

MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 0 • 6



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

Microbiology
MLE – M3

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2006 Evaluation Criteria 2

Microbiology

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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-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	184	88.46%	Acceptable
No growth (sterile)	10	4.81%	Acceptable
Branhamella catarrhalis	6	2.88%	Acceptable
Growth, referred for identification	3	1.44%	Acceptable

Organisms present in specimen TC-11: *Branhamella catarrhalis* and *Lactobacillus casei*.

Specimen TC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	108	51.67%	Acceptable
Presump. Pos. Group A Strep	88	42.11%	Acceptable
Streptococcus pyogenes	13	6.22%	Acceptable

Organism present in specimen TC-12: *Streptococcus pyogenes*.

Specimen TC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	92	97.87%	Acceptable
No growth (sterile)	1	1.06%	Acceptable

Organisms present in specimen TC-13: *Staphylococcus aureus* and *Corynebacterium sp.*

Specimen TC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	43	51.19%	Acceptable
Presump. Pos. Group A Strep	39	46.43%	Acceptable
Streptococcus pyogenes	1	1.19%	Acceptable

Organism present in specimen TC-14: *Streptococcus pyogenes*.

Specimen TC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	43	51.19%	Acceptable
Presump. Pos. Group A Strep	39	46.43%	Acceptable
Streptococcus pyogenes	1	1.19%	Acceptable

Organisms present in specimen TC-15: *Streptococcus pyogenes* and *Corynebacterium sp.*

STREP A ANTIGEN DETECTION

Specimen RS-11

<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	690	681	9	525	99	7
Abbott Signify Strep A-waived	31	31	-	25	5	-
Applied Biotech Signify	6	6	-	1	3	1
Applied Biotech SureStep II - waived	1	1	-	-	-	1
BD Directigen	4	4	-	2	2	-
BD Directigen 1-2-3	2	2	-	2	-	-
BD QTest	8	8	-	8	-	-
Beckman Coulter ICON DS	14	14	-	9	4	-
Beckman Coulter ICON SC	11	11	-	9	2	-
Binax NOW Strep A	3	3	-	2	-	-
BioStar Aceava Strep A Test	55	55	-	39	14	-
BioStar OIA	1	1	-	1	-	-
BioStar Strep A MAX OIA	27	27	-	22	3	-
Cardinal Health Strep A - waived	18	18	-	16	-	-
DE Healthcare TruView	1	1	-	-	1	-
Fisher HealthCare Sure-Vue	4	4	-	1	2	-
Fisher HealthCare Sure-Vue - waived	1	1	-	1	-	-
Genzyme OSOM	24	24	-	17	2	-
Genzyme OSOM Ultra Strep A	61	60	1	46	9	-
Henry Schein One Step	7	7	-	4	2	-
Instant Technologies i Strep	8	8	-	4	3	-
Inverness Signify Strep A Dipstick	23	23	-	19	2	-
LifeSign Status Strep A	1	1	-	1	-	-
Mainline Confirms	3	3	-	2	1	-
Mainline Confirms Strep A Dots	1	1	-	1	-	-
McKesson Strep A Cassette	10	10	-	10	-	-
McKesson Strep A Dipstick	9	9	-	4	-	-
Polymedco Poly Stat Strep A - moderate	25	25	-	17	8	-
Polymedco Poly Stat Strep A - waived	17	16	1	12	3	-
Quidel QuickVue Dipstick Strep	95	94	1	76	9	-
Quidel QuickVue In-Line	82	77	5	62	10	4
Quidel QuickVue+	80	79	1	70	5	-
Stanbio QuStick Strep A	1	1	-	1	-	-
Wampole Clearview	2	2	-	1	1	-

STREP A ANTIGEN DETECTION

Specimen RS-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	666	10	656
Abbott Signify Strep A-waived	30	-	30
Applied Biotech Signify	5	-	5
Applied Biotech SureStep II - waived	1	-	1
BD Directigen	4	-	4
BD Directigen 1-2-3	2	-	2
BD QTest	8	-	8
Beckman Coulter ICON DS	14	-	14
Beckman Coulter ICON SC	11	-	11
Binax NOW Strep A	3	-	3
BioStar Aceava Strep A Test	55	1	54
BioStar OIA	1	-	1
BioStar Strep A MAX OIA	26	-	26
Cardinal Health Strep A - waived	18	-	18
DE Healthcare TruView	1	-	1
Fisher HealthCare Sure-Vue	1	-	1
Fisher HealthCare Sure-Vue - waived	1	-	1
Genzyme OSOM	24	-	24
Genzyme OSOM Ultra Strep A	60	1	59
Henry Schein One Step	6	-	6
Instant Technologies i Strep	8	-	8
Inverness Signify Strep A Dipstick	22	-	22
LifeSign Status Strep A	1	-	1
Mainline Confirms	1	-	1
Mainline Confirms Strep A Dots	1	-	1
McKesson Strep A Cassette	9	-	9
McKesson Strep A Dipstick	9	-	9
Polymedco Poly Stat Strep A - moderate	25	1	24
Polymedco Poly Stat Strep A - waived	17	1	16
Quidel QuickVue Dipstick Strep	94	1	93
Quidel QuickVue In-Line	81	2	79
Quidel QuickVue+	75	2	73
Stanbio QuStick Strep A	1	1	-
Wampole Clearview	2	-	2

STREP A ANTIGEN DETECTION

Specimen RS-13

<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	361	357	4	267	59	5
Abbott Signify Strep A-waived	16	16	-	12	4	-
Applied Biotech Signify	5	4	1	2	1	-
Applied Biotech SureStep II - waived	1	1	-	1	-	-
BD Directigen	4	4	-	2	2	-
BD Directigen 1-2-3	2	2	-	-	-	2
BD QTest	8	8	-	8	-	-
Beckman Coulter ICON DS	6	6	-	2	4	-
Beckman Coulter ICON SC	8	8	-	6	2	-
Binax NOW Strep A	2	2	-	1	-	-
BioStar Aceava Strep A Test	23	23	-	18	3	1
BioStar OIA	1	1	-	1	-	-
BioStar Strep A MAX OIA	26	26	-	22	2	-
Cardinal Health Strep A - waived	7	7	-	4	1	-
DE Healthcare TruView	1	1	-	-	1	-
Fisher HealthCare Sure-Vue - waived	1	1	-	1	-	-
Genzyme OSOM	13	13	-	8	3	-
Genzyme OSOM Ultra Strep A	21	21	-	14	6	-
Henry Schein One Step	1	1	-	1	-	-
Instant Technologies i Strep	5	5	-	3	2	-
Inverness Signify Strep A Dipstick	8	8	-	7	1	-
Mainline Confirms	1	1	-	-	1	-
Mainline Confirms Strep A Dots	1	1	-	1	-	-
McKesson Strep A Cassette	7	7	-	4	3	-
McKesson Strep A Dipstick	5	5	-	2	-	-
Polymedco Poly Stat Strep A - moderate	22	22	-	16	6	-
Polymedco Poly Stat Strep A - waived	6	6	-	5	-	-
Quidel QuickVue Dipstick Strep	24	24	-	17	3	-
Quidel QuickVue In-Line	27	25	2	18	4	1
Quidel QuickVue+	71	70	1	61	6	-
Stanbio QuStick Strep A	1	1	-	1	-	-
Wampole Clearview	2	2	-	1	1	-

STREP A ANTIGEN DETECTION

Specimen RS-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	307	1	306
Abbott Signify Strep A-waived	14	-	14
Applied Biotech Signify	5	-	5
Applied Biotech SureStep II - waived	1	-	1
BD Directigen	4	-	4
BD Directigen 1-2-3	2	-	2
BD QTest	8	-	8
Beckman Coulter ICON DS	6	-	6
Beckman Coulter ICON SC	6	-	6
Binax NOW Strep A	2	-	2
BioStar Aceava Strep A Test	20	-	20
BioStar OIA	1	-	1
BioStar Strep A MAX OIA	26	-	26
Cardinal Health Strep A - waived	6	-	6
DE Healthcare TruView	1	-	1
Fisher HealthCare Sure-Vue - waived	1	-	1
Genzyme OSOM	10	-	10
Genzyme OSOM Ultra Strep A	16	-	16
Henry Schein One Step	1	-	1
Instant Technologies i Strep	3	-	3
Inverness Signify Strep A Dipstick	8	-	8
Mainline Confirms	1	-	1
Mainline Confirms Strep A Dots	1	-	1
McKesson Strep A Cassette	5	-	5
McKesson Strep A Dipstick	4	-	4
Polymedco Poly Stat Strep A - moderate	21	-	21
Polymedco Poly Stat Strep A - waived	4	-	4
Quidel QuickVue Dipstick Strep	16	-	16
Quidel QuickVue In-Line	25	-	25
Quidel QuickVue+	57	-	57
Stanbio QuStick Strep A	1	1	-
Wampole Clearview	2	-	2

STREP A ANTIGEN DETECTION

Specimen RS-15

<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	309	307	2	222	51	12
Abbott Signify Strep A-waived	14	14	-	10	3	1
Applied Biotech Signify	5	5	-	2	2	-
Applied Biotech SureStep II - waived	1	1	-	-	1	-
BD Directigen	4	4	-	2	2	-
BD Directigen 1-2-3	2	2	-	-	2	-
BD QTest	8	8	-	8	-	-
Beckman Coulter ICON DS	6	6	-	2	3	1
Beckman Coulter ICON SC	6	6	-	4	2	-
Binax NOW Strep A	2	2	-	2	-	-
BioStar Aceava Strep A Test	20	20	-	15	4	-
BioStar OIA	1	1	-	1	-	-
BioStar Strep A MAX OIA	26	26	-	22	2	-
Cardinal Health Strep A - waived	6	6	-	4	-	-
DE Healthcare TruView	1	1	-	-	1	-
Fisher HealthCare Sure-Vue - waived	1	1	-	1	-	-
Genzyme OSOM	10	10	-	8	1	-
Genzyme OSOM Ultra Strep A	16	16	-	11	4	-
Henry Schein One Step	1	1	-	1	-	-
Instant Technologies i Strep	3	3	-	2	1	-
Inverness Signify Strep A Dipstick	8	8	-	6	1	1
Mainline Confirms	1	1	-	1	-	-
Mainline Confirms Strep A Dots	1	1	-	-	1	-
McKesson Strep A Cassette	5	5	-	4	1	-
McKesson Strep A Dipstick	4	4	-	1	-	-
Polymedco Poly Stat Strep A - moderate	21	21	-	15	4	2
Polymedco Poly Stat Strep A - waived	4	4	-	4	-	-
Quidel QuickVue Dipstick Strep	16	16	-	12	2	-
Quidel QuickVue In-Line	25	23	2	16	1	4
Quidel QuickVue+	58	58	-	42	10	2
Stanbio QuStick Strep A	1	1	-	1	-	-
Wampole Clearview	2	2	-	1	1	-

GENERAL BACTERIOLOGY

Specimen UC-11 – Urine Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus aureus	9	90.00%	Acceptable
Gram positive cocci	1	10.00%	Acceptable
<u>Gram Stain</u>			
Gram positive	8	100%	Acceptable
<u>Gram Stain Morphology</u>			
Cocci	7	87.50%	
Cocci in pairs	1	12.50%	

Organism present in specimen UC-6: *Staphylococcus aureus*.

GENERAL BACTERIOLOGY

Specimen TC-11 – Throat Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Branhamella catarrhalis	5	50%	Acceptable
Negative for Group A Strep	2	20%	Acceptable
Growth, referred for identification	2	20%	Acceptable

Organisms present in specimen TC-11: *Branhamella catarrhalis* and *Lactobacillus casei*.

Specimen BA-7 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Proteus vulgaris	10	66.67%	Acceptable
Staphylococcus epidermidis	2	13.33%	Acceptable
Gram negative bacilli	1	6.67%	Acceptable
Staph – coagulase negative	1	6.67%	Acceptable

Organisms present in specimen BA-7: *Proteus vulgaris* and *Staphylococcus epidermidis*.

Specimen BA-8 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Enterococcus (Strep) faecalis	6	66.67%	Acceptable
Enterococcus sp.	3	33.33%	Acceptable

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

Specimen BA-9 – Respiratory Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Streptococcus pneumoniae	8	72.73%	Acceptable
Streptococcus alpha-hemolytic	1	9.09%	Acceptable
Gram positive cocci	1	9.09%	Acceptable

Organism present in specimen BA-9: *Streptococcus pneumoniae*.

URINE CULTURE

Specimen UC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus aureus	48	33.10%	Acceptable
Growth, referred for identification	40	27.59%	Acceptable
Presump. Gram positive	20	13.79%	Acceptable
Gram positive cocci	14	9.66%	Acceptable
Staphylococcus sp.	11	7.59%	Acceptable
Presump. Staphylococcus sp.	10	6.90%	Acceptable

Gram Stain

Gram positive	66	100%	Acceptable
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Gram Stain Morphology

Cocci	57	90.48%	
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Organism present in specimen UC-11: *Staphylococcus aureus*.

Specimen UC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Klebsiella pneumoniae	44	29.93%	Acceptable
Presump. Gram negative	28	19.05%	Acceptable
Growth, referred for identification	27	18.37%	Acceptable
Gram negative bacilli	20	13.61%	Acceptable
Klebsiella sp.	16	10.88%	Acceptable
Presump. Klebsiella sp.	8	5.44%	Acceptable

Organisms present in specimen UC-12: *Klebsiella pneumoniae* and *Lactobacillus casei*.

URINE CULTURE

Specimen UC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Escherichia coli	28	27.18%	Acceptable
Growth, referred for identification	26	25.24%	Acceptable
Presump. Gram negative	21	20.39%	Acceptable
Presump. Escherichia coli	12	11.65%	Acceptable
Gram negative bacilli	7	6.80%	Acceptable
Gram positive bacilli	4	3.88%	Acceptable

Organisms present in specimen UC-13: *Escherichia coli* and *Corynebacterium sp.*

Specimen UC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	19	33.33%	Acceptable
Persump. Gram negative	9	15.79%	Acceptable
Persump. Pseudomonas sp.	9	15.79%	Acceptable
Pseudomonas sp.	8	14.04%	Acceptable
Pseudomonas aeruginosa	7	12.28%	Acceptable
Gram negative bacilli	3	5.26%	Acceptable

Organisms present in specimen UC-14: *Pseudomonas aeruginosa* and *Staphylococcus epidermidis*.

Specimen UC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	22	37.93%	Acceptable
Growth, referred for identification	16	27.59%	Acceptable
Citrobacter freundii	8	13.79%	Acceptable
Citrobacter sp.	4	6.90%	Acceptable
Gram negative bacilli	2	3.45%	Acceptable

Organism present in specimen UC-15: *Citrobacter freundii*.

ANTIMICROBIAL SUSCEPTIBILITY TESTING
Specimen UC-11, CC-11 (SUS-11)

<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>	
Amoxicillin/Clavulanate	13	13	-	-	6	6	-	-	100%
Ampicillin	50	47	-	3	6	6	-	-	93.06%
Ampicillin/Sulbactam	-	-	-	-	4	4	-	-	100%
Carbenicillin	2	1	-	1	-	-	-	-	83.33%
Cefaclor	1	1	-	-	-	-	-	-	100%
Cefamandole	1	1	-	-	-	-	-	-	100%
Cefazolin	3	3	-	-	9	9	-	-	100%
Cefotaxime	1	1	-	-	3	3	-	-	100%
Cefoxitin	3	3	-	-	-	-	-	-	100%
Ceftazidime	2	2	-	-	-	-	-	-	100%
Ceftriaxone	5	5	-	-	4	4	-	-	100%
Cefuroxime	5	5	-	-	1	1	-	-	100%
Cephalexin	2	2	-	-	-	-	-	-	100%
Cephalothin	44	44	-	-	6	6	-	-	100%
Ciprofloxacin	47	47	-	-	13	13	-	-	98.67%
Clindamycin	3	3	-	-	6	6	-	-	100%
Doxycycline	3	3	-	-	1	1	-	-	100%
Erythromycin	4	4	-	-	2	2	-	-	Inappropriate drug ¹
Fosfomycin	1	1	-	-	-	-	-	-	Inappropriate drug ¹
Gatifloxacin	1	1	-	-	-	-	-	-	100%
Gentamicin	17	17	-	-	8	8	-	-	100%
Imipenem	-	-	-	-	3	3	-	-	100%
Levofloxacin	14	14	-	-	9	9	-	-	97.14%
Linezolid	-	-	-	-	2	2	-	-	100%
Lomefloxacin	1	1	-	-	-	-	-	-	100%
Loracarbef	1	1	-	-	-	-	-	-	100%
Nitrofurantoin	63	59	3	1	13	13	-	-	94.90%
Norfloxacin	11	11	-	-	3	3	-	-	100%
Ofloxacin	6	6	-	-	2	2	-	-	100%
Oxacillin	20	20	-	-	15	15	-	-	100%
Penicillin-G	7	7	-	-	12	10	-	2	92.86%
Piperacillin	1	1	-	-	1	1	-	-	100%
Piperacillin/Tazobactam	-	-	-	-	2	2	-	-	100%
Rifampin	1	1	-	-	1	1	-	-	100%
Sulfamethoxazole	5	5	-	-	-	-	-	-	100%
Sulfisoxazole	4	3	-	1	1	1	-	-	83.33%
Tetracycline	26	26	-	-	13	13	-	-	100%
Tobramycin	2	2	-	-	-	-	-	-	100%
Trimethoprim	6	6	-	-	1	1	-	-	100%
Trimethoprim/Sulfamethoxazole	58	58	-	-	17	17	-	-	100%
Vancomycin	17	17	-	-	12	12	-	-	100%

Organism present in specimen UC-11, CC-11 (SUS-11): *Staphylococcus aureus*.

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

GC CULTURE

Specimen GC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	24	50.00%	Acceptable
Neisseria gonorrhoeae	19	39.58%	Acceptable
Growth select media, referred	1	2.08%	Acceptable
Growth, referred for identification	1	2.08%	Acceptable

Beta-lactamase Testing

Negative	9	100%
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Gram Stain

Gram negative	36	97.30%	Acceptable
Gram positive	1	2.70%	

Gram Stain Morphology

Diplococci	37	90.24%
Cocci	2	4.88%
Cocci in pairs	2	4.88%

Organism present in specimen GC-11: *Neisseria gonorrhoeae*.

Specimen GC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for <i>N. gonorrhoeae</i>	18	69.23%	Acceptable
No growth (sterile)	7	26.92%	Acceptable

Organisms present in specimen GC-12: *Gardnerella vaginalis* and *Lactobacillus casei*.

Specimen GC-13

<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

Beta-lactamase Testing

Negative	4	100%
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Organisms present in specimen GC-13: *Neisseria gonorrhoeae* and *Corynebacterium sp.*

GC CULTURE

Specimen GC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Persump. GC, referred for ID	15	62.50%	Acceptable
Neisseria gonorrhoeae	7	29.17%	Acceptable

Beta-lactamase Testing

Negative	3	75%
Positive	1	25%

Organism present in specimen GC-14: *Neisseria gonorrhoeae*.

Specimen GC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	16	66.67%	Acceptable
No growth (sterile)	7	29.17%	Acceptable

Organisms present in specimen GC-15: *Staphylococcus epidermidis* and *Corynebacterium* sp.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-11

<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	105	5	2	18	80
Bacti-Star	1	-	-	-	1
Uri-Three	1	-	-	1	-
Bacturcult	1	-	-	-	1
Bulls Eye	6	-	-	1	5
Uri-Check	17	2	1	2	12
Uricult	47	2	1	11	33
Calibrated Loop	27	-	-	2	25

This specimen is ungraded due to the lack of 80% participant consensus.

Identification—Specimen CC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	18	45%	Acceptable
Presump. Staphylococcus sp.	12	30%	Acceptable
Growth, referred for identification	5	12.50%	Acceptable
Staphylococcus aureus	3	7.50%	Acceptable
Bacturcult Group II	1	2.50%	Acceptable

Gram Stain

Gram positive	6	100%	Acceptable
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Gram Stain Morphology

Cocci	4	57.14%
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Organism present in specimen CC-11: >100,000 CFU/mL of *Staphylococcus aureus*.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-12

<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	105	2	33	54	16
Bacti-Star	1	-	-	-	1
Uri-Three	1	-	-	1	-
Bacturcult	1	-	-	1	-
Bulls Eye	6	-	1	3	2
Uri-Check	17	2	5	8	2
Uricult	47	-	25	21	1
Calibrated Loop	27	-	2	16	9

Identification—Specimen CC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Klebsiella sp.	17	42.50%	Acceptable
Presump. Gram negative	15	37.50%	Acceptable
Growth, referred for identification	4	10.00%	Acceptable
Klebsiella pneumoniae	1	2.50%	Acceptable

Organisms present in specimen CC-12: approximately 74,000 CFU/mL *Klebsiella pneumoniae* and approximately 32,000 CFU/mL of *Lactobacillus casei*.

Identification—Specimen CC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Escherichia coli	17	56.67%	Acceptable
Presump. Gram negative	8	26.67%	Acceptable
Escherichia coli	2	6.67%	Acceptable
Growth, referred for identification	2	6.67%	Acceptable
Presump. Gram positive	1	3.33%	Acceptable

Organisms present in specimen CC-13: >100,000 CFU/mL of *Escherichia coli* and approximately 9,500 CFU/ml of *Corynebacterium sp.*

Identification—Specimen CC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Pseudomonas sp.	16	53.33%	Acceptable
Presump. Gram negative	8	26.67%	Acceptable
Pseudomonas aeruginosa	3	10.00%	Acceptable
Growth, referred for identification	2	6.67%	Acceptable
Presump. Gram positive	1	3.33%	Acceptable

Organisms present in specimen CC-14: > 100,000 CFU/mL of *Pseudomonas aeruginosa* and approximately 23,000 CFU/mL of *Staphylococcus epidermidis*.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	14	48.28%	Not graded
Growth, referred for identification	3	10.34%	
Bacturcult Group I	1	3.45%	
Citrobacter freundii	1	3.45%	
Citrobacter sp.	1	3.45%	
Presump. Enterobacter sp.	5	17.24%	

Organism present in specimen CC-15: >100,000 CFU/mL of *Citrobacter freundii*. This specimen is ungraded due to the lack of 80% referee consensus.

DERMATOPHYTE SCREEN

Specimen DM-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte present	16	84.21%	Acceptable
Dermatophyte absent	3	15.79%	

Organism present in specimen DM-11: *Epidermophyton floccosum*.

Specimen DM-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte absent	18	94.74%	Acceptable
Dermatophyte present	1	5.26%	

Organisms present in specimen DM-12: *Rhodotorula mucilaginosa* and *Lactobacillus casei*.

GRAM STAIN

Specimen GS-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	51	98.08%	Acceptable
Gram positive	1	1.92%	

Gram Stain Morphology

Rods/bacilli	45	95.74%
Cocci	1	2.13%
Cocco-bacilli	1	2.13%

Organism present in specimen GS-11: *Serratia marcescens*.

Specimen GS-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	35	67.31%	Not graded
Gram negative	17	32.69%	

This specimen is ungraded due to lack of 80% referee consensus.

Gram Stain Morphology

Cocci	15	32.61%
Diplococci	12	26.09%
Cocco-bacilli	11	23.91%
Cocci in pairs	7	15.22%
Rods/bacilli	1	2.17%

Organism present in specimen GS-12: *Streptococcus pneumoniae*.

Specimen GS-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	51	98.08%	Acceptable
Gram positive	1	1.92%	

Gram Stain Morphology

Rods/bacilli	33	70.21%
Cocco-bacilli	8	17.02%
Diplococci	2	4.26%
Cocci	2	4.26%
Cocci in pairs	2	4.26%

Organism present in specimen GS-13: *Haemophilus influenzae*.

GRAM STAIN

Specimen GS-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	49	94.23%	Acceptable
Gram negative	3	5.77%	

Gram Stain Morphology

Cocci in chains	31	65.96%
Cocci	12	25.53%
Cocci in pairs	3	6.38%
Diplococci	1	2.13%

Organism present in specimen GS-14: *Streptococcus pyogenes*.

Specimen GS-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	51	98.08%	Acceptable
Gram positive	1	1.92%	

Gram Stain Morphology

Rods/bacilli	42	89.36%
Cocco-bacilli	3	6.38%
Cocci	2	4.26%

Organism present in specimen GS-15: *Proteus vulgaris*.

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	28	100%	Acceptable

Organism present in specimen VP-11: *Gardnerella vaginalis*.

Specimen VP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	28	100%	Acceptable

Organism present in specimen VP-12: *Gardnerella vaginalis*.

AFFIRM VP III–*Trichomonas vaginalis*

Specimen VP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	27	96.43%	Acceptable
Negative	1	3.5%	

Organism present in specimen VP-13: *Trichomonas vaginalis*.

Specimen VP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	20	71.43%	Not graded
Negative	8	28.57%	

Organisms present in specimen VP-9: *Trichomonas vaginalis* and *Candida albicans*. This specimen is ungraded due to lack of 80% participant consensus.

Specimen VP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	28	100%	Acceptable

Organisms present in specimen VP-15: *Gardnerella vaginalis* and *Candida albicans*.

AFFIRM VP III–*Gardnerella vaginalis*

Specimen VP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	23	82.14%	Acceptable
Negative	5	17.86%	

Specimen VP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	25	89.29%	Acceptable
Negative	3	10.71%	

Specimen VP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	28	100%	Acceptable

AFFIRM VP III–Gardnerella vaginalis**Specimen VP-14**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	27	96.43%	Acceptable
Positive	1	3.57%	

Specimen VP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	23	82.14%	Acceptable
Negative	5	17.86%	

AFFIRM VP III–Candida sp.**Specimen VP-11**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	28	100%	Acceptable

Specimen VP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	28	100%	Acceptable

Specimen VP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	27	96.43%	Acceptable
Positive	1	3.57%	

Specimen VP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	26	92.86%	Acceptable
Negative	2	7.14%	

Specimen VP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	28	100%	Acceptable

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	-	25
BD ProbeTec	5	-	5
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	4	-	4
Gen-Probe	2	-	2
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	11	-	11

Organism present in specimen CY-11: *Neisseria gonorrhoeae*.

Specimen CY-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	25	-
BD ProbeTec	5	5	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	4	4	-
Gen-Probe	2	2	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	11	11	-

Organism present in specimen CY-12: *Chlamydia trachomatis*.

Specimen CY-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	19	-	19
BD ProbeTec	5	-	5
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	4	-	4
Gen-Probe	2	-	2
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	5	-	5

Organism present in specimen CY-13: *Neisseria gonorrhoeae*.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	19	19	-
BD ProbeTec	5	5	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	4	4	-
Gen-Probe	2	2	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	5	5	-

Organism present in specimen CY-14: *Chlamydia trachomatis*.

Specimen CY-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	19	1	18
BD ProbeTec	5	1	4
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	4	-	4
Gen-Probe	2	-	2
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	5	-	5

Organism present in specimen CY-10: Negative; sterile specimen.

GC (ANTIGEN DETECTION)

Specimen CY-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	12	-
BD ProbeTec	5	5	-
BioStar OIA	4	4	-
Gen-Probe	2	2	-
Gen-Probe APTIMA	1	1	-

Specimen CY-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	-	12
BD ProbeTec	5	-	5
BioStar OIA	4	-	4
Gen-Probe	2	-	2
Gen-Probe APTIMA	1	-	1

GC (ANTIGEN DETECTION)

Specimen CY-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	12	-
BD ProbeTec	5	5	-
BioStar OIA	4	4	-
Gen-Probe	2	2	-
Gen-Probe APTIMA	1	1	-

Specimen CY-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	-	12
BD ProbeTec	5	-	5
BioStar OIA	4	-	4
Gen-Probe	2	-	2
Gen-Probe APTIMA	1	-	1

Specimen CY-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	-	12
BD ProbeTec	5	-	5
BioStar OIA	4	-	4
Gen-Probe	2	-	2
Gen-Probe APTIMA	1	-	1

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-11

<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-11: *Giardia lamblia*.

Specimen LC-12

<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-12: *Cryptosporidium*.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-13

<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-13: *Giardia lamblia* and *Cryptosporidium*.

Specimen LC-14

<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-14: *Giardia lamblia*.

Specimen LC-15

<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-15: *Cryptosporidium*.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	8	-
Alexon (Hycor)	1	1	-
Meridian ImmunoCard STAT	1	1	-
Meridian Merifluor	1	1	-
Remel Xpect	4	4	-

Specimen LC-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	8
Alexon (Hycor)	1	-	1
Meridian ImmunoCard STAT	1	-	1
Meridian Merifluor	1	-	1
Remel Xpect	4	-	4

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	8	-
Alexon (Hycor)	1	1	-
Meridian ImmunoCard STAT	1	1	-
Meridian Merifluor	1	1	-
Remel Xpect	4	4	-

Specimen LC-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	8	-
Alexon (Hycor)	1	1	-
Meridian ImmunoCard STAT	1	1	-
Meridian Merifluor	1	1	-
Remel Xpect	4	4	-

Specimen LC-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	8
Alexon (Hycor)	1	-	1
Meridian ImmunoCard STAT	1	-	1
Meridian Merifluor	1	-	1
Remel Xpect	4	-	4

RSV ANTIGEN DETECTION

Specimen V-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	35	29	6
BD Directigen	2	2	-
BD Directigen EZ	1	1	-
Binax NOW - waived	12	11	1
BioStar OIA	7	6	1
Fisher HealthCare Sure-Vue - waived	2	2	-
Remel Xpect - waived	2	1	1
Wampole Clearview RSV - waived	5	4	1

Specimen V-11: Positive for RSV antigen.

RSV ANTIGEN DETECTION

Specimen V-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	34	2	32
BD Directigen	2	-	2
BD Directigen EZ	1	-	1
Binax NOW - waived	12	-	12
BioStar OIA	7	-	7
Fisher HealthCare Sure-Vue - waived	2	1	1
Remel Xpect - waived	2	-	2
Wampole Clearview RSV - waived	5	-	5

Specimen V-12: Negative for RSV antigen.

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	24	-	24
BD Directigen	2	-	2
BD Directigen EZ	1	-	1
Binax NOW - waived	7	-	7
BioStar OIA	7	-	7
Fisher HealthCare Sure-Vue - waived	1	-	1
Remel Xpect - waived	2	-	2
Wampole Clearview RSV - waived	2	-	2

Specimen V-13: Negative for RSV antigen.

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	24	22	2
BD Directigen	2	2	-
BD Directigen EZ	1	1	-
Binax NOW - waived	7	7	-
BioStar OIA	7	6	1
Fisher HealthCare Sure-Vue - waived	1	1	-
Remel Xpect - waived	2	1	1
Wampole Clearview RSV - waived	2	2	-

Specimen V-14: Positive for RSV antigen.

RSV ANTIGEN DETECTION

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	24	-	24
BD Directigen	2	-	2
BD Directigen EZ	1	-	1
Binax NOW - waived	7	-	7
BioStar OIA	7	-	7
Fisher HealthCare Sure-Vue - waived	1	-	1
Remel Xpect - waived	2	-	2
Wampole Clearview RSV - waived	2	-	2

Specimen V-15: Negative for RSV antigen.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	95	1	94
BioStar OIA	6	-	6
Quidel QuickVue Influenza	78	-	78

Specimen V-11: Negative for Influenza A/B antigen.

Specimen V-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	96	94	2
BioStar OIA	6	5	1
Quidel QuickVue Influenza	78	78	-

Specimen V-12: Positive for Influenza A/B antigen.

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	30	25	5
BioStar OIA	6	2	4
Quidel QuickVue Influenza	21	20	1

Specimen V-13: Positive for Influenza A/B antigen.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	30	-	30
BioStar OIA	6	-	6
Quidel QuickVue Influenza	21	-	21

Specimen V-14: Negative for Influenza A/B antigen.

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	30	25	5
BioStar OIA	6	2	4
Quidel QuickVue Influenza	21	20	1

Specimen V-15: Positive for Influenza A/B antigen.

INFLUENZA A ANTIGEN DETECTION

Specimen V-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	79	-	79
BD Directigen	2	-	2
Binax NOW - waived	11	-	11
BioStar Flu OIA A/B	6	-	6
Quidel QuickVue Influenza A+B	49	-	49
Remel Xpect	6	-	6

Specimen V-11: Negative for Influenza A antigen.

Specimen V-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	78	4	74
BD Directigen	2	2	-
Binax NOW - waived	11	-	11
BioStar Flu OIA A/B	6	-	6
Quidel QuickVue Influenza A+B	48	1	47
Remel Xpect	6	-	6

Specimen V-12: Negative for Influenza A antigen.

INFLUENZA A ANTIGEN DETECTION

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	39	38	1
BD Directigen	1	1	-
Binax NOW - waived	7	6	1
BioStar Flu OIA A/B	6	6	-
Quidel QuickVue Influenza A+B	17	17	-
Remel Xpect	6	6	-

Specimen V-13: Positive for Influenza A antigen.

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	39	-	39
BD Directigen	1	-	1
Binax NOW - waived	7	-	7
BioStar Flu OIA A/B	6	-	6
Quidel QuickVue Influenza A+B	17	-	17
Remel Xpect	6	-	6

Specimen V-14: Negative for Influenza A antigen.

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	39	37	2
BD Directigen	1	1	-
Binax NOW - waived	7	6	1
BioStar Flu OIA A/B	6	5	1
Quidel QuickVue Influenza A+B	17	17	-
Remel Xpect	6	6	-

Specimen V-15: Positive for Influenza A antigen.

INFLUENZA B ANTIGEN DETECTION

Specimen V-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	78	-	78
BD Directigen	2	-	2
Binax NOW - waived	11	-	11
BioStar Flu OIA A/B	6	-	6
Quidel QuickVue Influenza A+B	48	-	48
Remel Xpect	6	-	6

Specimen V-11: Negative for Influenza B antigen.

Specimen V-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	78	77	1
BD Directigen	2	2	-
Binax NOW - waived	11	11	-
BioStar Flu OIA A/B	6	6	-
Quidel QuickVue Influenza A+B	48	47	1
Remel Xpect	6	6	-

Specimen V-12: Positive for Influenza B antigen.

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	39	-	39
BD Directigen	1	-	1
Binax NOW - waived	7	-	7
BioStar Flu OIA A/B	6	-	6
Quidel QuickVue Influenza A+B	16	-	16
Remel Xpect	6	-	6

Specimen V-13: Negative for Influenza B antigen.

INFLUENZA B ANTIGEN DETECTION

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	39	-	39
BD Directigen	1	-	1
Binax NOW - waived	7	-	7
BioStar Flu OIA A/B	6	-	6
Quidel QuickVue Influenza A+B	16	-	16
Remel Xpect	6	-	6

Specimen V-14: Negative for Influenza B antigen.

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	39	-	39
BD Directigen	1	-	1
Binax NOW - waived	7	-	7
BioStar Flu OIA A/B	6	-	6
Quidel QuickVue Influenza A+B	16	-	16
Remel Xpect	6	-	6

Specimen V-15: Negative for Influenza B antigen.

LEGIONELLA ANTIGEN DETECTION

Specimen L-11

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

Specimen L-11: Positive for Legionella antigen.

Specimen L-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	84	84	-

Specimen L-12: Positive for Legionella antigen.

Specimen L-13

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

Specimen L-13: Positive for Legionella antigen.

LEGIONELLA ANTIGEN DETECTION

Specimen L-14

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

Specimen L-14: Negative for Legionella antigen.

Specimen L-15

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

Specimen L-15: Negative for Legionella antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	1	16
Alexon (Hycor)	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	4	-	4
BioStar OIA	5	-	5
Meridian ImmunoCard	1	-	1
Meridian Premier	1	-	1
Remel Xpect	1	1	-
Wampole	1	-	1

Antigen present in specimen AG-11: Rotavirus.

Specimen AG-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	17	-
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	4	4	-
BioStar OIA	5	5	-
Meridian ImmunoCard	1	1	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-
Wampole	1	1	-

Antigen present in specimen AG-12: *Clostridium difficile*.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	-	17
Alexon (Hycor)	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	4	-	4
BioStar OIA	5	-	5
Meridian ImmunoCard	1	-	1
Meridian Premier	1	-	1
Remel Xpect	1	-	1
Wampole	1	-	1

Antigen present in specimen AG-13: Rotavirus.

Specimen AG-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	17	-
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	4	4	-
BioStar OIA	5	5	-
Meridian ImmunoCard	1	1	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-
Wampole	1	1	-

Antigens present in specimen AG-14: Rotavirus and *Clostridium difficile*.

Specimen AG-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	17	-
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	4	4	-
BioStar OIA	5	5	-
Meridian ImmunoCard	1	1	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-
Wampole	1	1	-

Antigen present in specimen AG-15: *Clostridium difficile*.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-11

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

Specimen AG-12

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

Specimen AG-13

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

Specimen AG-14

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

Specimen AG-15

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

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	75	-	75

Specimen SP-11: Negative for *Streptococcus pneumoniae* antigen.

Specimen SP-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	75	-	75

Specimen SP-12: Negative for *Streptococcus pneumoniae* antigen.

Specimen SP-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	75	74	1

Specimen SP-13: Positive for *Streptococcus pneumoniae* antigen.

Specimen SP-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	75	75	-

Specimen SP-14: Positive for *Streptococcus pneumoniae* antigen.

Specimen SP-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	75	75	-

Specimen SP-15: Positive for *Streptococcus pneumoniae* antigen.

PARASITOLOGY

Specimen PA-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba histolytica	3	100%	Acceptable

Parasite present in specimen PA-11: *Entamoeba histolytica*.

PARASITOLOGY

Specimen PA-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	3	100%	Acceptable

Parasite present in specimen PA-12: *Giardia lamblia*.

Specimen PA-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	4	100%	Acceptable

Parasite present in specimen PA-13: No parasites present.

Specimen PA-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Trichuris trichiura eggs	4	100%	Acceptable

Parasite present in specimen PA-14: *Trichuris trichiura* eggs.

Specimen PA-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	3	75%	Not graded
Plasmodium sp., NOS	1	25%	

Parasite present in specimen PA-15: *Loa loa*. This is an ungraded challenge due to less than 80% participant consensus.

SUMMARY OF ISOLATES FOUND IN THE 2006 MLE-M3 CULTURE SPECIMENS

Organism	ATCC Strain
<i>Branhamella catarrhalis</i>	25238
<i>Lactobacillus casei</i>	393
<i>Streptococcus pyogenes</i>	19615
<i>Staphylococcus aureus</i>	25923
<i>Corynebacterium species</i>	49528
<i>Proteus vulgaris</i>	8427
<i>Staphylococcus epidermidis</i>	14990
<i>Enterococcus faecalis</i>	29212
<i>Streptococcus pneumoniae</i>	6305
<i>Klebsiella pneumoniae</i>	13883
<i>Escherichia coli</i>	25922
<i>Pseudomonas aeruginosa</i>	27853
<i>Citrobacter freundii</i>	8090
<i>Staphylococcus aureus</i>	25923
<i>Neisseria gonorrhoeae</i>	19424
<i>Gardnerella vaginalis</i>	14018

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