3.7	16	4.51	0.44	9.7	4.6	3.1 - 5.9

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	160	1.02	0.10	9.4	1.0	0.7 - 1.4
Dade Innovin						
Sysmex CA-500/560	29	1.10	0.05	4.5	1.1	0.9 - 1.3
All Coagulation Instruments	33	1.10	0.05	4.8	1.1	0.9 - 1.3
Dade Thromborel S						
Sysmex CA-500/560	11	1.15	0.40	34.6	1.0	0.0 - 2.4
All Coagulation Instruments	12	1.03	0.11	10.3	1.0	0.7 - 1.4
Diag Stago STA Neoplastine CI+						
RAL Clot-SP	11	1.03	0.06	6.3	1.0	0.8 - 1.3
All Coagulation Instruments	15	1.05	0.09	8.7	1.0	0.7 - 1.4
HUMAN HemoStat Thromboplastin - SI						
bioMerieux Thrombolyzer Compact						
X/XR	8	1.03	0.12	11.4	1.1	0.6 - 1.4
All Coagulation Instruments	10	1.05	0.14	12.9	1.1	0.6 - 1.5
IL TEST PT Fibrinogen						
IL ACL, all models	23	0.97	0.06	6.4	1.0	0.7 - 1.2
IL TEST PT-FIB HS PLUS						
IL ACL, all models	26	0.96	0.09	9.8	1.0	0.6 - 1.3
PH/CMS Thromboplastin-D						
All Coagulation Instruments	6	0.97	0.05	5.3	1.0	0.8 - 1.2
TriniCLOT PT Excel						
OTC Coag-A-Mate XM	10	0.93	0.05	5.2	0.9	0.7 - 1.1
All Coagulation Instruments	16	0.94	0.07	7.7	0.9	0.7 - 1.2

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

Specimen CG-11							Specimen CG-12					
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	101	27.2	2.7	9.9	27	23 - 32	103	39.5	4.1	10.5	40	33 - 46
Dade Actin												
Sysmex CA-500/560	12	27.4	2.7	10.0	27	23 - 32	12	41.2	2.9	7.0	41	34 - 48
All Coagulation Instruments	13	28.0	3.4	12.0	27	23 - 33	13	41.2	2.8	6.7	41	34 - 48
Dade Actin FSL												
Sysmex CA-500/560	19	28.6	0.7	2.4	29	24 - 33	18	33.2	1.2	3.7	33	28 - 39
All Coagulation Instruments	20	28.7	0.7	2.6	29	24 - 34	19	33.3	1.2	3.8	33	28 - 39
HUMAN HemoStat aPTT - EL												
bioMerieux Thrombolyzer Compact												
X/XR	7	28.9	1.6	5.5	28	24 - 34	7	39.7	2.1	5.2	40	33 - 46
All Coagulation Instruments	10	29.2	2.0	6.8	29	24 - 34	10	38.4	3.1	8.1	40	32 - 45
IL TEST APTT-SP												
IL ACL, all models	37	25.0	1.1	4.5	25	21 - 29	36	40.5	1.9	4.6	40	34 - 47
All Coagulation Instruments	38	25.1	1.2	4.8	25	21 - 29	38	40.9	2.5	6.1	41	34 - 48

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	96	59.1	9.7	16.5	55	50 - 68	99	77.6	15.8	20.3	72	65 - 90
Dade Actin												
Sysmex CA-500/560	10	80.4	8.6	10.7	81	68 - 93	12	112.8	9.5	8.4	112	95 - 130
All Coagulation Instruments	10	80.4	8.6	10.7	81	68 - 93	13	111.1	10.9	9.8	112	94 - 128
Dade Actin FSL												
Sysmex CA-500/560	18	55.6	3.1	5.7	55	47 - 64	18	71.5	4.1	5.8	72	60 - 83
All Coagulation Instruments	19	55.7	3.2	5.7	55	47 - 65	19	71.5	4.0	5.6	72	60 - 83
HUMAN HemoStat aPTT - EL												
bioMerieux Thrombolyzer Compact												
X/XR	7	66.3	3.7	5.6	67	56 - 77	7	83.4	5.5	6.6	85	70 - 96
All Coagulation Instruments	10	63.2	7.9	12.5	66	53 - 73	10	78.5	13.1	16.7	82	66 - 91
IL TEST APTT-SP												
IL ACL, all models	34	52.6	1.5	2.9	53	44 - 61	36	67.7	3.4	5.1	67	57 - 78
All Coagulation Instruments	38	52.5	2.9	5.4	53	44 - 61	37	67.8	3.4	5.1	67	57 - 78

ACTIVATED PARTIAL THROMBOPLASTIN (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	102	33.3	2.6	7.7	33	28 - 39
Dade Actin						
Sysmex CA-500/560	11	36.3	3.9	10.8	36	30 - 42
All Coagulation Instruments	12	36.0	3.8	10.7	36	30 - 42
Dade Actin FSL						
Sysmex CA-500/560	19	33.3	1.1	3.2	33	28 - 39
All Coagulation Instruments	20	33.4	1.0	3.1	33	28 - 39
HUMAN HemoStat aPTT - EL						
bioMerieux Thrombolyzer Compact						
X/XR	7	34.0	2.0	5.9	35	28 - 40
All Coagulation Instruments	10	33.4	2.0	5.9	33	28 - 39
IL TEST APTT-SP						
IL ACL, all models	37	31.8	1.8	5.7	32	27 - 37
All Coagulation Instruments	38	31.9	2.0	6.2	32	27 - 37

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	44	300.4	39.6	13.2	307	240 - 361	44	123.0	22.1	18.0	125	98 - 148
HUMAN HemoStat Fibrinogen bioMerieux Thrombolyzer Compact												
X/XR	7	292.7	41.5	14.2	290	234 - 352	7	104.9	17.4	16.6	101	83 - 126
All Coagulation Instruments	9	287.7	41.4	14.4	290	230 - 346	8	104.5	16.2	15.5	102	83 - 126
IL TEST PT-FIB HS PLUS												
IL ACL, all models	23	317.3	31.2	9.8	312	253 - 381	24	134.3	21.0	15.7	135	107 - 162
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	46	298.4	59.8	20.0	300	238 - 359	43	307.6	69.2	22.5	303	246 - 370
HUMAN HemoStat Fibrinogen bioMerieux Thrombolyzer Compact												
X/XR	7	263.6	33.0	12.5	260	210 - 317	7	273.3	37.0	13.5	266	218 - 328
All Coagulation Instruments	9	266.2	29.1	10.9	272	212 - 320	9	268.4	33.8	12.6	261	214 - 323
IL TEST PT-FIB HS PLUS												
IL ACL, all models	24	339.0	41.9	12.3	334	271 - 407	21	362.5	44.5	12.3	362	289 - 435
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	41	512.8	96.3	18.8	532	410 - 616						
HUMAN HemoStat Fibrinogen bioMerieux Thrombolyzer Compact												
X/XR	5	504.0	89.0	17.7	514	403 - 605						
All Coagulation Instruments	6	509.3	80.7	15.8	536	407 - 612						
IL TEST PT-FIB HS PLUS												
IL ACL, all models	23	555.8	60.9	11.0	545	444 - 667						

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	353	1.0203	0.0080	0.8	1.020	1.010 - 1.031
Arkray Aution Sticks	23	1.0233	0.0073	0.7	1.025	1.013 - 1.034
Bayer Clinitek Advantus	17	1.0271	0.0025	0.2	1.025	1.017 - 1.038
Other Analyzer Method	10	1.0229	0.0034	0.3	1.025	1.012 - 1.033
Roche Chemstrips / Combur	29	1.0100	0.0052	0.5	1.010	1.000 - 1.020
Roche cobas u 411	35	1.0143	0.0025	0.2	1.015	1.004 - 1.025
Roche Mditron Junior/II	17	1.0129	0.0050	0.5	1.015	1.002 - 1.023
Roche Urisys	58	1.0204	0.0087	0.8	1.015	1.010 - 1.031
UriScan Reagent Strips	63	1.0272	0.0031	0.3	1.028	1.017 - 1.038

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	371	-	-	-	1	-	-	1	11	12	210	64	72
Acon Laboratories	1	-	-	-	-	-	-	-	-	-	1	-	-
Analyticon CombiScan 500	7	-	-	-	-	-	-	-	-	-	7	-	-
Arkray Aution Jet	1	-	-	-	-	-	-	-	-	-	1	-	-
Arkray Aution Sticks	22	-	-	-	-	-	-	-	-	3	13	6	-
Arkray PocketChem UA	3	-	-	-	-	-	-	-	-	-	2	1	-
Bayer Clinitek 500	8	-	-	-	-	-	-	-	-	-	2	5	1
Bayer Clinitek Advantus	16	-	-	-	-	-	-	-	-	-	2	14	-
Bayer Clinitek Atlas	1	-	-	-	-	-	-	-	-	-	1	-	-
Bayer Clinitek Status / Status+	5	-	-	-	-	-	-	-	-	-	-	5	-
Bayer Reagent Strips	20	-	-	-	-	-	-	-	-	-	12	8	-
Combi-Screen Test Strips	4	-	-	-	-	-	-	-	-	-	3	-	1
CYBOW Urine Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-
HUMAN COMBINA Test Strips	6	-	-	-	-	-	-	-	1	1	4	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	-	-	-	-	-	-	1	-
Other Analyzer Method	11	-	-	-	-	-	-	-	-	2	3	6	-
Other Dipstick Method	6	-	-	-	-	-	-	-	1	-	3	2	-
pH Paper	1	-	-	-	-	-	-	-	-	-	1	-	-
Plasmatec URIPATH	2	-	-	-	-	-	-	-	-	-	2	-	-
Roche Chemstrip 101	1	-	-	-	-	-	-	-	-	-	-	1	-
Roche Chemstrips / Combur	33	-	-	-	-	-	-	-	2	-	11	4	16
Roche cobas u 411	34	-	-	-	-	-	-	-	1	-	20	-	13
Roche Mditron Junior/II	17	-	-	-	-	-	-	-	-	-	10	1	6
Roche Mini UA	1	-	-	-	-	-	-	-	-	-	1	-	-
Roche SuperUA/ChemstripUA	6	-	-	-	-	-	-	-	-	-	2	-	4
Roche Urilux S	1	-	-	-	-	-	-	-	-	-	-	-	1
Roche Urisys	61	-	-	-	-	-	-	-	1	-	31	2	27
SD UroColor Reagent Strips	8	-	-	-	-	-	-	-	-	-	6	2	-
TECO URS Strips	1	-	-	-	-	-	-	-	-	-	-	1	-
THME UDC-2020	6	-	-	-	1	-	-	-	2	-	1	-	2
UriScan Pro/II	4	-	-	-	-	-	-	-	-	-	4	-	-
UriScan Reagent Strips	63	-	-	-	-	-	-	1	2	4	55	1	-
URIT Medical Uritest Analyzers	1	-	-	-	-	-	-	-	-	-	1	-	-

URINALYSIS DIPSTICK--PROTEIN QUALITATIVE

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<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	371	5	1	8	266	76	12	3
Acon Laboratories	1	-	-	-	1	-	-	-
Analyticon CombiScan 500	7	-	-	-	5	1	-	1
Arkray Aution Jet	1	-	-	-	1	-	-	-
Arkray Aution Sticks	22	-	-	-	20	2	-	-
Arkray PocketChem UA	3	-	-	-	1	2	-	-
Bayer Clinitek 500	8	-	-	-	7	-	1	-
Bayer Clinitek Advantus	16	-	-	-	14	1	1	-
Bayer Clinitek Atlas	1	-	-	-	1	-	-	-
Bayer Clinitek Status / Status+	6	-	-	-	1	3	2	-
Bayer Multistix Pro	1	-	-	-	1	-	-	-
Bayer Reagent Strips	19	-	-	-	9	8	2	-
Combi-Screen Test Strips	4	-	-	2	2	-	-	-
CYBOW Urine Reagent Strips	1	-	-	-	-	-	1	-
HUMAN Combilyzer	1	-	-	-	1	-	-	-
HUMAN COMBINA Test Strips	3	-	-	-	2	1	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	1	-	-
Other Analyzer Method	11	-	-	1	5	4	-	1
Other Dipstick Method	6	-	-	-	2	4	-	-
Plasmatec URIPATH	2	-	-	-	1	1	-	-
Roche Chemstrip 101	1	-	-	-	1	-	-	-
Roche Chemstrips / Combur	33	1	-	-	28	4	-	-
Roche cobas u 411	34	-	-	-	27	7	-	-
Roche Mditron Junior/II	17	-	-	-	11	5	-	1
Roche Mini UA	1	-	-	-	1	-	-	-
Roche SuperUA/ChemstripUA	6	-	-	-	5	1	-	-
Roche Urilux S	1	-	-	-	-	1	-	-
Roche Urisys	61	1	-	1	43	15	1	-
SD UroColor Reagent Strips	8	-	-	-	8	-	-	-
Sulfosalicylic Acid	2	-	-	-	1	1	-	-
TECO URS Strips	1	-	-	-	-	-	1	-
THME UDC-2020	6	1	-	-	4	1	-	-
UriScan Pro/II	4	-	-	-	3	-	1	-
UriScan Reagent Strips	63	1	1	1	50	10	-	-
URIT Medical Uritest Analyzers	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	370	2	11	4	59	83	159	22	30
Acon Laboratories	1	-	-	-	-	-	1	-	-
Analyticon CombiScan 500	7	-	-	-	1	6	-	-	-
Arkray Aution Jet	1	-	-	-	-	1	-	-	-
Arkray Aution Sticks	22	-	-	1	10	9	1	1	-
Arkray PocketChem UA	3	-	-	-	1	1	-	1	-
Bayer Clinitek 500	8	-	1	-	2	5	-	-	-
Bayer Clinitek Advantus	16	-	-	-	4	12	-	-	-
Bayer Clinitek Atlas	1	-	-	-	-	1	-	-	-
Bayer Clinitek Status / Status+	6	-	-	-	1	5	-	-	-
Bayer Multistix Pro	1	-	-	-	-	-	1	-	-
Bayer Reagent Strips	20	-	-	-	9	7	4	-	-
Combi-Screen Test Strips	4	-	-	-	1	3	-	-	-
CYBOW Urine Reagent Strips	1	-	-	-	1	-	-	-	-
HUMAN COMBINA Test Strips	6	-	1	1	2	-	1	1	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	-	1	-	-	-
Other Analyzer Method	9	-	-	-	1	5	3	-	-
Other Dipstick Method	7	-	-	-	-	2	3	1	1
Plasmatec URIPATH	2	-	-	-	-	-	2	-	-
Roche Chemstrip 101	1	-	-	-	-	-	-	1	-
Roche Chemstrips / Combur	33	1	-	-	-	2	23	6	1
Roche cobas u 411	32	-	1	-	1	-	27	3	-
Roche Miditron Junior/II	17	-	-	-	-	1	13	3	-
Roche Mini UA	1	-	-	-	-	-	1	-	-
Roche SuperUA/ChemstripUA	6	-	-	-	-	-	5	1	-
Roche Urilux S	1	-	-	-	-	-	1	-	-
Roche Urisys	61	1	6	2	11	2	37	2	-
SD UroColor Reagent Strips	7	-	-	-	1	4	1	-	1
TECO URS Strips	1	-	-	-	1	-	-	-	-
THME UDC-2020	6	-	-	-	3	2	1	-	-
UriScan Pro/II	4	-	-	-	-	-	2	-	2
UriScan Reagent Strips	62	-	2	-	2	7	26	1	24
URIT Medical Uritest Analyzers	1	-	-	-	-	1	-	-	-

URINALYSIS DIPSTICK–KETONES

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace (5 mg/dL)</u>	<u>Small (1+, 15 mg/dL)</u>	<u>Moderate (2+, 40 mg/dL)</u>	<u>Large (3+, 80 mg/dL)</u>	<u>150 mg/dL</u>	<u>≥ 160 mg/dL</u>
ALL METHODS	370	4	3	17	232	68	43	3
Acon Laboratories	1	-	1	-	-	-	-	-
Analyticon CombiScan 500	7	-	-	1	6	-	-	-
Arkray Aution Jet	1	-	-	-	1	-	-	-
Arkray Aution Sticks	22	-	-	1	18	1	2	-
Arkray PocketChem UA	3	-	-	-	1	1	-	1
Bayer Clinitek 500	8	-	-	-	8	-	-	-
Bayer Clinitek Advantus	16	-	-	1	14	1	-	-
Bayer Clinitek Atlas	1	-	-	-	1	-	-	-
Bayer Clinitek Status / Status+	6	-	-	-	3	3	-	-
Bayer Multistix Pro	1	-	-	-	-	1	-	-
Bayer Reagent Strips	19	-	-	-	5	14	-	-
Combi-Screen Test Strips	4	-	-	1	2	1	-	-
CYBOW Urine Reagent Strips	1	-	-	1	-	-	-	-
HUMAN COMBINA Test Strips	5	-	-	-	5	-	-	-
Iris Diagnostics Aution Max AX-4280	1	-	-	-	1	-	-	-
Other Analyzer Method	11	-	-	-	9	2	-	-
Other Dipstick Method	7	-	-	1	6	-	-	-
Plasmatec URIPATH	2	-	-	-	2	-	-	-
Roche Chemstrip 101	1	-	-	-	1	-	-	-
Roche Chemstrips / Combur	32	1	-	-	19	5	7	-
Roche cobas u 411	33	-	-	1	14	5	13	-
Roche Mditron Junior/II	17	-	-	-	6	7	4	-
Roche Mini UA	1	-	-	-	1	-	-	-
Roche SuperUA/ChemstripUA	6	-	-	-	4	1	1	-
Roche Urilux S	1	-	-	-	1	-	-	-
Roche Urisys	62	1	1	2	32	9	16	1
SD UroColor Reagent Strips	8	-	-	-	7	1	-	-
TECO URS Strips	1	-	-	1	-	-	-	-
THME UDC-2020	6	1	-	1	2	2	-	-
UriScan Pro/II	4	-	-	-	3	1	-	-
UriScan Reagent Strips	63	1	1	4	47	10	-	-
URIT Medical Uritest Analyzers	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	358	84	90	98	86
Acon Laboratories	1	-	-	-	1
Analyticon CombiScan 500	7	-	4	3	-
Arkray Aution Jet	1	1	-	-	-
Arkray Aution Sticks	22	6	14	2	-
Arkray PocketChem UA	3	1	1	1	-
Bayer Clinitek 500	8	1	6	1	-
Bayer Clinitek Advantus	16	-	10	6	-
Bayer Clinitek Atlas	1	-	1	-	-
Bayer Clinitek Status / Status+	5	2	2	1	-
Bayer Multistix Pro	1	-	1	-	-
Bayer Reagent Strips	8	2	2	4	-
Combi-Screen Test Strips	4	-	1	3	-
CYBOW Urine Reagent Strips	1	-	1	-	-
HUMAN COMBINA Test Strips	6	1	2	3	-
Iris Diagnostics Aution Max AX-4280	1	-	-	1	-
Other Analyzer Method	10	3	6	1	-
Other Dipstick Method	7	2	3	1	1
Plasmatec URIPATH	2	-	-	2	-
Roche Chemstrip 101	1	-	-	-	1
Roche Chemstrips / Combur	32	3	-	8	21
Roche cobas u 411	33	-	2	13	18
Roche Mditron Junior/II	17	-	1	9	7
Roche Mini UA	1	-	-	-	1
Roche SuperUA/ChemstripUA	6	-	1	1	4
Roche Urilux S	1	-	-	1	-
Roche Urisys	62	1	11	22	28
SD UroColor Reagent Strips	8	-	-	6	2
TECO URS Strips	1	-	-	1	-
THME UDC-2020	6	2	2	2	-
UriScan Pro/II	4	4	-	-	-
UriScan Reagent Strips	63	49	12	1	1
URIT Medical Uritest Analyzers	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	356	61	35	46	132	82
Acon Laboratories	1	-	-	1	-	-
Analyticon CombiScan 500	7	1	-	1	-	5
Arkray Aution Jet	1	1	-	-	-	-
Arkray Aution Sticks	22	16	-	5	-	1
Arkray PocketChem UA	3	1	-	1	-	1
Bayer Clinitek 500	8	-	1	6	1	-
Bayer Clinitek Advantus	16	-	-	12	4	-
Bayer Clinitek Atlas	1	-	-	1	-	-
Bayer Clinitek Status / Status+	5	-	-	-	5	-
Bayer Multistix Pro	1	-	-	1	-	-
Bayer Reagent Strips	8	1	-	4	1	2
Combi-Screen Test Strips	4	-	-	-	-	4
CYBOW Urine Reagent Strips	1	1	-	-	-	-
HUMAN COMBINA Test Strips	6	2	1	-	2	1
Iris Diagnostics Aution Max AX-4280	1	1	-	-	-	-
Other Analyzer Method	9	5	2	1	1	-
Other Dipstick Method	6	2	-	1	1	2
Plasmatec URIPATH	2	-	-	1	1	-
Roche Chemstrip 101	1	-	-	-	1	-
Roche Chemstrips / Combur	31	3	5	1	17	5
Roche cobas u 411	33	-	-	-	23	10
Roche Mditron Junior/II	17	-	2	2	10	3
Roche Mini UA	1	-	-	-	1	-
Roche SuperUA/ChemstripUA	6	-	1	-	5	-
Roche Urilux S	1	-	1	-	-	-
Roche Urisys	62	2	16	2	35	7
SD UroColor Reagent Strips	8	8	-	-	-	-
TECO URS Strips	1	-	-	-	1	-
THME UDC-2020	6	3	1	1	1	-
UriScan Pro/II	4	-	-	-	1	3
UriScan Reagent Strips	63	3	3	3	19	35
URIT Medical Uritest Analyzers	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	369	4	-	-	23	342
Acon Laboratories	1	-	-	-	-	1
Analyticon CombiScan 500	6	-	-	-	-	6
Arkray Aution Jet	1	-	-	-	1	-
Arkray Aution Sticks	22	-	-	-	9	13
Arkray PocketChem UA	3	-	-	-	-	3
Bayer Clinitek 500	8	-	-	-	-	8
Bayer Clinitek Advantus	16	-	-	-	2	14
Bayer Clinitek Atlas	2	-	-	-	-	2
Bayer Clinitek Status / Status+	6	-	-	-	-	6
Bayer Multistix Pro	1	-	-	-	-	1
Bayer Reagent Strips	19	-	-	-	-	19
Combi-Screen Test Strips	4	-	-	-	-	4
CYBOW Urine Reagent Strips	1	-	-	-	-	1
HUMAN COMBINA Test Strips	6	-	-	-	1	5
Iris Diagnostics Aution Max AX-4280	1	-	-	-	1	-
Other Analyzer Method	11	-	-	-	-	11
Other Dipstick Method	6	-	-	-	-	6
Plasmatec URIPATH	2	-	-	-	-	2
Roche Chemstrip 101	1	-	-	-	-	1
Roche Chemstrips / Combur	32	1	-	-	-	31
Roche cobas u 411	32	-	-	-	-	32
Roche Miditron Junior/II	18	-	-	-	-	18
Roche Mini UA	1	-	-	-	-	1
Roche SuperUA/ChemstripUA	6	-	-	-	-	6
Roche Urilux S	1	-	-	-	-	1
Roche Urisys	62	1	-	-	1	60
SD UroColor Reagent Strips	7	-	-	-	-	7
TECO URS Strips	1	-	-	-	-	1
THME UDC-2020	6	1	-	-	-	5
UriScan Pro/II	3	-	-	-	-	3
UriScan Reagent Strips	63	1	-	-	6	56
URIT Medical Uritest Analyzers	1	-	-	-	-	1

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Negative</u>	<u>Trace</u>	<u>Small (1+)</u>	<u>Moderate (2+)</u>	<u>Large (3+)</u>
ALL METHODS	326	321	3	1	1	-
Acon Laboratories	2	2	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-
Arkray Aution Sticks	21	21	-	-	-	-
Arkray PocketChem UA	2	2	-	-	-	-
Bayer Clinitek 500	5	5	-	-	-	-
Bayer Clinitek Advantus	15	15	-	-	-	-
Bayer Clinitek Atlas	2	2	-	-	-	-
Bayer Clinitek Status / Status+	3	3	-	-	-	-
Bayer Multistix Pro	1	1	-	-	-	-
Bayer Reagent Strips	8	8	-	-	-	-
Bayer Uristix	1	1	-	-	-	-
Combi-Screen Test Strips	1	1	-	-	-	-
CYBOW Urine Reagent Strips	2	2	-	-	-	-
HUMAN Combilyzer	1	1	-	-	-	-
HUMAN COMBINA Test Strips	6	6	-	-	-	-
Iris Diagnostics Aution Max AX-4280	3	3	-	-	-	-
Other Analyzer Method	16	16	-	-	-	-
Other Dipstick Method	7	7	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-
Roche Chemstrips / Combur	20	20	-	-	-	-
Roche cobas u 411	33	33	-	-	-	-
Roche Mditron Junior/II	17	17	-	-	-	-
Roche Mini UA	1	1	-	-	-	-
Roche SuperUA/ChemstripUA	11	11	-	-	-	-
Roche Urilux S	1	1	-	-	-	-
Roche Urisys	62	60	-	1	1	-
SD UroColor Reagent Strips	10	8	2	-	-	-
TECO URS Strips	1	1	-	-	-	-
THME UDC-2020	5	5	-	-	-	-
Urinometer	1	1	-	-	-	-
UriScan Pro/II	5	5	-	-	-	-
UriScan Reagent Strips	55	54	1	-	-	-

URINALYSIS DIPSTICK–NITRITE

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	357	346	11
Acon Laboratories	1	1	-
Analyticon CombiScan 500	7	7	-
Arkray Aution Jet	1	1	-
Arkray Aution Sticks	22	22	-
Arkray PocketChem UA	3	3	-
Bayer Clinitek 500	8	8	-
Bayer Clinitek Advantus	16	16	-
Bayer Clinitek Atlas	1	1	-
Bayer Clinitek Status / Status+	5	5	-
Bayer Multistix Pro	1	1	-
Bayer Reagent Strips	8	8	-
Combi-Screen Test Strips	4	4	-
CYBOW Urine Reagent Strips	1	1	-
HUMAN COMBINA Test Strips	6	6	-
Iris Diagnostics Aution Max AX-4280	1	1	-
Other Analyzer Method	10	9	1
Other Dipstick Method	6	6	-
Plasmatec URIPATH	2	2	-
Roche Chemstrip 101	1	1	-
Roche Chemstrips / Combur	32	31	1
Roche cobas u 411	32	32	-
Roche Mditron Junior/II	17	17	-
Roche Mini UA	1	1	-
Roche SuperUA/ChemstripUA	6	6	-
Roche Urilux S	1	1	-
Roche Urisys	62	61	1
SD UroColor Reagent Strips	8	8	-
TECO URS Strips	1	1	-
THME UDC-2020	6	2	4
UriScan Pro/II	4	4	-
UriScan Reagent Strips	63	62	1
URIT Medical Uritest Analyzers	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	27	1	1	1	1	3	4	16
Bayer Clinitek Microalbumin	15	-	1	-	1	-	1	12
Roche Micral - 1 minute	6	-	-	1	-	2	1	2

URINALYSIS –URINE hCG

Specimen UA-3

Participant Results

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	68	67	1
Acon Laboratories	8	8	-
Biotron 1-Step	6	6	-
Henry Schein One Step	1	1	-
Inverness Acceva hCG-Urine	1	1	-
Inverness Clearview25 hCG Combo	1	1	-
Quidel QuickVue One-Step Combo	26	25	1
Stanbio QuStick	2	2	-
Veda lab	1	1	-

ANTIMICROBIAL SUSCEPTIBILITY TESTING
Specimen SUS-11

	-----Disk Diffusion-----				-----MIC-----				
	Interpretative category data				Interpretative category data				
<u>Antimicrobial</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Acceptable (%)</u>
Amikacin	15	3	1	11	8	3	-	5	Inappropriate drug ¹
Amoxicillin/Clavulanate	23	-	-	23	14	2	1	11	90.00%
Ampicillin	31	-	-	31	95	-	1	94	99.29%
Ampicillin/Sulbactam	12	-	-	12	10	2	-	8	88.89%
Aztreonam	3	-	-	3	2	2	-	-	Inappropriate drug ¹
Cefaclor	5	-	-	5	2	-	-	2	Inappropriate drug ¹
Cefazolin	1	-	-	1	5	3	-	2	Inappropriate drug ¹
Cefepime	8	-	-	8	6	3	-	3	Inappropriate drug ¹
Cefixime	6	-	-	6	2	1	-	1	Inappropriate drug ¹
Cefoperazone	3	-	-	3	-	-	-	-	Inappropriate drug ¹
Cefotaxime	8	-	-	8	5	2	-	3	Inappropriate drug ¹
Cefoxitin	4	-	-	4	4	3	-	1	Inappropriate drug ¹
Cefpodoxime	1	-	-	1	1	-	-	1	Inappropriate drug ¹
Ceftazidime	9	-	-	9	5	4	-	1	Inappropriate drug ¹
Ceftriaxone	18	-	-	18	7	3	-	4	Inappropriate drug ¹
Cefuroxime	17	-	-	17	7	3	-	4	Inappropriate drug ¹
Cephalexin	5	-	-	5	1	1	-	-	Inappropriate drug ¹
Cephalothin	6	-	-	6	3	3	-	-	Inappropriate drug ¹
Ciprofloxacin	35	2	-	33	94	5	1	88	93.66%
Clindamycin	11	-	-	11	9	-	-	9	Inappropriate drug ¹
Daptomycin	-	-	-	-	17	17	-	-	100.00%
Doxycycline	7	7	-	-	-	-	-	-	100.00%
Ertapenem	4	-	-	4	2	2	-	-	Inappropriate drug ¹
Erythromycin	4	1	-	3	13	-	-	13	Inappropriate drug ¹
Fosfomycin	2	1	1	-	-	-	-	-	Inappropriate drug ¹
Gentamicin	19	11	-	8	27	17	3	7	Inappropriate drug ¹
Gentamicin synergy	1	1	-	-	28	27	-	1	93.75%
Imipenem	10	1	-	9	4	2	-	2	Inappropriate drug ¹
Kanamycin	2	1	-	1	-	-	-	-	Inappropriate drug ¹
Levofloxacin	16	-	-	16	76	2	1	73	95.24%

¹ Inappropriate drug for organism and/or source.

ANTIMICROBIAL SUSCEPTIBILITY TESTING (cont'd)
Specimen SUS-11

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>
	Interpretative category data				Interpretative category data				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Linezolid	10	9	1	-	57	37	20	-	Not graded ¹
Lomefloxacin	1	-	-	1	-	-	-	-	Inappropriate drug ¹
Meropenem	6	1	-	5	3	2	-	1	Inappropriate drug ¹
Minocycline	-	-	-	-	3	3	-	-	100.00%
Moxifloxacin	6	-	-	6	6	1	-	5	Inappropriate drug ¹
Nalidixic Acid	6	-	-	6	4	2	-	2	Inappropriate drug ¹
Netilmicin	3	-	-	3	2	1	-	1	Inappropriate drug ¹
Nitrofurantoin	28	7	1	20	74	3	11	60	Not graded ²
Norfloxacin	17	2	-	15	4	2	-	2	81.82%
Ofloxacin	8	-	-	8	2	-	-	2	Inappropriate drug ¹
Oxacillin	4	-	-	4	5	-	-	5	Inappropriate drug ¹
Penicillin	21	-	-	21	39	1	-	38	98.57%
Piperacillin	1	-	-	1	-	-	-	-	Not graded ²
Piperacillin/Tazobactam	5	-	-	5	6	2	-	4	Not graded ²
Quinupristin/Dalfopristin	2	2	-	-	20	20	-	-	100.00%
Rifampin	8	1	1	6	17	4	5	8	Not graded ²
Streptomycin synergy	1	-	-	1	23	-	-	23	100.00%
Sulfisoxazole	-	-	-	-	1	-	-	1	Inappropriate drug ¹
Teicoplanin	1	1	-	-	11	-	-	11	92.31%
Tetracycline	20	19	1	-	74	70	2	2	95.28%
Ticarcillin	-	-	-	-	1	1	-	-	Inappropriate drug ¹
Ticarcillin/Clavulanate	-	-	-	-	1	1	-	-	Inappropriate drug ¹
Tobramycin	3	2	-	1	1	1	-	-	Inappropriate drug ¹
Trimethoprim	-	-	-	-	3	1	-	2	Inappropriate drug ¹
Trimethoprim/Sulfamethoxazole	19	2	1	16	45	4	-	41	Inappropriate drug ¹
Vancomycin	27	2	-	25	84	2	-	82	95.28%

Organism present in specimen SUS-11: *Enterococcus faecium*.

¹ This is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY (PA Specimens) – NOTE: ALL SPECIMENS ARE GRADED TO US STATS FOR CONSENSUS.

Specimen PA-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	5	83.33%	Graded exclusively to US Consensus
Hymenolepis diminuta eggs	1	16.67%	

Parasite present in specimen PA-11: *Dientamoeba fragilis*.

Specimen PA-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	3	42.86%	Acceptable
Endolimax nana	2	28.57%	
Hookworm	1	14.29%	
Blastocystis hominis	1	14.29%	

Parasite present in specimen PA-12: No parasite seen.

Specimen PA-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. eggs	11	73.33%	Acceptable
Ascaris lumbricoides eggs	2	13.33%	
Hymenolepis nana eggs	1	6.67%	
No parasite seen	1	6.67%	

Parasite present in specimen PA-13: *Taenia sp. eggs*.

PARASITOLOGY (PA Specimens) cont'd NOTE: ALL SPECIMENS ARE GRADED TO US STATS FOR CONSENSUS.

Specimen PA-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Clonorchis sinensis	8	50.00%	Acceptable
No parasite seen	2	12.50%	
Giardia lamblia	2	12.50%	
Diphyllbothrium latum	2	12.50%	
Entamoeba coli	1	6.25%	
Chilomastix mesnili	1	6.25%	

Parasite present in specimen PA-14: *Clonorchis sinensis*.

Specimen PA-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium vivax	10	71.43%	Acceptable
Plasmodium sp., not falciparum	2	14.29%	Acceptable
Plasmodium falciparum	1	7.14%	
Plasmodium malariae	1	7.14%	

Parasite present in specimen PA-15: *Plasmodium vivax*.

PARASITOLOGY (FP Specimens)

Specimen FP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. eggs	200	64.94%	Acceptable
Blastocystis hominis	47	15.26%	Acceptable
Ascaris lumbricoides eggs	20	6.49%	
No parasite seen	18	5.84%	
Endolimax nana	9	2.92%	
Hymenolepis nana eggs	6	1.95%	

Parasite present in specimen FP-11: *Taenia sp. eggs*.

Specimen FP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Clonorchis sinensis	71	25.36%	Acceptable
Parasite egg seen but no ID	2	0.71%	Acceptable
No parasite seen	151	53.93%	
Enterobius vermicularis eggs	7	2.50%	
Fasciola hepatica eggs	6	2.14%	
Hymenolepis nana eggs	6	2.14%	
Strongyloides stercoralis larvae	5	1.79%	
Hymenolepis diminuta eggs	5	1.79%	

Parasite present in specimen FP-12: *Clonorchis sinensis*. This challenge was graded by 81% referee consensus.

Specimen FP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Schistosoma haematobium eggs	185	68.01%	Acceptable
Schistosoma sp. eggs, NOS	31	11.40%	Acceptable
No parasite seen	30	11.03%	
Schistosoma mansoni eggs	5	1.84%	

Parasite present in specimen FP-13: *Schistosoma haematobium eggs*.

PARASITOLOGY (FP Specimens)

Specimen FP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	263	95.64%	Acceptable
No parasite seen	3	1.09%	

Parasite present in specimen FP-14: *Giardia lamblia*.

Specimen FP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium vivax	145	53.90%	Acceptable
Plasmodium sp., NOS	73	27.14%	Acceptable
Plasmodium sp., not falciparum	10	3.72%	Acceptable
Plasmodium falciparum	30	11.15%	
Plasmodium malariae	9	3.35%	

Parasite present in specimen FP-15: *Plasmodium vivax*.

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	10	1	10	1	-	11
Abbott Architect	1	-	1	-	-	1
Abbott AxSYM	1	-	1	-	-	1
Bayer ADVIA Centaur	2	-	2	-	-	2
Roche Elecsys 1010 / 2010	1	-	1	-	-	1
Roche Modular Analytics	1	-	1	-	-	1
VITROS ECI	3	1	3	1	-	4

<u>Method</u>	Specimen RU-14		Specimen RU-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	11	10	1
Abbott Architect	-	1	1	-
Abbott AxSYM	-	1	1	-
Bayer ADVIA Centaur	-	2	2	-
Roche Elecsys 1010 / 2010	-	1	1	-
Roche Modular Analytics	-	1	1	-
VITROS ECI	-	4	3	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	20	137.12	79.50	58.0	129.0	0.0 - 375.7
Abbott Architect	5	67.86	2.05	3.0	68.1	61.7 - 74.1
Bayer ADVIA Centaur	5	95.98	50.45	52.6	121.4	0.0 - 247.4
Specimen RU-12						
All Method	20	36.13	22.59	62.5	31.5	0.0 - 103.9
Abbott Architect	5	18.24	1.24	6.8	18.7	14.5 - 22.0
Bayer ADVIA Centaur	5	60.38	32.30	53.5	66.9	0.0 - 157.3
Specimen RU-13						
All Method	18	0.13	0.16	120.7	0.0	0.0 - 0.7
Abbott Architect	5	0.06	0.13	223.6	0.0	0.0 - 0.5
Bayer ADVIA Centaur	5	1.28	2.36	184.7	0.3	0.0 - 8.4
Specimen RU-14						
All Method	18	0.15	0.15	97.7	0.2	0.0 - 0.6
Abbott Architect	5	0.14	0.11	81.4	0.1	0.0 - 0.5
Bayer ADVIA Centaur	5	1.24	2.33	187.9	0.2	0.0 - 8.3
Specimen RU-15						
All Method	20	54.71	22.58	41.3	49.6	0.0 - 122.5
Abbott Architect	5	33.44	1.31	3.9	33.1	29.5 - 37.4
Bayer ADVIA Centaur	5	51.56	25.79	50.0	61.5	0.0 - 129.0

Syphilis Serology—Qualitative: VDRL Slide

	Specimen SY-11			Specimen SY-12			Specimen SY-13		
<u>Method</u>	<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	18	-	-	-	-	18	18	-	-
Acon Laboratories	1	-	-	-	-	1	1	-	-
BioBacter	1	-	-	-	-	1	1	-	-
Biokit	1	-	-	-	-	1	1	-	-
bioMerieux	1	-	-	-	-	1	1	-	-
Human	1	-	-	-	-	1	1	-	-
Omega Diagnostics	1	-	-	-	-	1	1	-	-
Other Total Method	1	-	-	-	-	1	1	-	-
Wiener Lab	9	-	-	-	-	9	9	-	-

	Specimen SY-14			Specimen SY-15		
ALL METHODS	-	-	18	1	-	17
Acon Laboratories	-	-	1	-	-	1
BioBacter	-	-	1	-	-	1
Biokit	-	-	1	-	-	1
bioMerieux	-	-	1	-	-	1
Human	-	-	1	-	-	1
Omega Diagnostics	-	-	1	-	-	1
Other Total Method	-	-	1	-	-	1
Wiener Lab	-	-	9	1	-	8

Syphilis Serology—Quantitative: VDRL Slide Titer

<u>Specimen/Method</u>	<u>0 dils</u>	<u>1 dil</u>	<u>2 dils</u>	<u>4 dils</u>	<u>8 dils</u>	<u>16 dils</u>	<u>32 dils</u>	<u>>32 dils</u>
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Specimen SY-11

ALL METHODS	-	1	1	7	4	-	-	-
BioBacter	-	-	-	-	1	-	-	-
bioMerieux	-	1	-	-	-	-	-	-
Wiener Lab	-	-	1	6	3	-	-	-

Specimen SY-13

ALL METHODS	-	1	2	7	2	1	-	-
BioBacter	-	-	-	1	-	-	-	-
bioMerieux	-	1	-	-	-	-	-	-
Wiener Lab	-	-	2	5	2	1	-	-

Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-11		Specimen SY-12		Specimen SY-13	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	15	-	-	15	15	-
Biokit	2	-	-	2	2	-
bioMerieux	1	-	-	1	1	-
Human	2	-	-	2	2	-
Omega Diagnostics	3	-	-	3	3	-
Serodia	3	-	-	3	3	-
Wiener Lab	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	-	15	-	15
Biokit	-	2	-	2
bioMerieux	-	1	-	1
Human	-	2	-	2
Omega Diagnostics	-	3	-	3
Serodia	-	3	-	3
Wiener Lab	-	1	-	1

Syphilis Serology—Qualitative: FTA-ABS (*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	15	-	1	14	15	-
Abbott Architect	1	-	-	1	1	-
bioMerieux	2	-	-	2	2	-
Human	2	-	-	2	2	-
Omega Diagnostics	3	-	-	3	3	-
Serodia	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	1	14	1	14
Abbott Architect	-	1	-	1
bioMerieux	-	2	-	2
Human	-	2	-	2
Omega Diagnostics	-	3	-	3
Serodia	-	3	-	3

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	43	-	1	42	43	-
Becton Dickinson	1	-	-	1	1	-
Biokit	1	-	-	1	1	-
bioMerieux	5	-	-	5	5	-
BioSystems	6	-	-	6	6	-
Human	4	-	-	4	4	-
Immunostics Inc.	1	-	-	1	1	-
Omega Diagnostics	10	-	-	10	10	-
Plasmatec	3	-	-	3	3	-
Serodia	1	-	-	1	1	-
SPINREACT	6	-	-	6	6	-
Wampole Impact RPR	3	-	1	2	3	-

	Specimen SY-14		Specimen SY-15	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	1	42	1	42
Becton Dickinson	-	1	-	1
Biokit	-	1	-	1
bioMerieux	-	5	-	5
BioSystems	-	6	-	6
Human	-	4	-	4
Immunostics Inc.	-	1	-	1
Omega Diagnostics	-	10	-	10
Plasmatec	-	3	-	3
Serodia	-	1	-	1
SPINREACT	-	6	-	6
Wampole Impact RPR	1	2	1	2

Syphilis Serology—Quantitative: RPR (Titer)

<u>Specimen/Method</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>
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Specimen SY-11

ALL METHODS	1	12	16	1	-	-	-	1
Becton Dickinson	-	-	1	-	-	-	-	-
Biokit	-	-	1	-	-	-	-	-
bioMerieux	-	2	1	-	-	-	-	-
BioSystems	-	2	2	1	-	-	-	-
Human	-	1	1	-	-	-	-	-
Immunostics Inc.	-	1	-	-	-	-	-	-
Omega Diagnostics	-	4	3	-	-	-	-	-
Plasmatec	-	1	-	-	-	-	-	-
Serodia	-	-	-	-	-	-	-	1
SPINREACT	1	-	5	-	-	-	-	-
Wampole Impact RPR	-	-	1	-	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-

Specimen SY-13

ALL METHODS	1	9	20	-	-	-	-	1
Becton Dickinson	-	-	1	-	-	-	-	-
Biokit	-	-	1	-	-	-	-	-
bioMerieux	-	2	1	-	-	-	-	-
BioSystems	-	2	3	-	-	-	-	-
Human	-	-	2	-	-	-	-	-
Immunostics Inc.	-	1	-	-	-	-	-	-
Omega Diagnostics	-	3	4	-	-	-	-	-
Plasmatec	-	-	1	-	-	-	-	-
Serodia	-	-	-	-	-	-	-	1
SPINREACT	1	-	5	-	-	-	-	-
Wampole Impact RPR	-	-	1	-	-	-	-	-
Wiener Lab	-	-	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	2	88	85	5	11	78
Abbott Architect	-	3	3	-	-	3
Abbott Architect - IgG	-	3	3	-	-	3
Abbott Architect - IgM	-	2	2	-	-	2
Abbott Architect - Total	-	15	15	-	-	15
Abbott AxSYM - Total	-	6	6	-	-	6
Bayer ADVIA Centaur - IgG	-	3	3	-	-	3
Bayer ADVIA Centaur - IgM	-	1	1	-	-	1
Bayer ADVIA Centaur - Total	-	7	7	-	3	4
Beckman ACCESS / 2 / Dxl	-	1	1	-	-	1
Bio-Rad Evolis	-	1	1	-	-	1
bioMerieux Vidas - IgM	-	2	2	-	-	2
bioMerieux Vidas - Total	-	2	2	-	-	2
Other IgG Method	1	-	1	-	-	1
Other IgM method	-	1	1	-	-	1
Other Total Method	-	7	6	1	3	4
Roche cobas 6000 / e 601	-	1	1	-	-	1
Roche cobas 6000/e601 - IgG	-	1	1	-	-	1
Roche Elecsys - IgG	-	5	5	-	-	5
Roche Elecsys - IgM	-	2	1	1	-	2
Roche Elecsys - Total	-	6	6	-	-	6
Roche Elecsys 1010 / 2010	-	1	1	-	-	1
Roche Modular Analytics	-	2	2	-	-	2
VITROS ECI - IgG	1	2	2	1	1	2
VITROS ECI - IgM	-	4	3	1	-	4
VITROS ECI - Total	-	6	5	1	3	2

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	57	33	70	20
Abbott Architect	2	1	2	1
Abbott Architect - IgG	3	-	3	-
Abbott Architect - IgM	-	2	-	2
Abbott Architect - Total	14	1	14	1
Abbott AxSYM - Total	6	-	6	-
Bayer ADVIA Centaur - IgG	-	3	3	-
Bayer ADVIA Centaur - IgM	-	1	-	1
Bayer ADVIA Centaur - Total	-	7	7	-
Beckman ACCESS / 2 / DxI	-	1	-	1
Bio-Rad Evolis	1	-	1	-
bioMerieux Vidas - IgM	-	2	-	2
bioMerieux Vidas - Total	2	-	2	-
Other IgG Method	1	-	1	-
Other IgM method	-	1	-	1
Other Total Method	2	5	5	2
Roche cobas 6000 / e 601	1	-	1	-
Roche cobas 6000/e601 - IgG	1	-	1	-
Roche Elecsys - IgG	5	-	5	-
Roche Elecsys - IgM	-	2	-	2
Roche Elecsys - Total	6	-	5	1
Roche Elecsys 1010 / 2010	1	-	1	-
Roche Modular Analytics	2	-	2	-
VITROS ECI - IgG	1	2	1	2
VITROS ECI - IgM	1	3	-	4
VITROS ECI - Total	5	1	6	-

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	4	189	1	192	1	192
Abbott Architect	-	20	-	20	-	20
Abbott Architect - IgG	-	1	-	1	-	1
Abbott Architect - Total	-	22	-	22	-	22
Abbott AxSYM	-	4	-	4	-	4
Abbott AxSYM - Total	1	9	-	10	-	10
Abbott IMx - Total	-	1	-	1	-	1
Bayer ADVIA Centaur	-	12	-	12	-	12
Bayer ADVIA Centaur - IgG	-	1	-	1	-	1
Bayer ADVIA Centaur - Total	-	11	-	11	-	11
Beckman ACCESS / 2 / Dxl	-	4	-	4	-	4
Bio-Rad Evolis	-	1	-	1	-	1
bioMerieux Vidas - IgG	-	1	-	1	-	1
bioMerieux Vidas - Total	-	11	-	11	-	11
bioMerieux Vidas, Mini Vidas	-	1	-	1	-	1
BioSystems	-	1	-	1	-	1
Other IgG Method	-	1	-	1	-	1
Other Total Method	-	15	-	15	-	15
Roche cobas 6000 / e 601	-	2	-	2	-	2
Roche Elecsys - IgG	-	2	-	2	-	2
Roche Elecsys - Total	1	21	1	21	-	22
Roche Elecsys 1010 / 2010	-	12	-	12	-	12
Roche Modular Analytics	-	11	-	11	-	11
VITROS ECI - IgM	-	1	-	1	-	1
VITROS ECI - Total	2	14	-	16	1	15

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	187	6	-	193
Abbott Architect	20	-	-	20
Abbott Architect - IgG	1	-	-	1
Abbott Architect - Total	22	-	-	22
Abbott AxSYM	4	-	-	4
Abbott AxSYM - Total	10	-	-	10
Abbott IMx - Total	1	-	-	1
Bayer ADVIA Centaur	11	1	-	12
Bayer ADVIA Centaur - IgG	1	-	-	1
Bayer ADVIA Centaur - Total	11	-	-	11
Beckman ACCESS / 2 / DxI	4	-	-	4
Bio-Rad Evolis	1	-	-	1
bioMerieux Vidas - IgG	1	-	-	1
bioMerieux Vidas - Total	11	-	-	11
bioMerieux Vidas, Mini Vidas	1	-	-	1
BioSystems	1	-	-	1
Other IgG Method	1	-	-	1
Other Total Method	15	-	-	15
Roche cobas 6000 / e 601	2	-	-	2
Roche Elecsys - IgG	2	-	-	2
Roche Elecsys - Total	21	1	-	22
Roche Elecsys 1010 / 2010	12	-	-	12
Roche Modular Analytics	11	-	-	11
VITROS ECI - IgM	1	-	-	1
VITROS ECI - Total	13	3	-	16

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	54	43	2	95	74	23
Abbott Architect - IgG	11	-	-	11	11	-
Abbott Architect - IgM	-	6	-	6	2	4
Abbott Architect - Total	3	1	-	4	3	1
Abbott AxSYM - IgG	2	-	-	2	2	-
Abbott AxSYM - IgM	-	3	-	3	1	2
Abbott AxSYM - Total	3	-	-	3	3	-
Bayer ADVIA Centaur	-	1	-	1	-	1
Bayer ADVIA Centaur - IgG	1	-	-	1	1	-
Bayer ADVIA Centaur - IgM	-	4	-	4	2	2
Bayer ADVIA Centaur - Total	5	1	-	6	6	-
Beckman ACCESS / 2 / DxI	-	1	-	1	-	1
bioMerieux Vidas - IgG	1	-	-	1	1	-
bioMerieux Vidas - IgM	-	9	-	9	2	7
bioMerieux Vidas - Total	2	1	1	2	3	-
Other IgG Method	-	2	-	2	2	-
Other IgM method	-	2	-	2	1	1
Other Total Method	3	-	-	3	3	-
Roche cobas 6000 / e 601	1	-	-	1	1	-
Roche Elecsys - IgG	7	-	1	6	7	-
Roche Elecsys - IgM	-	7	-	7	6	1
Roche Elecsys - Total	5	-	-	5	5	-
Roche Modular Analytics	3	-	-	3	3	-
VITROS ECI - IgM	-	3	-	3	1	2
VITROS ECI - Total	5	1	-	6	5	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	3	94	3	94
Abbott Architect - IgG	-	11	-	11
Abbott Architect - IgM	-	6	-	6
Abbott Architect - Total	-	4	-	4
Abbott AxSYM - IgG	-	2	-	2
Abbott AxSYM - IgM	-	3	-	3
Abbott AxSYM - Total	-	3	-	3
Bayer ADVIA Centaur	-	1	-	1
Bayer ADVIA Centaur - IgG	-	1	-	1
Bayer ADVIA Centaur - IgM	-	4	-	4
Bayer ADVIA Centaur - Total	-	6	-	6
Beckman ACCESS / 2 / DxI	-	1	-	1
bioMerieux Vidas - IgG	-	1	-	1
bioMerieux Vidas - IgM	-	9	1	8
bioMerieux Vidas - Total	1	2	1	2
Other IgG Method	-	2	-	2
Other IgM method	-	2	-	2
Other Total Method	1	2	-	3
Roche cobas 6000 / e 601	-	1	-	1
Roche Elecsys - IgG	-	7	-	7
Roche Elecsys - IgM	-	7	-	7
Roche Elecsys - Total	-	5	-	5
Roche Modular Analytics	-	3	-	3
VITROS ECI - IgM	-	3	-	3
VITROS ECI - Total	-	6	-	6

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	48	1	48	1	48
Abbott Architect - Total	-	10	-	10	-	10
Abbott AxSYM	-	4	-	4	-	4
Abbott AxSYM - Total	-	1	-	1	-	1
Bayer ADVIA Centaur - IgG	-	1	-	1	-	1
Bayer ADVIA Centaur - Total	-	7	-	7	-	7
bioMerieux Vidas - Total	-	3	-	3	-	3
bioMerieux Vidas, Mini Vidas	-	1	-	1	-	1
Other Total Method	-	1	-	1	-	1
Roche cobas 6000 / e 601	-	1	-	1	-	1
Roche Elecsys - IgG	-	1	-	1	-	1
Roche Elecsys - Total	-	4	-	4	-	4
Roche Modular Analytics	-	4	-	4	-	4
VITROS ECI - IgM	-	1	-	1	-	1
VITROS ECI - Total	1	4	1	4	1	4

	Specimen VM-14		Specimen VM-15	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	48	1	48
Abbott Architect - Total	-	10	-	10
Abbott AxSYM	-	4	-	4
Abbott AxSYM - Total	-	1	-	1
Bayer ADVIA Centaur - IgG	-	1	-	1
Bayer ADVIA Centaur - Total	-	7	-	7
bioMerieux Vidas - Total	-	3	-	3
bioMerieux Vidas, Mini Vidas	-	1	-	1
Other Total Method	-	1	-	1
Roche cobas 6000 / e 601	-	1	-	1
Roche Elecsys - IgG	-	1	-	1
Roche Elecsys - Total	-	4	-	4
Roche Modular Analytics	-	4	-	4
VITROS ECI - IgM	-	1	-	1
VITROS ECI - Total	1	4	1	4

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	2	136	13	125	134	4
Abbott Architect	-	10	1	9	10	-
Abbott Architect - IgG	-	2	-	2	2	-
Abbott Architect - Total	-	18	-	18	18	-
Abbott AxSYM	-	2	-	2	2	-
Abbott AxSYM - Total	-	9	1	8	9	-
Bayer ADVIA Centaur	-	11	1	10	11	-
Bayer ADVIA Centaur - IgG	-	2	1	1	2	-
Bayer ADVIA Centaur - Total	-	10	-	10	10	-
Beckman ACCESS / 2 / DxI	1	2	1	2	3	-
bioMerieux Vidas - IgG	-	1	-	1	1	-
bioMerieux Vidas - Total	-	2	-	2	2	-
BioSystems	-	1	-	1	-	1
DPC Immulite 2000	-	1	-	1	1	-
Other IgG Method	-	1	-	1	1	-
Other Total Method	-	8	-	8	8	-
Roche cobas 6000 / e 601	-	1	1	-	1	-
Roche cobas 6000/e601 - IgG	-	1	-	1	1	-
Roche Elecsys - IgG	-	1	-	1	1	-
Roche Elecsys - Total	-	12	1	11	11	1
Roche Elecsys 1010 / 2010	-	9	1	8	9	-
Roche Modular Analytics	1	10	4	7	11	-
VITROS ECI - IgM	-	1	-	1	1	-
VITROS ECI - Total	-	13	1	12	12	1

Viral Markers – HBsAb (cont'd)

	Specimen VM-14		Specimen VM-15	
ALL METHODS	11	127	134	4
Abbott Architect	1	9	10	-
Abbott Architect - IgG	-	2	2	-
Abbott Architect - Total	1	17	18	-
Abbott AxSYM	-	2	2	-
Abbott AxSYM - Total	-	9	8	1
Bayer ADVIA Centaur	1	10	11	-
Bayer ADVIA Centaur - IgG	-	2	2	-
Bayer ADVIA Centaur - Total	-	10	10	-
Beckman ACCESS / 2 / DxI	1	2	3	-
bioMerieux Vidas - IgG	-	1	1	-
bioMerieux Vidas - Total	-	2	2	-
BioSystems	-	1	-	1
DPC Immulite 2000	-	1	1	-
Other IgG Method	-	1	1	-
Other Total Method	-	8	8	-
Roche cobas 6000 / e 601	1	-	1	-
Roche cobas 6000/e601 - IgG	-	1	1	-
Roche Elecsys - IgG	-	1	1	-
Roche Elecsys - Total	1	11	12	-
Roche Elecsys 1010 / 2010	1	8	9	-
Roche Modular Analytics	4	7	11	-
VITROS ECI - IgM	-	1	1	-
VITROS ECI - Total	-	13	12	1

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	5	183	180	8	5	181
Abbott Architect	-	19	19	-	-	19
Abbott Architect - IgG	-	1	1	-	-	1
Abbott Architect - Total	-	23	23	-	-	23
Abbott AxSYM	2	4	5	1	-	6
Abbott AxSYM - Total	1	5	6	-	1	5
Bayer ADVIA Centaur	-	14	14	-	-	14
Bayer ADVIA Centaur - IgM	-	1	1	-	-	1
Bayer ADVIA Centaur - Total	-	10	10	-	-	10
Beckman ACCESS / 2 / DxI	-	5	5	-	1	4
Bio-Rad Evolis	-	1	1	-	-	1
bioMerieux Vidas - IgG	-	1	1	-	-	1
bioMerieux Vidas - Total	-	7	6	1	-	7
bioMerieux Vidas, Mini Vidas	-	2	2	-	-	2
DPC Immulite 2000	-	1	1	-	-	1
Human	1	-	-	1	-	1
Other IgG Method	-	1	1	-	-	1
Other Total Method	-	14	12	2	1	13
Roche cobas 6000 / e 601	-	1	1	-	-	1
Roche Elecsys - IgG	-	2	2	-	-	2
Roche Elecsys - Total	-	21	20	1	1	20
Roche Elecsys 1010 / 2010	-	11	11	-	-	11
Roche Modular Analytics	-	12	12	-	1	11
VITROS ECI - IgM	-	1	1	-	-	1
VITROS ECI - Total	1	14	15	-	-	13

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	1	187	3	185
Abbott Architect	-	19	1	18
Abbott Architect - IgG	-	1	-	1
Abbott Architect - Total	-	23	1	22
Abbott AxSYM	-	6	-	6
Abbott AxSYM - Total	-	6	-	6
Bayer ADVIA Centaur	-	14	-	14
Bayer ADVIA Centaur - IgM	-	1	-	1
Bayer ADVIA Centaur - Total	-	10	-	10
Beckman ACCESS / 2 / DxI	-	5	-	5
Bio-Rad Evolis	-	1	-	1
bioMerieux Vidas - IgG	-	1	-	1
bioMerieux Vidas - Total	-	7	-	7
bioMerieux Vidas, Mini Vidas	-	2	-	2
DPC Immulite 2000	-	1	-	1
Human	-	1	-	1
Other IgG Method	-	1	-	1
Other Total Method	-	14	-	14
Roche cobas 6000 / e 601	-	1	-	1
Roche Elecsys - IgG	-	2	-	2
Roche Elecsys - Total	-	21	-	21
Roche Elecsys 1010 / 2010	-	11	-	11
Roche Modular Analytics	-	12	-	12
VITROS ECI - IgM	-	1	-	1
VITROS ECI - Total	1	14	-	15

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	166	2	-	167	3	164
Abbott Architect	18	-	-	18	-	18
Abbott Architect - IgG	6	-	-	6	-	6
Abbott Architect - Total	22	-	-	22	-	22
Abbott AxSYM	5	-	-	5	1	4
Abbott AxSYM - Total	8	-	-	8	-	8
Bayer ADVIA Centaur	12	-	-	12	-	12
Bayer ADVIA Centaur - IgG	4	-	-	4	-	4
Bayer ADVIA Centaur - Total	9	-	-	9	-	9
Beckman ACCESS / 2 / Dxl	5	-	-	5	-	5
Bio-Rad Evolis	3	-	-	3	-	3
Human	1	-	-	1	-	1
Other IgG Method	4	-	-	4	-	4
Other Total Method	13	-	-	13	1	12
Roche Elecsys - Total	15	-	-	15	-	15
Roche Elecsys 1010 / 2010	5	-	-	5	-	5
Roche Modular Analytics	9	-	-	9	-	9
VITROS ECI - IgG	1	-	-	1	-	1
VITROS ECI - IgM	1	-	-	1	-	1
VITROS ECI - Total	15	2	-	16	1	15

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	-	167	2	165
Abbott Architect	-	18	-	18
Abbott Architect - IgG	-	6	-	6
Abbott Architect - Total	-	22	-	22
Abbott AxSYM	-	5	-	5
Abbott AxSYM - Total	-	8	-	8
Bayer ADVIA Centaur	-	12	-	12
Bayer ADVIA Centaur - IgG	-	4	-	4
Bayer ADVIA Centaur - Total	-	9	-	9
Beckman ACCESS / 2 / Dxl	-	5	-	5
Bio-Rad Evolis	-	3	-	3
Human	-	1	-	1
Other IgG Method	-	4	1	3
Other Total Method	-	13	-	13
Roche Elecsys - Total	-	15	-	15
Roche Elecsys 1010 / 2010	-	5	-	5
Roche Modular Analytics	-	9	-	9
VITROS ECI - IgG	-	1	-	1
VITROS ECI - IgM	-	1	-	1
VITROS ECI - Total	-	16	-	16

Toxoplasma gondii Antibody

<u>Method</u>	Specimen TOX-11		Specimen TOX-12			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	-	9	6	3		
Abbott Architect - IgG	-	2	2	-		
Bayer ADVIA Centaur - IgG	-	1	1	-		
Other IgM method	-	1	-	1		
VITROS ECI - IgG	-	3	2	1		
VITROS ECI - IgM	-	1	-	1		
	Specimen TOX-13		Specimen TOX-14		Specimen TOX-15	
ALL METHODS	4	-	4	-	1	3
Other IgM method	1	-	1	-	-	1
VITROS ECI - IgG	2	-	2	-	1	1
VITROS ECI - IgM	1	-	1	-	-	1

Cytomegalovirus (CMV) Antibodies

<u>Method</u>	Specimen CMV-11		Specimen CMV-12			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	6	-	3	3		
Abbott Architect - IgG	2	-	2	-		
Other IgM method	1	-	-	1		
VITROS ECI - IgG	2	-	1	1		
VITROS ECI - IgM	1	-	-	1		
	Specimen CMV-13		Specimen CMV-14		Specimen CMV-15	
ALL METHODS	4	-	1	3	-	4
Other IgM method	1	-	-	1	-	1
VITROS ECI - IgG	2	-	1	1	-	2
VITROS ECI - IgM	1	-	-	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>
Specimen TOX-11						
All Method	11	0.3	0.5	171.3	0	0 - 2
Abbott Architect - IgG	5	0.2	0.4	223.6	0	0 - 2
Specimen TOX-12						
All Method	11	62.0	81.6	131.6	11	0 - 307
Abbott Architect - IgG	5	11.0	1.2	11.1	11	7 - 15
Specimen TOX-13						
All Method	3	-	-	-	122	Not graded
Specimen TOX-14						
All Method	3	-	-	-	72	Not graded
Specimen TOX-15						
All Method	3	-	-	-	22	Not graded

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>
Specimen CMV-11						
All Method	7	53.3	41.4	77.7	60	0 - 178
Specimen CMV-12						
All Method	7	38.7	23.8	61.4	45	0 - 111
Specimen CMV-13						
All Method	3	-	-	-	8	Not graded
Specimen CMV-14						
All Method	3	-	-	-	294	Not graded
Specimen CMV-15						
All Method	3	-	-	-	0	Not graded

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	18.68	2.97	15.9	17.8	9.7 - 27.6
Specimen CK-12						
All Method	5	75.18	15.11	20.1	66.0	29.8 - 120.6
Specimen CK-13						
All Method	5	9.06	0.99	10.9	9.0	6.0 - 12.1
Specimen CK-14						
All Method	5	36.34	8.51	23.4	31.8	10.8 - 61.9
Specimen CK-15						
All Method	5	52.78	11.00	20.8	46.8	19.7 - 85.8

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