

MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 0 • 6



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

Microbiology
MLE – M2

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2006 Evaluation Criteria

The evaluation criteria used in the 2006 MLE Program is in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) federal requirements for proficiency testing. The criteria are included below.

Qualitative

For qualitative procedures, evaluation is based on participant or referee consensus. If participant consensus is not reached, CMS requirements call for grading by referee consensus. A minimum percentage of participants or referee laboratories must receive a passing score or the challenge is not evaluated due to lack of consensus. These percentages are listed below.

Bacterial Identification	80% Consensus	Rotavirus Antigen Detection	80% Consensus
Urine Presumptive Identification	80% Consensus	RSV Antigen Detection	80% Consensus
Colony Count	80% Consensus	GC (EIA, DNA)	80% Consensus
Parasite Identification	80% Consensus	Antimicrobial Susceptibility Testing	80% Consensus
Strep A Antigen Detection	80% Consensus	Gram Stain	80% Consensus
Affirm VP III Gardnerella Ag Detection	80% Consensus	Gram Stain Morphology	Not Graded
Affirm VP III Candida Antigen Detection	80% Consensus	Beta-lactamase Testing	Not Graded
Affirm VP III Trichomonas Ag Detection	80% Consensus	C. Difficile Toxin/Antigen Detection	80% Consensus
Chlamydia (EIA, DNA)	80% Consensus	Dermatophyte Screen	80% Consensus
Cryptosporidium Antigen Detection	80% Consensus	Legionella Antigen Detection	80% Consensus
Giardia lamblia Antigen Detection	80% Consensus	Streptococcus pneumoniae Antigen Detection	80% Consensus
Influenza A/B Antigen Detection	80% Consensus		
Influenza A Antigen Detection	80% Consensus		
Influenza B Antigen Detection	80% Consensus		

THROAT CULTURE

Specimen TC-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	109	51.66%	Acceptable
Presump. Pos. Group A Strep	84	39.81%	Acceptable
Streptococcus pyogenes	15	7.11%	Acceptable

Organism present in specimen TC-6: *Streptococcus pyogenes*.

Specimen TC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	109	51.66%	Acceptable
Presump. Pos. Group A Strep	85	40.28%	Acceptable
Streptococcus pyogenes	15	7.11%	Acceptable

Organisms present in specimen TC-7: *Streptococcus pyogenes* and *Lactobacillus casei*.

Specimen TC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	89	94.68%	Acceptable
No growth (sterile)	3	3.19%	Acceptable

Organisms present in specimen TC-8: *Haemophilus influenzae* and *Corynebacterium sp.*

Specimen TC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	42	51.85%	Acceptable
Presump. Pos. Group A Strep	35	43.21%	Acceptable
Streptococcus pyogenes	2	2.47%	Acceptable

Organisms present in specimen TC-9: *Streptococcus pyogenes* and *Corynebacterium sp.*

Specimen TC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	75	92.59%	Acceptable
No growth (sterile)	4	4.94%	Acceptable

Organism present in specimen TC-10: *Neisseria mucosa*.

STREP A ANTIGEN DETECTION

Specimen RS-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>	<u>Strength of Reaction</u>		
				<u>Strong</u>	<u>Moderate</u>	<u>Weak</u>
ALL METHODS	693	681	12	507	116	11
Abbott Signify Strep A-waived	33	33	-	24	7	-
Applied Biotech Signify	9	9	-	3	3	1
Applied Biotech SureStep II - waived	1	1	-	-	-	1
BD Directigen	4	4	-	2	2	-
BD LINK 2	1	1	-	-	1	-
BD QTest	13	13	-	11	1	1
Beckman Coulter ICON DS	17	17	-	12	5	-
Beckman Coulter ICON Fx Strep A	4	4	-	3	1	-
Beckman Coulter ICON SC	9	9	-	7	2	-
Binax NOW Strep A	4	4	-	2	-	-
BioStar Aceava Strep A Test	55	54	1	40	12	1
BioStar Strep A MAX OIA	30	30	-	25	1	-
Cardinal Health Strep A - waived	27	27	-	18	3	-
DE Healthcare TruView	5	5	-	2	1	1
Fisher HealthCare Sure-Vue	5	5	-	1	2	-
Fisher HealthCare Sure-Vue - waived	2	2	-	1	-	-
Genzyme OSOM	6	6	-	6	-	-
Genzyme OSOM Ultra Strep A	71	71	-	52	13	-
Henry Schein One Step	4	4	-	3	1	-
Instant Technologies i Strep	8	8	-	4	3	-
Inverness Signify Strep A Dipstick	24	24	-	16	7	-
LifeSign Status Strep A	1	1	-	1	-	-
Mainline Confirms	1	1	-	1	-	-
Mainline Confirms Strep A Dots	1	1	-	1	-	-
McKesson Strep A Cassette	10	10	-	8	1	1
McKesson Strep A Dipstick	7	7	-	4	1	-
Polymedco Poly Stat Strep A - moderate	20	19	1	15	4	-
Polymedco Poly Stat Strep A - waived	20	20	-	15	4	-
Polymedco Strep A Liquid Test	3	3	-	2	1	-
Quidel QuickVue Dipstick Strep	95	94	1	68	17	-
Quidel QuickVue In-Line	85	76	9	60	9	5
Quidel QuickVue+	83	83	-	72	6	-
Wampole Clearview	2	2	-	2	-	-
Wyntek OSOM Strep A - waived	1	1	-	-	1	-

STREP A ANTIGEN DETECTION

Specimen RS-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>	<u>Strength of Reaction</u>		
				<u>Strong</u>	<u>Moderate</u>	<u>Weak</u>
ALL METHODS	671	660	11	475	126	13
Abbott Signify Strep A-waived	32	32	-	20	8	2
Applied Biotech Signify	8	8	-	5	1	-
Applied Biotech SureStep II - waived	1	1	-	1	-	-
BD Directigen	4	4	-	4	-	-
BD LINK 2	1	1	-	-	1	-
BD QTest	13	13	-	10	2	1
Beckman Coulter ICON DS	17	17	-	10	6	1
Beckman Coulter ICON Fx Strep A	4	4	-	2	2	-
Beckman Coulter ICON SC	9	9	-	6	2	1
Binax NOW Strep A	4	4	-	2	-	-
BioStar Aceveva Strep A Test	55	55	-	36	15	1
BioStar Strep A MAX OIA	29	29	-	24	1	-
Cardinal Health Strep A - waived	27	27	-	20	1	-
DE Healthcare TruView	4	4	-	2	2	-
Fisher HealthCare Sure-Vue	2	2	-	1	1	-
Fisher HealthCare Sure-Vue - waived	2	2	-	1	-	-
Genzyme OSOM	6	6	-	6	-	-
Genzyme OSOM Ultra Strep A	70	70	-	40	22	1
Henry Schein One Step	4	4	-	4	-	-
Instant Technologies i Strep	8	8	-	4	3	-
Inverness Signify Strep A Dipstick	23	23	-	17	6	-
LifeSign Status Strep A	1	1	-	1	-	-
Mainline Confirms Strep A Dots	1	1	-	1	-	-
McKesson Strep A Cassette	9	9	-	7	2	-
McKesson Strep A Dipstick	7	7	-	5	-	-
Polymedco Poly Stat Strep A - moderate	20	20	-	12	8	-
Polymedco Poly Stat Strep A - waived	20	20	-	10	7	2
Polymedco Strep A Liquid Test	3	3	-	2	1	-
Quidel QuickVue Dipstick Strep	93	93	-	72	11	1
Quidel QuickVue In-Line	84	74	10	62	7	2
Quidel QuickVue+	78	78	-	66	7	-
Wampole Clearview	2	2	-	2	-	-
Wyntek OSOM Strep A - waived	1	1	-	-	1	-

STREP A ANTIGEN DETECTION

Specimen RS-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	365	2	363
Abbott Signify Strep A-waived	16	-	16
Applied Biotech Signify	6	-	6
Applied Biotech SureStep II - waived	1	-	1
BD Directigen	4	-	4
BD QTest	12	-	12
Beckman Coulter ICON DS	7	-	7
Beckman Coulter ICON Fx Strep A	3	-	3
Beckman Coulter ICON SC	6	-	6
Binax NOW Strep A	4	-	4
BioStar Acceava Strep A Test	22	-	22
BioStar Strep A MAX OIA	29	-	29
Cardinal Health Strep A - waived	20	-	20
DE Healthcare TruView	2	-	2
Fisher HealthCare Sure-Vue	1	-	1
Fisher HealthCare Sure-Vue - waived	2	-	2
Genzyme OSOM	4	-	4
Genzyme OSOM Ultra Strep A	29	-	29
Henry Schein One Step	1	-	1
Instant Technologies i Strep	4	-	4
Inverness Signify Strep A Dipstick	8	-	8
Mainline Confirms Strep A Dots	1	-	1
McKesson Strep A Cassette	6	-	6
McKesson Strep A Dipstick	4	-	4
Polymedco Poly Stat Strep A - moderate	20	-	20
Polymedco Poly Stat Strep A - waived	6	-	6
Polymedco Strep A Liquid Test	1	-	1
Quidel QuickVue Dipstick Strep	28	1	27
Quidel QuickVue In-Line	26	-	26
Quidel QuickVue+	74	1	73
Wampole Clearview	2	-	2

STREP A ANTIGEN DETECTION

Specimen RS-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	308	-	308
Abbott Signify Strep A-waived	13	-	13
Applied Biotech Signify	6	-	6
Applied Biotech SureStep II - waived	1	-	1
BD Directigen	4	-	4
BD QTest	11	-	11
Beckman Coulter ICON DS	7	-	7
Beckman Coulter ICON Fx Strep A	2	-	2
Beckman Coulter ICON SC	4	-	4
Binax NOW Strep A	3	-	3
BioStar Aceava Strep A Test	20	-	20
BioStar Strep A MAX OIA	29	-	29
Cardinal Health Strep A - waived	19	-	19
DE Healthcare TruView	2	-	2
Fisher HealthCare Sure-Vue - waived	2	-	2
Genzyme OSOM	2	-	2
Genzyme OSOM Ultra Strep A	23	-	23
Henry Schein One Step	1	-	1
Instant Technologies i Strep	3	-	3
Inverness Signify Strep A Dipstick	8	-	8
Mainline Confirms Strep A Dots	1	-	1
McKesson Strep A Cassette	4	-	4
McKesson Strep A Dipstick	3	-	3
Polymedco Poly Stat Strep A - moderate	19	-	19
Polymedco Poly Stat Strep A - waived	4	-	4
Polymedco Strep A Liquid Test	1	-	1
Quidel QuickVue Dipstick Strep	19	-	19
Quidel QuickVue In-Line	24	-	24
Quidel QuickVue+	59	-	59
Wampole Clearview	1	-	1

STREP A ANTIGEN DETECTION

Specimen RS-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>	<u>Strength of Reaction</u>		
				<u>Strong</u>	<u>Moderate</u>	<u>Weak</u>
ALL METHODS	308	305	3	229	52	3
Abbott Signify Strep A-waived	13	13	-	10	2	-
Applied Biotech Signify	6	6	-	2	2	1
Applied Biotech SureStep II - waived	1	1	-	-	1	-
BD Directigen	4	4	-	3	1	-
BD QTest	11	11	-	10	-	1
Beckman Coulter ICON DS	7	7	-	5	2	-
Beckman Coulter ICON Fx Strep A	2	2	-	1	1	-
Beckman Coulter ICON SC	4	4	-	3	1	-
Binax NOW Strep A	3	3	-	2	-	-
BioStar Aceava Strep A Test	20	20	-	16	4	-
BioStar Strep A MAX OIA	29	29	-	25	-	-
Cardinal Health Strep A - waived	19	19	-	11	2	-
DE Healthcare TruView	2	2	-	1	1	-
Fisher HealthCare Sure-Vue - waived	2	2	-	1	-	-
Genzyme OSOM	2	2	-	2	-	-
Genzyme OSOM Ultra Strep A	23	23	-	10	9	1
Henry Schein One Step	1	1	-	1	-	-
Instant Technologies i Strep	3	3	-	2	1	-
Inverness Signify Strep A Dipstick	8	8	-	5	3	-
Mainline Confirms Strep A Dots	1	1	-	-	1	-
McKesson Strep A Cassette	4	4	-	2	2	-
McKesson Strep A Dipstick	3	3	-	1	-	-
Polymedco Poly Stat Strep A - moderate	19	18	1	12	6	-
Polymedco Poly Stat Strep A - waived	4	4	-	4	-	-
Polymedco Strep A Liquid Test	1	1	-	1	-	-
Quidel QuickVue Dipstick Strep	19	19	-	15	2	-
Quidel QuickVue In-Line	24	22	2	19	2	-
Quidel QuickVue+	59	59	-	51	6	-
Wampole Clearview	1	1	-	1	-	-

GENERAL BACTERIOLOGY

Specimen UC-6 – Urine Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pseudomonas aeruginosa	8	88.89%	Acceptable
<u>Gram Stain</u>			
Gram negative	6	100%	
<u>Gram Stain Morphology</u>			
Rods/bacilli	6	100%	

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

GENERAL BACTERIOLOGY

Specimen GC-6 – GC Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus pyogenes	7	77.78%	Acceptable
Staphylococcus epidermidis	1	11.11%	Acceptable
Staphylococcus – coagulase negative	1	11.11%	Acceptable

Organisms present in specimen GC-6: *Staphylococcus aureus* and *Staphylococcus epidermidis*.

Specimen BA-4 – Spinal Fluid Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Listeria monocytogenes	6	75%	Acceptable
Gram positive bacilli	2	25%	Acceptable

Organism present in specimen BA-4: *Listeria monocytogenes*.

Specimen BA-5 – Stool Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Salmonella species	5	71.43%	Acceptable
Escherichia coli	1	14.29%	Acceptable

Organisms present in specimen BA-5: *Escherichia coli* and *Salmonella choleraesuis* (Group C).

Specimen BA-6 – Respiratory Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Enterobacter species	3	25.00%	Acceptable
Gram negative bacilli	2	16.67%	Acceptable
Growth, referred for identification	2	16.67%	Acceptable
Enterobacter agglomerans	2	16.67%	Acceptable
Neisseria sicca	1	8.33%	Acceptable

Organisms present in specimen BA-6: *Enterobacter agglomerans* and *Neisseria sicca*.

URINE CULTURE

Specimen UC-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pseudomonas aeruginosa	45	30.61%	Acceptable
Growth, referred for identification	39	26.53%	Acceptable
Presump. Pseudomonas species	17	11.56%	Acceptable
Presump. Gram negative	15	10.20%	Acceptable
Pseudomonas species	14	9.52%	Acceptable
Gram negative bacilli	12	8.16%	Acceptable

Gram Stain

Gram negative	64	98.46%	Acceptable
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Gram Stain Morphology

Rods/bacilli	62	98.41%	
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Organism present in specimen UC-6: *Pseudomonas aeruginosa*.

Specimen UC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	38	25.17%	Acceptable
Staphylococcus saprophyticus	31	20.53%	Acceptable
Presump. Gram positive	21	13.91%	Acceptable
Gram positive cocci	17	11.26%	Acceptable
Staph – coagulase negative	15	9.93%	Acceptable
Presump. Staphylococcus species	11	7.28%	Acceptable
Staphylococcus species	9	5.96%	Acceptable
Gram positive bacilli	2	1.32%	Acceptable
Corynebacterium species	1	0.66%	Acceptable

Organisms present in specimen UC-7: *Staphylococcus saprophyticus* and *Corynebacterium* species.

URINE CULTURE

Specimen UC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	34	35.79%	Acceptable
Presump. Gram positive	19	20.00%	Acceptable
Enterococcus species	11	11.58%	Acceptable
Gram positive cocci	9	9.47%	Acceptable
Enterococcus (Strep) faecalis	7	7.37%	Acceptable
Strep. Group D – enterococcus	4	4.21%	Acceptable
Streptococcus non-hemolytic	2	2.11%	Acceptable
Presump. Enterococcus species	1	1.05%	Acceptable
Presumptive Streptococcus species	1	1.05%	Acceptable

Organism present in specimen UC-8: *Enterococcus faecalis*.

Specimen UC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	19	33.33%	Acceptable
Growth, referred for identification	12	21.05%	Acceptable
Klebsiella oxytoca	9	15.79%	Acceptable
Klebsiella species	3	5.26%	Acceptable
Gram negative bacilli	3	5.26%	Acceptable

Organisms present in specimen UC-9: *Klebsiella oxytoca* and *Lactobacillus casei*.

Specimen UC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	21	32.31%	Acceptable
Presump. Gram positive	14	21.54%	Acceptable
Streptococcus agalactiae	8	12.31%	Acceptable
Gram positive cocci	5	7.69%	Acceptable
Staphylococcus epidermidis	4	6.15%	Acceptable
Staphylococcus species	3	4.62%	Acceptable
Staph – coagulase negative	3	4.62%	Acceptable
Strep – beta hemo; not Group A	2	3.08%	Acceptable

Organisms present in specimen UC-10: *Streptococcus* Group B and *Staphylococcus epidermidis*.

ANTIMICROBIAL SUSCEPTIBILITY TESTING
Specimen UC-6, CC-6 (SUS-6)

<i>Antimicrobial</i>	-----Agar Diffusion-----				-----MIC-----				<i>Acceptable (%)</i>
	<i>Interpretative category data</i>				<i>Interpretative category data</i>				
	<i>Labs</i>	<i>S</i>	<i>I</i>	<i>R</i>	<i>Labs</i>	<i>S</i>	<i>I</i>	<i>R</i>	
Amikacin	2	2	-	-	7	7	-	-	100%
Amoxicillin/Clavulanate	7	-	-	7	3	-	-	3	Inappropriate drug ¹
Ampicillin	36	-	-	36	7	-	-	7	Inappropriate drug ¹
Ampicillin/Sulbactam	1	-	-	1	1	-	-	1	100%
Aztreonam	-	-	-	-	5	5	-	-	100%
Carbenicillin	27	25	-	2	1	1	-	-	92.68%
Cefaclor	1	-	-	1	-	-	-	-	Inappropriate drug ¹
Cefazolin	7	-	-	7	1	-	-	1	Inappropriate drug ¹
Cefixime	5	1	-	4	-	-	-	-	Inappropriate drug ¹
Cefotaxime	1	1	-	-	4	2	1	1	Not graded ²
Ceftazidime	6	6	-	-	9	9	-	-	100%
Ceftizoxime	1	-	1	-	-	-	-	-	100%
Ceftriaxone	6	5	1	-	7	4	3	-	Not graded ²
Cefuroxime	1	-	-	1	-	-	-	-	Inappropriate drug ¹
Cephalothin	36	-	-	36	8	-	-	8	Inappropriate drug ¹
Cinoxacin	1	-	-	1	1	-	-	1	Inappropriate drug ¹
Ciprofloxacin	61	59	1	1	18	18	-	-	98.13%
Doxycycline	5	-	-	5	2	-	-	2	100%
Fosfomycin	1	1	-	-	-	-	-	-	Inappropriate drug ¹
Gatifloxacin	1	1	-	-	1	1	-	-	100%
Gentamicin	37	36	-	1	15	15	-	-	98.72%
Imipenem	1	1	-	-	6	6	-	-	100%
Kanamycin	1	-	-	1	-	-	-	-	Inappropriate drug ¹
Levofloxacin	13	13	-	-	13	13	-	-	100%
Lomefloxacin	1	1	-	-	2	1	1	-	Not graded ²
Loracarbef	1	-	-	1	-	-	-	-	Inappropriate drug ¹
Meropenem	-	-	-	-	1	1	-	-	100%
Mezlocillin	1	1	-	-	1	1	-	-	100%
Nalidixic Acid	3	-	-	3	-	-	-	-	Inappropriate drug ¹
Nitrofurantoin	47	1	-	46	8	-	-	8	Inappropriate drug ¹
Norfloxacin	18	18	-	-	4	4	-	-	97.06%
Ofloxacin	14	12	2	-	2	1	1	-	Not graded ²
Oxacillin	-	-	-	-	1	-	-	1	Inappropriate drug ¹
Piperacillin	1	1	-	-	7	7	-	-	100%
Piperacillin/Tazobactam	-	-	-	-	3	3	-	-	100%
Sulfamethoxazole	4	-	-	4	2	-	-	2	Inappropriate drug ¹
Sulfisoxazole	5	-	-	5	2	-	-	2	100%
Tetracycline	29	4	4	21	5	1	-	4	Not graded ²
Ticarcillin	-	-	-	-	1	1	-	-	100%
Ticarcillin/Clavulanate	-	-	-	-	2	2	-	-	100%
Tobramycin	5	5	-	-	11	11	-	-	100%
Trimethoprim	5	-	-	5	3	-	-	3	100%
Trimethoprim/Sulfamethoxazole	42	1	-	41	11	1	-	10	97.18%
Vancomycin	1	-	-	1	1	1	-	-	Inappropriate drug ¹

Organism present in specimen UC-6, CC-6 (SUS-6): *Pseudomonas aeruginosa*.

¹ This drug is an inappropriate drug for this organism. Please see the following page for further information.

² This is an ungraded challenge due to less than 80% participant consensus.

GC CULTURE

Specimen GC-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	36	65.45%	Acceptable
No growth (sterile)	12	21.82%	Acceptable
Staphylococcus aureus	6	10.91%	Acceptable
Gram positive cocci	1	1.82%	Acceptable

Gram Stain

Gram positive	25	100%
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Gram Stain Morphology

Cocci	22	88%
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Organisms present in specimen GC-6: *Staphylococcus aureus* and *Staphylococcus epidermidis*.

Specimen GC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	18	66.67%	Acceptable
Neisseria gonorrhoeae	8	29.63%	Acceptable

Beta-lactamase Testing

Negative	4	100%
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Organisms present in specimen GC-7: *Neisseria gonorrhoeae* and *Lactobacillus casei*.

Specimen GC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	16	66.67%	Acceptable
Neisseria gonorrhoeae	7	29.17%	Acceptable
Growth select media, referred	1	4.17%	Acceptable

Beta-lactamase Testing

Negative	4	100%
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Organism present in specimen GC-8: *Neisseria gonorrhoeae*.

GC CULTURE

Specimen GC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	19	79.17%	Acceptable
No growth (sterile)	2	8.33%	Acceptable
Growth select media, referred	2	8.33%	Acceptable
Gram positive cocci	1	4.17%	Acceptable

Organism present in specimen GC-9: *Enterococcus faecalis*.

Specimen GC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	15	62.50%	Acceptable
No growth (sterile)	9	37.50%	Acceptable

Organisms present in specimen GC-10: *Streptococcus* Group B and *Staphylococcus epidermidis*.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-6

<u>Method</u>	<u>Labs</u>	<u>No growth</u>	<u><10,000 organisms/mL</u>	<u>10,000-100,000 organisms/mL</u>	<u>>100,000 organisms/mL</u>
ALL METHODS	119	9	2	9	99
Bacti-Star	1	-	-	-	1
Bacturcult	1	-	-	-	1
Bulls Eye	7	-	-	-	7
Calibrated Loop	30	1	1	3	25
HealthLink	1	-	-	-	1
Uri-Check	16	2	-	2	12
Uricult	54	5	1	4	44

Identification—Specimen CC-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Pseudomonas sp.	22	48.89%	Acceptable
Presump. Gram negative	13	28.89%	Acceptable
Growth, referred for identification	5	11.11%	Acceptable
Pseudomonas aeruginosa	3	6.67%	Acceptable

Gram Stain

Gram negative	6	100%	Acceptable
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Gram Stain Morphology

Rods/bacilli	7	100%
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Organism present in specimen CC-6: >100,000 CFU/mL of *Pseudomonas aeruginosa*.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-7

<u>Method</u>	<u>Labs</u>	<u>No growth</u>	<u><10,000 organisms/mL</u>	<u>10,000-100,000 organisms/mL</u>	<u>>100,000 organisms/mL</u>
ALL METHODS	117	4	4	21	88
Bacti-Star	1	-	-	-	1
Bacturcult	1	-	-	-	1
Bulls Eye	6	-	-	1	5
Calibrated Loop	29	-	-	4	25
HealthLink	1	-	-	-	1
Uri-Check	16	1	2	2	11
Uricult	54	1	2	11	40

Identification–Specimen CC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	18	38.30%	Acceptable
Presump. Staphylococcus sp.	10	21.28%	Acceptable
Growth, referred for identification	5	10.64%	Acceptable
Staph – coagulase negative	2	4.26%	Acceptable
Staphylococcus saprophyticus	1	2.13%	Acceptable
Staphylococcus sp.	1	2.13%	Acceptable
Presump. Enterococcus sp.	6	12.77%	

Organisms present in specimen CC-7: >100,000 CFU/mL *Staphylococcus saprophyticus* and approximately 46,500 CFU/mL of *Corynebacterium* species.

Identification–Specimen CC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Enterococcus sp.	14	41.18%	Acceptable
Presump. Gram positive	12	35.29%	Acceptable
Growth, referred for identification	3	8.82%	Acceptable
Enterococcus (Strep) faecalis	2	5.88%	Acceptable
Presumptive Streptococcus sp.	1	2.94%	Acceptable

Organism present in specimen CC-8: >100,000 CFU/mL of *Enterococcus faecalis*.

Identification–Specimen CC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	9	26.47%	Not graded
Presump. Klebsiella sp.	4	11.76%	
Growth, referred for identification	3	8.82%	
Klebsiella sp.	1	2.94%	
Klebsiella oxytoca	1	2.94%	
Presump. Escherichia coli	11	32.35%	

Organisms present in specimen CC-9: approximately 13,000 CFU/mL *Klebsiella oxytoca* and approximately 11,000 CFU/mL *Lactobacillus casei*. This specimen is ungraded due to the lack of 80% referee consensus.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	17	42.50%	Acceptable
Presump. Staphylococcus sp.	5	12.50%	Acceptable
Presumptive Streptococcus sp.	4	10.00%	Acceptable
Growth, referred for identification	3	7.50%	Acceptable
Streptococcus agalactiae	2	5.00%	Acceptable
Staph – coagulase negative	1	2.50%	Acceptable
Bacturcult Group I	1	2.50%	Acceptable

Organisms present in specimen CC-10: >100,000 CFU/mL of *Streptococcus* Group B and approximately 29,000 CFU/mL of *Staphylococcus epidermidis*.

DERMATOPHYTE SCREEN

Specimen DM-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte absent	20	100%	Acceptable

Organism present in specimen DM-6: *Candida glabrata*.

Specimen DM-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte present	19	100%	Acceptable

Organism present in specimen DM-7: *Microsporum canis*.

GRAM STAIN

Specimen GS-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	48	94.12%	Acceptable
Gram negative	3	5.88%	

Gram Stain Morphology

Cocci	35	77.78%
Cocci in pairs	6	13.33%
Diplococci	2	4.44%
Cocci in chains	2	4.44%

Organism present in specimen GS-6: *Staphylococcus epidermidis*.

Specimen GS-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	48	94.12%	Acceptable
Gram positive	3	5.88%	

Gram Stain Morphology

Diplococci	29	64.44%
Cocci	6	13.33%
Cocco-bacilli	6	13.33%
Cocci in pairs	2	4.44%
Cocci in chains	1	2.22%
Rods/bacilli	1	2.22%

Organism present in specimen GS-7: *Neisseria gonorrhoeae*.

GRAM STAIN

Specimen GS-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	51	100%	Acceptable

Gram Stain Morphology

Rods/bacilli	42	91.30%
Cocci in chains	3	6.52%
Cocco-bacilli	1	2.17%

Organism present in specimen GS-8: *Escherichia coli*.

Specimen GS-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	49	96.08%	Acceptable
Gram positive	2	3.92%	

Gram Stain Morphology

Rods/bacilli	45	100%
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Organism present in specimen GS-9: *Proteus vulgaris*.

Specimen GS-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	48	96.00%	Acceptable
Gram negative	2	4.00%	

Gram Stain Morphology

Cocci	28	62.22%
Cocci in pairs	9	20.00%
Cocci in chains	6	13.33%
Diplococci	2	4.44%

Organism present in specimen GS-10: *Staphylococcus aureus*.

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	25	100%	Acceptable

Organism present in specimen VP-6: *Trichomonas vaginalis*.

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	25	100%	Acceptable

Organism present in specimen VP-7: *Candida albicans*.

Specimen VP-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	25	100%	Acceptable

Organism present in specimen VP-8: *Gardnerella vaginalis*.

Specimen VP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	24	96%	Acceptable
Negative	1	4%	

Organisms present in specimen VP-9: *Candida albicans* and *Trichomonas vaginalis*.

Specimen VP-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	25	100%	Acceptable

Organism present in specimen VP-10: *Gardnerella vaginalis*.

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	24	96%	Acceptable
Positive	1	4%	

Specimen VP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	24	96%	Acceptable
Positive	1	4%	

Specimen VP-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	19	76%	Acceptable
Negative	6	24%	

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	25	100%	Acceptable

Specimen VP-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	20	80%	Acceptable
Negative	5	20%	

AFFIRM VP III–Candida sp.

Specimen VP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	25	100%	Acceptable

Specimen VP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	24	96%	Acceptable
Negative	1	4%	

Specimen VP-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	24	96%	Acceptable
Positive	1	4%	

Specimen VP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	25	100%	Acceptable

Specimen VP-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	25	100%	Acceptable

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	20	-	20
BD ProbeTec	2	-	2
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	2	-	2
Gen-Probe	3	-	3
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	10	-	10

Organism present in specimen CY-6: *Neisseria gonorrhoeae*.

Specimen CY-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	20	20	-
BD ProbeTec	2	2	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	2	2	-
Gen-Probe	3	3	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	10	10	-

Organism present in specimen CY-7: *Chlamydia trachomatis*.

Specimen CY-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	1	13
BD ProbeTec	2	-	2
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	2	-	2
Gen-Probe	3	-	3
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	4	1	3

Organism present in specimen CY-8: *Neisseria gonorrhoeae*.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	14	-
BD ProbeTec	2	2	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	2	2	-
Gen-Probe	3	3	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	4	4	-

Organisms present in specimen CY-9: *Neisseria gonorrhoeae* and *Chlamydia trachomatis*.

Specimen CY-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	14	-
BD ProbeTec	2	2	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	2	2	-
Gen-Probe	3	3	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	4	4	-

Organism present in specimen CY-10: *Chlamydia trachomatis*.

GC (ANTIGEN DETECTION)

Specimen CY-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	9	-
BD ProbeTec	2	2	-
BioStar OIA	3	3	-
Gen-Probe	3	3	-
Gen-Probe APTIMA	1	1	-

Specimen CY-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	-	9
BD ProbeTec	2	-	2
BioStar OIA	3	-	3
Gen-Probe	3	-	3
Gen-Probe APTIMA	1	-	1

GC (ANTIGEN DETECTION)

Specimen CY-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	8	1
BD ProbeTec	2	2	-
BioStar OIA	3	3	-
Gen-Probe	3	2	1
Gen-Probe APTIMA	1	1	-

Specimen CY-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	9	-
BD ProbeTec	2	2	-
BioStar OIA	3	3	-
Gen-Probe	3	3	-
Gen-Probe APTIMA	1	1	-

Specimen CY-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	-	9
BD ProbeTec	2	-	2
BioStar OIA	3	-	3
Gen-Probe	3	-	3
Gen-Probe APTIMA	1	-	1

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	4	1
Meridian ImmunoCard STAT	1	1	-
Remel Xpect	4	3	1

Antigen present in specimen LC-6: *Cryptosporidium*.

Specimen LC-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Meridian ImmunoCard STAT	1	-	1
Remel Xpect	4	-	4

Antigen present in specimen LC-7: No antigens present.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Meridian ImmunoCard STAT	1	-	1
Remel Xpect	4	-	4

Antigen present in specimen LC-8: *Giardia lamblia*.

Specimen LC-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Meridian ImmunoCard STAT	1	1	-
Remel Xpect	4	4	-

Antigen present in specimen LC-9: *Cryptosporidium*.

Specimen LC-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Meridian ImmunoCard STAT	1	-	1
Remel Xpect	4	-	4

Antigens present in specimen LC-10: *Giardia lamblia*.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	7
Meridian ImmunoCard STAT	1	-	1
Meridian Merifluor	1	-	1
Remel Xpect	4	-	4

Specimen LC-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	7
Meridian ImmunoCard STAT	1	-	1
Meridian Merifluor	1	-	1
Remel Xpect	4	-	4

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	7	-
Meridian ImmunoCard STAT	1	1	-
Meridian Merifluor	1	1	-
Remel Xpect	4	4	-

Specimen LC-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	7
Meridian ImmunoCard STAT	1	-	1
Meridian Merifluor	1	-	1
Remel Xpect	4	-	4

Specimen LC-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	7	-
Meridian ImmunoCard STAT	1	1	-
Meridian Merifluor	1	1	-
Remel Xpect	4	4	-

RSV ANTIGEN DETECTION

Specimen V-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	34	1	33
BD Directigen	2	-	2
BD Directigen EZ	1	-	1
Binax NOW - waived	13	-	13
BioStar OIA	6	-	6
Fisher HealthCare Sure-Vue - waived	1	-	1
Remel Xpect - waived	2	-	2
Wampole Clearview RSV - waived	6	-	6

Specimen V-6: Negative for RSV antigen.

RSV ANTIGEN DETECTION

Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	34	29	5
BD Directigen	2	2	-
BD Directigen EZ	1	1	-
Binax NOW - waived	13	12	1
BioStar OIA	6	6	-
Fisher HealthCare Sure-Vue - waived	1	1	-
Remel Xpect - waived	2	2	-
Wampole Clearview RSV - waived	6	3	3

Specimen V-7: Positive for RSV antigen.

Specimen V-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	24	1
BD Directigen	2	2	-
BD Directigen EZ	1	1	-
Binax NOW - waived	10	9	1
BioStar OIA	6	6	-
Remel Xpect - waived	2	2	-
Wampole Clearview RSV - waived	2	2	-

Specimen V-8: Positive for RSV antigen.

Specimen V-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	-	25
BD Directigen	2	-	2
BD Directigen EZ	1	-	1
Binax NOW - waived	10	-	10
BioStar OIA	6	-	6
Remel Xpect - waived	2	-	2
Wampole Clearview RSV - waived	2	-	2

Specimen V-9: Negative for RSV antigen.

RSV ANTIGEN DETECTION

Specimen V-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	-	25
BD Directigen	2	-	2
BD Directigen EZ	1	-	1
Binax NOW - waived	10	-	10
BioStar OIA	6	-	6
Remel Xpect - waived	2	-	2
Wampole Clearview RSV - waived	2	-	2

Specimen V-10: Negative for RSV antigen.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	90	90	-
BioStar OIA	7	7	-
Quidel QuickVue Influenza	72	72	-

Specimen V-6: Positive for Influenza A/B antigen.

Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	91	2	89
BioStar OIA	7	1	6
Quidel QuickVue Influenza	73	1	72

Specimen V-7: Negative for Influenza A/B antigen.

Specimen V-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	29	-	29
BioStar OIA	6	-	6
Quidel QuickVue Influenza	20	-	20

Specimen V-8: Negative for Influenza A/B antigen.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	29	29	-
BioStar OIA	6	6	-
Quidel QuickVue Influenza	20	20	-

Specimen V-9: Positive for Influenza A/B antigen.

Specimen V-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	29	-	29
BioStar OIA	6	-	6
Quidel QuickVue Influenza	20	-	20

Specimen V-10: Negative for Influenza A/B antigen.

INFLUENZA A ANTIGEN DETECTION

Specimen V-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	85	80	5
BD Directigen	3	2	1
Binax NOW - waived	11	11	-
BioStar Flu OIA A/B	7	7	-
Quidel QuickVue Influenza A+B	48	47	1
Remel Xpect	6	6	-
Wampole Clearview	2	2	-

Specimen V-6: Positive for Influenza A antigen.

Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	81	4	77
BD Directigen	3	1	2
Binax NOW - waived	11	-	11
BioStar Flu OIA A/B	7	-	7
Quidel QuickVue Influenza A+B	46	2	44
Remel Xpect	6	1	5
Wampole Clearview	2	-	2

Specimen V-7: Negative for Influenza A antigen.

INFLUENZA A ANTIGEN DETECTION

Specimen V-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	39	1	38
BD Directigen	2	-	2
Binax NOW - waived	6	-	6
BioStar Flu OIA A/B	7	-	7
Quidel QuickVue Influenza A+B	12	-	12
Remel Xpect	6	1	5
Wampole Clearview	2	-	2

Specimen V-8: Negative for Influenza A antigen.

Specimen V-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	39	38	1
BD Directigen	2	2	-
Binax NOW - waived	6	6	-
BioStar Flu OIA A/B	7	7	-
Quidel QuickVue Influenza A+B	12	12	-
Remel Xpect	6	6	-
Wampole Clearview	2	2	-

Specimen V-9: Positive for Influenza A antigen.

Specimen V-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	39	3	36
BD Directigen	2	-	2
Binax NOW - waived	6	-	6
BioStar Flu OIA A/B	7	-	7
Quidel QuickVue Influenza A+B	12	-	12
Remel Xpect	6	3	3
Wampole Clearview	2	-	2

Specimen V-10: Negative for Influenza A antigen.

INFLUENZA B ANTIGEN DETECTION

Specimen V-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	80	2	78
BD Directigen	2	-	2
Binax NOW - waived	11	-	11
BioStar Flu OIA A/B	7	-	7
Quidel QuickVue Influenza A+B	45	-	45
Remel Xpect	5	1	4
Wampole Clearview	2	-	2

Specimen V-6: Negative for Influenza B antigen.

Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	81	-	81
BD Directigen	2	-	2
Binax NOW - waived	11	-	11
BioStar Flu OIA A/B	7	-	7
Quidel QuickVue Influenza A+B	47	-	47
Remel Xpect	5	-	5
Wampole Clearview	2	-	2

Specimen V-7: Negative for Influenza B antigen.

Specimen V-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	39	2	37
BD Directigen	1	-	1
Binax NOW - waived	6	-	6
BioStar Flu OIA A/B	7	-	7
Quidel QuickVue Influenza A+B	12	-	12
Remel Xpect	5	1	4
Wampole Clearview	2	-	2

Specimen V-8: Negative for Influenza B antigen.

INFLUENZA B ANTIGEN DETECTION

Specimen V-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	39	1	38
BD Directigen	1	-	1
Binax NOW - waived	6	-	6
BioStar Flu OIA A/B	7	-	7
Quidel QuickVue Influenza A+B	12	-	12
Remel Xpect	5	1	4
Wampole Clearview	2	-	2

Specimen V-9: Negative for Influenza B antigen.

Specimen V-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	39	-	39
BD Directigen	1	-	1
Binax NOW - waived	6	-	6
BioStar Flu OIA A/B	7	-	7
Quidel QuickVue Influenza A+B	12	-	12
Remel Xpect	5	-	5
Wampole Clearview	2	-	2

Specimen V-10: Negative for Influenza B antigen.

LEGIONELLA ANTIGEN DETECTION

Specimen L-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	85	85	-

Specimen L-6: Positive for Legionella antigen.

Specimen L-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	85	-	85

Specimen L-7: Negative for Legionella antigen.

Specimen L-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	85	-	85

Specimen L-8: Negative for Legionella antigen.

LEGIONELLA ANTIGEN DETECTION

Specimen L-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	85	85	-

Specimen L-9: Positive for Legionella antigen.

Specimen L-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	85	84	1

Specimen L-10: Positive for Legionella antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	16	-
bioMerieux Vitek, Mini Vidas	1	1	-
Biosite Triage	5	5	-
BioStar OIA	6	6	-
Meridian ImmunoCard	1	1	-

Antigen present in specimen AG-6: *Clostridium difficile*.

Specimen AG-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	16	-
bioMerieux Vitek, Mini Vidas	1	1	-
Biosite Triage	5	5	-
BioStar OIA	6	6	-
Meridian ImmunoCard	1	1	-

Antigen present in specimen AG-7: *Clostridium difficile*.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	-	16
bioMerieux Vitek, Mini Vidas	1	-	1
Biosite Triage	5	-	5
BioStar OIA	6	-	6
Meridian ImmunoCard	1	-	1

Antigen present in specimen AG-8: Rotavirus.

Specimen AG-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	-	16
bioMerieux Vitek, Mini Vidas	1	-	1
Biosite Triage	5	-	5
BioStar OIA	6	-	6
Meridian ImmunoCard	1	-	1

Antigen present in specimen AG-9: No antigens present.

Specimen AG-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	-	16
bioMerieux Vitek, Mini Vidas	1	-	1
Biosite Triage	5	-	5
BioStar OIA	6	-	6
Meridian ImmunoCard	1	-	1

Antigen present in specimen AG-10: Rotavirus.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	8
Fisher HealthCare Sure-Vue	2	-	2
Meridian ImmunoCard	3	-	3
SA Scientific Rota Test	1	-	1

Specimen AG-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	1	7
Fisher HealthCare Sure-Vue	2	-	2
Meridian ImmunoCard	3	-	3
SA Scientific Rota Test	1	1	-

Specimen AG-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	6	2
Fisher HealthCare Sure-Vue	2	2	-
Meridian ImmunoCard	3	3	-
SA Scientific Rota Test	1	-	1

Specimen AG-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	8
Fisher HealthCare Sure-Vue	2	-	2
Meridian ImmunoCard	3	-	3
SA Scientific Rota Test	1	-	1

Specimen AG-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	7	1
Fisher HealthCare Sure-Vue	2	2	-
Meridian ImmunoCard	3	3	-
SA Scientific Rota Test	1	1	-

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	73	73	-

Specimen SP-6: Positive for *Streptococcus pneumoniae* antigen.

Specimen SP-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	73	-	73

Specimen SP-7: Negative for *Streptococcus pneumoniae* antigen.

Specimen SP-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	74	-	74

Specimen SP-8: Negative for *Streptococcus pneumoniae* antigen.

Specimen SP-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	74	-	74

Specimen SP-9: Negative for *Streptococcus pneumoniae* antigen.

Specimen SP-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	74	73	1

Specimen SP-10: Positive for *Streptococcus pneumoniae* antigen.

PARASITOLOGY

Specimen PA-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	2	100%	Acceptable

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

PARASITOLOGY

Specimen PA-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dientamoeba fragilis	2	66.67%	Not graded
Endolimax nana	1	33.33%	

Parasite present in specimen PA-7: *Dientamoeba fragilis*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis	3	100%	Acceptable

Parasite present in specimen PA-8: *Strongyloides stercoralis*.

Specimen PA-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	3	75.00%	Not graded
Blastocystis hominis	1	25.00%	

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

Specimen PA-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	3	100%	Acceptable

Parasite present in specimen PA-10: *Ascaris lumbricoides* eggs.

SUMMARY OF ISOLATES FOUND IN THE 2006 MLE-M2 CULTURE SPECIMENS

Organism	ATCC Strain
<i>Listeria monocytogenes</i>	7644
<i>Escherichia coli</i>	25922
<i>Salmonella choleraesuis sub. Choleraesuis sero type enteritidis</i>	25285
<i>Enterobacter agglomerans</i>	49014
<i>Neisseria sicca</i>	29256
<i>Pseudomonas aeruginosa</i>	27853
<i>Staphylococcus saprophyticus</i>	35552
<i>Corynebacterium species</i>	49528
<i>Enterococcus faecalis</i>	29212
<i>Klebsiella oxytoca</i>	8724
<i>Lactobacillus casei</i>	393
<i>Streptococcus species Group B</i>	12386
<i>Staphylococcus epidermidis</i>	14990
<i>Staphylococcus aureus</i>	25923
<i>Neisseria gonorrhoeae</i>	19424
<i>Streptococcus pyogenes</i>	19615
<i>Haemophilus influenzae</i>	10211
<i>Neisseria mucosa</i>	19695

Medical Laboratory Evaluation
2011 Pennsylvania Avenue, NW, Suite 800
Washington, DC 20006-1813
800-338-2746 • 202-261-4500 • Fax: 202-835-0440