MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

MLE
MedicalLaboratoryEvaluation

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

International Data Supplement
MLE – M1

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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 5 or more laboratories. Acceptable performance is established based on a target value ± the intervals below. An explanation on how to calculate the range of acceptability based upon these limits is also provided in your MLE Program Guide on pages 39-40 under the heading "Acceptable Ranges for Quantitative Results."

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

BLOOD BANK

ABO GROUP

Specimen	Results	Labs	Percent	Performance
BB-1	Group O	111	100%	Acceptable
BB-2	Group A	110	99.10%	Acceptable
	Group O	1	0.90%	
BB-3	Group B	111	100%	Acceptable
BB-4	Group AB	111	100%	Acceptable
BB-5	Group A	110	99.10%	Acceptable
	Group B	1	0.90%	

RH FACTOR (D TYPE)

Specimen	Results	Labs	Percent	Performance
BB-1	Rh Positive	110	100%	Acceptable
BB-2	Rh Negative	109	99.09%	Acceptable
	Rh Positive	1	0.91%	
BB-3	Rh Negative	109	99.09%	Acceptable
	Rh Positive	1	0.91%	
BB-4	Rh Negative	108	98.18%	Acceptable
	Rh Positive	2	1.82%	
BB-5	Rh Positive	110	100%	Acceptable

ANTIBODY DETECTION

Specimen	Results	Labs	Percent	Performance
AB-1	No unexpected antibody detected	89	98.89%	Acceptable
	Unexpected antibody detected	1	1.11%	
AB-2	Unexpected antibody detected	87	96.67%	Acceptable
	No unexpected antibody detected	3	3.33%	
AB-3	Unexpected antibody dectected	88	97.78%	Acceptable
	No unexpected antibody detected	2	2.22%	
AB-4	No unexpected antibody detected	89	98.89%	Acceptable
	Unexpected antibody detected	1	1.11%	
AB-5	No unexpected antibody detected	90	100%	Acceptable

BLOOD BANK

ANTIBODY IDENTIFICATION

Specimen	Identification	Labs	Percent	Performance
AB-1	No antibody detected	24	100%	Acceptable
AB-2	Anti-Fy(a)	23	100%	Acceptable
AB-3	Anti-D	23	100%	Acceptable
AB-4	No antibody detected	24	100%	Acceptable
AB-5	No antibody detected	24	100%	Acceptable

COMPATIBILITY TESTING

Specimen	Results	Labs	Percent	Performance
AB-1	Compatible	94	100%	Acceptable
AB-2	Not Compatible	89	94.68%	Acceptable
	Compatible	5	5.32%	
AB-3	Not Compatible	91	96.81%	Acceptable
	Compatible	3	3.19%	
AB-4	Compatible	93	98.94%	Acceptable
	Not Compatible	1	1.06%	
AB-5	Compatible	92	97.87%	Acceptable
	Not Compatible	2	2.13%	

Coagulation

PROTHROMBIN TIME (seconds)

Reagent/Instrument	Specimen CG-1 Labs	Mean	SD	CV	Median	Range	Specimen CG-2 Labs	Mean	SD	CV	Median	Range
All Method	52	52.33	6.57	12.5	53.7	44.4 - 60.2	60	13.08	1.03	7.9	13.3	11.1 - 15.1
Diag Stago STA Neoplastine CI+												
RAL Clot-SP	11	52.71	1.39	2.6	52.1	44.8 - 60.7	11	13.67	0.30	2.2	13.6	11.6 - 15.8
All Coagulation Instruments	13	52.62	1.45	2.8	52.1	44.7 - 60.6	13	13.75	0.50	3.6	13.6	11.6 - 15.9
HUMAN HemoStat Thromboplastin - SI												
bioMerieux Thrombolyzer Compact												
X/XR	5	62.78	5.03	8.0	64.2	53.3 - 72.2	8	13.11	0.75	5.7	13.0	11.1 - 15.1
All Coagulation Instruments	7	58.41	8.63	14.8	62.2	49.6 - 67.2	11	13.07	0.70	5.3	13.0	11.1 - 15.1
IL TEST PT-FIB HS PLUS												
IL ACL, all models	23	54.25	3.69	6.8	54.1	46.1 - 62.4	26	13.34	0.65	4.9	13.3	11.3 - 15.4

Reagent/Instrument	Specimen CG-3 Labs	Mean	SD	CV	Median	Range	Specimen CG-4 Labs	Mean	SD	CV	Median	Range
All Method	59	16.54	1.25	7.5	16.7	14.0 - 19.1	60	12.87	0.97	7.6	13.0	10.9 - 14.8
Diag Stago STA Neoplastine CI+												
RAL Clot-SP	11	17.34	0.23	1.3	17.3	14.7 - 20.0	11	13.57	0.40	2.9	13.6	11.5 - 15.7
All Coagulation Instruments	13	17.32	0.39	2.3	17.3	14.7 - 20.0	13	13.61	0.47	3.5	13.6	11.5 - 15.7
HUMAN HemoStat Thromboplastin - SI												
bioMerieux Thrombolyzer Compact												
X/XR	8	16.75	1.05	6.3	16.7	14.2 - 19.3	8	12.74	0.44	3.5	12.8	10.8 - 14.7
All Coagulation Instruments	10	16.35	1.26	7.7	16.4	13.8 - 18.9	11	12.65	0.51	4.0	12.7	10.7 - 14.6
IL TEST PT-FIB HS PLUS												
IL ACL, all models	26	16.84	0.96	5.7	16.8	14.3 - 19.4	26	13.16	0.56	4.3	13.2	11.1 - 15.2

Reagent/Instrument	Specimen CG-5 Labs	Mean	SD	CV	Median	Range
All Method	56	35.47	3.96	11.2	36.2	30.1 - 40.8
Diag Stago STA Neoplastine CI+						
RAL Clot-SP	11	36.60	1.01	2.8	36.8	31.1 - 42.1
All Coagulation Instruments	13	36.19	1.59	4.4	36.3	30.7 - 41.7
HUMAN HemoStat Thromboplastin - SI						
bioMerieux Thrombolyzer Compact						
X/XR	6	39.00	2.55	6.5	39.6	33.1 - 44.9
All Coagulation Instruments	9	37.41	4.17	11.2	38.5	31.7 - 43.1
IL TEST PT-FIB HS PLUS						
IL ACL, all models	24	36.64	3.13	8.5	37.7	31.1 - 42.2

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

Specimen CG-1

Reagent/Instrument	Labs	Mean	SD	CV	Median	Range
All Method	50	5.12	0.94	18.4	5.0	2.2 - 8.0
Diag Stago STA Neoplastine CI+						
RAL Clot-SP	11	5.46	0.20	3.6	5.4	4.8 - 6.1
All Coagulation Instruments	14	5.57	0.36	6.5	5.4	4.4 - 6.7
HUMAN HemoStat Thromboplastin - SI						
bioMerieux Thrombolyzer Compact						
X/XR	6	6.80	0.83	12.2	7.0	4.3 - 9.3
IL TEST PT-FIB HS PLUS						
IL ACL, all models	22	4.75	0.47	10.0	4.8	3.3 - 6.2

Specimen CG-2

Reagent/Instrument	Labs	Mean	SD	CV	Median	Range
All Method	55	0.97	0.12	11.9	1.0	0.6 - 1.4
Diag Stago STA Neoplastine CI+						
RAL Clot-SP	11	1.04	0.05	4.9	1.0	0.8 - 1.2
All Coagulation Instruments	14	1.06	0.06	6.1	1.1	0.8 - 1.3
HUMAN HemoStat Thromboplastin - SI						
bioMerieux Thrombolyzer Compact						
X/XR	8	0.98	0.15	15.3	1.0	0.5 - 1.5
IL TEST PT-FIB HS PLUS						
IL ACL, all models	24	0.91	0.11	11.8	0.9	0.5 - 1.3

Specimen CG-3

Reagent/Instrument	Labs	Mean	SD	CV	Median	Range
All Method	55	1.29	0.14	10.5	1.3	0.8 - 1.8
Diag Stago STA Neoplastine CI+						
RAL Clot-SP	11	1.40	0.00	0.0	1.4	1.4 - 1.4
All Coagulation Instruments	13	1.40	0.00	0.0	1.4	1.4 - 1.4
HUMAN HemoStat Thromboplastin - SI						
bioMerieux Thrombolyzer Compact						
X/XR	8	1.29	0.20	15.8	1.3	0.6 - 1.9
IL TEST PT-FIB HS PLUS						
IL ACL, all models	24	1.22	0.13	10.2	1.3	0.8 - 1.6

Specimen CG-4

Reagent/Instrument	Labs	Mean	SD	CV	Median	Range
All Method	54	0.95	0.10	10.9	1.0	0.6 - 1.3
Diag Stago STA Neoplastine CI+						
RAL Clot-SP	11	1.04	0.05	4.9	1.0	0.8 - 1.2
All Coagulation Instruments	14	1.04	0.05	4.8	1.0	0.8 - 1.2
HUMAN HemoStat Thromboplastin - SI						
bioMerieux Thrombolyzer Compact						
X/XR	8	0.94	0.11	11.3	1.0	0.6 - 1.3
IL TEST PT-FIB HS PLUS						
IL ACL, all models	23	0.90	0.10	11.6	0.9	0.5 - 1.3

Specimen CG-5

Reagent/Instrument	Labs	Mean	SD	CV	Median	Range
All Method	53	3.21	0.52	16.2	3.2	1.6 - 4.8
Diag Stago STA Neoplastine CI+						
RAL Clot-SP	11	3.49	0.10	3.0	3.5	3.1 - 3.9
All Coagulation Instruments	14	3.51	0.22	6.3	3.5	2.8 - 4.2
HUMAN HemoStat Thromboplastin - SI						
bioMerieux Thrombolyzer Compact						
X/XR	8	4.08	1.28	31.4	4.1	0.2 - 8.0
IL TEST PT-FIB HS PLUS						
IL ACL, all models	22	2.98	0.32	10.6	3.0	2.0 - 4.0

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

	Specimen CG-1						Specimen CG-2					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	47	63.2	7.7	12.1	60	53 - 73	48	29.8	2.4	8.2	30	25 - 35
Dade Actin FSL												
All Coagulation Instruments	4	-	-	-	65	55 - 76	5	29.8	1.6	5.5	30	25 - 35
HUMAN HemoStat aPTT - EL												
bioMerieux Thrombolyzer Compact X/XR	7	67.6	5.0	7.4	66	57 - 78	7	33.1	1.7	5.1	33	28 - 39
All Coagulation Instruments	9	69.7	7.2	10.4	67	59 - 81	8	32.5	2.4	7.4	33	27 - 38
IL TEST APTT-SP												
IL ACL, all models	27	58.6	2.6	4.4	58	49 - 68	27	28.7	1.7	6.1	29	24 - 34

	Specimen CG-3						Specimen CG-4					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	49	41.9	3.2	7.7	42	35 - 49	47	26.9	2.4	8.9	26	22 - 31
Dade Actin FSL												
All Coagulation Instruments	5	37.6	1.3	3.6	37	31 - 44	5	28.8	0.8	2.9	29	24 - 34
HUMAN HemoStat aPTT - EL												
bioMerieux Thrombolyzer Compact X/XR	7	42.0	1.7	4.1	42	35 - 49	7	30.0	1.6	5.4	30	25 - 35
All Coagulation Instruments	9	41.9	2.7	6.5	42	35 - 49	9	30.4	3.4	11.3	30	25 - 36
IL TEST APTT-SP												
IL ACL, all models	27	42.3	2.5	5.8	42	35 - 49	26	25.3	1.1	4.3	25	21 - 30

	Specimen CG-5					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	47	55.7	6.4	11.5	55	47 - 65
Dade Actin FSL						
All Coagulation Instruments	5	56.2	1.8	3.2	56	47 - 65
HUMAN HemoStat aPTT - EL						
bioMerieux Thrombolyzer Compact X/XR	7	63.7	3.5	5.5	62	54 - 74
All Coagulation Instruments	8	63.5	3.3	5.2	62	53 - 74
IL TEST APTT-SP						
IL ACL, all models	27	51.7	3.1	6.0	51	43 - 60

FIBRINOGEN (mg/dL)

	Specimen CG-1						Specimen CG-2					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	33	331.1	59.1	17.9	324	264 - 398	38	446.6	69.3	15.5	448	357 - 536
HUMAN HemoStat Fibrinogen bioMerieux Thrombolyzer Compact X/XR	7	294.3	30.1	10.2	297	235 - 354	5	414.8	45.1	10.9	430	331 - 498
IL TEST PT-FIB HS PLUS IL ACL, all models	20	364.7	42.6	11.7	367	291 - 438	26	469.0	63.0	13.4	465	375 - 563

	Specimen CG-3						Specimen CG-4					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	38	135.2	23.2	17.2	133	108 - 163	39	326.2	42.1	12.9	331	260 - 392
HUMAN HemoStat Fibrinogen bioMerieux Thrombolyzer Compact X/XR	6	124.0	16.9	13.6	124	99 - 149	7	328.0	35.7	10.9	338	262 - 394
IL TEST PT-FIB HS PLUS IL ACL, all models	25	142.3	22.5	15.8	134	113 - 171	25	338.5	34.4	10.2	338	270 - 407

	Specimen CG-5					
Reagent/Instrument	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	39	316.9	51.3	16.2	315	253 - 381
HUMAN HemoStat Fibrinogen bioMerieux Thrombolyzer Compact X/XR	7	306.6	48.6	15.9	297	245 - 368
IL TEST PT-FIB HS PLUS IL ACL, all models	25	338.4	38.1	11.2	335	270 - 407

URINALYSIS DIPSTICK–SPECIFIC GRAVITY

	Specimen UA-1					
Method	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
All Method	288	1.0129	0.0047	0.5	1.013	1.002 - 1.023
Arkray Aution Sticks	18	1.0147	0.0040	0.4	1.015	1.004 - 1.025
Bayer Clinitek Advantus	14	1.0129	0.0032	0.3	1.015	1.002 - 1.023
Bayer Reagent Strips	11	1.0136	0.0032	0.3	1.015	1.003 - 1.024
Roche Chemstrips / Combur	22	1.0081	0.0029	0.3	1.010	0.998 - 1.019
Roche cobas u 411	23	1.0096	0.0037	0.4	1.010	0.999 - 1.020
Roche Miditron Junior/II	21	1.0095	0.0026	0.3	1.010	0.999 - 1.020
Roche Urisys	54	1.0101	0.0028	0.3	1.010	1.000 - 1.021
UriScan Reagent Strips	58	1.0174	0.0033	0.3	1.015	1.007 - 1.028

URINALYSIS DIPSTICK–pH

Specimen UA-1

Participant Results

Method	***Labs***	***3.5 or less***	***4.0***	***4.5***	***5.0***	***5.5***	***6.0***	***6.5***	***7.0***	***7.5***	***8.0***	***8.5***	***9.0***
ALL METHODS	303	-	-	-	3	-	8	33	220	24	15	-	-
Acon Laboratories	1	-	-	-	-	-	1	-	-	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	-	1	-	-	-	-	-
Arkray Aution Sticks	18	-	-	-	-	-	-	10	8	-	-	-	-
Arkray PocketChem UA	2	-	-	-	-	-	-	2	-	-	-	-	-
Bayer Clinitek 500	7	-	-	-	-	-	-	2	5	-	-	-	-
Bayer Clinitek Advantus	13	-	-	-	-	-	-	1	8	4	-	-	-
Bayer Clinitek Atlas	2	-	-	-	-	-	-	-	2	-	-	-	-
Bayer Clinitek Status / Status+	2	-	-	-	-	-	-	-	2	-	-	-	-
Bayer Reagent Strips	22	-	-	-	-	-	-	-	11	11	-	-	-
BioScan Reagent Strips	1	-	-	-	-	-	-	-	1	-	-	-	-
CYBOW Urine Reagent Strips	1	-	-	-	-	-	-	1	-	-	-	-	-
HUMAN COMBINA Test Strips	1	-	-	-	-	-	-	-	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	-	-	-	1	1	-	-	-	-
Iris Diagnostics iChem 100	1	-	-	-	-	-	-	-	1	-	-	-	-
Other Analyzer Method	7	-	-	-	1	-	-	-	6	-	-	-	-
Other Dipstick Method	6	-	-	-	-	-	-	1	4	1	-	-	-
Roche Chemstrip 101	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche Chemstrips / Combur	25	-	-	-	-	-	-	-	19	4	2	-	-
Roche cobas u 411	23	-	-	-	1	-	-	-	20	-	2	-	-
Roche Miditron Junior/II	21	-	-	-	-	-	-	-	18	-	3	-	-
Roche SuperUA/ChemstripUA	6	-	-	-	-	-	-	-	4	-	2	-	-
Roche Urilux S	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche Urisys	53	-	-	-	-	-	1	-	47	-	5	-	-
SD UroColor Reagent Strips	5	-	-	-	-	-	-	-	2	3	-	-	-
TECO URS Strips	2	-	-	-	-	-	-	1	1	-	-	-	-
THME UDC-2020	6	-	-	-	-	-	2	-	4	-	-	-	-
UriScan Pro/II	3	-	-	-	-	-	-	-	3	-	-	-	-
UriScan Reagent Strips	57	-	-	-	-	-	4	12	40	1	-	-	-

URINALYSIS DIPSTICK–PROTEIN QUALITATIVE

Specimen UA-1

Participant Results

Method	***Labs***	***Negative***	***Trace***	***30mg/dL (1+)***	***100 mg/dL (2+)***	***300-500mg/dL (3+)***	***>300mg/dl***	***≥1000mg/dL (4+)***
ALL METHODS	302	241	27	33	-	1	-	-
Acon Laboratories	1	1	-	-	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-	-	-
Arkray Aution Sticks	18	17	-	1	-	-	-	-
Arkray PocketChem UA	2	1	-	1	-	-	-	-
Bayer Clinitek 500	7	7	-	-	-	-	-	-
Bayer Clinitek Advantus	13	13	-	-	-	-	-	-
Bayer Clinitek Atlas	2	2	-	-	-	-	-	-
Bayer Clinitek Status / Status+	3	1	2	-	-	-	-	-
Bayer Reagent Strips	21	8	12	1	-	-	-	-
CYBOW Urine Reagent Strips	1	1	-	-	-	-	-	-
HUMAN COMBINA Test Strips	1	1	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-	-	-
Iris Diagnostics iChem 100	1	1	-	-	-	-	-	-
Other Analyzer Method	7	5	1	1	-	-	-	-
Other Dipstick Method	6	5	1	-	-	-	-	-
Roche Chemstrip 101	1	-	1	-	-	-	-	-
Roche Chemstrips / Combur	25	17	2	6	-	-	-	-
Roche cobas u 411	23	11	1	11	-	-	-	-
Roche Miditron Junior/II	21	14	2	5	-	-	-	-
Roche SuperUA/ChemstripUA	6	6	-	-	-	-	-	-
Roche Urilux S	1	1	-	-	-	-	-	-
Roche Urisys	53	45	2	6	-	-	-	-
SD UroColor Reagent Strips	5	5	-	-	-	-	-	-
TECO URS Strips	2	2	-	-	-	-	-	-
THME UDC-2020	6	5	-	1	-	-	-	-
UriScan Pro/II	3	3	-	-	-	-	-	-
UriScan Reagent Strips	57	53	3	-	-	1	-	-

Specimen UA-1 is an ungraded challenge due to less than 80% participant consensus.

URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-1

Participant Results

Method	***Labs***	***Negative***	***50-100 mg/dL (Trace)***	***150 mg/dL***	***250 mg/dL***	***500 mg/dL***	***1000 mg/dL***	***>1000 mg/dL***	***≥2000 mg/dL***
ALL METHODS	303	4	220	22	49	5	2	1	-
Acon Laboratories	1	-	1	-	-	-	-	-	-
Arkray Aution Jet	1	-	1	-	-	-	-	-	-
Arkray Aution Sticks	17	-	16	1	-	-	-	-	-
Arkray PocketChem UA	2	-	2	-	-	-	-	-	-
Bayer Clinitek 500	7	-	7	-	-	-	-	-	-
Bayer Clinitek Advantus	13	-	7	-	6	-	-	-	-
Bayer Clinitek Atlas	3	-	3	-	-	-	-	-	-
Bayer Clinitek Status / Status+	3	-	2	-	1	-	-	-	-
Bayer Reagent Strips	22	-	21	1	-	-	-	-	-
CYBOW Urine Reagent Strips	1	-	-	-	1	-	-	-	-
HUMAN COMBINA Test Strips	1	-	-	1	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	2	-	-	-	-	-	-
Iris Diagnostics iChem 100	1	-	-	1	-	-	-	-	-
Other Analyzer Method	7	1	4	1	-	1	-	-	-
Other Dipstick Method	6	1	3	-	2	-	-	-	-
Roche Chemstrip 101	1	-	1	-	-	-	-	-	-
Roche Chemstrips / Combur	25	-	18	2	4	1	-	-	-
Roche cobas u 411	22	-	20	1	1	-	-	-	-
Roche Miditron Junior/II	21	-	17	1	2	-	1	-	-
Roche SuperUA/ChemstripUA	6	-	5	-	-	-	1	-	-
Roche Urilux S	1	-	1	-	-	-	-	-	-
Roche Urisys	53	-	47	2	3	-	-	1	-
SD UroColor Reagent Strips	5	-	1	1	3	-	-	-	-
TECO URS Strips	2	-	2	-	-	-	-	-	-
THME UDC-2020	6	1	-	4	-	1	-	-	-
UriScan Pro/II	3	-	2	-	1	-	-	-	-
UriScan Reagent Strips	57	1	28	4	23	1	-	-	-

URINALYSIS DIPSTICK–KETONES

Specimen UA-1

Participant Results

Method	*Labs*	*Negative*	*Trace (5 mg/dL)*	*Small (1+, 15 mg/dL)*	*Moderate (2+, 40 mg/dL)*	*Large (3+, 80 mg/dL)*	*150 mg/dL*	*≥ 160 mg/dL*
ALL METHODS	302	7	16	239	34	5	1	-
Acon Laboratories	1	-	-	1	-	-	-	-
Arkray Aution Jet	1	-	-	1	-	-	-	-
Arkray Aution Sticks	17	-	1	16	-	-	-	-
Arkray PocketChem UA	2	-	-	1	1	-	-	-
Bayer Clinitek 500	7	-	1	6	-	-	-	-
Bayer Clinitek Advantus	13	-	-	13	-	-	-	-
Bayer Clinitek Atlas	3	-	-	3	-	-	-	-
Bayer Clinitek Status / Status+	3	-	-	3	-	-	-	-
Bayer Reagent Strips	22	-	1	17	4	-	-	-
CYBOW Urine Reagent Strips	1	-	-	-	1	-	-	-
HUMAN COMBINA Test Strips	1	-	-	-	1	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	2	-	-	-	-
Iris Diagnostics iChem 100	1	-	-	1	-	-	-	-
Other Analyzer Method	7	1	2	3	1	-	-	-
Other Dipstick Method	6	-	2	3	1	-	-	-
Roche Chemstrip 101	1	-	-	-	1	-	-	-
Roche Chemstrips / Combur	24	1	1	21	1	-	-	-
Roche cobas u 411	23	1	-	18	4	-	-	-
Roche Miditron Junior/II	21	-	3	12	4	2	-	-
Roche SuperUA/ChemstripUA	6	-	-	5	-	-	1	-
Roche Urilux S	1	-	-	1	-	-	-	-
Roche Urisys	53	-	4	40	7	2	-	-
SD UroColor Reagent Strips	5	-	-	4	1	-	-	-
TECO URS Strips	2	-	-	2	-	-	-	-
THME UDC-2020	6	3	1	2	-	-	-	-
UriScan Pro/II	2	-	-	1	1	-	-	-
UriScan Reagent Strips	58	-	-	51	6	1	-	-

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-1

Participant Results

Method	***Labs***	***Negative***	***Small (1+)***	***Moderate (2+)***	***Large (3+)***
ALL METHODS	291	290	-	-	1
Acon Laboratories	1	1	-	-	-
Arkray Aution Jet	1	1	-	-	-
Arkray Aution Sticks	18	18	-	-	-
Arkray PocketChem UA	2	2	-	-	-
Bayer Clinitek 500	7	7	-	-	-
Bayer Clinitek Advantus	13	13	-	-	-
Bayer Clinitek Atlas	2	2	-	-	-
Bayer Clinitek Status / Status+	2	2	-	-	-
Bayer Reagent Strips	12	12	-	-	-
CYBOW Urine Reagent Strips	1	1	-	-	-
HUMAN COMBINA Test Strips	1	1	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-
Iris Diagnostics iChem 100	1	1	-	-	-
Other Analyzer Method	7	7	-	-	-
Other Dipstick Method	6	6	-	-	-
Roche Chemstrip 101	1	1	-	-	-
Roche Chemstrips / Combur	24	24	-	-	-
Roche cobas u 411	23	23	-	-	-
Roche Miditron Junior/II	21	21	-	-	-
Roche SuperUA/ChemstripUA	6	6	-	-	-
Roche Urilux S	1	1	-	-	-
Roche Urisys	53	53	-	-	-
SD UroColor Reagent Strips	5	5	-	-	-
TECO URS Strips	2	2	-	-	-
THME UDC-2020	6	6	-	-	-
UriScan Pro/II	3	3	-	-	-
UriScan Reagent Strips	57	56	-	-	1

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-1

Participant Results

Method	***Labs***	***0.2/Normal mg/dL***	***1.0 mg/dL***	***2.0 mg/dL***	***4.0 mg/dL***	***>8.0 mg/dL***
ALL METHODS	291	276	12	1	-	2
Acon Laboratories	1	1	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-
Arkray Aution Sticks	18	18	-	-	-	-
Arkray PocketChem UA	2	2	-	-	-	-
Bayer Clinitek 500	7	6	1	-	-	-
Bayer Clinitek Advantus	13	8	5	-	-	-
Bayer Clinitek Atlas	2	-	2	-	-	-
Bayer Clinitek Status / Status+	2	-	2	-	-	-
Bayer Reagent Strips	12	11	-	-	-	1
CYBOW Urine Reagent Strips	1	1	-	-	-	-
HUMAN COMBINA Test Strips	1	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-
Iris Diagnostics iChem 100	1	1	-	-	-	-
Other Analyzer Method	7	7	-	-	-	-
Other Dipstick Method	6	5	1	-	-	-
Roche Chemstrip 101	1	1	-	-	-	-
Roche Chemstrips / Combur	24	24	-	-	-	-
Roche cobas u 411	23	23	-	-	-	-
Roche Miditron Junior/II	21	21	-	-	-	-
Roche SuperUA/ChemstripUA	6	6	-	-	-	-
Roche Urilux S	1	1	-	-	-	-
Roche Urisys	53	52	-	1	-	-
SD UroColor Reagent Strips	5	5	-	-	-	-
TECO URS Strips	2	1	1	-	-	-
THME UDC-2020	6	6	-	-	-	-
UriScan Pro/II	3	3	-	-	-	-
UriScan Reagent Strips	57	56	-	-	-	1

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN

Specimen UA-1

Participant Results

Method	***Labs***	***Negative***	***Trace***	***Small (1+)***	***Moderate (2+)***	***Large (3+)***
ALL METHODS	302	295	3	3	1	-
Acon Laboratories	1	1	-	-	-	-
Arkray Aution Jet	1	1	-	-	-	-
Arkray Aution Sticks	18	18	-	-	-	-
Arkray PocketChem UA	2	2	-	-	-	-
Bayer Clinitek 500	7	7	-	-	-	-
Bayer Clinitek Advantus	13	13	-	-	-	-
Bayer Clinitek Atlas	2	2	-	-	-	-
Bayer Clinitek Status / Status+	3	3	-	-	-	-
Bayer Reagent Strips	22	21	-	1	-	-
CYBOW Urine Reagent Strips	1	1	-	-	-	-
HUMAN COMBINA Test Strips	1	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	2	-	-	-	-
Iris Diagnostics iChem 100	1	1	-	-	-	-
Other Analyzer Method	7	6	1	-	-	-
Other Dipstick Method	6	6	-	-	-	-
Roche Chemstrip 101	1	1	-	-	-	-
Roche Chemstrips / Combur	23	22	1	-	-	-
Roche cobas u 411	23	23	-	-	-	-
Roche Miditron Junior/II	21	20	-	1	-	-
Roche SuperUA/ChemstripUA	7	7	-	-	-	-
Roche Urilux S	1	1	-	-	-	-
Roche Urisys	53	53	-	-	-	-
SD UroColor Reagent Strips	4	3	1	-	-	-
TECO URS Strips	2	2	-	-	-	-
THME UDC-2020	6	6	-	-	-	-
UriScan Pro/II	2	2	-	-	-	-
UriScan Reagent Strips	58	57	-	-	1	-

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-1

		Participant Results				
Method	***Labs***	***Negative***	***Trace***	***Small (1+)***	***Moderate (2+)***	***Large (3+)***
ALL METHODS	284	19	26	73	78	88
Acon Laboratories	1	1	-	-	-	-
Arkray Aution Jet	1	-	-	-	1	-
Arkray Aution Sticks	18	-	-	9	6	3
Arkray PocketChem UA	2	-	-	-	1	1
Bayer Clinitek 500	7	-	2	2	3	-
Bayer Clinitek Advantus	13	-	4	6	3	-
Bayer Clinitek Atlas	2	-	-	2	-	-
Bayer Clinitek Status / Status+	2	-	-	2	-	-
Bayer Reagent Strips	12	-	5	6	1	-
CYBOW Urine Reagent Strips	1	-	-	-	1	-
HUMAN COMBINA Test Strips	1	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	2	-	-	-	2	-
Iris Diagnostics iChem 100	1	-	-	-	1	-
Other Analyzer Method	6	2	1	2	-	1
Other Dipstick Method	6	3	-	1	1	1
Roche Chemstrip 101	1	-	-	-	1	-
Roche Chemstrips / Combur	24	-	1	1	10	12
Roche cobas u 411	23	-	-	1	4	18
Roche Miditron Junior/II	21	1	-	1	7	12
Roche SuperUA/ChemstripUA	6	-	-	-	2	4
Roche Urilux S	1	-	-	-	1	-
Roche Urisys	53	1	1	4	16	31
SD UroColor Reagent Strips	5	1	-	3	1	-
TECO URS Strips	2	2	-	-	-	-
THME UDC-2020	5	2	-	2	-	1
UriScan Pro/II	1	-	1	-	-	-
UriScan Reagent Strips	56	3	10	28	13	2

URINALYSIS DIPSTICK–NITRITE

Specimen UA-1

Participant Results

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	286	285	1
Acon Laboratories	1	1	-
Arkray Aution Jet	1	1	-
Arkray Aution Sticks	18	18	-
Arkray PocketChem UA	2	2	-
Bayer Clinitek 500	7	7	-
Bayer Clinitek Advantus	13	13	-
Bayer Clinitek Atlas	2	2	-
Bayer Clinitek Status / Status+	2	2	-
Bayer Reagent Strips	11	11	-
BioScan Reagent Strips	1	1	-
CYBOW Urine Reagent Strips	1	1	-
HUMAN COMBINA Test Strips	1	1	-
Iris Diagnostics Aution Max AX-4280	2	2	-
Iris Diagnostics iChem 100	1	1	-
Other Analyzer Method	7	7	-
Other Dipstick Method	6	6	-
Roche Chemstrip 101	1	1	-
Roche Chemstrips / Combur	23	23	-
Roche cobas u 411	23	23	-
Roche Miditron Junior/II	21	21	-
Roche SuperUA/ChemstripUA	5	5	-
Roche Urilux S	1	1	-
Roche Urisys	53	53	-
SD UroColor Reagent Strips	5	5	-
TECO URS Strips	2	2	-
THME UDC-2020	6	6	-
UriScan Pro/II	3	3	-
UriScan Reagent Strips	55	54	1

URINALYSIS –MICROALBUMIN (dipstick only)

Specimen UA-1

Participant Results

Method	***Labs***	***Negative***	***10 mg/L(Pos)***	***20/30 mg/L***	***50 mg/L (+)***	***80 mg/L***	***100 mg/L (++)***	***150 mg/L***
ALL METHODS	26	6	-	5	1	12	-	2
Bayer Clinitek Microalbumin	17	1	-	2	-	12	-	2
Beckman Coulter ICON mircoALB	1	1	-	-	-	-	-	-
Roche Micral - 1 minute	2	1	-	-	1	-	-	-

URINALYSIS –URINE hCG

Specimen UA-1

Participant Results

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	62	62	-
Acon Laboratories	6	6	-
Biotron 1-Step	2	2	-
Genzyme OSOM hCG Combo Test	1	1	-
Inverness Acceva hCG-Urine	1	1	-
Inverness Clearview hCG Combo II	1	1	-
Quidel QuickVue One-Step Combo	29	29	-
Quidel QuickVue One-Step Urine	1	1	-
Stanbio QuStick	1	1	-
Sure-Vue hCG - 25mIU	1	1	-
Veda lab	1	1	-

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen SUS-1

	------Disk Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Amikacin	21	21	-	-	69	69	-	-	99.06%
Amoxicillin/Clavulanate	22	17	2	3	40	28	10	2	Ungraded[1]
Ampicillin	23	1	-	22	75	-	-	75	99.14%
Ampicillin/Sulbactam	16	14	2	-	60	17	20	23	Ungraded[1]
Aztreonam	9	9	-	-	31	30	-	1	97.78%
Carbenicillin	2	-	-	2	-	-	-	-	100.00%
Cefaclor	3	2	-	1	1	1	-	-	Ungraded[1]
Cefamandole	-	-	-	-	1	1	-	-	100.00%
Cefazolin	6	5	1	-	21	18	2	1	85.71%
Cefepime	11	11	-	-	66	66	-	-	100.00%
Cefixime	5	5	-	-	11	11	-	-	100.00%
Cefoperazone	3	3	-	-	1	1	-	-	100.00%
Cefotaxime	15	15	-	-	46	46	-	-	100.00%
Cefotetan	1	1	-	-	15	15	-	-	100.00%
Cefoxitin	5	5	-	-	33	33	-	-	100.00%
Cefpodoxime	1	1	-	-	-	-	-	-	100.00%
Ceftazidime	19	19	-	-	64	64	-	-	100.00%
Ceftizoxime	1	1	-	-	2	2	-	-	100.00%
Ceftriaxone	25	25	-	-	56	55	1	-	98.95%
Cefuroxime	16	15	-	1	50	46	1	3	92.31%
Cephalexin	3	3	-	-	5	5	-	-	100.00%
Cephalothin	13	9	2	2	52	38	10	4	Ungraded[1]
Ciprofloxacin	31	31	-	-	87	86	-	1	98.54%
Clindamycin	1	-	-	1	-	-	-	-	100.00%
Doxycycline	1	1	-	-	-	-	-	-	100.00%
Ertapenem	3	3	-	-	33	33	-	-	97.56%
Fosfomycin	8	8	-	-	11	11	-	-	100.00%
Gatifloxacin	-	-	-	-	3	3	-	-	100.00%
Gentamicin	27	27	-	-	87	86	1	-	98.48%
Imipenem	19	19	-	-	71	71	-	-	100.00%

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

ANTIMICROBIAL SUSCEPTIBILIY TESTING (cont'd)

Specimen SUS-1

	------Disk Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Kanamycin	1	1	-	-	-	-	-	-	100.00%
Levofloxacin	11	11	-	-	39	38	-	1	96.49%
Linezolid	2	-	-	2	1	1	-	-	Ungraded[1]
Lomefloxacin	-	-	-	-	1	1	-	-	100.00%
Meropenem	15	15	-	-	37	37	-	-	100.00%
Moxifloxacin	2	2	-	-	4	4	-	-	100.00%
Nalidixic Acid	11	11	-	-	32	32	-	-	100.00%
Netilmicin	7	7	-	-	5	5	-	-	100.00%
Nitrofurantoin	27	26	1	-	73	73	-	-	99.17%
Norfloxacin	18	18	-	-	18	18	-	-	100.00%
Ofloxacin	8	8	-	-	2	2	-	-	100.00%
Oxacillin	1	-	-	1	-	-	-	-	100.00%
Penicillin	1	-	-	1	2	-	-	2	100.00%
Piperacillin	1	-	-	1	20	2	1	17	81.48%
Piperacillin/Tazobactam	11	11	-	-	62	60	-	2	97.56%
Rifampin	2	-	-	2	-	-	-	-	100.00%
Tetracycline	3	3	-	-	30	29	-	1	97.56%
Ticarcillin/Clavulanate	3	3	-	-	11	8	3	-	Ungraded[1]
Tobramycin	5	5	-	-	37	37	-	-	97.96%
Trimethoprim	-	-	-	-	6	6	-	-	100.00%
Trimethoprim/Sulfamethoxazole	34	34	-	-	80	79	-	1	99.25%
Vancomycin	1	-	-	1	-	-	-	-	100.00%

Organism present in specimen SUS-1: *Escherichia coli.*

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

PARASITOLOGY (PA Specimens)

Specimen PA-1

Identification	***Labs***	***Percent***	***Performance***
No parasite seen	4	80%	Acceptable
Entamoeba histolytica	1	20%	

Parasite present in specimen PA-1: No parasite seen.

Specimen PA-2

Identification	***Labs***	***Percent***	***Performance***
Entamoeba histolytica	3	60%	Not graded
Entamoeba hartmanni	1	20%	
Giardia lamblia	1	20%	

Parasite present in specimen PA-2: *Entamoeba coli*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-3

Identification	***Labs***	***Percent***	***Performance***
Ascaris lumbricoides eggs	9	69.23%	Acceptable
Trichuris trichiura eggs	2	15.38%	Acceptable
No parasite seen	1	7.69%	
Schistosoma mansoni eggs	1	7.69%	

Parasite present in specimen PA-3: *Ascaris lumbricoides eggs*.

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-4

Identification	***Labs***	***Percent***	***Performance***
Diphyllobothrium latum	8	61.54%	Not graded
Endolimax nana	2	15.38%	
Fasciola hepatica eggs	1	7.69%	
Trichuris trichiura eggs	1	7.69%	
Ascaris lumbricoides eggs	1	7.69%	

Parasite present in specimen PA-4: *Diphyllobothrium latum.* This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-5

Identification	***Labs***	***Percent***	***Performance***
Microfilaria, sheathed, NOS	1	8.33%	Not graded
Microfilaria, unsheathed, NOS	1	8.33%	
Microfilaria-Brugia species	1	8.33%	
Microfilaria-Wuchereria Bancrofti	3	25.00%	
Plasmodium vivax	2	16.67%	
Microfilaria-Loa loa	2	16.67%	
No parasite seen	1	8.33%	

Parasite present in specimen PA-5: *Brugia malayi*. This is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY (FP Specimens)

Specimen FP-1

Identification	***Labs***	***Percent***	***Performance***
Hookworm	172	72.88%	Acceptable
Parasite egg seen but no ID	9	3.81%	Acceptable
Other parasite seen but no ID	2	0.85%	Acceptable
No parasite seen	19	8.05%	
Entamoeba coli	5	2.12%	
Ascaris lumbricoides eggs	5	2.12%	

Parasite present in specimen FP-1: *Hookworm eggs.*

Specimen FP-2

Identification	***Labs***	***Percent***	***Performance***
Ascaris lumbricoides eggs	202	80.48%	Acceptable
Trichuris trichiura eggs	18	7.17%	Acceptable
No parasite seen	11	4.38%	
Endolimax nana	5	1.99%	

Parasite present in specimen FP-2: *Ascaris lumbricoides eggs*.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-3

Identification	***Labs***	***Percent***	***Performance***
Diphyllobothrium latum	144	58.30%	Not graded
Fasciola hepatica eggs	26	10.53%	
Endolimax nana	16	6.48%	
Paragonimus westermani eggs	11	4.45%	
No parasite seen	8	3.24%	
Ascaris lumbricoides eggs	6	2.43%	
Blastocystis hominis	5	2.02%	

Parasite present in specimen FP-3: *Diphyllobothrium latum.* This is an ungraded challenge due to less than 80% participant consensus.

Specimen FP-4

Identification	***Labs***	***Percent***	***Performance***
No parasite seen	201	91.78	Acceptable

Parasite present in specimen FP-4: No parasite seen.

PARASITOLOGY (FP Specimens) cont'd

Specimen FP-5

Identification	***Labs***	***Percent***	***Performance***
Microfilaria, NOS	99	45.41%	Not graded
Microfilaria-Brugia species	9	4.13%	
Microfilaria, sheathed, NOS	3	1.38%	
Other parasite seen but no ID	2	0.92%	
No parasite seen	30	13.76%	
Plasodium falciparum	9	4.13%	
Plasmodium sp., NOS	8	3.67%	
Microfilaria-Onchocerca volvu	8	3.67%	
Plasmodium vivax	7	3.21%	
Babesia sp.	5	2.29%	

Parasite present in specimen FP-5: *Micofilaria-Brugia species.* This is an ungraded challenge due to less than 80% participant consensus.

Rubella—Qualitative

Method	**Specimen RU-1**		**Specimen RU-2**		**Specimen RU-3**	
	Positive	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	6	-	-	6	-	6
bioMerieux Vidas, Mini Vidas	1	-	-	1	-	1
Roche Modular Analytics	1	-	-	1	-	1
VITROS ECi	3	-	-	3	-	3

Method	**Specimen RU-4**		**Specimen RU-5**	
	Positive	***Negative***	***Positive***	***Negative***
ALL METHODS	6	-	6	-
bioMerieux Vidas, Mini Vidas	1	-	1	-
Roche Modular Analytics	1	-	1	-
VITROS ECi	3	-	3	-

Rubella—Quantitative (IU/mL)

Specimen/Method	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
Specimen RU-1						
All Method	12	89.53	45.19	50.5	66.0	0.0 - 225.2
Specimen RU-2						
All Method	11	0.06	0.10	161.4	0.0	0.0 - 0.4
Specimen RU-3						
All Method	11	0.07	0.11	151.8	0.0	0.0 - 0.5
Specimen RU-4						
All Method	12	60.20	50.61	84.1	34.0	0.0 - 212.1
Specimen RU-5						
All Method	12	170.89	75.96	44.4	146.0	0.0 - 398.8

Syphilis Serology—Qualitative: VDRL Slide

Method	Specimen SY-1			Specimen SY-2			Specimen SY-3		
	Reactive	Weakly Reactive	Non-Reactive	Reactive	Weakly Reactive	Non-Reactive	Reactive	Weakly Reactive	Non-Reactive
ALL METHODS	13	-	-	13	-	-	-	-	13
Omega Diagnostics	2	-	-	2	-	-	-	-	2
Wiener Lab	8	-	-	8	-	-	-	-	8

	Specimen SY-4			Specimen SY-5		
ALL METHODS	13	-	-	-	-	13
Omega Diagnostics	2	-	-	-	-	2
Wiener Lab	8	-	-	-	-	8

Syphilis Serology—Quantitative: VDRL Slide Titer

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

Syphilis Serology—Qualitative: MHA-TP

	Specimen SY-1		Specimen SY-2		Specimen SY-3	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	15	-	15	-	-	15
Biokit	2	-	2	-	-	2
Human	2	-	2	-	-	2
Omega Diagnostics	1	-	1	-	-	1
Serodia	5	-	5	-	-	5
SPINREACT	1	-	1	-	-	1

	Specimen SY-4		Specimen SY-5	
	Reactive	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	15	-	-	15
Biokit	2	-	-	2
bioMerieux	2	-	-	2
Human	1	-	-	1
Omega Diagnostics	5	-	-	5
Serodia	1	-	-	1

Syphilis Serology—Qualitative: FTA-ABS (*Treponema pallidum* Antibodies)

	Specimen SY-1		Specimen SY-2		Specimen SY-3	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	10	-	10	-	-	10
Abbott Architect	1	-	1	-	-	1
bioMerieux	1	-	1	-	-	1
Serodia	3	-	3	-	-	3

	Specimen SY-4		Specimen SY-5	
	Reactive	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	10	-	1	9
Abbott Architect	1	-	-	1
bioMerieux	1	-	-	1
Serodia	3	-	-	3

Syphilis Serology—Qualitative: RPR

	Specimen SY-1		Specimen SY-2		Specimen SY-3	
Method	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	35	-	35	-	-	35
Becton Dickinson	1	-	1	-	-	1
bioMerieux	3	-	3	-	-	3
bioMerieux Vidas, Mini Vidas	1	-	1	-	-	1
BioSystems	4	-	4	-	-	4
Human	2	-	2	-	-	2
Immunostics Inc.	2	-	2	-	-	2
Omega Diagnostics	7	-	7	-	-	7
Serodia	1	-	1	-	-	1
SPINREACT	7	-	7	-	-	7
Wiener Lab	2	-	2	-	-	2

	Specimen SY-4		Specimen SY-5	
	Reactive	***Non-Reactive***	***Reactive***	***Non-Reactive***
ALL METHODS	35	-	-	35
Becton Dickinson	1	-	-	1
bioMerieux	3	-	-	3
bioMerieux Vidas, Mini Vidas	1	-	-	1
BioSystems	4	-	-	4
Human	2	-	-	2
Immunostics Inc.	2	-	-	2
Omega Diagnostics	7	-	-	7
Serodia	1	-	-	1
SPINREACT	7	-	-	7
Wiener Lab	2	-	-	2

Syphilis Serology—Quantitative: RPR (Titer)

Specimen/Method	***1***	***2***	***4***	***8***	***16***	***32***	***64***	***>64***
Specimen SY-1								
ALL METHODS	-	4	16	4	-	-	1	-
Becton Dickinson	-	-	-	1	-	-	-	-
bioMerieux	-	-	1	-	-	-	-	-
bioMerieux Vidas, Mini Vidas	-	-	1	-	-	-	-	-
BioSystems	-	-	1	1	-	-	-	-
Human	-	-	1	1	-	-	-	-
Immunostics Inc.	-	-	1	-	-	-	-	-
Omega Diagnostics	-	-	5	1	-	-	-	-
Serodia	-	-	-	-	-	-	1	-
SPINREACT	-	2	5	-	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-
Specimen SY-2								
ALL METHODS	3	15	6	-	-	1	-	-
Becton Dickinson	-	-	1	-	-	-	-	-
bioMerieux	-	1	-	-	-	-	-	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	-	-	-	-
BioSystems	-	1	1	-	-	-	-	-
Human	-	1	1	-	-	-	-	-
Immunostics Inc.	-	1	-	-	-	-	-	-
Omega Diagnostics	-	5	1	-	-	-	-	-
Serodia	-	-	-	-	-	1	-	-
SPINREACT	2	4	1	-	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-

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

Specimen/Method	***1***	***2***	***4***	***8***	***16***	***32***	***64***	***>64***
Specimen SY-4								
ALL METHODS	-	3	18	2	1	-	1	-
Becton Dickinson	-	-	-	1	-	-	-	-
bioMerieux	-	-	1	-	-	-	-	-
bioMerieux Vidas, Mini Vidas	-	-	1	-	-	-	-	-
BioSystems	-	-	2	-	-	-	-	-
Human	-	-	1	-	1	-	-	-
Immunostics Inc.	-	-	1	-	-	-	-	-
Omega Diagnostics	-	-	5	1	-	-	-	-
Serodia	-	-	-	-	-	-	1	-
SPINREACT	-	2	5	-	-	-	-	-
Wiener Lab	-	-	1	-	-	-	-	-

Viral Markers – Anti-HBc

Method	Specimen VM-1 *Positive*	Specimen VM-1 *Negative*	Specimen VM-2 *Positive*	Specimen VM-2 *Negative*	Specimen VM-3 *Positive*	Specimen VM-3 *Negative*
ALL METHODS	54	20	63	11	4	70
Abbott Architect	1	-	1	-	-	1
Abbott Architect - IgG	3	-	3	-	-	3
Abbott Architect - Total	10	-	10	-	-	10
Abbott AxSYM - IgG	1	-	1	-	-	1
Abbott AxSYM - IgM	-	1	-	1	-	1
Abbott AxSYM - Total	9	-	9	-	1	8
Bayer ADVIA Centaur - Total	-	4	4	-	-	4
Beckman ACCESS / 2 / DxI	-	1	-	1	-	1
Bio-Rad Evolis	1	-	1	-	-	1
bioMerieux Vidas - IgM	-	3	-	3	-	3
bioMerieux Vidas - Total	2	-	2	-	-	2
Other IgG Method	1	1	1	1	1	1
Other Total Method	3	4	6	1	1	6
Roche Elecsys - IgG	4	-	4	-	-	4
Roche Elecsys - IgM	-	2	-	2	-	2
Roche Elecsys - Total	2	1	3	-	-	3
Roche Elecsys 1010 / 2010	3	-	3	-	-	3
Roche Modular Analytics	2	-	2	-	-	2
VITROS ECi - IgG	2	-	2	-	-	2
VITROS ECi - IgM	-	2	-	2	-	2
VITROS ECi - Total	7	1	8	-	1	7

Viral Markers – Anti-HBc (cont'd)

	Specimen VM-4		Specimen VM-5	
	Positive	***Negative***	***Positive***	***Negative***
ALL METHODS	69	5	4	70
Abbott Architect	1	-	-	1
Abbott Architect - IgG	3	-	-	3
Abbott Architect - Total	10	-	-	10
Abbott AxSYM - IgG	1	-	-	1
Abbott AxSYM - IgM	1	-	-	1
Abbott AxSYM - Total	9	-	-	9
Bayer ADVIA Centaur - Total	4	-	-	4
Beckman ACCESS / 2 / DxI	1	-	-	1
Bio-Rad Evolis	1	-	-	1
bioMerieux Vidas - IgM	3	-	-	3
bioMerieux Vidas - Total	2	-	-	2
Other IgG Method	1	1	1	1
Other Total Method	6	1	1	6
Roche Elecsys - IgG	4	-	-	4
Roche Elecsys - IgM	2	-	-	2
Roche Elecsys - Total	3	-	-	3
Roche Elecsys 1010 / 2010	3	-	-	3
Roche Modular Analytics	2	-	-	2
VITROS ECi - IgG	2	-	-	2
VITROS ECi - IgM	2	-	-	2
VITROS ECi - Total	6	2	1	7

Viral Markers – Anti-HIV

	Specimen VM-1		Specimen VM-2		Specimen VM-3	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	137	-	1	136	1	136
Abbott Architect	6	-	-	6	-	6
Abbott Architect - Total	15	-	-	15	-	15
Abbott AxSYM	6	-	-	6	-	6
Abbott AxSYM - Total	10	-	-	10	-	10
Bayer ADVIA Centaur	2	-	-	2	-	2
Bayer ADVIA Centaur - Total	5	-	-	5	-	5
Beckman ACCESS / 2 / DxI	4	-	-	4	-	4
Bio-Rad Evolis	3	-	-	3	-	3
bioMerieux Vidas - IgG	2	-	-	2	-	2
bioMerieux Vidas - Total	10	-	-	10	-	10
bioMerieux Vidas, Mini Vidas	2	-	-	2	-	2
Other Total Method	14	-	1	13	1	13
Roche Elecsys - IgG	1	-	-	1	-	1
Roche Elecsys - Total	19	-	-	19	-	19
Roche Elecsys 1010 / 2010	8	-	-	8	-	8
Roche Modular Analytics	4	-	-	4	-	4
VITROS ECi - Total	16	-	-	16	-	16

Viral Markers – Anti-HIV (cont'd)

	Specimen VM-4		Specimen VM-5	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	2	135	-	137
Abbott Architect	-	6	-	6
Abbott Architect - Total	1	14	-	15
Abbott AxSYM	-	6	-	6
Abbott AxSYM - Total	-	10	-	10
Bayer ADVIA Centaur	-	2	-	2
Bayer ADVIA Centaur - Total	-	5	-	5
Beckman ACCESS / 2 / DxI	-	4	-	4
Bio-Rad Evolis	-	3	-	3
bioMerieux Vidas - IgG	-	2	-	2
bioMerieux Vidas - Total	-	10	-	10
bioMerieux Vidas, Mini Vidas	-	2	-	2
Other Total Method	1	13	-	14
Roche Elecsys - IgG	-	1	-	1
Roche Elecsys - Total	-	19	-	19
Roche Elecsys 1010 / 2010	-	8	-	8
Roche Modular Analytics	-	4	-	4
VITROS ECi - Total	-	16	-	16

Viral Markers – HAV

Method	**Specimen VM-1**		**Specimen VM-2**		**Specimen VM-3**	
	Positive	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	76	47	28	46	29
Abbott Architect - IgG	-	8	8	-	8	-
Abbott Architect - IgM	-	3	-	3	-	3
Abbott Architect - Total	-	1	1	-	1	-
Abbott AxSYM - IgG	-	3	3	-	3	-
Abbott AxSYM - IgM	-	3	-	3	-	3
Abbott AxSYM - Total	-	4	3	1	3	1
Bayer ADVIA Centaur - Total	-	3	3	-	3	-
Beckman ACCESS / 2 / DxI	-	2	1	1	1	1
bioMerieux Vidas - IgM	-	10	-	9	-	9
bioMerieux Vidas - Total	-	2	2	-	1	1
Other IgG Method	-	1	1	-	1	-
Other IgM method	-	4	-	4	-	4
Other Total Method	-	1	1	-	1	-
Roche Elecsys - IgG	-	5	5	-	5	-
Roche Elecsys - IgM	-	5	-	5	-	5
Roche Elecsys - Total	-	8	7	1	7	1
Roche Modular Analytics	-	3	3	-	3	-
VITROS ECi - IgG	-	1	1	-	1	-
VITROS ECi - Total	-	6	5	1	5	1

Viral Markers – HAV (cont'd)

	Specimen VM-4		Specimen VM-5	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	-	75	47	28
Abbott Architect - IgG	-	8	8	-
Abbott Architect - IgM	-	3	-	3
Abbott Architect - Total	-	1	1	-
Abbott AxSYM - IgG	-	3	3	-
Abbott AxSYM - IgM	-	3	-	3
Abbott AxSYM - Total	-	4	3	1
Bayer ADVIA Centaur - Total	-	3	3	-
Beckman ACCESS / 2 / DxI	-	2	1	1
bioMerieux Vidas - IgM	-	9	-	9
bioMerieux Vidas - Total	-	2	2	-
Other IgG Method	-	1	1	-
Other IgM method	-	4	-	4
Other Total Method	-	1	1	-
Roche Elecsys - IgG	-	5	5	-
Roche Elecsys - IgM	-	5	-	5
Roche Elecsys - Total	-	8	7	1
Roche Modular Analytics	-	3	3	-
VITROS ECi - IgG	-	1	1	-
VITROS ECi - Total	-	6	5	1

Viral Markers – HBeAg

	Specimen VM-1		Specimen VM-2		Specimen VM-3	
Method	***Positive***	***Negative***	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	1	35	1	35	-	36
Abbott Architect - Total	-	6	-	6	-	6
Abbott AxSYM	1	1	-	2	-	2
Abbott AxSYM - Total	-	6	-	6	-	6
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 - Total	-	3	-	3	-	3
Roche Modular Analytics	-	4	-	4	-	4
VITROS ECi - Total	-	5	1	4	-	5

	Specimen VM-4		Specimen VM-5	
ALL METHODS	35	1	2	34
Abbott Architect - Total	6	-	1	5
Abbott AxSYM	2	-	-	2
Abbott AxSYM - Total	6	-	-	6
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 - Total	3	-	-	3
Roche Modular Analytics	4	-	-	4
VITROS ECi - Total	4	1	1	4

Viral Markers – HBsAb

Method	Specimen VM-1 *Positive*	Specimen VM-1 *Negative*	Specimen VM-2 *Positive*	Specimen VM-2 *Negative*	Specimen VM-3 *Positive*	Specimen VM-3 *Negative*
ALL METHODS	52	41	88	5	2	91
Abbott Architect	1	-	1	-	-	1
Abbott Architect - IgG	1	-	1	-	-	1
Abbott Architect - Total	12	2	14	-	-	14
Abbott AxSYM - IgG	-	1	1	-	-	1
Abbott AxSYM - Total	1	8	9	-	-	9
Bayer ADVIA Centaur	1	-	1	-	-	1
Bayer ADVIA Centaur - Total	5	1	5	1	-	6
Beckman ACCESS / 2 / DxI	-	2	2	-	-	2
bioMerieux Vidas - IgG	-	2	2	-	-	2
bioMerieux Vidas - Total	-	3	2	1	-	3
Other IgG Method	1	-	1	-	-	1
Other Total Method	1	5	3	3	-	6
Roche Elecsys - IgG	2	-	2	-	1	1
Roche Elecsys - Total	11	-	11	-	-	11
Roche Elecsys 1010 / 2010	9	-	9	-	-	9
Roche Modular Analytics	4	1	5	-	1	4
VITROS ECi - Total	1	12	13	-	-	13

Viral Markers – HBsAb (cont'd)

	Specimen VM-4		Specimen VM-5	
ALL METHODS	3	90	89	4
Abbott Architect	-	1	1	-
Abbott Architect - IgG	-	1	1	-
Abbott Architect - Total	-	14	14	-
Abbott AxSYM - IgG	-	1	1	-
Abbott AxSYM - Total	-	9	9	-
Bayer ADVIA Centaur	-	1	1	-
Bayer ADVIA Centaur - Total	-	6	6	-
Beckman ACCESS / 2 / DxI	-	2	2	-
bioMerieux Vidas - IgG	-	2	2	-
bioMerieux Vidas - Total	-	3	3	-
Other IgG Method	-	1	1	-
Other Total Method	-	6	5	1
Roche Elecsys - IgG	-	2	2	-
Roche Elecsys - Total	-	11	11	-
Roche Elecsys 1010 / 2010	-	9	9	-
Roche Modular Analytics	1	4	5	-
VITROS ECi - Total	-	13	12	1

Viral Markers – Anti-HBsAg

Method	Specimen VM-1		Specimen VM-2		Specimen VM-3	
	Positive	Negative	Positive	Negative	Positive	Negative
ALL METHODS	1	133	134	-	5	129
Abbott Architect	-	5	5	-	-	5
Abbott Architect - IgG	-	1	1	-	-	1
Abbott Architect - Total	-	18	18	-	-	18
Abbott AxSYM	-	5	5	-	-	5
Abbott AxSYM - Total	-	7	7	-	1	6
Bayer ADVIA Centaur	-	2	2	-	-	2
Bayer ADVIA Centaur - Total	-	6	6	-	-	6
Beckman ACCESS / 2 / DxI	-	4	4	-	-	4
Bio-Rad Evolis	-	3	3	-	-	3
bioMerieux Vidas - IgG	-	2	2	-	-	2
bioMerieux Vidas - Total	-	9	9	-	-	9
bioMerieux Vidas, Mini Vidas	-	2	2	-	-	2
Other Total Method	1	9	10	-	-	10
Roche Elecsys - IgG	-	1	1	-	-	1
Roche Elecsys - Total	-	18	18	-	1	17
Roche Elecsys 1010 / 2010	-	10	10	-	1	9
Roche Modular Analytics	-	4	4	-	-	4
VITROS ECi - Total	-	14	14	-	1	13

Viral Markers – Anti-HBsAg (cont'd)

	Specimen VM-4		Specimen VM-5	
Method	***Positive***	***Negative***	***Positive***	***Negative***
ALL METHODS	133	1	-	134
Abbott Architect	5	-	-	5
Abbott Architect - IgG	1	-	-	1
Abbott Architect - IgM	18	-	-	18
Abbott Architect - Total	5	-	-	5
Abbott AxSYM	7	-	-	7
Abbott AxSYM - Total	2	-	-	2
Bayer ADVIA Centaur - Total	6	-	-	6
Bio-Rad Evolis	4	-	-	4
bioMerieux Vidas - IgG	3	-	-	3
bioMerieux Vidas - IgM	2	-	-	2
bioMerieux Vidas - Total	9	-	-	9
bioMerieux Vidas, Mini Vidas	2	-	-	2
Other Total Method	10	-	-	10
Roche Elecsys - IgG	1	-	-	1
Roche Elecsys - Total	17	1	-	18
Roche Elecsys 1010 / 2010	10	-	-	10
Roche Modular Analytics	4	-	-	4
VITROS ECi - Total	14	-	-	14

Viral Markers – HCV

Method	Specimen VM-1 Positive	Specimen VM-1 Negative	Specimen VM-2 Positive	Specimen VM-2 Negative	Specimen VM-3 Positive	Specimen VM-3 Negative
ALL METHODS	-	116	1	115	116	-
Abbott Architect	-	5	-	5	5	-
Abbott Architect - IgG	-	2	-	2	2	-
Abbott Architect - Total	-	18	-	18	18	-
Abbott AxSYM	-	7	-	7	7	-
Abbott AxSYM - Total	-	8	-	8	8	-
Bayer ADVIA Centaur	-	2	-	2	2	-
Bayer ADVIA Centaur - IgG	-	1	-	1	1	-
Bayer ADVIA Centaur - Total	-	6	-	6	6	-
Beckman ACCESS / 2 / DxI	-	2	-	2	2	-
Bio-Rad Evolis	-	4	-	4	4	-
Other IgG Method	-	3	-	3	3	-
Other Total Method	-	13	-	13	13	-
Roche Elecsys - Total	-	12	-	12	12	-
Roche Modular Analytics	-	4	-	4	4	-
VITROS ECi - IgG	-	1	-	1	1	-
VITROS ECi - Total	-	18	-	18	18	-

Method	Specimen VM-4 Positive	Specimen VM-4 Negative	Specimen VM-5 Positive	Specimen VM-5 Negative
ALL METHODS	-	116	1	115
Abbott Architect	-	5	-	5
Abbott Architect - IgG	-	2	-	2
Abbott Architect - Total	-	18	-	18
Abbott AxSYM	-	7	-	7
Abbott AxSYM - Total	-	8	-	8
Bayer ADVIA Centaur	-	2	-	2
Bayer ADVIA Centaur - IgG	-	1	-	1
Bayer ADVIA Centaur - Total	-	6	-	6
Beckman ACCESS / 2 / DxI	-	2	-	2
Bio-Rad Evolis	-	4	-	4
Other IgG Method	-	3	-	3
Other Total Method	-	13	-	13
Roche Elecsys - Total	-	12	-	12
Roche Modular Analytics	-	4	-	4
VITROS ECi - IgG	-	1	-	1
VITROS ECi - Total	-	18	-	18

Toxoplasma gondii Antibody

Method	Specimen TOX-1 Positive	Specimen TOX-1 Negative	Specimen TOX-2 Positive	Specimen TOX-2 Negative	Specimen TOX-3 Positive	Specimen TOX-3 Negative
ALL METHODS	2	3	5	-	-	3
Abbott Architect - IgG	-	1	1	-	-	-
Other IgM method	-	1	1	-	-	1
VITROS ECi - IgG	2	-	2	-	-	2
VITROS ECi - IgM	-	1	1	-	-	-

	Specimen TOX-4		Specimen TOX-5	
ALL METHODS	2	1	3	-
Other IgM method	-	1	1	-
VITROS ECi - IgG	2	-	2	-

Cytomegalovirus (CMV) Antibodies

Method	Specimen CMV-1 Positive	Specimen CMV-1 Negative	Specimen CMV-2 Positive	Specimen CMV-2 Negative	Specimen CMV-3 Positive	Specimen CMV-3 Negative
ALL METHODS	5	-	4	1	4	-
Abbott Architect - IgG	1	-	1	-	-	-
Other IgM method	1	-	-	1	1	-
VITROS ECi - IgG	3	-	3	-	3	-

	Specimen CMV-4		Specimen CMV-5	
ALL METHODS	-	4	3	1
Other IgM method	-	1	-	1
VITROS ECi - IgG	-	3	3	-

Toxoplasma gondii Antibody —Quantitative (IU/mL)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen TOX-1						
All Method	5	144.6	85.8	59.3	189	0 - 402
Specimen TOX-2						
All Method	5	91.0	21.6	23.8	95	26 - 156
Specimen TOX-3						
All Method	2	-	-	-	0	Not graded
Specimen TOX-4						
All Method	2	-	-	-	24	Not graded
Specimen TOX-5						
All Method	2	-	-	-	164	Not graded

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

Specimen/Method	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Range***
Specimen CMV-1						
All Method	5	29.8	28.2	94.7	21	0 - 115
Specimen CMV-2						
All Method	5	49.0	64.4	131.5	20	0 - 243
Specimen CMV-3						
All Method	3	-	-	-	23	Not graded
Specimen CMV-4						
All Method	3	-	-	-	0	Not graded
Specimen CMV-5						
All Method	3	-	-	-	373	Not graded

CK-MB - Quantitative (U/L)

Specimen/Method	*Labs*	*Mean*	*SD*	*CV*	*Median*	*Range*
Specimen CK-1						
All Method	6	97.95	14.15	14.5	100.9	55.4 - 140.5
Specimen CK-2						
All Method	6	67.67	8.81	13.0	69.8	41.2 - 94.1
Specimen CK-3						
All Method	6	23.15	3.02	13.0	22.7	14.0 - 32.3
Specimen CK-4						
All Method	6	46.48	6.84	14.7	46.4	25.9 - 67.0
Specimen CK-5						
All Method	6	9.32	0.74	8.0	9.4	7.0 - 11.6

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