MEDICAL LABORATORY EVALUATION

INTERNATIONAL PARTICIPANT SUMMARY

2 • 0 • 0 • 3

Hematology, Coagulation,
Blood Bank, Urinalysis,
Microbiology
MLE – A2

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

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Microbiology

2003 Evaluation Criteria

Qualitative

For qualitative procedures, evaluation is based on 80% participant consensus

Blood Cell Identification	80% Consensus
Urine Dipstick	80% Consensus
Urine hCG	80% Consensus
Microalbumin (Semi-Quantitative)	80% Consensus
Urine Sediment Identification	80% Consensus
KOH Skin Preparation	80% Consensus
ABO/Rh	80% Consensus
Unexpected Antibody Detection	80% Consensus
Compatibility Testing	80% Consensus
Bacterial Identification	80% Consensus
Parasite Identification	Vendor Assay
Strep A Antigen Detection	80% Consensus
Antimicrobial Susceptibility Testing	80% Consensus
Gram Stain	80% Consensus
Gram Stain Morphology	Not Graded

Quantitative

For quantitative procedures, a mean and standard deviation (SD) are calculated for each analyte's "All Method" group. Acceptable performance is established 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 44-45 under the heading "Acceptable Ranges for Quantitative Results."

Hemoglobin	± 3 SD
Hematocrit	± 3 SD
White Blood Cell Count	± 3 SD
Red Blood Cell Count	± 3 SD
Platelet Count	± 3 SD
Automated Differential	± 3 SD
Prothrombin Time	± 2 SD
Activated Partial Thromboplastin Time	± 2 SD
Fibrinogen	± 3 SD
International Normalized Ratio (All other samples)	Not Graded
Specific Gravity	± 3 SD

BASIC HEMATOLOGY W/ 3-PART DIFFERENTIAL - WHITE BLOOD CELL COUNT (x 10^9/L)

	Specimen HD-6					Specimen HD-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
Abbott Cell-Dyn 1700	2	-	-	-	11.1	1	-	-	-	5.3

	Specimen HD-8					Specimen HD-9				
Abbott Cell-Dyn 1700	2	-	-	-	5.5	2	-	-	-	4.6

	Specimen HD-10				
Abbott Cell-Dyn 1700	2	-	-	-	7.9

BASIC HEMATOLOGY W/3-PART DIFFERENTIAL - RED BLOOD CELL COUNT (x 10^{12}/L)

	Specimen HD-6					Specimen HD-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
Abbott Cell-Dyn 1700	2	-	-	-	4.95	1	-	-	-	5.14

	Specimen HD-8					Specimen HD-9				
Abbott Cell-Dyn 1700	2	-	-	-	5.06	2	-	-	-	4.66

	Specimen HD-10				
Abbott Cell-Dyn 1700	2	-	-	-	3.88

BASIC HEMATOLOGY W/3-PART DIFFERENTIAL - HEMOGLOBIN (g/dL)

	Specimen HD-6					Specimen HD-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
Abbott Cell-Dyn 1700	2	-	-	-	14.2	1	-	-	-	15.6

	Specimen HD-8					Specimen HD-9				
Abbott Cell-Dyn 1700	2	-	-	-	15.4	2	-	-	-	14.2

	Specimen HD-10				
Abbott Cell-Dyn 1700	2	-	-	-	11.6

BASIC HEMATOLOGY W/3-PART DIFFERENTIAL - HEMATOCRIT (percent)

	Specimen HD-6					Specimen HD-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
Abbott Cell-Dyn 1700	2	-	-	-	52.5	1	-	-	-	55.9

	Specimen HD-8					Specimen HD-9				
Abbott Cell-Dyn 1700	2	-	-	-	53.6	2	-	-	-	52.6

	Specimen HD-10				
Abbott Cell-Dyn 1700	2	-	-	-	41.9

BASIC HEMATOLOGY W/3-PART DIFFERENTIAL - PLATELET COUNT (x 10^9/L)

	Specimen HD-6					Specimen HD-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
Abbott Cell-Dyn 1700	2	-	-	-	469	1	-	-	-	647

	Specimen HD-8					Specimen HD-9				
Abbott Cell-Dyn 1700	2	-	-	-	643	2	-	-	-	374

	Specimen HD-10				
Abbott Cell-Dyn 1700	2	-	-	-	132

BASIC HEMATOLOGY W/3-PART DIFFERENTIAL - LYMPHOCYTES (percent)

	Specimen HD-6					Specimen HD-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
Abbott Cell-Dyn 1700	2	-	-	-	35.1	1	-	-	-	49.8

	Specimen HD-8					Specimen HD-9				
Abbott Cell-Dyn 1700	2	-	-	-	47.7	2	-	-	-	38.9

	Specimen HD-10				
Abbott Cell-Dyn 1700	2	-	-	-	40.9

BASIC HEMATOLOGY W/3-PART DIFFERENTIAL - MONO/MID/MIXED/MCR (percent)

	Specimen HD-6					Specimen HD-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
Abbott Cell-Dyn 1700	2	-	-	-	7.9	1	-	-	-	12.1

	Specimen HD-8					Specimen HD-9				
Abbott Cell-Dyn 1700	2	-	-	-	13.6	2	-	-	-	10.9

	Specimen HD-10				
Abbott Cell-Dyn 1700	2	-	-	-	9.7

BASIC HEMATOLOGY W/3-PART DIFFERENTIAL - GRANULOCYTES/NEUT (percent)

	Specimen HD-6					Specimen HD-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
Abbott Cell-Dyn 1700	2	-	-	-	57.0	1	-	-	-	38.0

	Specimen HD-8					Specimen HD-9				
Abbott Cell-Dyn 1700	2	-	-	-	38.7	2	-	-	-	50.3

	Specimen HD-10				
Abbott Cell-Dyn 1700	2	-	-	-	49.4

HEMATOLOGY W/ 5-PART DIFFERENTIAL - WHITE BLOOD CELL COUNT (x 10^9/L)

	Specimen DIF-6					Specimen DIF-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
All Methods	4	-	-	-	7.5	4	-	-	-	2.8
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	7.1	2	-	-	-	2.6
COULTER GEN-S	2	-	-	-	7.8	2	-	-	-	2.9

	Specimen DIF-8					Specimen DIF-9				
All Methods	4	-	-	-	13.7	4	-	-	-	2.8
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	12.6	2	-	-	-	2.5
COULTER GEN-S	2	-	-	-	14.9	2	-	-	-	2.8

	Specimen DIF-10				
All Methods	4	-	-	-	22.7
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	21.2
COULTER GEN-S	2	-	-	-	24.4

HEMATOLOGY W/ 5-PART DIFFERENTIAL - RED BLOOD CELL COUNT (x 10^{12}/L)

	Specimen DIF-6					Specimen DIF-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
All Methods	4	-	-	-	4.57	4	-	-	-	4.80
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	4.57	2	-	-	-	4.82
COULTER GEN-S	2	-	-	-	4.57	2	-	-	-	4.80

	Specimen DIF-8					Specimen DIF-9				
All Methods	4	-	-	-	4.07	4	-	-	-	2.94
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	4.03	2	-	-	-	2.98
COULTER GEN-S	2	-	-	-	4.07	2	-	-	-	2.94

	Specimen DIF-10				
All Methods	4	-	-	-	5.86
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	5.77
COULTER GEN-S	2	-	-	-	5.86

HEMATOLOGY W/ 5-PART DIFFERENTIAL - HEMOGLOBIN (g/dL)

	Specimen DIF-6					Specimen DIF-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
All Methods	4	-	-	-	13.8	4	-	-	-	14.3
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	14.1	2	-	-	-	14.6
COULTER GEN-S	2	-	-	-	13.5	2	-	-	-	14.1

	Specimen DIF-8					Specimen DIF-9				
All Methods	4	-	-	-	12.0	4	-	-	-	7.9
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	12.2	2	-	-	-	8.1
COULTER GEN-S	2	-	-	-	11.7	2	-	-	-	7.7

	Specimen DIF-10				
All Methods	4	-	-	-	19.0
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	19.4
COULTER GEN-S	2	-	-	-	18.6

HEMATOLOGY W/ 5-PART DIFFERENTIAL - HEMATOCRIT (percent)

	Specimen DIF-6					Specimen DIF-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
All Methods	4	-	-	-	38.5	4	-	-	-	41.1
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	39.4	2	-	-	-	41.7
COULTER GEN-S	2	-	-	-	38.5	2	-	-	-	40.9

	Specimen DIF-8					Specimen DIF-9				
All Methods	4	-	-	-	32.8	4	-	-	-	22.3
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	33.0	2	-	-	-	22.8
COULTER GEN-S	2	-	-	-	32.8	2	-	-	-	22.1

	Specimen DIF-10				
All Methods	4	-	-	-	53.4
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	53.0
COULTER GEN-S	2	-	-	-	53.4

HEMATOLOGY W/ 5-PART DIFFERENTIAL - PLATELET COUNT (x 10^9/L))

	Specimen DIF-6					Specimen DIF-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
All Methods	4	-	-	-	258	4	-	-	-	327
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	279	2	-	-	-	360
COULTER GEN-S	2	-	-	-	238	2	-	-	-	307

	Specimen DIF-8					Specimen DIF-9				
All Methods	4	-	-	-	159	4	-	-	-	99
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	172	2	-	-	-	106
COULTER GEN-S	2	-	-	-	145	2	-	-	-	88

	Specimen DIF-10				
All Methods	4	-	-	-	495
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	554
COULTER GEN-S	2	-	-	-	442

HEMATOLOGY W/ 5-PART DIFFERENTIAL - NEUTROPHILS (percent)

	Specimen DIF-6					Specimen DIF-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
All Methods	4	-	-	-	66.6	4	-	-	-	72.7
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	67.3	2	-	-	-	73.0
COULTER GEN-S	2	-	-	-	64.1	2	-	-	-	71.9

	Specimen DIF-8					Specimen DIF-9				
All Methods	4	-	-	-	66.2	4	-	-	-	61.3
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	68.8	2	-	-	-	60.8
COULTER GEN-S	2	-	-	-	62.3	2	-	-	-	62.8

	Specimen DIF-10				
All Methods	4	-	-	-	71.7
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	72.6
COULTER GEN-S	2	-	-	-	69.3

HEMATOLOGY W/ 5-PART DIFFERENTIAL - LYMPHOCYTES (percent)

	Specimen DIF-6					Specimen DIF-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
All Methods	4	-	-	-	28.7	4	-	-	-	23.3
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	30.3	2	-	-	-	24.7
COULTER GEN-S	2	-	-	-	26.5	2	-	-	-	22.9

	Specimen DIF-8					Specimen DIF-9				
All Methods	4	-	-	-	24.9	4	-	-	-	34.8
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	26.9	2	-	-	-	38.2
COULTER GEN-S	2	-	-	-	21.8	2	-	-	-	32.6

	Specimen DIF-10				
All Methods	4	-	-	-	18.7
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	22.5
COULTER GEN-S	2	-	-	-	15.1

HEMATOLOGY W/ 5-PART DIFFERENTIAL - MONOCYTES (percent)

	Specimen DIF-6					Specimen DIF-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
All Methods	4	-	-	-	2.0	4	-	-	-	0.6
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	0.3	2	-	-	-	0.5
COULTER GEN-S	2	-	-	-	4.7	2	-	-	-	1.9

	Specimen DIF-8					Specimen DIF-9				
All Methods	4	-	-	-	2.5	4	-	-	-	0.4
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	0.5	2	-	-	-	0.4
COULTER GEN-S	2	-	-	-	5.4	2	-	-	-	2.6

	Specimen DIF-10				
All Methods	4	-	-	-	1.8
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	0.3
COULTER GEN-S	2	-	-	-	4.5

HEMATOLOGY W/ 5-PART DIFFERENTIAL - EOSINOPHILS (percent)

	Specimen DIF-6					Specimen DIF-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
All Methods	4	-	-	-	3.2	4	-	-	-	2.3
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	1.8	2	-	-	-	1.1
COULTER GEN-S	2	-	-	-	4.7	2	-	-	-	3.2

	Specimen DIF-8					Specimen DIF-9				
All Methods	4	-	-	-	6.7	4	-	-	-	1.1
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	3.4	2	-	-	-	0.4
COULTER GEN-S	2	-	-	-	10.5	2	-	-	-	1.9

	Specimen DIF-10				
All Methods	4	-	-	-	7.8
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	4.1
COULTER GEN-S	2	-	-	-	11.0

HEMATOLOGY W/ 5-PART DIFFERENTIAL - BASOPHILS (percent)

	Specimen DIF-6					Specimen DIF-7				
Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
All Methods	2	-	-	-	0.2	3	-	-	-	0.3
Abbott Cell-Dyn 3500 / 3700	1	-	-	-	0.2	2	-	-	-	0.7
COULTER GEN-S	1	-	-	-	0.2	1	-	-	-	0.2
	Specimen DIF-8					**Specimen DIF-9**				
All Methods	4	-	-	-	0.2	2	-	-	-	0.5
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	0.5	1	-	-	-	0.6
COULTER GEN-S	2	-	-	-	0.2	1	-	-	-	0.3
	Specimen DIF-10									
All Methods	4	-	-	-	0.5					
Abbott Cell-Dyn 3500 / 3700	2	-	-	-	0.6					
COULTER GEN-S	2	-	-	-	0.2					

BLOOD CELL IDENTIFICATION

BLOOD CELL CASE HISTORY, 2003-A2

This 45-year-old African-American male returned from a hiking during which he experienced shortness of breath and slight joint pain. He suspected that these complaints were being aggravated by his life-long condition, anemia, but this time the effects seemed more intense. He had watched his parents struggle to maintain health against the same condition. He went to his internist for an evaluation and a CBC was ordered. The significant results of the CBC, performed at his doctor's office, are listed below. The following blood cells were reported on the differential.

Total WBC	10.0 x 10^9/L
RBC	2.66x 10^{12}/L
Hgb	8.8 g/dL
Hct	25%
MCV	89 fL
Plt	400 x 10^9/ L
Granulocytes	65 %
Lymphocytes	28 %
Monocytes	7%

This patient was diagnosed with Hemoglobin CC disease.

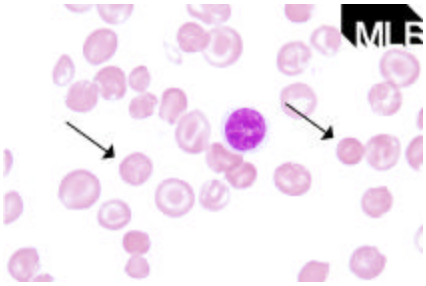
References:

E. Anne Steine-Martin et al, *Clinical Hematology: Principles, Procedures, Correlations*, Lippincott, Philadelphia, PA, 1992.

Handin, Robert I, Disorders Of The Platelet And Vessel Wall, *Harrison's Principles of Internal Medicine*, New York, NY, McGraw-Hill, 1998.

BLOOD CELL IDENTIFICATION

Specimen BC-7

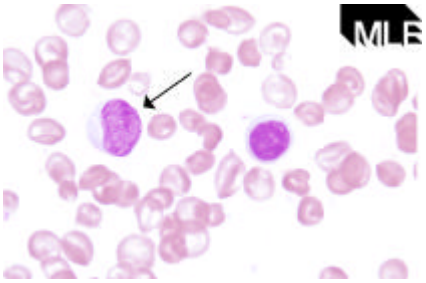


Identification	Labs	Percent	Performance
Spherocyte	6	66.7%	Acceptable
Microcyte	3	33.3%	Acceptable

The arrows in this photograph point to two microcytic red blood cells. When you compare the size of these cells to the lymphocyte nucleus, the cells are smaller. Using the nucleus of a normal lymphocyte to gauge the red blood cell size is an accepted practice in hematology. Cells smaller than the nucleus are microcytes, cells equal to the size of the nucleus are normocytes, and cells larger than the nucleus are macrocytes.

Many participants identified these cells as spherocytes, which is a marginally acceptable response. However, both of these cells have a blush of central pallor. Spherocytes often appear microcytic but have very dense central areas with an even dark red color. The controversy between microcytes and spherocytes is ongoing.

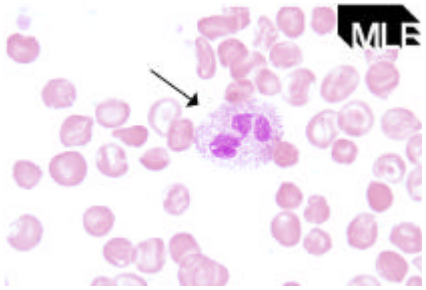
Specimen BC-8



Identification	Labs	Percent	Performance
Monocyte	8	88.9%	Not graded
Lymphocyte, reactive	1	11.1%	

The arrow in this photograph points to a large normal lymphocyte. Normal lymphocytes range in size from 7-18µ. The size variation challenged many participants who wanted to identify this cell as a monocyte. A monocyte nucleus has folds, which some hematologists describe as “brainlike” convolutions.[1] The cytoplasm on the monocyte is usually described as being ground glass due to many minute granules. The cytoplasm on this cell does not have any granules. Other participants called this a reactive lymphocyte, a cell often confused with the large normal lymphocyte. Reactive lymphocytes have a vast range of appearances but quite often the cytoplasm of the reactive lymphocyte is indented by nearby cells. This is an ungraded challenge due to less than 80% participant consensus.

Specimen BC-9



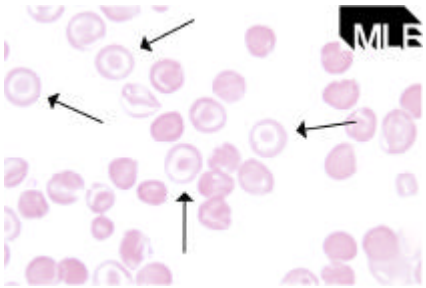
Identification	Labs	Percent	Performance
Seg/band neut. with toxic granulation	5	55.6%	Acceptable
Segmented or band neutrophil	4	44.4%	Acceptable

The arrow in this photograph points to a segmented neutrophil with toxic granulation. The dense granules in the cytoplasm of toxic granulation are distinct.

[1] J. H. Carr and B. Rodak, *Clinical Hematology Atlas*, W. B. Saunders, Philadelphia, PA, 1999.

BLOOD CELL IDENTIFICATION

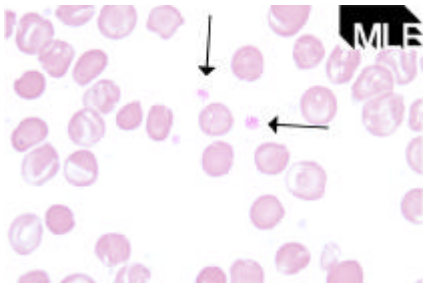
Specimen BC-10



Identification	Labs	Percent	Performance
Target cell	9	100%	Acceptable

The arrows in this photograph are pointing to target red cells. Target cells can be seen in a number of hemoglobinopathies such as hemoglobin SS, C, SC, and E disease. The cells have a distinct bulls eye appearance.

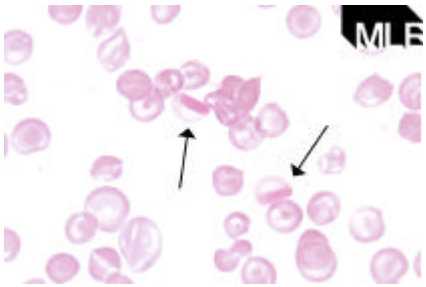
Specimen BC-11



Identification	Labs	Percent	Performance
Platelet, normal	9	100%	Acceptable

The arrows in this photograph point to normal platelets. The center of these cells, the granulomere, contains azurophilic granules and is surrounded by cytoplasm without granules, the halomere. Platelets will vary in size and shape but normal platelets will always be smaller than the red blood cells.

Specimen BC-12



Identification	Labs	Percent	Performance
Hemoglobin CC Crystal	9	100%	Not graded

The arrows in this ungraded, educational challenge point to a Hemoglobin CC crystals. Notice how these crystals are pushed to one side of the red cells. These crystals form during the slides air drying process because of the decreased solubility of hemoglobin C. Hemoglobin CC crystals are a significant finding and similar cells may be seen in thalassemias and sickling disorders.

ABO GROUP / RH FACTOR

One participant reported results. The vendor assay for these specimens are as follows:

Specimen

BB-6 – O Positive
BB-7 – A Negative
BB-8 – AB Positive
BB-9 – O Negative
BB-10 – B Positive

UNEXPECTED ANTIBODY DETECTION / COMPATIBILITY

One participant reported results. The vendor assay for these specimens are as follows:

Specimen

AB-6 – Unexpected antibody detected (Anti-Jk^a present). Not compatible with XM-2.
AB-7 – Unexpected antibody detected (Anti-C present). Not compatible with XM-2.
AB-8 – No unexpected antibody detected. Compatible with XM-2.
AB-9 – Unexpected antibody detected (Anti-S present). Not compatible with XM-2.
AB-10 – No unexpected antibody detected. Compatible with XM-2.

PROTHROMBIN TIME (seconds)

	Specimen CG-6					Specimen CG-7				
Reagent/Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
All Methods	42	16.57	2.57	15.5	15.9	42	20.84	3.31	15.9	20.8
BioMerieux Simplastin HTF										
BehnK Electronik Compact X	2	-	-	-	14.3	2	-	-	-	20.3
OTC Coag-A-Mate MTX / II	2	-	-	-	13.8	2	-	-	-	18.6
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	19.1	1	-	-	-	23.3
All Coagulation Instruments	5	15.06	2.30	15.3	14.2	5	20.20	2.04	10.1	19.6
Dade Innovin										
Sysmex CA-1000	1	-	-	-	14.8	1	-	-	-	23.8
Sysmex CA-500	1	-	-	-	14.4	1	-	-	-	19.2
All Coagulation Instruments	2	-	-	-	14.6	2	-	-	-	21.5
Dade Thrombo-C Plus										
Sysmex CA-500	1	-	-	-	14.2	1	-	-	-	15.1
Tilt Tube	1	-	-	-	13.2	1	-	-	-	15.1
All Coagulation Instruments	2	-	-	-	13.7	2	-	-	-	15.1
Diag Stago STA Neoplastine CL+										
Diagnostica Stago STart 4/8	1	-	-	-	17.1	1	-	-	-	21.9
Helena Thromboplastin MI										
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	18.3	1	-	-	-	23.7
Tilt Tube	2	-	-	-	18.0	2	-	-	-	23.6
All Coagulation Instruments	3	-	-	-	18.3	3	-	-	-	23.7
IL TEST PT-FIB HS										
IL ACL, all models	9	15.51	1.50	9.7	15.8	9	18.67	1.04	5.6	18.3
IL TEST PT-FIB Recombinant										
IL ACL, all models	5	15.40	0.40	2.6	15.3	5	21.44	0.97	4.5	21.0
OTC Simplastin Excel S										
BehnK Electronik Compact X	1	-	-	-	19.5	1	-	-	-	27.4
OTC Coag-A-Mate MTX / II	2	-	-	-	19.5	2	-	-	-	23.3
OTC Coag-A-Mate Single Chann	1	-	-	-	21.5	1	-	-	-	19.5
All Coagulation Instruments	7	19.37	1.27	6.6	19.5	7	-	-	-	22.4
OTC Simplastin Excel										
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	23.7	1	-	-	-	29.5
All Coagulation Instruments	2	-	-	-	18.6	2	-	-	-	21.8

	Specimen CG-8					Specimen CG-9				
All Methods	42	13.11	1.54	11.7	12.8	41	33.17	6.56	19.8	33.0
BioMerieux Simplastin HTF										
BehnK Electronik Compact X	2	-	-	-	12.0	2	-	-	-	33.1
OTC Coag-A-Mate MTX / II	2	-	-	-	11.5	2	-	-	-	29.3
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	12.0	1	-	-	-	39.7
All Coagulation Instruments	5	11.76	0.29	2.5	11.9	5	32.86	4.34	13.2	32.1
Dade Innovin										
Sysmex CA-1000	1	-	-	-	14.1	1	-	-	-	36.1
Sysmex CA-500	1	-	-	-	12.0	1	-	-	-	31.8
All Coagulation Instruments	2	-	-	-	13.1	2	-	-	-	34.0

PROTHROMBIN TIME (seconds)

	Specimen CG-8 (cont'd)					Specimen CG-9 (cont'd)				
Reagent/Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
Dade Thrombo-C Plus										
Sysmex CA-500	1	-	-	-	11.4	1	-	-	-	22.4
Tilt Tube	1	-	-	-	11.2	1	-	-	-	20.1
All Coagulation Instruments	2	-	-	-	11.3	2	-	-	-	21.3
Diag Stago STA Neoplastine CL+										
Diagnostica Stago STart 4/8	1	-	-	-	12.7	1	-	-	-	35.7
Helena Thromboplastin MI										
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	14.0	1	-	-	-	39.9
Tilt Tube	2	-	-	-	14.3	2	-	-	-	38.8
All Coagulation Instruments	3	-	-	-	14.0	3	-	-	-	39.9
IL TEST PT-FIB HS										
IL ACL, all models	9	12.52	0.40	3.2	12.6	8	29.16	2.49	8.6	28.2
IL TEST PT-FIB Recombinant										
IL ACL, all models	5	11.96	0.57	4.8	11.6	5	34.28	2.14	6.3	33.5
OTC Simplastin Excel S										
BehnK Electronik Compact X	1	-	-	-	15.6	1	-	-	-	41.6
OTC Coag-A-Mate MTX / II	2	-	-	-	15.0	2	-	-	-	37.3
OTC Coag-A-Mate Single Chann	1	-	-	-	14.2	1	-	-	-	33.9
All Coagulation Instruments	7	14.86	0.61	4.1	15.0	7	35.10	5.68	16.2	33.9
OTC Simplastin Excel										
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	16.5	1	-	-	-	52.2
All Coagulation Instruments	2	-	-	-	13.2	2	-	-	-	35.9

	Specimen CG-10				
All Methods	42	13.11	1.74	13.3	12.7
bioMerieux Simplastin HTF					
BehnK Electronik Compact X	2	-	-	-	10.6
OTC Coag-A-Mate MTX / II	2	-	-	-	10.8
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	14.2
All Coagulation Instruments	5	11.36	1.71	15.0	11.0
Dade Innovin					
Sysmex CA-1000	1	-	-	-	11.9
Sysmex CA-500	1	-	-	-	12.0
All Coagulation Instruments	2	-	-	-	12.0
Dade Thrombo-C Plus					
Sysmex CA-500	1	-	-	-	11.8
Tilt Tube	1	-	-	-	12.8
All Coagulation Instruments	2	-	-	-	12.3
Diag Stago STA Neoplastine CL+					
Diagnostica Stago STart 4/8	1	-	-	-	13.1
Helena Thromboplastin MI					
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	14.7
Tilt Tube	2	-	-	-	14.0
All Coagulation Instruments	3	-	-	-	14.7
IL TEST PT-FIB HS					
IL ACL, all models	9	12.62	0.32	2.5	12.6
IL TEST PT-FIB Recombinant					
IL ACL, all models	5	12.08	0.36	3.0	11.9
OTC Simplastin Excel S					
BehnK Electronik Compact X	1	-	-	-	15.2
OTC Coag-A-Mate MTX / II	2	-	-	-	15.8
OTC Coag-A-Mate Single Chann	1	-	-	-	15.5
All Coagulation Instruments	7	14.83	1.17	7.9	15.2
OTC Simplastin Excel					
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	18.1
All Coagulation Instruments	2	-	-	-	14.5

PROTHROMBIN TIME - INTERNATIONAL NORMALIZED RATIO (INR)

	Specimen CG-6					Specimen CG-7				
Reagent/Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
All Methods	39	1.37	1.23	16.9	1.4	40	1.78	0.29	16.5	1.8
bioMerieux Simplastin HTF										
BehnK Electronik Compact X	2	-	-	-	1.3	2	-	-	-	1.9
OTC Coag-A-Mate MTX / II	2	-	-	-	1.2	2	-	-	-	1.7
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	2.0	1	-	-	-	2.6
All Coagulation Instruments	5	1.38	0.36	26.3	1.2	5	1.96	0.38	19.3	1.9
Dade Innovin										
Sysmex CA-1000	1	-	-	-	1.3	1	-	-	-	1.8
Sysmex CA-500	1	-	-	-	1.5	1	-	-	-	2.1
All Coagulation Instruments	2	-	-	-	1.4	2	-	-	-	2.0
Dade Thrombo-C Plus										
Sysmex CA-500	1	-	-	-	1.9	1	-	-	-	2.3
Tilt Tube	1	-	-	-	1.1	1	-	-	-	1.2
All Coagulation Instruments	2	-	-	-	1.5	2	-	-	-	1.8
Diag Stago STA Neoplastine CL+										
Diagnostica Stago STart 4/8	1	-	-	-	1.5	1	-	-	-	2.1
Helena Thromboplastin MI										
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	1.3	1	-	-	-	1.7
Tilt Tube	2	-	-	-	1.4	2	-	-	-	1.9
All Coagulation Instruments	3	-	-	-	1.3	3	-	-	-	1.8
IL TEST PT-FIB HS										
IL ACL, all models	8	1.30	0.24	18.4	1.4	9	1.66	0.14	8.6	1.7
IL TEST PT-FIB Recombinant										
IL ACL, all models	4	-	-	-	1.3	4	-	-	-	1.8
OTC Simplastin Excel S										
BehnK Electronik Compact X	1	-	-	-	1.3	1	-	-	-	1.9
OTC Coag-A-Mate MTX / II	2	-	-	-	1.5	2	-	-	-	1.7
OTC Coag-A-Mate Single Chann	1	-	-	-	1.7	1	-	-	-	1.8
All Coagulation Instruments	7	1.47	0.14	9.4	1.4	7	1.71	0.25	14.5	1.8
OTC Simplastin Excel										
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	1.7	1	-	-	-	2.3
All Coagulation Instruments	2	-	-	-	1.3	2	-	-	-	1.7

	Specimen CG-8					Specimen CG-9				
All Methods	40	1.03	0.10	9.6	1.0	40	3.22	0.73	22.8	3.1
bioMerieux Simplastin HTF										
BehnK Electronik Compact X	2	-	-	-	1.0	2	-	-	-	3.4
OTC Coag-A-Mate MTX / II	2	-	-	-	0.9	2	-	-	-	2.9
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	1.0	1	-	-	-	5.0
All Coagulation Instruments	5	0.96	0.09	9.3	0.9	5	3.50	0.87	24.9	3.3
Dade Innovin										
Sysmex CA-1000	1	-	-	-	1.0	1	-	-	-	3.2
Sysmex CA-500	1	-	-	-	1.2	1	-	-	-	3.6
All Coagulation Instruments	2	-	-	-	1.1	2	-	-	-	3.4
Dade Thrombo-C Plus										
Sysmex CA-500	1	-	-	-	1.2	1	-	-	-	5.2
Tilt Tube	1	-	-	-	1.0	1	-	-	-	1.7
All Coagulation Instruments	2	-	-	-	1.1	2	-	-	-	3.5
Diag Stago STA Neoplastine CL+										
Diagnostica Stago STart 4/8	1	-	-	-	1.1	1	-	-	-	3.9
Helena Thromboplastin MI										
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	1.1	1	-	-	-	3.1
Tilt Tube	2	-	-	-	1.0	2	-	-	-	3.1
All Coagulation Instruments	3	-	-	-	1.0	3	-	-	-	3.1
IL TEST PT-FIB HS										
IL ACL, all models	8	0.99	0.06	6.5	1.0	8	3.05	0.36	11.8	3.1

PROTHROMBIN TIME - INTERNATIONAL NORMALIZED RATIO (INR)

	Specimen CG-8 (cont'd)					Specimen CG-9 (cont'd)				
Reagent/Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
IL TEST PT-FIB Recombinant										
IL ACL, all models	5	0.98	0.08	8.5	1.0	5	2.98	0.20	6.9	3.0
OTC Simplastin Excel S										
BehnK Electronik Compact X	1	-	-	-	1.0	1	-	-	-	3.1
OTC Coag-A-Mate MTX / II	2	-	-	-	1.1	2	-	-	-	3.7
OTC Coag-A-Mate Single Chann	1	-	-	-	1.1	1	-	-	-	3.5
All Coagulation Instruments	7	1.07	0.08	7.1	1.1	7	3.17	0.61	19.2	3.4
OTC Simplastin Excel										
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	1.2	1	-	-	-	5.2
All Coagulation Instruments	2	-	-	-	0.9	2	-	-	-	3.6

	Specimen CG-10				
All Methods	39	1.02	0.11	11.2	1.0
bioMerieux Simplastin HTF					
BehnK Electronik Compact X	2	-	-	-	0.9
OTC Coag-A-Mate MTX / II	2	-	-	-	0.9
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	1.3
All Coagulation Instruments	5	0.96	0.19	20.3	0.9
Dade Innovin					
Sysmex CA-1000	1	-	-	-	1.1
Sysmex CA-500	1	-	-	-	1.2
All Coagulation Instruments	2	-	-	-	1.2
Dade Thrombo-C Plus					
Sysmex CA-500	1	-	-	-	1.3
Tilt Tube	1	-	-	-	1.0
All Coagulation Instruments	2	-	-	-	1.2
Diag Stago STA Neoplastine CL+					
Diagnostica Stago STart 4/8	1	-	-	-	1.1
Helena Thromboplastin MI					
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	1.0
Tilt Tube	2	-	-	-	1.0
All Coagulation Instruments	3	-	-	-	1.0
IL TEST PT-FIB HS					
IL ACL, all models	8	1.00	0.09	9.3	1.0
IL TEST PT-FIB Recombinant					
IL ACL, all models	5	0.98	0.04	4.6	1.0
OTC Simplastin Excel S					
BehnK Electronik Compact X	1	-	-	-	1.0
OTC Coag-A-Mate MTX / II	2	-	-	-	1.1
OTC Coag-A-Mate Single Chann	1	-	-	-	1.1
All Coagulation Instruments	7	1.06	0.08	7.4	1.0
OTC Simplastin Excel					
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	2.1
All Coagulation Instruments	2	-	-	-	1.4

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

	Specimen CG-6					Specimen CG-7				
Reagent/Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
All Methods	39	56.0	10.2	18.2	53	40	39.4	3.3	8.4	39
Dade Actin FS										
BMC CoagChek System	1	-	-	-	40	1	-	-	-	43
Dade Actin										
IL ACL, all models	-	-	-	-	-	1	-	-	-	38
Sysmex CA-500	2	-	-	-	58	2	-	-	-	41
Tilt Tube	1	-	-	-	51	1	-	-	-	40
All Coagulation Instruments	3	-	-	-	55	4	-	-	-	40
Diagnostica Stago STA-PTT										
Diagnostica Stago STart 4/8	1	-	-	-	41	1	-	-	-	39
Helena aPTT-SA										
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	43	1	-	-	-	34
Tilt Tube	2	-	-	-	48	2	-	-	-	48
All Coagulation Instruments	3	-	-	-	43	3	-	-	-	42
IL TEST APTT-SP										
IL ACL, all models	11	74.5	36.1	48.4	67	12	37.5	2.6	7.0	38
IL TEST PT Fibrinogen										
IL ACL, all models	1	-	-	-	76	1	-	-	-	39
IL TEST PT-FIB, ISI 1.8-2.2										
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	58	1	-	-	-	44
OTC APTT Reagent										
BehnK Electronik Compact X	2	-	-	-	58	2	-	-	-	42
OTC Coag-A-Mate MTX / II	4	-	-	-	51	4	-	-	-	37
OTC Coag-A-Mate Single Chann	2	-	-	-	61	2	-	-	-	45
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	46	1	-	-	-	40
All Coagulation Instruments	12	52.8	6.4	12.0	51	12	40.8	3.2	7.8	41
OTC MDA Simplastin L										
BehnK Electronik Compact X	1	-	-	-	59	1	-	-	-	46
OTC Simplastin Excel										
All Coagulation Instruments	1	-	-	-	46	1	-	-	-	35

	Specimen CG-8					Specimen CG-9				
All Methods	42	28.9	3.2	11.1	28	41	52.4	8.1	15.4	52
Dade Actin FS										
BMC CoagChek System	1	-	-	-	37	1	-	-	-	54
Dade Actin										
IL ACL, all models	1	-	-	-	28	1	-	-	-	50
Sysmex CA-500	2	-	-	-	26	2	-	-	-	57
Tilt Tube	1	-	-	-	31	1	-	-	-	54
All Coagulation Instruments	4	-	-	-	27	4	-	-	-	55
Diagnostica Stago STA-PTT										
Diagnostica Stago STart 4/8	1	-	-	-	35	1	-	-	-	50
Helena aPTT-SA										
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	33	1	-	-	-	42
Tilt Tube	2	-	-	-	28	2	-	-	-	61
All Coagulation Instruments	3	-	-	-	29	3	-	-	-	57
IL TEST APTT-SP										
IL ACL, all models	12	27.2	1.5	5.4	27	11	47.0	3.5	7.4	47
IL TEST PT Fibrinogen										
IL ACL, all models	1	-	-	-	29	1	-	-	-	47
IL TEST PT-FIB, ISI 1.8-2.2										
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	28	1	-	-	-	60

ACTIVATED PARTIAL THROMBOPLASTIN (seconds)

	Specimen CG-8 (cont'd)					Specimen CG-9 (cont'd)				
Reagent/Instruments	***Labs***	***Mean***	***SD***	***CV***	***Median***	***Labs***	***Mean***	***SD***	***CV***	***Median***
OTC APTT Reagent										
BehnK Electronik Compact X	2	-	-	-	31	2	-	-	-	60
OTC Coag-A-Mate MTX / II	4	-	-	-	27	4	-	-	-	50
OTC Coag-A-Mate Single Chann	2	-	-	-	33	2	-	-	-	68
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	28	1	-	-	-	54
All Coagulation Instruments	12	29.6	2.6	8.8	29	12	55.3	8.8	15.9	56
OTC MDA Simplastin L										
BehnK Electronik Compact X	1	-	-	-	33	1	-	-	-	65
OTC Simplastin Excel										
All Coagulation Instruments	1	-	-	-	23	1	-	-	-	40

	Specimen CG-10				
All Methods	41	31.8	3.9	12.2	32
Dade Actin FS					
BMC CoagChek System	1	-	-	-	30
Dade Actin					
IL ACL, all models	1	-	-	-	32
Sysmex CA-500	2	-	-	-	32
Tilt Tube	1	-	-	-	32
All Coagulation Instruments	4	-	-	-	32
Diagnostica Stago STA-PTT					
Diagnostica Stago STart 4/8	1	-	-	-	32
Helena aPTT-SA					
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	29
Tilt Tube	2	-	-	-	41
All Coagulation Instruments	3	-	-	-	38
IL TEST APTT-SP					
IL ACL, all models	12	32.4	1.8	5.7	32
IL TEST PT Fibrinogen					
IL ACL, all models	1	-	-	-	35
IL TEST PT-FIB, ISI 1.8-2.2					
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	35
OTC APTT Reagent					
BehnK Electronik Compact X	2	-	-	-	32
OTC Coag-A-Mate MTX / II	3	-	-	-	30
OTC Coag-A-Mate Single Chann	2	-	-	-	35
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	33
All Coagulation Instruments	11	30.8	3.5	11.2	30
OTC MDA Simplastin L					
BehnK Electronik Compact X	1	-	-	-	34
OTC Simplastin Excel					
All Coagulation Instruments	1	-	-	-	24

FIBRINOGEN (mg/dL)

Reagent/Instruments	Specimen CG-6 Labs	Mean	SD	CV	Median	Specimen CG-7 Labs	Mean	SD	CV	Median
All Methods	22	154.6	61.6	39.9	145	23	332.3	75.5	22.7	342
Dade Fibrinogen Set										
IL ACL, all models	1	-	-	-	105	1	-	-	-	410
Sysmex CA-500	2	-	-	-	294	2	-	-	-	427
All Coagulation Instruments	3	-	-	-	266	3	-	-	-	410
IL TEST PT-FIB HS										
IL ACL, all models	6	150.8	13.2	8.7	147	6	368.7	19.9	5.4	371
IL TEST PT-FIB Recombinant										
IL ACL, all models	4	-	-	-	134	4	-	-	-	283
OTC Fibriquik Fibrinogen										
OTC Coag-A-Mate MTX / II	3	-	-	-	151	3	-	-	-	316
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	106	1	-	-	-	189
All Coagulation Instruments	5	120.8	36.7	30.4	132	5	280.2	90.4	32.3	296

Reagent/Instruments	Specimen CG-8 Labs	Mean	SD	CV	Median	Specimen CG-9 Labs	Mean	SD	CV	Median
All Methods	22	350.1	58.7	16.8	340	21	346.3	97.8	28.2	350
Dade Fibrinogen Set										
IL ACL, all models	1	-	-	-	339	1	-	-	-	409
Sysmex CA-500	2	-	-	-	433	2	-	-	-	381
All Coagulation Instruments	3	-	-	-	406	3	-	-	-	409
IL TEST PT-FIB HS										
IL ACL, all models	6	343.2	22.5	6.6	335	5	390.4	28.9	7.4	387
IL TEST PT-FIB Recombinant										
IL ACL, all models	4	-	-	-	314	4	-	-	-	301
OTC Fibriquik Fibrinogen										
OTC Coag-A-Mate MTX / II	3	-	-	-	372	3	-	-	-	315
OTC Coag-A-Mate XC/XCPlus/RA	-	-	-	-	-	1	-	-	-	139
All Coagulation Instruments	4	-	-	-	358	5	292.0	120.5	41.3	298

Reagent/Instruments	Specimen CG-10 Labs	Mean	SD	CV	Median
All Methods	21	260.0	51.1	19.7	251
Dade Fibrinogen Set					
IL ACL, all models	1	-	-	-	249
Sysmex CA-500	2	-	-	-	363
All Coagulation Instruments	3	-	-	-	348
IL TEST PT-FIB HS					
IL ACL, all models	6	261.0	30.5	11.7	265
IL TEST PT-FIB Recombinant					
IL ACL, all models	4	-	-	-	219
OTC Fibriquik Fibrinogen					
OTC Coag-A-Mate MTX / II	3	-	-	-	255
OTC Coag-A-Mate XC/XCPlus/RA	1	-	-	-	188
All Coagulation Instruments	5	245.6	46.5	18.9	238

URINALYSIS – URINE hCG

Specimen UA-2

Participant Results

Method	Negative	Positive
All Methods	8	-
Acon Laboratories	1	-
Organon Teknika Contrast	1	-
Organon Teknika Prenospia Plus	6	-

URINALYSIS DIPSTICK – SPECIFIC GRAVITY

Specimen UA-2

Method	*Labs*	*Mean*	*SD*	*CV*	*Median*
All Methods	46	1.0113	0.0025	0.2	1.010
Aution Jet	1	-	-	-	1.025
Bayer Clinitek 50	10	1.0100	0.0000	0.0	1.010
Bayer Clinitek 500	18	1.0128	0.0035	0.3	1.015
Bayer Clinitek Atlas	1	-	-	-	1.015
Bayer Reagent Strips	3	-	-	-	1.010
Roche (BMC) Chemstrips	4	-	-	-	1.010
Roche (BMC) Criterion Analyzer	3	-	-	-	1.010
Roche (BMC) Mini UA	3	-	-	-	1.010
Roche (BMC) SuperUA/ChemstripUA	4	-	-	-	1.010

URINALYSIS DIPSTICK - pH

Specimen UA-2

	Participant Results									
Method	*4.0*	*5.0*	*5.5*	*6.0*	*6.5*	*7.0*	*7.5*	*8.0*	*8.5*	*9.0*
All Methods	-	-	-	-	2	45	1	1	-	-
Aution Jet	-	-	-	-	-	-	1	-	-	-
Bayer Clinitek 50	-	-	-	-	-	10	-	-	-	-
Bayer Clinitek 500	-	-	-	-	1	17	-	-	-	-
Bayer Clinitek Atlas	-	-	-	-	-	1	-	-	-	-
Bayer Reagent Strips	-	-	-	-	1	3	-	-	-	-
Roche (BMC) Chemstrips	-	-	-	-	-	4	-	-	-	-
Roche (BMC) Criterion Analyzer	-	-	-	-	-	3	-	-	-	-
Roche (BMC) Mini UA	-	-	-	-	-	2	-	1	-	-
Roche (BMC) Super UA/ChemstripUA	-	-	-	-	-	4	-	-	-	-

URINALYSIS DIPSTICK - PROTEIN QUALITATIVE

Specimen UA-2

	Participant Results					
Method	*Negative*	*Trace*	*30mg/dL (1+)*	*100 mg/dL (2+)*	*300-500mg/dL (3+)*	*≥1000mg/dL (4+)*
All Methods	39	5	4	-	-	-
Aution Jet	1	-	-	-	-	-
Bayer Clinitek 50	10	-	-	-	-	-
Bayer Clinitek 500	18	-	-	-	-	-
Bayer Clinitek Atlas	1	-	-	-	-	-
Bayer Reagent Strips	3	-	-	-	-	-
Roche (BMC) Chemstrips	1	2	1	-	-	-
Roche (BMC) Criterion Analyzer	-	1	2	-	-	-
Roche (BMC) Mini UA	1	2	-	-	-	-
Roche (BMC) Super UA/ChemstripUA	3	-	1	-	-	-

URINALYSIS DIPSTICK - GLUCOSE OR REDUCING SUBSTANCE

Specimen UA-2

	Participant Results							
Method	***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	48	1	-	-	-	-	-	-
Aution Jet	1	-	-	-	-	-	-	-
Bayer Clinitek 50	10	-	-	-	-	-	-	-
Bayer Clinitek 500	17	1	-	-	-	-	-	-
Bayer Clinitek Atlas	1	-	-	-	-	-	-	-
Bayer Clinitest, 5 drop	1	-	-	-	-	-	-	-
Bayer Reagent Strips	4	-	-	-	-	-	-	-
Roche (BMC) Chemstrips	4	-	-	-	-	-	-	-
Roche (BMC) Criterion Analyzer	3	-	-	-	-	-	-	-
Roche (BMC) Mini UA	3	-	-	-	-	-	-	-
Roche (BMC) Super UA/ChemstripUA	4	-	-	-	-	-	-	-

URINALYSIS DIPSTICK - KETONES

Specimen UA-2

	Participant Results				
Method	***Negative***	***Trace (5 mg/dL)***	***Small (1+, 15 mg/dL)***	***Moderate (2+, 40 mg/dL)***	***Large (3+, 80 mg/dL)***
All Methods	-	-	12	14	22
Aution Jet	-	-	-	-	1
Bayer Clinitek 50	-	-	3	7	-
Bayer Clinitek 500	-	-	8	7	3
Bayer Clinitek Atlas	-	-	-	-	1
Bayer Reagent Strips	-	-	1	-	4
Roche (BMC) Chemstrips	-	-	-	-	3
Roche (BMC) Criterion Analyzer	-	-	-	-	3
Roche (BMC) Mini UA	-	-	-	-	3
Roche (BMC) Super UA/ChemstripUA	-	-	-	-	4

URINALYSIS DIPSTICK - BILIRUBIN

Specimen UA-2

	Participant Results			
Method	***Negative***	***Small (1+)***	***Moderate (2+)***	***Large (3+)***
All Methods	-	10	11	26
Aution Jet	-	-	1	-
Bayer Clinitek 50	-	-	-	9
Bayer Clinitek 500	-	8	9	1
Bayer Clinitek Atlas	-	1	-	-
Bayer Reagent Strips	-	-	-	4
Roche (BMC) Chemstrips	-	-	-	4
Roche (BMC) Criterion Analyzer	-	-	-	2
Roche (BMC) Mini UA	-	-	-	3
Roche (BMC) Super UA/ChemstripUA	-	-	1	3

URINALYSIS DIPSTICK - BLOOD/HEMOGLOBIN

Specimen UA-2

	Participant Results				
Method	***Negative***	***Trace***	***Small (1+)***	***Moderate (2+)***	***Large (3+)***
All Methods	-	-	-	1	48
Aution Jet	-	-	-	-	1
Bayer Clinitek 50	-	-	-	1	9
Bayer Clinitek 500	-	-	-	-	18
Bayer Clinitek Atlas	-	-	-	-	1
Bayer Reagent Strips	-	-	-	-	4
Roche (BMC) Chemstrips	-	-	-	-	4
Roche (BMC) Criterion Analyzer	-	-	-	-	3
Roche (BMC) Mini UA	-	-	-	-	3
Roche (BMC) Super UA/ChemstripUA	-	-	-	-	4

URINALYSIS DIPSTICK - LEUKOCYTE ESTERASE

Specimen UA-2

	Participant Results				
Method	***Negative***	***Trace***	***Small (1+)***	***Moderate (2+)***	***Large (3+)***
All Methods	-	-	1	7	41
Aution Jet	-	-	-	-	1
Bayer Clinitek 50	-	-	-	-	10
Bayer Clinitek 500	-	-	-	5	13
Bayer Clinitek Atlas	-	-	-	-	1
Bayer Reagent Strips	-	-	1	-	3
Roche (BMC) Chemstrips	-	-	-	1	3
Roche (BMC) Criterion Analyzer	-	-	-	-	3
Roche (BMC) Mini UA	-	-	-	-	3
Roche (BMC) Super UA/ChemstripUA	-	-	-	1	3

URINALYSIS DIPSTICK - NITRITE

Specimen UA-2

	Participant Results	
Method	***Negative***	***Positive***
All Methods	-	49
Aution Jet	-	1
Bayer Clinitek 50	-	10
Bayer Clinitek 500	-	17
Bayer Clinitek Atlas	-	1
Bayer Reagent Strips	-	4
Roche (BMC) Chemstrips	-	4
Roche (BMC) Criterion Analyzer	-	3
Roche (BMC) Mini UA	-	3
Roche (BMC) Super UA/ChemstripUA	-	4

URINALYSIS DIPSTICK – MICROALBUMIN

Specimen UA-2

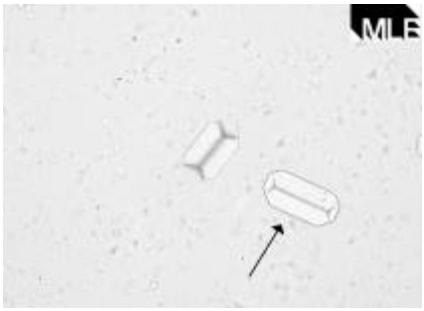
	Participant Results						
Method	***Negative***	***10 mg/L***	***20/30 mg/L***	***50 mg/L (+)***	***80 mg/L***	***100 mg/L (++)***	***150 mg/L***
All Methods	2	1	-	-	-	-	-

KOH SKIN PREPARATION

Specimen	Identification	Labs	Percent	Performance
K-3	No yeast/fungus present	5	83.3%	Acceptable
	Yeast/fungal element present	1	16.7%	
K-4	Yeast/fungal element present	6	100%	Acceptable

URINE SEDIMENT IDENTIFICATION

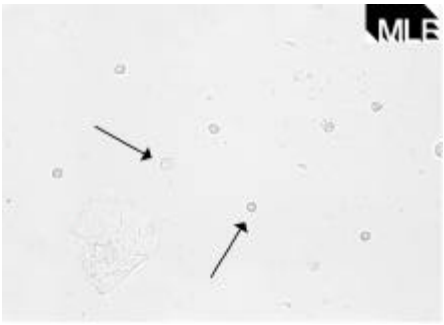
Specimen US-3



Identification	Labs	Percent	Performance
Triple phosphate crystal	49	100%	Acceptable

The arrow in this photograph points to a triple phosphate crystal, the “coffin lid.” These crystals are often found in alkaline urine. This colorless prism has the name “coffin lid” since the crystals resemble the top of an old-fashioned coffin. Triple phosphate crystals have limited clinical significance. Their appearance in fresh urine sediment could indicate a possible byproduct of urea-splitting bacteria secondary to a urinary tract obstruction.

Specimen US-4



Identification	Labs	Percent	Performance
Red blood cell (RBC)	48	98.0%	Acceptable
RBC/blood/hgb cast	1	2.0%	

The arrows in this photograph point to two red blood cells. Normal urine may have 0-3 red blood cells per high power field.[2] Increased blood cells in urine, hematuria, in the absence of menses, may indicate disease in the kidney or lower urinary tract. Red blood cells have a consistent size and the biconcave shape is often obvious. The red cells in this field have the smooth membrane of an intact red blood cell.

THROAT CULTURE

Specimen TC-6

Identification	Labs	Percent	Performance
Neg. Group A Strep	20	100%	Acceptable

Organism present in specimen TC-6: *Neisseria mucosa.*

[2] Haber, Meryl H., Urinary Sediment : A Textbook Atlas, ASCP Press, Chicago, 1981.

THROAT CULTURE

Specimen TC-7

Identification	***Labs***	***Percent***	***Performance***
Pos. Group A Strep	12	60.0%	Not graded
Presump. Pos. Group A Strep	3	15.0%	
Neg. Group A Strep	5	25.0%	

Organisms present in specimen TC-7: *Streptococcus pyogenes* and *Staphylococcus epidermidis.* This is an ungraded challenge due to less than 80% participant consensus.

STREP A ANTIGEN DETECTION

Specimen RS-6

Method	***Labs***	***Positive***	***Negative***
All Methods	10	1	9
Acon Laboratories	1	-	1
BD LINK 2	5	-	5
Veda Lab	1	-	1

GENERAL BACTERIOLOGY

Specimen UC-6 - Urine Culture

Identification	***Labs***	***Percent***	***Performance***
Escherichia coli	2	100%	Acceptable
Gram Stain			
Gram negative	1	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	1	100%	

Organism present in specimen UC-6: *Escherichia coli.*

Specimen TC-6 – Throat Culture

Identification	***Labs***	***Percent***	***Performance***
Contaminated specimen	1	50.0%	Not graded
Streptococcus alpha-hemolytic	1	50.0%	

Organism present in specimen TC-6: *Neisseria mucosa.* This is an ungraded challenge due to less than 80% participant consensus.

GENERAL BACTERIOLOGY

Specimen BA-4 - Stool Culture

Identification	***Labs***	***Percent***	***Performance***
Klebsiella pneumoniae	2	50.0%	Not graded
Enterococcus (Strep) faecalis	1	25.0%	
Klebsiella oxytoca	1	25.0%	

Organisms present in specimen BA-4: *Enterococcus faecalis* and *Klebsiella pneumoniae.* This is an ungraded challenge due to less than 80% participant consensus.

Specimen BA-5 – Wound Culture

Identification	***Labs***	***Percent***	***Performance***
Proteus mirabilis	2	100%	Acceptable

Organisms present in specimen BA-5: *Proteus mirabilis* and *Staphylococcus epidermidis*.

Specimen BA-6 – Blood Culture

Identification	***Labs***	***Percent***	***Performance***
Pseudomonas aeruginosa	2	100%	Acceptable

Organism present in specimen BA-6: *Pseudomonas aeruginosa.*

URINE CULTURE

Specimen UC-6

Identification	***Labs***	***Percent***	***Performance***
Escherichia coli	20	100%	Acceptable
Gram Stain			
Gram negative	18	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	15	79.0%	
Cocco-bacilli	4	21.1%	

Organism present in specimen UC-6: *Escherichia coli.*

Specimen UC-7

Identification	***Labs***	***Percent***	***Performance***
Enterococcus (Strep) faecalis	13	68.4%	Acceptable
Enterococcus sp.	2	10.5%	Acceptable
Strep. Grp. D – enterococcus	1	5.3%	Acceptable
Staphylococcus aureus	2	10.5%	
Staphylococcus saprophyticus	1	5.3%	

Organisms present in specimen UC-7: *Enterococcus faecalis* and *Lactobacillus casei.*

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen UC-6

	------Agar Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Amikacin	5	4	1	-	10	10	-	-	93.8%
Amoxicillin/Clavulanate	2	2	-	-	8	8	-	-	100%
Ampicillin	-	-	-	-	9	8	-	1	90.0%
Ampicillin/Sulbactam	2	2	-	-	6	6	-	-	100%
Aztreonam	2	2	-	-	1	1	-	-	100%
Carbenicillin	1	1	-	-	1	1	-	-	100%
Cefazolin	1	-	1	-	10	9	-	1	81.8%
Cefoperazone	1	1	-	-	-	-	-	-	100%
Cefoperazone/Sulbactam	1	1	-	-	-	-	-	-	100%
Cefotaxime	1	1	-	-	2	2	-	-	100%
Cefoxitin	-	-	-	-	2	2	-	-	100%
Cefpodoxime	-	-	-	-	2	2	-	-	100%
Ceftazidime	-	-	-	-	4	4	-	-	100%
Ceftriaxone	3	3	-	-	7	7	-	-	100%
Cefuroxime	1	1	-	-	6	6	-	-	100%
Cephalexin	1	1	-	-	1	1	-	-	100%
Cephalothin	2	2	-	-	4	2	1	1	Not graded[3]
Ciprofloxacin	3	3	-	-	13	13	-	-	100%
Fosfomycin	-	-	-	-	1	1	-	-	100%
Gentamicin	5	5	-	-	12	12	-	-	100%
Imipenem	-	-	-	-	3	3	-	-	100%
Levofloxacin	-	-	-	-	4	4	-	-	100%
Lomefloxacin	-	-	-	-	2	2	-	-	100%
Meropenem	-	-	-	-	3	3	-	-	100%
Nalidixic Acid	3	3	-	-	5	5	-	-	100%
Nitrofurantoin	3	3	-	-	10	10	-	-	100%
Norfloxacin	4	4	-	-	7	7	-	-	100%
Ofloxacin	1	1	-	-	3	3	-	-	100%
Oxacillin	1	-	-	1	-	-	-	-	100%
Penicillin-G	-	-	-	-	1	1	-	-	100%
Piperacillin	-	-	-	-	6	5	1	-	83.3%
Piperacillin/Tazobactam	-	-	-	-	2	2	-	-	100%
Tetracycline	-	-	-	-	2	2	-	-	100%
Ticarcillin	-	-	-	-	1	1	-	-	100%
Tobramycin	-	-	-	-	7	7	-	-	100%
Trimethoprim	-	-	-	-	1	1	-	-	100%
Trimethoprim/Sulfamethoxazole	4	4	-	-	7	7	-	-	100%

Organism present in specimen UC-6: *Escherichia coli.*

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

GC CULTURE

Specimen GC-6

Identification	***Labs***	***Percent***	***Performance***
Neg. for N. gonorrhoeae	17	94.4%	Acceptable
Presp. N. gonorrhoeae, refer	1	5.6%	

Gram Stain	***Labs***	***Percent***	***Performance***
Gram positive	11	84.6%	Acceptable
Gram negative	2	15.4%	

Gram Stain Morphology	***Labs***	***Percent***
Cocci	8	66.7%
Cocci in pairs	2	16.7%
Diplococci	1	8.3%
Cocci in chains	1	8.3%

Organism present in specimen GC-6: *Enterococcus faecalis.*

GRAM STAIN

Specimen GS-6

Identification	***Labs***	***Percent***	***Performance***
Gram negative	5	83.3%	Acceptable
Gram positive	1	16.7%	

Gram Stain Morphology			
Diplococci	5	83.3%	
Cocci in pairs	1	16.7%	

Organism present in specimen GS-6: *Branhamella catarrhalis.*

Specimen GS-7

Identification	***Labs***	***Percent***	***Performance***
Gram positive	5	83.3%	Acceptable
Gram negative	1	16.7%	

Gram Stain Morphology			
Cocci in chains	6	100%	

Organism present in specimen GS-7: *Streptococcus pneumoniae.*

GRAM STAIN

Specimen GS-8

Identification	***Labs***	***Percent***	***Performance***
Gram positive	6	100%	Acceptable
Gram Stain Morphology			
Cocci	5	83.3%	
Cocci in pairs	1	16.7%	

Organism present in specimen GS-8: *Staphylococcus aureus*.

Specimen GS-9

Identification	***Labs***	***Percent***	***Performance***
Gram positive	6	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	6	100%	

Organism present in specimen GS-9: *Bacillus species.*

Specimen GS-10

Identification	***Labs***	***Percent***	***Performance***
Gram negative	6	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	5	83.3%	
Cocco-bacilli	1	16.7%	

Organism present in specimen GS-10: *Pseudomonas aeruginosa.*

PARASITOLOGY

Specimen PA-6

Identification	***Labs***	***Percent***	***Performance***
No parasite seen	2	66.7%	Not graded
Ascaris lumbricoides eggs	1	33.3%	

Parasite present in specimen PA-6: *Entamoeba coli.* This is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY

Specimen PA-7

Identification	***Labs***	***Percent***	***Performance***
Blastocystis hominis	1	33.3%	Not graded
Entamoeba histolytica	1	33.3%	
No parasite seen	1	33.3%	

Parasite present in specimen PA-7: *Dientamoeba fragilis*.

Specimen PA-8

Identification	***Labs***	***Percent***	***Performance***
Giardia lamblia	22	84.6%	Acceptable
Blastocystis hominis	1	3.9%	
Endolimax nana	1	3.9%	
Enamoeba coli	1	3.9%	
Entamoeba histolytica	1	3.9%	

Parasite present in specimen PA-8: *Giardia lamblia*.

Specimen PA-9

Identification	***Labs***	***Percent***	***Performance***
Hookworm	19	65.5%	Not graded
Trichuris trichiura eggs	4	13.8%	
Enterobius vermicularis eggs	2	6.9%	
Trichostrongylus sp. eggs	2	6.9%	
Ascaris lumbricoides eggs	1	3.5%	
Hymenolepis nana eggs	1	3.5%	

Parasite present in specimen PA-9: Hookworm. This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-10

Identification	***Labs***	***Percent***	***Performance***
Strongyloides stercoralis larvae	21	95.5%	Acceptable
Taenia sp. eggs	1	4.6%	

Parasite present in specimen PA-10: *Strongyloides stercoralis larvae.*

SUMMARY OF ISOLATES FOUND IN THE 2003 MLE-A2 CULTURE SPECIMENS

Organism	ATCC Strain
Enterococcus faecalis	29212
Klebsiella pneumoniae	13883
Proteus mirabilis	12453
Staphylococcus epidermidis	14990
Pseudomonas aeruginosa	27853
Escherichia coli	25922
Lactobacillus casei	393
Streptococcus sp. Group B	12386
Corynebacterium sp.	49528
Proteus vulgaris	13315
Neisseria gonorrhoeae	19424
Gardnerella vaginalis	14018
Neisseria mucosa	19695
Streptococcus pyogenes	19615
Streptococcus pneumoniae	6305
Staphylococcus aureus	25923

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