

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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



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**International Data Supplement
MLE – M2**

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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 \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-6	Group A	75	100%	Acceptable
BB-7	Group O	74	98.67%	Acceptable
	Group AB	1	1.33%	
BB-8	Group AB	74	98.67%	Acceptable
	Group O	1	1.33%	
BB-9	Group O	74	98.67%	Acceptable
	Group B	1	1.33%	
BB-10	Group B	73	97.33%	Acceptable
	Group A	2	2.67%	

RH FACTOR (D TYPE)

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
BB-6	Rh Positive	74	100%	Acceptable
BB-7	Rh Positive	73	98.65%	Acceptable
	Rh Negative	1	1.35%	
BB-8	Rh Negative	74	100%	Acceptable
BB-9	Rh Negative	73	98.65%	Acceptable
	Rh Positive	1	1.35%	
BB-10	Rh Positive	73	98.65%	Acceptable
	Rh Negative	1	1.35%	

ANTIBODY DETECTION

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	Unexpected antibody detected	48	100%	Acceptable
AB-7	Unexpected antibody detected	45	93.75%	Acceptable
	No unexpected antibody detected	3	6.25%	
AB-8	Unexpected antibody detected	46	95.83%	Acceptable
	No unexpected antibody detected	2	4.17%	
AB-9	No unexpected antibody detected	48	100%	Acceptable
AB-10	No unexpected antibody detected	48	100%	Acceptable

Specimen AB-7 is graded by 100% referee consensus.

BLOOD BANK

ANTIBODY IDENTIFICATION

<u>Specimen</u>	<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	Anti-k	4	20.00%	Acceptable
	Unable to identify, referred	14	70.00%	Acceptable
	Anti-K	1	5.00%	
	No antibody detected	1	5.00%	
AB-6	Anti-E	19	95.00%	Acceptable
	Anti-D	1	5.00%	
AB-8	Anti-Jk ^a	20	100%	Acceptable
AB-9	No antibody detected	20	100%	Acceptable
AB-10	No antibody detected	20	100%	Acceptable

Specimen AB-6 is graded by 100% referee consensus.

COMPATIBILITY TESTING

<u>Specimen</u>	<u>Results</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
AB-6	Not Compatible	49	100%	Acceptable
AB-7	Compatible	49	100%	Acceptable
AB-8	Not Compatible	44	89.80%	Acceptable
	Compatible	5	10.20%	
AB-9	Compatible	49	100%	Acceptable
AB-10	Compatible	48	97.96%	Acceptable
	Not Compatible	1	2.04%	

Specimen AB-8 is graded by 100% referee consensus.

Coagulation

PROTHROMBIN TIME (seconds)

<u>Reagent/Instrument</u>	Specimen CG-6						Specimen CG-7					
	<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	70	12.91	1.21	9.4	13.0	10.9 - 14.9	68	52.30	10.94	20.9	51.8	44.4 - 60.2
Dade Innovin												
All Coagulation Instruments	5	11.18	0.53	4.7	11.2	9.5 - 12.9	5	39.56	2.35	5.9	40.3	33.6 - 45.5
Diag Stago STA Neoplastine Cl+												
RAL Clot-SP	11	13.50	0.33	2.5	13.5	11.4 - 15.6	11	53.94	1.23	2.3	53.9	45.8 - 62.1
All Coagulation Instruments	15	13.50	0.81	6.0	13.3	11.4 - 15.6	15	53.73	1.54	2.9	53.4	45.6 - 61.8
HUMAN HemoStat Thromboplastin - SI												
bioMerieux Thrombolyzer Compact X/XR	7	12.90	0.36	2.8	12.8	10.9 - 14.9	7	66.77	2.99	4.5	67.0	56.7 - 76.8
All Coagulation Instruments	10	13.47	1.15	8.5	13.0	11.4 - 15.5	10	69.88	6.32	9.0	69.9	59.3 - 80.4
IL TEST PT-FIB HS PLUS												
IL ACL, all models	26	13.36	0.73	5.5	13.2	11.3 - 15.4	24	51.53	4.08	7.9	51.1	43.7 - 59.3
<u>Reagent/Instrument</u>	Specimen CG-8						Specimen CG-9					
	<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	69	12.82	1.14	8.9	13.1	10.9 - 14.8	69	35.29	5.27	14.9	36.5	29.9 - 40.6
Dade Innovin												
All Coagulation Instruments	5	11.10	0.45	4.1	11.1	9.4 - 12.8	5	28.18	1.33	4.7	29.0	23.9 - 32.5
Diag Stago STA Neoplastine Cl+												
RAL Clot-SP	11	13.45	0.42	3.1	13.4	11.4 - 15.5	11	36.76	0.47	1.3	36.8	31.2 - 42.3
All Coagulation Instruments	15	13.37	0.59	4.4	13.3	11.3 - 15.4	15	36.49	0.89	2.4	36.8	31.0 - 42.0
HUMAN HemoStat Thromboplastin - SI												
bioMerieux Thrombolyzer Compact X/XR	7	12.96	0.36	2.8	12.9	11.0 - 15.0	7	39.34	1.84	4.7	39.3	33.4 - 45.3
All Coagulation Instruments	10	13.36	0.80	6.0	13.1	11.3 - 15.4	10	40.41	3.66	9.0	39.9	34.3 - 46.5
IL TEST PT-FIB HS PLUS												
IL ACL, all models	26	13.31	0.65	4.9	13.3	11.3 - 15.4	25	36.56	2.60	7.1	36.5	31.0 - 42.1
<u>Reagent/Instrument</u>	Specimen CG-10											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	68	16.14	1.43	8.9	16.5	13.7 - 18.6						
Dade Innovin												
All Coagulation Instruments	5	13.98	0.91	6.5	14.4	11.8 - 16.1						
Diag Stago STA Neoplastine Cl+												
RAL Clot-SP	11	16.99	0.32	1.9	17.0	14.4 - 19.6						
All Coagulation Instruments	15	16.89	0.56	3.3	16.9	14.3 - 19.5						
HUMAN HemoStat Thromboplastin - SI												
bioMerieux Thrombolyzer Compact X/XR	6	16.22	0.40	2.5	16.3	13.7 - 18.7						
All Coagulation Instruments	9	16.51	1.10	6.7	16.3	14.0 - 19.0						
IL TEST PT-FIB HS PLUS												
IL ACL, all models	26	16.84	0.96	5.7	16.7	14.3 - 19.4						

PROTHROMBIN TIME–INTERNATIONAL NORMALIZED RATIO (INR)

Specimen CG-6							Specimen CG-7					
<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	66	0.98	0.11	10.9	1.0	0.6 - 1.3	63	5.10	1.21	23.7	4.8	1.4 - 8.8
Diag Stago STA Neoplastine Cl+ RAL Clot-SP	10	1.00	0.00	0.0	1.0	1.0 - 1.0	11	5.64	0.17	3.1	5.6	5.1 - 6.2
All Coagulation Instruments	15	1.01	0.08	7.9	1.0	0.7 - 1.3	15	5.65	0.30	5.3	5.6	4.7 - 6.6
HUMAN HemoStat Thromboplastin - SI bioMerieux Thrombolyzer Compact X/XR	7	0.94	0.11	12.0	1.0	0.6 - 1.3	7	7.00	1.32	18.8	7.6	3.0 - 11.0
All Coagulation Instruments	9	0.97	0.11	11.6	1.0	0.6 - 1.4	9	7.19	1.22	17.0	7.6	3.5 - 10.9
IL TEST PT-FIB HS PLUS IL ACL, all models	24	0.94	0.12	12.5	0.9	0.5 - 1.3	21	4.52	0.36	8.1	4.5	3.4 - 5.7
Specimen CG-8							Specimen CG-9					
<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	65	0.97	0.10	10.2	1.0	0.6 - 1.3	65	3.16	0.49	15.5	3.1	1.6 - 4.7
Diag Stago STA Neoplastine Cl+ RAL Clot-SP	11	1.02	0.04	4.0	1.0	0.8 - 1.2	11	3.50	0.06	1.8	3.5	3.3 - 3.7
All Coagulation Instruments	15	1.01	0.07	7.0	1.0	0.7 - 1.3	15	3.49	0.13	3.7	3.5	3.0 - 3.9
HUMAN HemoStat Thromboplastin - SI bioMerieux Thrombolyzer Compact X/XR	7	0.99	0.12	12.3	1.0	0.6 - 1.4	7	3.69	0.64	17.3	3.7	1.7 - 5.6
All Coagulation Instruments	9	1.00	0.11	11.2	1.0	0.6 - 1.4	9	3.70	0.60	16.1	3.7	1.9 - 5.5
IL TEST PT-FIB HS PLUS IL ACL, all models	24	0.93	0.10	11.2	0.9	0.6 - 1.3	23	3.09	0.31	10.0	3.1	2.1 - 4.1
Specimen CG-10												
<u>Reagent/Instrument</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method	63	1.27	0.13	9.9	1.3	0.8 - 1.7						
Diag Stago STA Neoplastine Cl+ RAL Clot-SP	11	1.35	0.05	3.9	1.4	1.1 - 1.6						
All Coagulation Instruments	15	1.35	0.09	6.8	1.4	1.0 - 1.7						
HUMAN HemoStat Thromboplastin - SI bioMerieux Thrombolyzer Compact X/XR	6	1.30	0.11	8.4	1.3	0.9 - 1.7						
All Coagulation Instruments	8	1.29	0.12	9.7	1.3	0.9 - 1.7						
IL TEST PT-FIB HS PLUS IL ACL, all models	24	1.22	0.13	10.5	1.2	0.8 - 1.7						

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

<u>Reagent/Instrument</u>	Specimen CG-6						Specimen CG-7					
	<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 HUMAN HemoStat aPTT - EL bioMerieux Thrombolyzer Compact	55	30.0	2.3	7.6	29	25 - 35	51	63.5	6.7	10.5	63	53 - 73
X/XR	6	33.8	1.8	5.4	35	28 - 39	6	68.0	4.4	6.4	67	57 - 79
All Coagulation Instruments	9	32.8	2.4	7.4	33	27 - 38	9	67.1	5.7	8.5	65	57 - 78
IL TEST APTT-SP IL ACL, all models	26	28.7	1.3	4.7	28	24 - 33	25	59.3	3.4	5.7	59	50 - 69
<u>Reagent/Instrument</u>	Specimen CG-8						Specimen CG-9					
	<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 HUMAN HemoStat aPTT - EL bioMerieux Thrombolyzer Compact	56	29.3	2.6	8.8	29	24 - 34	54	57.3	8.1	14.1	55	48 - 66
X/XR	6	32.8	2.0	6.2	33	27 - 38	6	63.7	4.1	6.4	65	54 - 74
All Coagulation Instruments	9	32.0	2.1	6.6	32	27 - 37	9	63.4	5.8	9.2	65	53 - 73
IL TEST APTT-SP IL ACL, all models	26	27.8	1.3	4.7	28	23 - 33	26	52.3	2.8	5.4	52	44 - 61
<u>Reagent/Instrument</u>	Specimen CG-10											
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>						
All Method HUMAN HemoStat aPTT - EL bioMerieux Thrombolyzer Compact	55	42.6	3.9	9.2	43	36 - 50						
X/XR	6	42.8	1.6	3.7	43	36 - 50						
All Coagulation Instruments	9	41.7	2.4	5.8	41	35 - 48						
IL TEST APTT-SP IL ACL, all models	26	42.9	2.3	5.5	43	36 - 50						

FIBRINOGEN (mg/dL)

<u>Reagent/Instrument</u>	<u>Specimen CG-6</u>						<u>Specimen CG-7</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 HUMAN HemoStat Fibrinogen bioMerieux Thrombolyzer Compact X/XR	41	421.9	47.9	11.4	425	337 - 507	40	320.8	57.1	17.8	332	256 - 385
All Coagulation Instruments	7	438.0	59.0	13.5	406	350 - 526	7	280.7	29.6	10.5	279	224 - 337
IL TEST PT-FIB HS PLUS	8	427.8	61.9	14.5	406	342 - 514	9	274.9	28.4	10.3	277	219 - 330
IL ACL, all models	23	428.7	37.1	8.6	427	342 - 515	22	360.9	37.8	10.5	359	288 - 434

<u>Reagent/Instrument</u>	<u>Specimen CG-8</u>						<u>Specimen CG-9</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 HUMAN HemoStat Fibrinogen bioMerieux Thrombolyzer Compact X/XR	41	312.7	35.0	11.2	309	250 - 376	41	297.8	39.0	13.1	294	238 - 358
All Coagulation Instruments	7	329.3	36.8	11.2	315	263 - 396	7	285.3	21.5	7.5	288	228 - 343
IL TEST PT-FIB HS PLUS	9	318.2	38.9	12.2	307	254 - 382	9	275.8	28.2	10.2	288	220 - 331
IL ACL, all models	23	317.8	28.0	8.8	313	254 - 382	23	321.5	27.6	8.6	322	257 - 386

<u>Reagent/Instrument</u>	<u>Specimen CG-10</u>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method HUMAN HemoStat Fibrinogen bioMerieux Thrombolyzer Compact X/XR	38	128.3	17.3	13.5	129	102 - 154
All Coagulation Instruments	6	115.2	15.7	13.6	114	92 - 139
IL TEST PT-FIB HS PLUS	8	112.0	14.5	13.0	104	89 - 135
IL ACL, all models	22	138.7	13.0	9.3	138	110 - 167

URINALYSIS DIPSTICK–SPECIFIC GRAVITY

<u>Method</u>	<u>Specimen UA-2</u>					
	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
All Method	325	1.0081	0.0032	0.3	1.010	0.998 - 1.019
Arkray Aution Sticks	20	1.0092	0.0039	0.4	1.010	0.999 - 1.020
Bayer Clinitek Advantus	14	1.0050	0.0000	0.0	1.005	0.995 - 1.015
Other Analyzer Method	16	1.0078	0.0058	0.6	1.005	0.997 - 1.018
Roche Chemstrips / Combur	18	1.0092	0.0026	0.3	1.010	0.999 - 1.020
Roche cobas u 411	36	1.0108	0.0026	0.3	1.010	1.000 - 1.021
Roche Mditron Junior/II	16	1.0091	0.0038	0.4	1.010	0.999 - 1.020
Roche SuperUA/ChemstripUA	12	1.0100	0.0021	0.2	1.010	1.000 - 1.020
Roche Urisys	59	1.0080	0.0035	0.3	1.010	0.998 - 1.019
SD UroColor Reagent Strips	10	1.0090	0.0046	0.5	1.010	0.999 - 1.019
UriScan Reagent Strips	57	1.0077	0.0025	0.2	1.010	0.997 - 1.018

URINALYSIS DIPSTICK-pH

Specimen UA-2

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	343	-	-	1	2	1	93	159	85	2	-	-	-
Acon Laboratories	2	-	-	-	-	-	2	-	-	-	-	-	-
Arkray Aution Jet	1	-	-	-	-	-	1	-	-	-	-	-	-
Arkray Aution Sticks	21	-	-	-	-	-	20	1	-	-	-	-	-
Arkray PocketChem UA	2	-	-	-	-	-	2	-	-	-	-	-	-
Bayer Clinitek 500	5	-	-	-	-	-	1	4	-	-	-	-	-
Bayer Clinitek Advantus	15	-	-	-	-	1	-	14	-	-	-	-	-
Bayer Clinitek Atlas	2	-	-	-	-	-	1	1	-	-	-	-	-
Bayer Clinitek Status / Status+	3	-	-	-	-	-	2	1	-	-	-	-	-
Bayer Multistix Pro	1	-	-	-	-	-	1	-	-	-	-	-	-
Bayer Reagent Strips	19	-	-	-	-	-	5	14	-	-	-	-	-
Bayer Uristix	1	-	-	-	-	-	-	1	-	-	-	-	-
Combi-Screen Test Strips	1	-	-	-	-	-	1	-	-	-	-	-	-
CYBOW Urine Reagent Strips	2	-	-	-	-	-	1	1	-	-	-	-	-
HUMAN Combilyzer	1	-	-	-	-	-	1	-	-	-	-	-	-
HUMAN COMBINA Test Strips	6	-	-	1	-	-	2	2	1	-	-	-	-
Iris Diagnostics Aution Max AX-4280	3	-	-	-	-	-	3	-	-	-	-	-	-
Other Analyzer Method	17	-	-	-	-	-	12	4	1	-	-	-	-
Other Dipstick Method	9	-	-	-	-	-	3	5	1	-	-	-	-
Plasmatec URIPATH	1	-	-	-	-	-	-	1	-	-	-	-	-
Roche Chemstrips / Combur	22	-	-	-	1	-	3	7	11	-	-	-	-
Roche cobas u 411	35	-	-	-	-	-	-	14	20	1	-	-	-
Roche Mditron Junior/II	16	-	-	-	-	-	1	6	9	-	-	-	-
Roche Mini UA	1	-	-	-	-	-	-	1	-	-	-	-	-
Roche SuperUA/ChemstripUA	11	-	-	-	-	-	-	1	10	-	-	-	-
Roche Urilux S	1	-	-	-	-	-	-	-	1	-	-	-	-
Roche Urisys	61	-	-	-	-	-	1	38	22	-	-	-	-
SD UroColor Reagent Strips	10	-	-	-	-	-	-	6	3	1	-	-	-
TECO URS Strips	1	-	-	-	-	-	-	-	1	-	-	-	-
THME UDC-2020	6	-	-	-	-	-	4	-	2	-	-	-	-
Urinometer	1	-	-	-	-	-	-	1	-	-	-	-	-
UriScan Pro/II	5	-	-	-	-	-	1	4	-	-	-	-	-
UriScan Reagent Strips	55	-	-	-	1	-	23	29	2	-	-	-	-

URINALYSIS DIPSTICK--PROTEIN QUALITATIVE

Specimen UA-2

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	341	337	4	-	-	-	-	-
Acon Laboratories	2	1	1	-	-	-	-	-
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+	4	4	-	-	-	-	-	-
Bayer Multistix Pro	1	1	-	-	-	-	-	-
Bayer Reagent Strips	18	18	-	-	-	-	-	-
Bayer Uristix	1	1	-	-	-	-	-	-
Combi-Screen Test Strips	1	1	-	-	-	-	-	-
CYBOW Urine Reagent Strips	2	2	-	-	-	-	-	-
HUMAN Combilyzer	2	2	-	-	-	-	-	-
HUMAN COMBINA Test Strips	3	3	-	-	-	-	-	-
Iris Diagnostics Aution Max AX-4280	3	3	-	-	-	-	-	-
Other Analyzer Method	17	16	1	-	-	-	-	-
Other Dipstick Method	8	7	1	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-
Roche Chemstrips / Combur	21	21	-	-	-	-	-	-
Roche cobas u 411	35	35	-	-	-	-	-	-
Roche Mditron Junior/II	16	16	-	-	-	-	-	-
Roche Mini UA	1	1	-	-	-	-	-	-
Roche SuperUA/ChemstripUA	11	11	-	-	-	-	-	-
Roche Urilux S	1	1	-	-	-	-	-	-
Roche Urisys	61	60	1	-	-	-	-	-
SD UroColor Reagent Strips	9	9	-	-	-	-	-	-
Sulfosalicylic Acid	2	2	-	-	-	-	-	-
TECO URS Strips	1	1	-	-	-	-	-	-
THME UDC-2020	6	6	-	-	-	-	-	-
UriScan Pro/II	5	5	-	-	-	-	-	-
UriScan Reagent Strips	57	57	-	-	-	-	-	-

URINALYSIS DIPSTICK–GLUCOSE

Specimen UA-2

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	342	338	3	-	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+	4	4	-	-	-	-	-	-	-
Bayer Multistix Pro	1	1	-	-	-	-	-	-	-
Bayer Reagent Strips	18	18	-	-	-	-	-	-	-
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	17	16	1	-	-	-	-	-	-
Other Dipstick Method	8	8	-	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-	-
Roche Chemstrips / Combur	21	21	-	-	-	-	-	-	-
Roche cobas u 411	33	33	-	-	-	-	-	-	-
Roche Miditron 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	9	1	-	-	-	-	-	-
TECO URS Strips	1	1	-	-	-	-	-	-	-
THME UDC-2020	6	6	-	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-	-
UriScan Pro/II	5	5	-	-	-	-	-	-	-
UriScan Reagent Strips	55	55	-	-	-	-	-	-	-

URINALYSIS DIPSTICK–KETONES

Specimen UA-2

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	341	337	2	2	-	-	-	-
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+	4	4	-	-	-	-	-	-
Bayer Multistix Pro	1	1	-	-	-	-	-	-
Bayer Reagent Strips	18	18	-	-	-	-	-	-
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	17	16	1	-	-	-	-	-
Other Dipstick Method	8	8	-	-	-	-	-	-
Plasmatec URIPATH	1	1	-	-	-	-	-	-
Roche Chemstrips / Combur	20	20	-	-	-	-	-	-
Roche cobas u 411	34	34	-	-	-	-	-	-
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	-	2	-	-	-	-
SD UroColor Reagent Strips	10	9	1	-	-	-	-	-
TECO URS Strips	1	1	-	-	-	-	-	-
THME UDC-2020	6	6	-	-	-	-	-	-
Urinometer	1	1	-	-	-	-	-	-
UriScan Pro/II	5	5	-	-	-	-	-	-
UriScan Reagent Strips	55	55	-	-	-	-	-	-

URINALYSIS DIPSTICK–BILIRUBIN

Specimen UA-2

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	330	330	-	-	-
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	17	17	-	-	-
Other Dipstick Method	8	8	-	-	-
Plasmatec URIPATH	1	1	-	-	-
Roche Chemstrips / Combur	20	20	-	-	-
Roche cobas u 411	34	34	-	-	-
Roche Mditron Junior/II	17	17	-	-	-
Roche Mini UA	1	1	-	-	-
Roche SuperUA/ChemstripUA	11	11	-	-	-
Roche Urilux S	1	1	-	-	-
Roche Urisys	62	62	-	-	-
SD UroColor Reagent Strips	10	10	-	-	-
TECO URS Strips	1	1	-	-	-
THME UDC-2020	6	6	-	-	-
Urinometer	1	1	-	-	-
UriScan Pro/II	5	5	-	-	-
UriScan Reagent Strips	55	55	-	-	-

URINALYSIS DIPSTICK–UROBILINOGEN

Specimen UA-2

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	329	328	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	17	17	-	-	-	-
Other Dipstick Method	8	8	-	-	-	-
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	62	-	-	-	-
SD UroColor Reagent Strips	10	10	-	-	-	-
TECO URS Strips	1	1	-	-	-	-
THME UDC-2020	6	6	-	-	-	-
Urinometer	1	1	-	-	-	-
UriScan Pro/II	5	5	-	-	-	-
UriScan Reagent Strips	55	54	1	-	-	-

URINALYSIS DIPSTICK–BLOOD/HEMOGLOBIN

Specimen UA-2

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	339	339	-	-	-	-
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+	4	4	-	-	-	-
Bayer Multistix Pro	1	1	-	-	-	-
Bayer Reagent Strips	18	18	-	-	-	-
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	8	8	-	-	-	-
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	62	-	-	-	-
SD UroColor Reagent Strips	9	9	-	-	-	-
TECO URS Strips	1	1	-	-	-	-
THME UDC-2020	6	6	-	-	-	-
Urinometer	1	1	-	-	-	-
UriScan Pro/II	5	5	-	-	-	-
UriScan Reagent Strips	54	54	-	-	-	-
URIT Medical Uritest Reagent Strips	1	1	-	-	-	-

URINALYSIS DIPSTICK–LEUKOCYTE ESTERASE

Specimen UA-2

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-2*****Participant Results***

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	328	5	323
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	17	1	16
Other Dipstick Method	8	-	8
Plasmatec URIPATH	1	-	1
Roche Chemstrips / Combur	20	-	20
Roche cobas u 411	34	-	34
Roche Mditron Junior/II	17	-	17
Roche Mini UA	1	-	1
Roche SuperUA/ChemstripUA	11	-	11
Roche Urilux S	1	-	1
Roche Urisys	61	3	58
SD UroColor Reagent Strips	10	1	9
TECO URS Strips	1	-	1
THME UDC-2020	6	-	6
Urinometer	1	-	1
UriScan Pro/II	5	-	5
UriScan Reagent Strips	54	-	54

URINALYSIS –MICROALBUMIN (dipstick only)**Specimen UA-2***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	35	24	10	-	1	-	-	-
Bayer Clinitek Microalbumin	13	5	8	-	-	-	-	-
Roche Micral - 1 minute	6	6	-	-	-	-	-	-
Roche Urisys	1	1	-	-	-	-	-	-

URINALYSIS –URINE hCG**Specimen UA-2***Participant Results*

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	62	1	61
Acon Laboratories	9	-	9
Biotron 1-Step	8	-	8
Inverness Acceva hCG-Urine	1	-	1
Inverness Clearview25 hCG Combo	1	-	1
Quidel QuickVue One-Step Combo	25	1	24
Stanbio QuStick	1	-	1
Sure-View hCG - 25mIU	1	-	1
Veda lab	1	-	1

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Specimen SUS-6

<u>Antimicrobial</u>	-----Disk Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>
	<u>Interpretative category data</u>				<u>Interpretative category data</u>				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Amikacin	29	29	-	-	89	87	-	2	98.47%
Amoxicillin/Clavulanate	26	3	3	20	48	-	-	48	90.24%
Ampicillin	20	3	3	14	73	3	1	69	89.42%
Ampicillin/Sulbactam	17	16	-	1	47	12	1	34	Not graded ¹
Aztreonam	9	9	-	-	24	23	1	-	97.22%
Carbenicillin	2	2	-	-	-	-	-	-	100.00%
Cefaclor	4	3	1	-	2	-	-	2	Not graded ¹
Cefazolin	6	2	-	4	27	1	-	26	92.11%
Cefepime	17	17	-	-	86	85	-	1	99.14%
Cefixime	12	12	-	-	12	3	-	9	Not graded ¹
Cefoperazone	1	1	-	-	1	1	-	-	100.00%
Cefotaxime	20	20	-	-	46	43	-	3	95.89%
Cefotetan	1	-	-	1	6	6	-	-	Not graded ¹
Cefoxitin	5	-	1	4	48	2	-	46	94.55%
Cefpodoxime	2	2	-	-	-	-	-	-	100.00%
Ceftazidime	20	20	-	-	70	66	1	3	94.95%
Ceftizoxime	1	1	-	-	2	1	-	1	Not graded ¹
Ceftriaxone	32	32	-	-	54	51	-	3	95.79%
Cefuroxime	26	25	-	1	39	29	-	10	83.10%
Cephalexin	5	-	-	5	5	-	-	5	100.00%
Cephalothin	11	-	1	10	51	2	1	48	91.78%
Ciprofloxacin	40	40	-	-	100	99	1	-	99.36%
Clindamycin	2	-	-	2	1	1	-	-	Not graded ¹
Doxycycline	3	3	-	-	-	-	-	-	100.00%
Ertapenem	4	4	-	-	43	43	-	-	100.00%
Fosfomycin	1	1	-	-	4	4	-	-	100.00%
Gatifloxacin	-	-	-	-	1	1	-	-	100.00%
Gentamicin	31	31	-	-	99	98	1	-	99.31%
Imipenem	21	21	-	-	76	75	1	-	99.09%
Kanamycin	2	2	-	-	-	-	-	-	100.00%

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

ANTIMICROBIAL SUSCEPTIBILITY TESTING (cont'd)

Specimen SUS-6

<u>Antimicrobial</u>	<u>-----Disk Diffusion-----</u>				<u>-----MIC-----</u>				<u>Acceptable (%)</u>
	<u>Interpretative category data</u>				<u>Interpretative category data</u>				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Levofloxacin	13	13	-	-	46	46	-	-	100.00%
Linezolid	2	-	-	2	1	1	-	-	Not graded ¹
Lomefloxacin	1	1	-	-	-	-	-	-	100.00%
Meropenem	15	15	-	-	44	44	-	-	100.00%
Moxifloxacin	4	4	-	-	6	6	-	-	100.00%
Nalidixic Acid	16	16	-	-	26	24	-	2	95.74%
Netilmicin	6	6	-	-	5	5	-	-	100.00%
Nitrofurantoin	32	31	1	-	74	73	-	1	98.33%
Norfloxacin	24	24	-	-	27	27	-	-	100.00%
Ofloxacin	13	13	-	-	3	3	-	-	100.00%
Oxacillin	1	-	-	1	1	1	-	-	Not graded ¹
Penicillin	1	-	-	1	2	1	1	-	Not graded ¹
Piperacillin	1	1	-	-	22	21	-	1	96.00%
Piperacillin/Tazobactam	15	15	-	-	59	57	1	1	97.56%
Rifampin	2	-	-	2	1	1	-	-	Not graded ¹
Sulfisoxazole	-	-	-	-	1	1	-	-	100.00%
Tetracycline	6	6	-	-	31	31	-	-	100.00%
Ticarcillin	-	-	-	-	2	2	-	-	100.00%
Ticarcillin/Clavulanate	2	2	-	-	11	9	1	1	86.67%
Tigecycline	-	-	-	-	5	5	-	-	100.00%
Tobramycin	5	5	-	-	40	39	1	-	98.04%
Trimethoprim	2	2	-	-	4	4	-	-	100.00%
Trimethoprim/Sulfamethoxazole	33	33	-	-	91	90	-	1	99.28%
Vancomycin	2	-	-	2	1	1	-	-	Not graded ¹

Organism present in specimen SUS-6: *Citrobacter freundii*.

PARASITOLOGY (PA Specimens)

Specimen PA-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	4	80.00%	Acceptable
Entamoeba histolytica	1	20.00%	

Parasite present in specimen PA-6: *Giardia lamblia*.

Specimen PA-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Endolimax nana	1	20.00%	Acceptable
No parasite seen	3	60.00%	
Trichomonas hominis	1	20.00%	

Parasite present in specimen PA-7: *Endolimax nana*.

Specimen PA-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	7	77.78%	Acceptable
Entamoeba histolytica	1	11.11%	
Hymenolepis diminuta eggs	1	11.11%	

Parasite present in specimen PA-8: No parasite seen.

PARASITOLOGY (PA Specimens) cont'd

Specimen PA-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis larvae	8	88.89%	Acceptable
Taenia sp. eggs	1	11.11%	

Parasite present in specimen PA-9: *Strongyloides stercoralis* larvae.

Specimen PA-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hymenolepis nana eggs	8	88.89%	Acceptable
Hookworm	1	11.11%	

Parasite present in specimen PA-10: *Hymenolepis nana* eggs.

PARASITOLOGY (FP Specimens)

Specimen FP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	240	96.77%	Acceptable
Ascaris lumbricoides eggs	2	0.81%	
Endolimax nana	2	0.81%	

Parasite present in specimen FP-6: No parasite seen.

Specimen FP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis larvae	220	86.27%	Acceptable
Parasite larva seen but no ID	1	0.39%	Acceptable
No parasite seen	19	7.45%	
Parasite egg seen but no ID	3	1.18%	
Hookworm	3	1.18%	

Parasite present in specimen FP-7: *Strongyloides stercoralis* larvae.

Specimen FP-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hymenolepis nana eggs	182	67.91%	Acceptable
Hymenolepis diminuta eggs	20	7.46%	Acceptable
Taenia sp. eggs	33	12.31%	
No parasite seen	7	2.61%	
Entamoeba coli	5	1.87%	
Ascaris lumbricoides eggs	5	1.87%	
Endolimax nana	4	1.49%	
Giardia lamblia	3	1.12%	
Blastocystis hominis	3	1.12%	

Parasite present in specimen FP-8: *Hymenolepis nana* eggs.

PARASITOLOGY (FP Specimens)

Specimen FP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba coli	216	62.25%	Acceptable
Endolimax nana	87	25.07%	Acceptable
Entamoeba histolytica	23	6.63%	
No parasite seen	6	1.73%	
Hymenolepis nana eggs	3	0.86%	

Parasite present in specimen FP-9: *Entamoeba coli*.

Specimen FP-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium falciparum	139	55.38%	Acceptable
Plasmodium sp., NOS	53	21.12%	Acceptable
Plasmodium vivax	47	18.73%	
Plasmodium sp., not falciparum	4	1.59%	

Parasite present in specimen FP-10: *Plasmodium falciparum*. Specimen FP-10 was graded by 92% referee consensus.

Rubella—Qualitative

<u>Method</u>	Specimen RU-6		Specimen RU-7		Specimen RU-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	6	1	6	1
Bayer ADVIA Centaur	-	1	1	-	1	-
Roche Modular Analytics	-	1	1	-	1	-
VITROS ECI	-	4	3	1	3	1

<u>Method</u>	Specimen RU-9		Specimen RU-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	1	-	7
bioMerieux Vidas, Mini Vidas	1	-	-	1
Roche Modular Analytics	1	-	-	1
VITROS ECI	3	1	-	4

Rubella—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 RU-6						
All Method	16	0.14	0.22	156.5	0.1	0.0 - 0.9
Specimen RU-7						
All Method	17	33.11	24.36	73.6	25.0	0.0 - 106.2
Specimen RU-8						
All Method	17	121.42	74.76	61.6	101.0	0.0 - 345.7
Specimen RU-9						
All Method	17	66.92	57.06	85.3	40.0	0.0 - 238.1
Specimen RU-10						
All Method	16	0.19	0.28	149.4	0.0	0.0 - 1.1

Syphilis Serology—Qualitative: VDRL Slide

<u>Method</u>	<u>Specimen SY-6</u>			<u>Specimen SY-7</u>			<u>Specimen SY-8</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	-	-	13	13	-	-	12	-	1
bioMerieux	-	-	1	1	-	-	-	-	1
Wiener Lab	-	-	10	10	-	-	10	-	-

<u>Method</u>	<u>Specimen SY-9</u>			<u>Specimen SY-10</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	13	-	-	-	-	13
bioMerieux	1	-	-	-	-	1
Wiener Lab	10	-	-	-	-	10

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>
Specimen SY-7								
ALL METHODS	-	2	1	7	3	-	-	-
bioMerieux	-	1	-	-	-	-	-	-
Wiener Lab	-	1	1	7	2	-	-	-
Specimen SY-8								
ALL METHODS	2	1	6	3	-	-	-	-
bioMerieux	-	-	-	-	-	-	-	-
Wiener Lab	2	1	6	2	-	-	-	-
Specimen SY-9								
ALL METHODS	1	-	1	8	3	-	-	-
bioMerieux	1	-	-	-	-	-	-	-
Wiener Lab	-	-	1	8	2	-	-	-

Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<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	-
Human	-	2	2	-	2	-
Omega Diagnostics	-	3	3	-	3	-
Serodia	-	4	4	-	4	-

	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	15	-	-	15
Biokit	2	-	-	2
Human	2	-	-	2
Omega Diagnostics	3	-	-	3
Serodia	4	-	-	4

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

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	14	14	-	14	-
Abbott Architect	-	1	1	-	1	-
bioMerieux	-	2	2	-	2	-
Human	-	2	2	-	2	-
Omega Diagnostics	-	1	1	-	1	-

	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	14	-	-	14
Abbott Architect	1	-	-	1
bioMerieux	2	-	-	2
Human	2	-	-	2
Omega Diagnostics	1	-	-	1

Syphilis Serology—Qualitative: RPR

<u>Method</u>	<u>Specimen SY-6</u>		<u>Specimen SY-7</u>		<u>Specimen SY-8</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	41	41	-	37	4
Abbott Syfacard-R	-	1	1	-	1	-
Becton Dickinson	-	1	1	-	1	-
bioMerieux	-	4	4	-	3	1
bioMerieux Vidas, Mini Vidas	-	1	1	-	1	-
BioSystems	-	4	4	-	4	-
Human	-	5	5	-	5	-
Immunostics Inc.	-	1	1	-	1	-
Omega Diagnostics	-	11	11	-	11	-
Plasmatec	-	2	2	-	-	2
Serodia	-	1	1	-	1	-
SPINREACT	-	5	5	-	5	-
Wampole Impact RPR	-	1	1	-	1	-

	<u>Specimen SY-9</u>		<u>Specimen SY-10</u>	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	41	-	-	41
Abbott Syfacard-R	1	-	-	1
Becton Dickinson	1	-	-	1
bioMerieux	4	-	-	4
bioMerieux Vidas, Mini Vidas	1	-	-	1
BioSystems	4	-	-	4
Human	5	-	-	5
Immunostics Inc.	1	-	-	1
Omega Diagnostics	11	-	-	11
Plasmatec	2	-	-	2
Serodia	1	-	-	1
SPINREACT	5	-	-	5
Wampole Impact RPR	1	-	-	1

Syphilis Serology—Quantitative: RPR (Titer)

<u>Specimen/Method</u>	<u>1</u>	<u>2</u>	<u>4</u>	<u>8</u>	<u>16</u>	<u>32</u>	<u>64</u>	<u>>64</u>
Specimen SY-7								
ALL METHODS	1	10	17	4	-	-	1	-
Abbott Syfacard-R	-	-	1	-	-	-	-	-
Becton Dickinson	-	-	-	1	-	-	-	-
bioMerieux	-	-	1	-	-	-	-	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	-	-	-	-
BioSystems	-	-	4	-	-	-	-	-
Human	1	1	2	-	-	-	-	-
Immunostics Inc.	-	1	-	-	-	-	-	-
Omega Diagnostics	-	1	4	2	-	-	-	-
Plasmatec	-	2	-	-	-	-	-	-
Serodia	-	-	-	-	-	-	1	-
SPINREACT	-	1	4	-	-	-	-	-
Wampole Impact RPR	-	1	-	-	-	-	-	-
Specimen SY-8								
ALL METHODS	10	15	4	-	-	-	-	1
Abbott Syfacard-R	-	1	-	-	-	-	-	-
Becton Dickinson	-	1	-	-	-	-	-	-
bioMerieux	-	1	-	-	-	-	-	-
bioMerieux Vidas, Mini Vidas	1	-	-	-	-	-	-	-
BioSystems	-	4	-	-	-	-	-	-
Human	2	1	1	-	-	-	-	-
Immunostics Inc.	1	-	-	-	-	-	-	-
Omega Diagnostics	1	5	1	-	-	-	-	-
Plasmatec	-	-	-	-	-	-	-	-
Serodia	-	-	-	-	-	-	-	1
SPINREACT	3	1	1	-	-	-	-	-
Wampole Impact RPR	1	-	-	-	-	-	-	-

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

<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>
Specimen SY-9								
ALL METHODS	4	9	14	3	2	1	-	-
Abbott Syfacard-R	-	-	1	-	-	-	-	-
Becton Dickinson	-	-	1	-	-	-	-	-
bioMerieux	-	-	1	-	-	-	-	-
bioMerieux Vidas, Mini Vidas	-	1	-	-	-	-	-	-
BioSystems	-	-	4	-	-	-	-	-
Human	1	1	-	1	1	-	-	-
Immunostics Inc.	-	1	-	-	-	-	-	-
Omega Diagnostics	-	2	3	1	1	-	-	-
Plasmatec	2	-	-	-	-	-	-	-
Serodia	-	-	-	-	-	1	-	-
SPINREACT	-	2	3	-	-	-	-	-
Wampole Impact RPR	1	-	-	-	-	-	-	-

Viral Markers – Anti-HBc

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	83	82	3	2	84
Abbott Architect	-	4	4	-	-	4
Abbott Architect - IgG	-	4	4	-	-	4
Abbott Architect - Total	-	11	11	-	-	11
Abbott AxSYM - IgG	-	2	2	-	-	2
Abbott AxSYM - IgM	-	2	2	-	-	2
Abbott AxSYM - Total	-	8	8	-	-	8
Bayer ADVIA Centaur - Total	-	8	8	-	-	8
Beckman ACCESS / 2 / DxI	1	1	2	-	-	2
bioMerieux Vidas - IgM	-	2	2	-	-	2
bioMerieux Vidas - Total	-	4	4	-	-	4
bioMerieux Vidas, Mini Vidas	-	1	1	-	-	1
Other IgG Method	-	1	1	-	-	1
Other IgM method	-	1	1	-	-	1
Other Total Method	1	5	5	1	1	5
Roche Elecsys - IgG	-	5	5	-	-	5
Roche Elecsys - IgM	-	2	2	-	-	2
Roche Elecsys - Total	-	4	4	-	-	4
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	-	3	3	-	-	3
VITROS Eci - Total	-	5	5	-	-	5

Viral Markers – Anti-HBc (cont'd)

	Specimen VM-9		Specimen VM-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	83	2	83
Abbott Architect	-	4	-	4
Abbott Architect - IgG	-	4	-	4
Abbott Architect - Total	-	11	-	11
Abbott AxSYM - IgG	-	2	-	2
Abbott AxSYM - IgM	-	2	-	2
Abbott AxSYM - Total	-	8	-	8
Bayer ADVIA Centaur - Total	-	8	-	8
Beckman ACCESS / 2 / DxI	-	2	-	2
bioMerieux Vidas - IgM	-	2	-	2
bioMerieux Vidas - Total	-	4	-	4
bioMerieux Vidas, Mini Vidas	-	1	-	1
Other IgG Method	-	1	-	1
Other IgM method	-	1	-	1
Other Total Method	1	5	1	5
Roche Elecsys - IgG	-	5	-	5
Roche Elecsys - IgM	-	2	-	2
Roche Elecsys - Total	-	4	-	4
Roche Elecsys 1010 / 2010	-	1	-	1
Roche Modular Analytics	-	2	-	2
VITROS ECI - IgG	1	2	1	2
VITROS ECI - IgM	-	3	-	3
VITROS ECI - Total	-	5	-	5

Viral Markers – Anti-HIV

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	170	-	171	170	1
Abbott Architect	1	15	-	16	16	-
Abbott Architect - IgG	-	2	-	2	2	-
Abbott Architect - IgM	-	1	-	1	1	-
Abbott Architect - Total	-	15	-	15	15	-
Abbott AxSYM	-	7	-	7	7	-
Abbott AxSYM - Total	-	13	-	13	13	-
Bayer ADVIA Centaur	-	3	-	3	3	-
Bayer ADVIA Centaur - Total	-	6	-	6	6	-
Beckman ACCESS / 2 / DxI	-	4	-	4	4	-
Bio-Rad Evolis	-	2	-	2	2	-
bioMerieux Vidas - IgG	-	2	-	2	2	-
bioMerieux Vidas - Total	-	12	-	12	11	1
bioMerieux Vidas, Mini Vidas	-	2	-	2	2	-
BioSystems	-	1	-	1	1	-
Other IgG Method	-	1	-	1	1	-
Other Total Method	-	15	-	15	15	-
Roche Elecsys - IgG	-	1	-	1	1	-
Roche Elecsys - Total	-	19	-	19	19	-
Roche Elecsys 1010 / 2010	-	12	-	12	12	-
Roche Modular Analytics	-	9	-	9	9	-
VITROS ECI - IgM	-	1	-	1	1	-
VITROS ECI - Total	-	15	-	15	15	-

Viral Markers – Anti-HIV (cont'd)

<u>Method</u>	Specimen VM-9		Specimen VM-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	170	-	171
Abbott Architect	-	16	-	16
Abbott Architect - IgG	-	2	-	2
Abbott Architect - IgM	-	1	-	1
Abbott Architect - Total	-	15	-	15
Abbott AxSYM	-	7	-	7
Abbott AxSYM - Total	-	13	-	13
Bayer ADVIA Centaur	-	3	-	3
Bayer ADVIA Centaur - Total	-	6	-	6
Beckman ACCESS / 2 / DxI	-	4	-	4
Bio-Rad Evolis	-	2	-	2
bioMerieux Vidas - IgG	-	2	-	2
bioMerieux Vidas - Total	-	12	-	12
bioMerieux Vidas, Mini Vidas	-	2	-	2
BioSystems	-	1	-	1
Other IgG Method	-	1	-	1
Other Total Method	-	15	-	15
Roche Elecsys - IgG	-	1	-	1
Roche Elecsys - Total	-	19	-	19
Roche Elecsys 1010 / 2010	-	12	-	12
Roche Modular Analytics	-	9	-	9
VITROS ECI - IgM	-	1	-	1
VITROS ECI - Total	1	14	-	15

Viral Markers – HAV

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	92	3	90	1	92
Abbott Architect - IgG	-	12	-	12	-	12
Abbott Architect - IgM	-	5	-	5	-	5
Abbott Architect - Total	-	2	-	2	-	2
Abbott AxSYM - IgG	-	3	-	3	-	3
Abbott AxSYM - IgM	-	3	-	3	-	3
Abbott AxSYM - Total	-	6	-	6	-	6
Bayer ADVIA Centaur - IgM	-	1	-	1	-	1
Bayer ADVIA Centaur - Total	-	6	-	6	-	6
Beckman ACCESS / 2 / DxI	-	1	-	1	-	1
bioMerieux Vidas - IgM	-	9	-	9	-	9
bioMerieux Vidas - Total	-	4	-	4	-	4
bioMerieux Vidas, Mini Vidas	-	1	-	1	-	1
Other IgG Method	-	1	-	1	-	1
Other IgM method	-	4	-	4	-	4
Other Total Method	1	2	1	2	1	2
Roche Elecsys - IgG	-	7	-	7	-	7
Roche Elecsys - IgM	-	7	1	6	-	7
Roche Elecsys - Total	-	5	-	5	-	5
Roche Modular Analytics	-	3	-	3	-	3
VITROS ECI - IgM	-	3	-	3	-	3
VITROS ECI - Total	-	5	1	4	-	5

Viral Markers – HAV (cont'd)

<u>Method</u>	Specimen VM-9		Specimen VM-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	55	38	85	8
Abbott Architect - IgG	12	-	12	-
Abbott Architect - IgM	-	5	2	3
Abbott Architect - Total	1	1	2	-
Abbott AxSYM - IgG	3	-	3	-
Abbott AxSYM - IgM	-	3	3	-
Abbott AxSYM - Total	5	1	5	1
Bayer ADVIA Centaur - IgM	-	1	1	-
Bayer ADVIA Centaur - Total	6	-	6	-
Beckman ACCESS / 2 / DxI	-	1	-	1
bioMerieux Vidas - IgM	-	9	9	-
bioMerieux Vidas - Total	3	1	4	-
bioMerieux Vidas, Mini Vidas	-	1	1	-
Other IgG Method	1	-	1	-
Other IgM method	-	4	3	1
Other Total Method	3	-	3	-
Roche Elecsys - IgG	7	-	7	-
Roche Elecsys - IgM	-	7	6	1
Roche Elecsys - Total	5	-	5	-
Roche Modular Analytics	3	-	3	-
VITROS ECI - IgM	-	3	3	-
VITROS ECI - Total	4	1	4	1

Viral Markers – HBsAb

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	119	1	2	118	1	119
Abbott Architect	9	-	-	9	-	9
Abbott Architect - IgG	2	-	-	2	-	2
Abbott Architect - Total	17	-	-	17	-	17
Abbott AxSYM	1	-	-	1	-	1
Abbott AxSYM - IgG	2	-	-	2	-	2
Abbott AxSYM - Total	13	-	-	13	-	13
Bayer ADVIA Centaur	3	-	-	3	-	3
Bayer ADVIA Centaur - Total	7	-	-	7	-	7
Beckman ACCESS / 2 / DxI	3	-	-	3	-	3
bioMerieux Vidas - IgG	2	-	-	2	-	2
bioMerieux Vidas - Total	3	-	-	3	-	3
BioSystems	-	1	1	-	-	1
DPC Immulite 2000	1	-	-	1	-	1
Other IgG Method	2	-	-	2	-	2
Other Total Method	6	-	-	6	-	6
Roche Elecsys - IgG	2	-	-	2	-	2
Roche Elecsys - Total	9	-	-	9	-	9
Roche Elecsys 1010 / 2010	9	-	-	9	-	9
Roche Modular Analytics	10	-	1	9	1	9
VITROS ECI - IgM	1	-	-	1	-	1
VITROS ECI - Total	11	-	-	11	-	11

Viral Markers – HBsAb (cont'd)

	Specimen VM-9		Specimen VM-10	
ALL METHODS	2	118	-	120
Abbott Architect	-	9	-	9
Abbott Architect - IgG	-	2	-	2
Abbott Architect - Total	-	17	-	17
Abbott AxSYM	-	1	-	1
Abbott AxSYM - IgG	-	2	-	2
Abbott AxSYM - Total	-	13	-	13
Bayer ADVIA Centaur	-	3	-	3
Bayer ADVIA Centaur - Total	-	7	-	7
Beckman ACCESS / 2 / DxI	-	3	-	3
bioMerieux Vidas - IgG	-	2	-	2
bioMerieux Vidas - Total	-	3	-	3
BioSystems	-	1	-	1
DPC Immulite 2000	-	1	-	1
Other IgG Method	-	2	-	2
Other Total Method	-	6	-	6
Roche Elecsys - IgG	-	2	-	2
Roche Elecsys - Total	-	9	-	9
Roche Elecsys 1010 / 2010	-	9	-	9
Roche Modular Analytics	2	8	-	10
VITROS ECI - IgM	-	1	-	1
VITROS ECI - Total	-	11	-	11

Viral Markers – HBsAg

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	165	166	1	2	165
Abbott Architect	-	16	16	-	-	16
Abbott Architect - IgG	-	2	2	-	-	2
Abbott Architect - Total	-	20	20	-	-	20
Abbott AxSYM	-	6	6	-	-	6
Abbott AxSYM - Total	2	7	9	-	-	9
Bayer ADVIA Centaur	-	3	3	-	1	2
Bayer ADVIA Centaur - Total	-	8	8	-	1	7
Beckman ACCESS / 2 / Dxl	-	6	6	-	-	6
Bio-Rad Evolis	-	2	2	-	-	2
bioMerieux Vidas - IgG	-	1	1	-	-	1
bioMerieux Vidas - Total	-	10	10	-	-	10
bioMerieux Vidas, Mini Vidas	-	2	2	-	-	2
DPC Immulite 2000	-	1	1	-	-	1
Other IgG Method	-	1	1	-	-	1
Other Total Method	-	15	15	-	-	15
Roche Elecsys - IgG	-	1	1	-	-	1
Roche Elecsys - Total	-	16	16	-	-	16
Roche Elecsys 1010 / 2010	-	11	11	-	-	11
Roche Modular Analytics	-	8	7	1	-	8
VITROS Eci - IgM	-	1	1	-	-	1
VITROS Eci - Total	-	15	15	-	-	15

Viral Markers – HBsAg (cont'd)

<u>Method</u>	<u>Specimen VM-9</u>		<u>Specimen VM-10</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	64	102	-	167
Abbott Architect	10	6	-	16
Abbott Architect - IgG	2	-	-	2
Abbott Architect - Total	16	4	-	20
Abbott AxSYM	2	4	-	6
Abbott AxSYM - Total	6	3	-	9
Bayer ADVIA Centaur	-	3	-	3
Bayer ADVIA Centaur - Total	2	6	-	8
Beckman ACCESS / 2 / DxI	-	6	-	6
Bio-Rad Evolis	-	2	-	2
bioMerieux Vidas - IgG	-	1	-	1
bioMerieux Vidas - Total	-	10	-	10
bioMerieux Vidas, Mini Vidas	-	2	-	2
DPC Immulite 2000	-	1	-	1
Other IgG Method	1	-	-	1
Other Total Method	3	12	-	15
Roche Elecsys - IgG	1	-	-	1
Roche Elecsys - Total	10	5	-	16
Roche Elecsys 1010 / 2010	3	8	-	11
Roche Modular Analytics	4	4	-	8
VITROS ECI - IgM	-	1	-	1
VITROS ECI - Total	-	15	-	15

Specimen VM-9 is not graded due to lack of participant consensus. The vendor assay for VM-9 is negative, following neutralization. If you receive a positive Hepatitis B Surface Antigen result, it is recommended that this be confirmed by a neutralization test. If you do not perform a neutralization confirmation test, you may be reporting false positive results on your patients.

Viral Markers – HCV

<u>Method</u>	Specimen VM-6		Specimen VM-7		Specimen VM-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	149	1	148	2	147
Abbott Architect	-	14	-	14	-	14
Abbott Architect - IgG	-	6	-	6	-	6
Abbott Architect - Total	-	18	-	18	-	18
Abbott AxSYM	-	5	-	5	-	5
Abbott AxSYM - Total	-	13	-	13	-	13
Bayer ADVIA Centaur	-	3	-	3	-	3
Bayer ADVIA Centaur - IgG	-	2	-	2	-	2
Bayer ADVIA Centaur - Total	-	7	-	7	-	7
Beckman ACCESS / 2 / Dxl	-	6	-	6	-	6
Bio-Rad Evolis	-	3	-	3	-	3
bioMerieux Vidas - Total	-	1	-	1	1	-
Other IgG Method	-	4	-	4	-	4
Other Total Method	-	13	-	13	1	12
Roche Elecsys - Total	-	12	1	11	-	12
Roche Elecsys 1010 / 2010	-	5	-	5	-	5
Roche Modular Analytics	-	6	-	6	-	6
VITROS ECi - IgG	-	1	-	1	-	1
VITROS ECi - IgM	-	1	-	1	-	1
VITROS ECi - Total	-	17	-	17	-	17

Viral Markers – HCV (cont'd)

<u>Method</u>	<u>Specimen VM-9</u>		<u>Specimen VM-10</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	147	2	-	149
Abbott Architect	14	-	-	14
Abbott Architect - IgG	6	-	-	6
Abbott Architect - Total	18	-	-	18
Abbott AxSYM	5	-	-	5
Abbott AxSYM - Total	13	-	-	13
Bayer ADVIA Centaur	3	-	-	3
Bayer ADVIA Centaur - IgG	2	-	-	2
Bayer ADVIA Centaur - Total	7	-	-	7
Beckman ACCESS / 2 / Dxl	6	-	-	6
Bio-Rad Evolis	3	-	-	3
bioMerieux Vidas - Total	-	1	-	1
Other IgG Method	4	-	-	4
Other Total Method	12	1	-	13
Roche Elecsys - Total	12	-	-	12
Roche Elecsys 1010 / 2010	5	-	-	5
Roche Modular Analytics	6	-	-	6
VITROS Eci - IgG	1	-	-	1
VITROS Eci - IgM	1	-	-	1
VITROS Eci - Total	17	-	-	17

Toxoplasma gondii Antibody

<u>Method</u>	Specimen TOX-6		Specimen TOX-7		Specimen TOX-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	3	5	2	2
Abbott Architect - IgG	1	-	1	-	-	-
Abbott Architect - IgM	2	-	-	2	-	-
Other IgM method	1	-	-	1	-	1
VITROS ECi - IgG	2	-	1	1	2	-
VITROS ECi - IgM	2	-	1	1	-	1

<u>Method</u>	Specimen TOX-9		Specimen TOX-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	4	4	-
Abbott Architect – IgG	-	-	-	-
Abbott Architect – IgM	-	-	-	-
Other IgM method	-	1	1	-
VITROS ECi - IgG	-	2	2	-
VITROS ECi - IgM	-	1	1	-

Cytomegalovirus (CMV) Antibodies

<u>Method</u>	Specimen CMV-6		Specimen CMV-7		Specimen CMV-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	2	-	5	4	-
Abbott Architect - IgG	1	-	-	1	-	-
Other IgM method	-	1	-	1	1	-
VITROS ECi - IgG	2	-	-	2	2	-
VITROS ECi - IgM	-	1	-	1	1	-

<u>Method</u>	Specimen CMV-9		Specimen CMV-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	-	2	2
Abbott Architect - IgG	-	-	-	-
Other IgM method	1	-	-	1
VITROS ECi - IgG	2	-	2	-
VITROS ECi - IgM	1	-	-	1

Toxoplasma gondii Antibody—Quantitative (IU/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen TOX-6						
All Method	7	338.6	169.6	50.1	300	0 - 848
Specimen TOX-7						
All Method	8	203.4	144.8	71.2	179	0 - 638
Specimen TOX-8						
All Method	3	-	-	-	110	Not graded
Specimen TOX-9						
All Method	3	-	-	-	0	Not graded
Specimen TOX-10						
All Method	3	-	-	-	500	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-6						
All Method	5	109.0	85.1	78.1	153	0 - 365
Specimen CMV-7						
All Method	6	22.7	32.8	144.7	3	0 - 122
Specimen CMV-8						
All Method	3	-	-	-	106	Not graded
Specimen CMV-9						
All Method	3	-	-	-	43	Not graded
Specimen CMV-10						
All Method	3	-	-	-	15	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-6						
All Method	6	8.68	2.07	23.8	8.0	2.4 - 14.9
Specimen CK-7						
All Method	6	40.02	9.19	23.0	38.2	12.4 - 67.6
Specimen CK-8						
All Method	6	20.95	4.85	23.1	20.5	6.4 - 35.5
Specimen CK-9						
All Method	6	60.85	15.65	25.7	58.2	13.9 - 107.8
Specimen CK-10						
All Method	6	86.75	20.00	23.1	85.3	26.7 - 146.8

Medical Laboratory Evaluation
25 Massachusetts Ave NW Ste 700
Washington, DC 20001-7401
800-338-2746 • 202-261-4500 • Fax: 202-835-0440
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