

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

Microbiology
MLE – M2

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2004 Evaluation Criteria

The evaluation criteria used in the 2004 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, HCFA 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	106	45.3%	Acceptable
Presump. Pos. Group A Strep	87	37.2%	Acceptable
Streptococcus pyogenes	18	7.7%	Acceptable
Gram positive	3	1.3%	Acceptable
Staphylococcus epidermidis	2	0.9%	Acceptable
Staphylococcus sp.	1	0.4%	Acceptable
Staph – coagulase neg.	1	0.4%	Acceptable
Negative for Group A Strep	16	6.8%	

Organisms present in specimen TC-6: *Streptococcus pyogenes* and *Staphylococcus epidermidis*.

Specimen TC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	207	90.4%	Acceptable
Staphylococcus aureus	11	4.8%	Acceptable
Staphylococcus sp.	2	0.9%	Acceptable
Gram positive cocci	1	0.4%	Acceptable

Organism present in specimen TC-7: *Staphylococcus aureus*.

Specimen TC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	70	93.3%	Acceptable
No growth (sterile)	3	4.0%	Acceptable

Organisms present in specimen TC-8: *Moraxella catarrhalis* and *Corynebacterium sp.*

Specimen TC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	35	54.7%	Acceptable
Presump. Pos. Group A Strep	22	34.4%	Acceptable
Streptococcus pyogenes	1	1.6%	Acceptable
Negative for Group A Strep	6	9.4%	

Organism present in specimen TC-9: *Streptococcus pyogenes*.

Specimen TC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative For Group A Strep	63	100%	Acceptable

Organisms present in specimen TC-10: *Haemophilus influenzae* and *Streptococcus gordonii*.

STREP A ANTIGEN DETECTION

Specimen RS-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	735	4	731
Abbott Signify Strep A-waived	91	-	91
Applied Biotech Signify	9	-	9
Applied Biotech SureStep	4	-	4
Applied Biotech SureStep II	7	-	7
Bacti-Lab DIPTEC/DIPCUL	1	-	1
BD LINK 2	3	-	3
BD QTest	32	-	32
Beckman Coulter ICON DS	22	1	21
Beckman Coulter ICON Fx Strep A	13	-	13
Beckman Coulter ICON SC	24	-	24
Bio Diagnostics Systems	1	-	1
BioStar Acceava Strep A Test	74	-	74
BioStar Strep A MAX OIA	40	-	40
DE Healthcare TruView	9	-	9
Fisher HealthCare Sure-Vue	2	-	2
Fisher Sure-Vue Select	1	-	1
Fisher Sure-Vue Strep A-waived	3	-	3
Genzyme OSOM Ultra Strep A	26	1	25
Henry Schein One Step	4	-	4
LifeSign Status Strep A	1	-	1
Mainline Confirms	3	-	3
Mainline Confirms Strep A Dots	2	-	2
Polymedco Polystat Strep A (I)	29	1	28
Polymedco Polystat Strep A (II)	22	-	22
Quidel Cards QS	1	-	1
Quidel QuickVue Dipstick Strep	28	-	28
Quidel QuickVue In-Line	92	1	91
Quidel QuickVue+	131	-	131
Stanbio QuStick Strep A	1	-	1
Wampole Clearview	4	-	4
Wyntek OSOM	8	-	8
Wyntek OSOM Ultra Strep A	23	-	23

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	700	687	13	414	198	17
Abbott Signify Strep A-waived	88	88	-	62	23	1
Applied Biotech Signify	7	7	-	3	3	1
Applied Biotech SureStep	4	4	-	2	2	-
Applied Biotech SureStep II	7	7	-	2	3	2
Bacti-Lab DIPTEC/DIPCUL	1	1	-	1	-	-
BD LINK 2	3	3	-	-	2	-
BD QTest	27	27	-	10	14	-
Beckman Coulter ICON DS	21	20	1	6	11	3
Beckman Coulter ICON Fx Strep A	13	13	-	7	4	1
Beckman Icon SC	23	23	-	8	12	2
Bio Diagnostics Systems	1	1	-	1	-	-
BioStar Acceava Strep A Test	73	73	-	47	18	1

STREP A ANTIGEN DETECTION

Specimen RS-7 (cont'd)

<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>
BioStar Strep A MAX OIA	40	40	-	31	6	-
DE Healthcare TruView	8	8	-	5	2	-
Fisher HealthCare Sure-Vue	2	2	-	-	2	-
Fisher Sure-Vue Strep A-waived	2	2	-	1	1	-
Genzyme OSOM Ultra Strep A	24	23	1	15	2	-
Henry Schein One Step	3	3	-	-	2	-
LifeSign Status Strep A	1	1	-	1	-	-
Mainline Confirms	1	1	-	1	-	-
Mainline Confirms Strep A Dots	2	2	-	-	1	1
Polymedco Polystat Strep A (I)	29	28	1	5	18	-
Polymedco Polystat Strep A (II)	21	20	1	5	15	-
Quidel Cards QS	1	1	-	-	1	-
Quidel QuickVue Dipstick Strep	25	25	-	16	3	-
Quidel QuickVue In-Line	91	82	9	49	19	4
Quidel QuickVue+	126	126	-	101	18	-
Stanbio QuStick Strep A	1	1	-	1	-	-
Wampole Clearview	3	3	-	-	2	-
Wyntek OSOM	8	8	-	6	-	-
Wyntek OSOM Ultra Strep A	22	22	-	13	6	-

Specimen RS-8

<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	449	443	6	279	114	11
Abbott Signify Strep A-waived	45	45	-	31	10	3
Applied Biotech Signify	7	7	-	2	5	-
Applied Biotech SureStep	2	2	-	1	1	-
Applied Biotech SureStep II	6	6	-	1	4	1
Bacti-Lab DIPTEC/DIPCUL	1	1	-	1	-	-
BD LINK 2	1	1	-	-	1	-
BD QTest	25	25	-	10	12	-
Beckman Coulter ICON DS	9	9	-	5	3	1
Beckman Coulter ICON Fx Strep A	11	11	-	4	6	1
Beckman Coulter ICON SC	14	14	-	7	5	1
Bio Diagnostics Systems	1	1	-	1	-	-
BioStar Acceava Strep A Test	21	21	-	14	1	-
BioStar Strep A MAX OIA	39	38	1	29	6	-
DE Healthcare TruView	1	1	-	-	-	-
Fisher Sure-Vue Strep A-waived	1	1	-	-	1	-
Genzyme OSOM Ultra Strep A	16	16	-	10	3	-
Henry Schein One Step	2	2	-	-	1	-
Mainline Confirms	1	1	-	1	-	-
Mainline Confirms Strep A Dots	2	2	-	-	1	1
Polymedco Polystat Strep A (I)	22	22	-	7	12	-
Polymedco Polystat Strep A (II)	10	9	1	1	8	-

STREP A ANTIGEN DETECTION

Specimen RS-8 (cont'd)

<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>
Quidel Cards QS	1	1	-	-	1	-
Quidel QuickVue Dipstick Strep	12	12	-	8	-	-
Quidel QuickVue In-Line	36	33	3	19	9	2
Quidel QuickVue+	123	123	-	103	14	-
Stanbio QuStick Strep A	1	1	-	1	-	-
Wampole Clearview	2	2	-	-	1	-
Wyntek OSOM	7	6	1	4	1	-
Wyntek OSOM Ultra Strep A	15	15	-	8	4	-

Specimen RS-9

<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	377	371	6	214	103	26
Abbott Signify Strep A-waived	34	34	-	25	6	2
Applied Biotech Signify	7	7	-	1	5	1
Applied Biotech SureStep	2	2	-	2	-	-
Applied Biotech SureStep II	6	6	-	1	4	1
Bacti-Lab DIPTEC/DIPCUL	1	1	-	1	-	-
BD LINK 2	1	1	-	-	-	1
BD QTest	20	18	2	3	8	5
Beckman Coulter ICON DS	8	8	-	4	2	2
Beckman Coulter ICON Fx Strep A	10	10	-	2	7	1
Beckman Coulter ICON SC	10	10	-	3	4	3
Bio Diagnostics Systems	1	1	-	1	-	-
BioStar Acceava Strep A Test	17	17	-	9	3	-
BioStar Strep A MAX OIA	37	37	-	27	5	2
DE Healthcare TruView	1	1	-	-	-	-
Fisher Sure-Vue Strep A- waived	1	1	-	1	-	-
Genzyme OSOM Ultra Strep A	14	14	-	8	4	-
Henry Schein One Step	2	2	-	-	1	-
Mainline Confirms	1	1	-	-	1	-
Mainline Confirms Strep A Dots	2	2	-	-	1	1
Polymedco Polystat Strep A (I)	20	20	-	5	12	1
Polymedco Polystat Strep A (II)	7	6	1	2	2	2
Quidel Cards QS	1	1	-	-	1	-
Quidel QuickVue Dipstick Strep	6	6	-	3	2	1
Quidel QuickVue In-Line	33	30	3	18	7	2
Quidel QuickVue+	105	105	-	77	25	-
Stanbio QuStick Strep A	1	1	-	1	-	-
Wampole Clearview	2	2	-	-	-	1
Wyntek OSOM	7	7	-	5	-	-
Wyntek OSOM Ultra Strep A	8	8	-	5	1	-

STREP A ANTIGEN DETECTION

Specimen RS-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	376	3	373
Abbott Signify Strep A-waived	34	-	34
Applied Biotech Signify	7	-	7
Applied Biotech SureStep	2	-	2
Applied Biotech SureStep II	6	-	6
Bacti-Lab DIPTEC/DIPCUL	1	-	1
BD LINK 2	1	-	1
BD QTest	20	1	19
Beckman Coulter ICON DS	8	-	8
Beckman Coulter ICON Fx Strep A	10	-	10
Beckman Coulter ICON SC	10	-	10
Bio Diagnostics Systems	1	-	1
BioStar Acceava Strep A Test	17	-	17
BioStar Strep A MAX OIA	37	-	37
DE Healthcare TruView	1	-	1
Fisher Sure-Vue Strep A-waived	1	-	1
Genzyme OSOM Ultra Strep A	13	-	13
Henry Schein One Step	2	-	2
Mainline Confirms	1	-	1
Mainline Confirms Strep A Dots	2	-	2
Polymedco Polystat Strep A (I)	20	-	20
Polymedco Polystat Strep A (II)	7	1	6
Quidel Cards QS	1	-	1
Quidel QuickVue Dipstick Strep	6	-	6
Quidel QuickVue In-Line	33	1	32
Quidel QuickVue+	105	-	105
Stanbio QuStick Strep A	1	-	1
Wampole Clearview	2	-	2
Wyntek OSOM	7	-	7
Wyntek OSOM Ultra Strep A	8	-	8

GENERAL BACTERIOLOGY

Specimen UC-6 – Urine Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus saprophyticus	3	100%	Acceptable
<u>Gram Stain</u>			
Gram positive	2	100%	Acceptable
<u>Gram Stain Morphology</u>			
Cocci	2	100%	

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

GENERAL BACTERIOLOGY

Specimen TC-6 – Throat Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Streptococcus pyogenes	3	60.0%	Acceptable
Staphylococcus epidermidis	2	40.0%	Acceptable

Organisms present in specimen TC-6: *Streptococcus pyogenes* and *Staphylococcus epidermidis*.

Specimen BA-4 – Sputum Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Streptococcus pneumoniae	3	100%	Acceptable

Organism present in specimen BA-4: *Streptococcus pneumoniae*.

Specimen BA-5 – Spinal Fluid Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Listeria monocytogenes	3	100%	Acceptable

Organism present in specimen BA-5: *Listeria monocytogenes*.

Specimen BA-6 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus epidermidis	2	40.0%	Acceptable
Growth, referred for identification	2	40.0%	Acceptable
Bacteroides fragilis	1	20.0%	Acceptable

Organisms present in specimen BA-6: *Bacteroides fragilis* and *Staphylococcus epidermidis*.

URINE CULTURE

Specimen UC-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	42	25.9%	Acceptable
Staphylococcus saprophyticus	37	22.8%	Acceptable
Presump. Gram positive	24	14.8%	Acceptable
Gram positive cocci	16	9.9%	Acceptable
Staph – coagulase neg.	14	8.6%	Acceptable
Presump. Staphylococcus sp.	10	6.2%	Acceptable
Staphylococcus sp.	6	3.7%	Acceptable

Gram Stain

Gram positive	70	100%	Acceptable
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URINE CULTURE

Specimen UC-6 (cont'd)

<u>Gram Stain Morphology</u>	<u>Labs</u>	<u>Percent</u>
Cocci	60	92.3%
Cocci in chains	2	3.1%
Cocci in pairs	2	3.1%
Diplococci	1	1.5%

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

Specimen UC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pseudomonas aeruginosa	46	27.1%	Acceptable
Growth, referred for identification	37	21.8%	Acceptable
Presump. Gram negative	22	12.9%	Acceptable
Presump. Pseudomonas sp.	19	11.2%	Acceptable
Pseudomonas sp.	18	10.6%	Acceptable
Gram negative bacilli	18	10.6%	Acceptable
Staphylococys epidermidis	3	1.8%	Acceptable
Staph – coagulase neg.	2	1.2%	Acceptable
Presump. Gram positive	2	1.2%	Acceptable

Organisms present in specimen UC-7: *Pseudomonas aeruginosa* and *Staphylococcus epidermidis*.

Specimen UC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	31	33.7%	Acceptable
Presump. Gram positive	22	23.9%	Acceptable
Streptococcus agalactiae	14	15.2%	Acceptable
Gram positive cocci	9	9.8%	Acceptable
Presumptive Streptococcus sp.	4	4.4%	Acceptable
Strep – beta hemo; not Grp A	2	2.2%	Acceptable
No growth (sterile)	5	5.4%	

Organisms present in specimen UC-8: *Streptococcus sp. Group B* and *Lactobacillus casei*.

Specimen UC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	23	41.8%	Acceptable
Klebsiella pneumoniae	10	18.2%	Acceptable
Growth, referred for identification	10	18.2%	Acceptable
Gram negative bacilli	5	9.1%	Acceptable
Klebsiella sp.	3	5.5%	Acceptable
Presump. Klebsiella sp.	2	3.6%	Acceptable

Organism present in specimen UC-9: *Klebsiella pneumoniae*.

URINE CULTURE

Specimen UC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	17	29.8%	Acceptable
Presump. Gram positive	17	29.8%	Acceptable
Enterococcus sp.	9	15.8%	Acceptable
Gram positive cocci	6	10.5%	Acceptable
Enterococcus (Strep) faecalis	3	5.3%	Acceptable
Strep. Grp. D – enterococcus	1	1.8%	Acceptable
Presump. Enterococcus sp.	1	1.8%	Acceptable

Organisms present in specimen UC-10: *Enterococcus faecalis* and *Corynebacterium sp.*

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Specimen UC-6, CC-6 (SUS-6)

<u>Antimicrobial</u>	<u>-----Agar Diffusion-----</u>				<u>-----MIC-----</u>				<u>Acceptable (%)</u>
	<u>Interpretative category data</u>				<u>Interpretative category data</u>				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Amikacin	-	-	-	-	1	1	-	-	100%
Amoxicillin/Clavulanate	12	8	-	4	10	7	-	3	Not graded ¹
Ampicillin	72	67	-	5	10	8	-	2	89.5%
Ampicillin/Sulbactam	-	-	-	-	3	2	-	1	Not graded ¹
Carbenicillin	12	12	-	-	4	4	-	-	100%
Cefaclor	4	4	-	-	1	1	-	-	100%
Cefamandole	1	1	-	-	-	-	-	-	100%
Cefazolin	3	2	-	1	4	2	-	2	Not graded ¹
Cefixime	2	-	-	2	-	-	-	-	100%
Cefotaxime	1	1	-	-	-	-	-	-	Not graded ¹
Cefpodoxime	1	-	-	1	-	-	-	-	100%
Ceftazidime	1	-	1	-	-	-	-	-	100%
Ceftriaxone	4	2	-	2	2	1	-	1	Not graded ¹
Cefuroxime	2	2	-	-	-	-	-	-	100%
Cephalothin	71	55	-	16	11	10	-	1	83.0%
Chloramphenicol	1	1	-	-	-	-	-	-	100%
Cinoxacin	2	-	-	2	-	-	-	-	100%
Ciprofloxacin	60	59	1	-	17	16	-	1	98.0%
Clarithromycin	-	-	-	-	2	2	-	-	100%
Clindamycin	-	-	-	-	1	1	-	-	100%
Doxycycline	10	9	1	-	-	-	-	-	90.9%
Fosfomycin	1	1	-	-	-	-	-	-	100%
Gatifloxacin	1	1	-	-	-	-	-	-	100%
Gentamicin	31	30	-	1	7	7	-	-	98.0%
Imipenem	-	-	-	-	2	1	-	1	Not graded ¹
Kanamycin	-	-	-	-	1	1	-	-	100%
Levofloxacin	20	20	-	-	9	8	1	-	97.4%
Loracarbef	1	1	-	-	-	-	-	-	100%
Methicillin	1	-	-	1	-	-	-	-	100%

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

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Specimen UC-6, CC-6 (SUS-6) (cont'd)

<u>Antimicrobial</u>	<u>-----Agar Diffusion-----</u> <u>Interpretative category data</u>				<u>-----MIC-----</u> <u>Interpretative category data</u>				<u>Acceptable (%)</u>
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Nalidixic Acid	4	-	-	4	-	-	-	-	100%
Nitrofurantoin	79	77	1	1	16	15	-	1	97.5%
Norfloxacin	15	15	-	-	4	4	-	-	100%
Novobiacin	1	-	1	-	-	-	-	-	100%
Ofloxacin	5	5	-	-	5	4	-	1	93.3%
Oxacillin	27	7	2	18	5	2	-	3	Not graded ¹
Penicillin-G	6	5	-	1	5	4	-	1	Not graded ¹
Rifampin	-	-	-	-	3	3	-	-	100%
Spectinomycin	1	1	-	-	-	-	-	-	100%
Sulfamethoxazole	7	6	-	1	-	-	-	-	88.9%
Sulfisoxazole	9	7	-	2	1	1	-	-	81.8%
Sulfonamide	-	-	-	-	1	1	-	-	100%
Tetracycline	36	35	1	-	12	12	-	-	98.5%
Tobramycin	3	3	-	-	-	-	-	-	100%
Trimethoprim	9	9	-	-	-	-	-	-	100%
Trimethoprim/Sulfamethoxazole	72	71	-	1	17	17	-	-	99.1%
Vancomycin	20	20	-	-	5	5	-	-	100%

Organism present in specimen UC-6, CC-6 (SUS-6): *Staphylococcus saprophyticus*.

GC CULTURE

Specimen GC-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Neisseria gonorrhoeae	25	48.1%	Acceptable
Presump. GC, referred for identification	24	46.2%	Acceptable
Growth select media, referred	2	3.9%	Acceptable
 <u>Beta-lactamase Testing</u>			
Negative	10	100%	
 <u>Gram Stain</u>			
Gram negative	36	100%	Acceptable
 <u>Gram Stain Morphology</u>			
Diplococci	41	95.4%	
Cocci in chains	1	2.3%	
Cocco-bacilli	1	2.3%	

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

GC CULTURE

Specimen GC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	12	57.1%	Acceptable
No growth (sterile)	9	42.9%	Acceptable

Organisms present in specimen GC-7: *Gardnerella vaginalis* and *Lactobacillus casei*.

Specimen GC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	11	57.9%	Acceptable
No growth (sterile)	8	42.1%	Acceptable

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

Specimen GC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for identification	13	68.4%	Acceptable
Neisseria gonorrhoeae	5	26.3%	Acceptable

Beta-lactamase Testing

Negative	4	100%
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Organisms present in specimen GC-9: *Neisseria gonorrhoeae* and *Staphylococcus epidermidis*.

Specimen GC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	11	57.9%	Acceptable
No growth (sterile)	7	36.8%	Acceptable

Organism present in specimen GC-10: *Streptococcus sp. Group B*.

COLONY COUNT

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	123	6	2	11	104
Bactercult	2	-	-	-	2
Bacti-Star	1	-	-	-	1
Bulls Eye	8	-	-	1	7
Calibrated Loop	30	-	-	1	29
Dip-N-Count	1	-	-	-	1
HealthLink	1	-	-	-	1
Uri-Check	19	3	1	1	14
Uri-Three	2	-	-	-	2
Uricult	55	3	1	6	45

Identification—Specimen CC-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	19	33.9%	Acceptable
Presump. Staphylococcus sp.	15	26.8%	Acceptable
Growth, referred for identification	6	10.7%	Acceptable
Staphylococcus sp.	1	1.8%	Acceptable
Staphylococcus saprophyticus	1	1.8%	Acceptable
Gram positive cocci	1	1.8%	Acceptable
Presump. Enterococcus sp.	8	14.3%	

Gram Stain

Gram positive	8	100%	Acceptable
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Gram Stain Morphology

Cocci	8	80.0%
Cocci in pairs	2	20.0%

Organism present in specimen CC-6: *Staphylococcus saprophyticus*.

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	122	1	3	66	52
Bactercult	2	-	-	-	2
Bacti-Star	1	-	-	-	1
Bulls Eye	8	-	-	4	4
Calibrated Loop	29	-	-	19	10
Dip-N-Count	1	-	-	1	-
HealthLink	1	-	-	1	-
Uri-Check	19	1	2	10	6
Uri-Three	2	-	-	2	-
Uricult	55	-	1	28	26

COLONY COUNT

Identification–Specimen CC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Pseudomonas sp.	27	48.2%	Acceptable
Presump. Gram negative	12	21.4%	Acceptable
Growth, referred for identification	4	7.1%	Acceptable
Presump. Gram positive	4	7.1%	Acceptable
Pseudomonas aeruginosa	2	3.6%	Acceptable
Pseudomonas sp.	1	1.8%	Acceptable
Presump. Staphylococcus sp.	1	1.8%	Acceptable
Bacturcult Group III	1	1.8%	Acceptable

Organisms present in specimen CC-7: *Pseudomonas aeruginosa* and *Staphylococcus epidermidis*.

Identification–Specimen CC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	15	40.5%	Acceptable
Presumptive Streptococcus sp.	7	18.9%	Acceptable
Growth, referred for identification	4	10.8%	Acceptable
Streptococcus agalactiae	2	5.4%	Acceptable

Organisms present in specimen CC-8: *Streptococcus sp. Group B* and *Lactobacillus casei*.

Identification–Specimen CC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	14	37.8%	Not graded
Growth, referred for identification	6	16.2%	
Serratia marcescens	2	5.4%	
Serratia sp.	1	2.7%	
Presump. Proteus sp.	8	21.6%	

Organism present in specimen CC-9: *Serratia marcescens*. This is an ungraded challenge due to less than 80% referee consensus.

Identification–Specimen CC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	17	38.6%	Acceptable
Presump. Enterococcus sp.	13	29.6%	Acceptable
Growth, referred for identification	7	15.9%	Acceptable
Enterococcus sp.	1	2.3%	Acceptable
Enterococcus (Strep) faecalis	1	2.3%	Acceptable
Presump. Enterobacter sp.	1	2.3%	Acceptable

Organisms present in specimen CC-10: *Enterococcus faecalis* and *Corynebacterium sp.*

DERMATOPHYTE SCREEN

Specimen DM-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte present	20	95.2%	Acceptable
Dermatophyte absent	1	4.8%	

Organisms present in specimen DM-6: *Microsporum canis* and *Staphylococcus epidermidis*.

Specimen DM-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte absent	20	95.2%	Acceptable
Dermatophyte present	1	4.8%	

Organism present in specimen DM-7: *Staphylococcus epidermidis*.

GRAM STAIN

Specimen GS-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	68	97.1%	Acceptable
Gram negative	2	2.9%	

Gram Stain Morphology

Cocci	54	83.1%
Cocci in pairs	8	12.3%
Diplococci	2	3.1%
Cocci in chains	1	1.5%

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

Specimen GS-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	67	95.7%	Acceptable
Gram positive	3	4.3%	

Gram Stain Morphology

Rods/bacilli	57	87.7%
Cocco-bacilli	7	10.8%
Cocci in chains	1	1.5%

Organism present in specimen GS-7: *Proteus mirabilis*.

GRAM STAIN

Specimen GS-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	47	68.1%	Acceptable
Gram negative	22	31.9%	

Gram Stain Morphology

Cocci	39	61.9%
Cocci in chains	13	20.6%
Diplococci	5	7.9%
Cocco-bacilli	3	4.8%
Cocci in pairs	2	3.2%
Rods/bacilli	1	1.6%

Organism present in specimen GS-8: *Streptococcus pyogenes*.

Specimen GS-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	68	97.1%	Acceptable
Gram positive	2	2.9%	

Gram Stain Morphology

Rods/bacilli	62	95.4%
Cocco-bacilli	2	3.1%
Cocci	1	1.5%

Organism present in specimen GS-9: *Pseudomonas aeruginosa*.

Specimen GS-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	67	95.7%	Acceptable
Gram positive	3	4.3%	

Gram Stain Morphology

Diplococci	44	67.7%
Cocci	17	26.2%
Cocci in pairs	2	3.1%
Cocco-bacilli	2	3.1%

Organism present in specimen GS-10: *Neisseria gonorrhoeae*.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	26	2	24
BD ProbeTec	3	1	2
Beckman (Sanofi) ACCESS	1	-	1
bioMerieux Vitek, Mini Vidas	1	-	1
BioStar OIA	4	-	4
Gen-Probe	6	1	5
Quidel QuickVue	9	-	9
Wampole Clearview	1	-	1

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	26	25	1
BD ProbeTec	3	3	-
Beckman (Sanofi) ACCESS	1	1	-
bioMerieux Vitek, Mini Vidas	1	1	-
BioStar OIA	4	4	-
Gen-Probe	6	6	-
Quidel QuickVue	9	8	1
Wampole Clearview	1	1	-

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	23	22	1
BD ProbeTec	3	3	-
Beckman (Sanofi) ACCESS	1	1	-
BioMerieux Vitek, Mini Vidas	1	1	-
BioStar OIA	4	4	-
Gen-Probe	6	6	-
Quidel Quick Vue	6	5	1
Wampole Clearview	1	1	-

Organism present in specimen CY-8: *Chlamydia trachomatis*.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	23	2	21
BD ProbeTec	3	-	3
Beckman (Sanofi) ACCESS	1	-	1
bioMerieux Vitek, Mini Vidas	1	-	1
BioStar OIA	4	-	4
Gen-Probe	6	1	5
Quidel QuickVue	6	1	5
Wampole Clearview	1	-	1

Organism present in specimen CY-9: *Neisseria gonorrhoeae*.

Specimen CY-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	23	21	2
BD ProbeTec	3	3	-
Beckman (Sanofi) ACCESS	1	1	-
bioMerieux Vitek, Mini Vidas	1	1	-
BioStar OIA	4	4	-
Gen-Probe	6	6	-
Quidel QuickVue	6	4	2
Wampole Clearview	1	1	-

Organisms present in specimen CY-10: *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

GC (ANTIGEN DETECTION)

Specimen CY-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	12	12	-
BD ProbeTec	2	2	-
BioStar OIA	3	3	-
Gen-Probe	6	6	-

Specimen CY-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	12	-	12
BD ProbeTec	2	-	2
BioStar OIA	3	-	3
Gen-Probe	6	-	6

GC (ANTIGEN DETECTION)

Specimen CY-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	11	-	11
BD ProbeTec	2	-	2
BioStar OIA	3	-	3
Gen-Probe	5	-	5

Specimen CY-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	12	12	-
BD ProbeTec	2	2	-
BioStar OIA	3	3	-
Gen-Probe	6	6	-

Specimen CY-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	12	12	-
BD ProbeTec	2	2	-
BioStar OIA	3	3	-
Gen-Probe	6	6	-

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	29	78.4%	Not graded
Negative	8	21.6%	

Organism present in specimen VP-6: *Trichomonas vaginalis*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen VP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	36	97.3%	Acceptable
Positive	1	2.7%	

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

Specimen VP-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	37	97.4%	Acceptable
Positive	1	2.6%	

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

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	35	92.1%	Acceptable
Negative	3	7.9	

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	38	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	36	97.3%	Acceptable
Positive	1	2.7%	

Specimen VP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	36	97.3%	Acceptable
Positive	1	2.7%	

Specimen VP-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	35	92.1%	Acceptable
Negative	3	7.9%	

Specimen VP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	37	100%	Acceptable

Specimen VP-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	35	92.1%	Acceptable
Negative	3	7.9%	

AFFIRM VP III–Candida sp.**Specimen VP-6**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	37	100%	Acceptable

Specimen VP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	37	100%	Acceptable

Specimen VP-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	38	100%	Acceptable

Specimen VP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	37	97.4%	Acceptable
Negative	1	2.6	

Specimen VP-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	37	97.4%	Acceptable
Positive	1	2.6%	

RSV ANTIGEN DETECTION**Specimen V-6**

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	22	-	22
BD Directigen	11	-	11
Binax NOW – waived	7	-	7
BioStar OIA	4	-	4

Specimen V-6: Negative for RSV antigen.

Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	22	16	6
BD Directigen	11	9	2
Binax NOW – waived	7	6	1
BioStar OIA	4	3	1

Specimen V-7: Positive for RSV antigen.

RSV ANTIGEN DETECTION

Specimen V-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	22	1	21
BD Directigen	11	-	11
Binax NOW – waived	7	-	7
BioStar OIA	4	1	3

Specimen V-8: Negative for RSV antigen.

Specimen V-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	22	-	22
BD Directigen	11	-	11
Binax NOW – waived	7	-	7
BioStar OIA	4	-	4

Specimen V-9: Negative for RSV antigen.

Specimen V-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	22	22	-
BD Directigen	11	11	-
Binax NOW – waived	7	7	-
BioStar OIA	4	4	-

Specimen V-10: Positive 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	59	53	6
BioStar OIA	8	7	1
Quidel QuickVue Influenza	40	37	3
ZymeTx	3	2	1

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	59	1	58
BioStar OIA	8	-	8
Quidel QuickVue Influenza	40	1	39
ZymeTx	3	-	3

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

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	18	14	4
BioStar OIA	6	5	1
Quidel QuickVue Influenza	9	9	-
ZymeTx	2	-	2

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

Specimen V-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	18	15	3
BioStar OIA	6	5	1
Quidel QuickVue Influenza	9	9	-
ZymeTx	2	1	1

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	18	-	18
BioStar OIA	6	-	6
Quidel QuickVue Influenza	9	-	9
ZymeTx	2	-	2

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	16	14	2
BD Directigen	7	7	-
Binax NOW – waived	7	5	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	16	-	16
BD Directigen	7	-	7
Binax NOW – waived	7	-	7

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	10	-	10
BD Directigen	7	-	7
Binax NOW – waived	3	-	3

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	10	10	-
BD Directigen	7	7	-
Binax NOW – waived	3	3	-
BioStar Flu OIA A/B			

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	10	-	10
BD Directigen	7	-	7
Binax NOW – waived	3	-	3

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	12	-	12
BD Directigen	4	-	4
Binax NOW – waived	7	-	7

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	12	-	12
BD Directigen	4	-	4
Binax NOW – waived	7	-	7

Specimen V-7: Negative for Influenza B antigen.

INFLUENZA B ANTIGEN DETECTION

Specimen V-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	7	7	-
BD Directigen	4	4	-
Binax NOW – waived	3	3	-

Specimen V-8: Positive for Influenza B antigen.

Specimen V-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	7	-	7
BD Directigen	4	-	4
Binax NOW – waived	3	-	3

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	7	-	7
BD Directigen	4	-	4
Binax NOW – waived	3	-	3

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	160	159	1

Specimen L-6: Positive for *Legionella* antigen.

Specimen L-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	160	1	159

Specimen L-7: Negative for *Legionella* antigen.

LEGIONELLA ANTIGEN DETECTION

Specimen L-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	160	-	160

Specimen L-8: Negative for *Legionella* antigen.

Specimen L-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	161	161	-

Specimen L-9: Positive for *Legionella* antigen.

Specimen L-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	161	158	3

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	17	-	17
Alexon (Hycor)	1	-	1
Becton Dickinson Toxin CD	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	6	-	6
BioStar OIA	4	-	4

Specimen AG-6: Negative for *Clostridium difficile* antigen.

Specimen AG-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	17	-	17
Alexon (Hycor)	1	-	1
Becton Dickinson Toxin CD	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	6	-	6
BioStar OIA	4	-	4

Specimen AG-7: Negative for *Clostridium difficile* antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	20	20	-
Alexon (Hycor)	1	1	-
Becton Dickinson Toxin CD	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	6	6	-
BioStar OIA	6	6	-

Specimen AG-8: Positive for *Clostridium difficile* antigen.

Specimen AG-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	20	-	20
Alexon (Hycor)	1	-	1
Becton Dickinson Toxin CD	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	6	-	6
BioStar OIA	6	-	6

Specimen AG-9: Negative for *Clostridium difficile* antigen.

Specimen AG-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	20	20	-
Alexon (Hycor)	1	1	-
Becton Dickinson Toxin CD	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	6	6	-
BioStar OIA	6	6	-

Specimen AG-10: Positive for *Clostridium difficile* antigen.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	11	-	11
Fisher HealthCare Sure-Vue	3	-	3
Meridian ImmunoCard	4	-	4

Specimen AG-6: Negative for Rotavirus antigen.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	10	-	10
Fisher HealthCare Sure-Vue	3	-	3
Meridian ImmunoCard	4	-	4

Specimen AG-7: Negative for Rotavirus antigen.

Specimen AG-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	11	-	11
Fisher HealthCare Sure-Vue	3	-	3
Meridian ImmunoCard	4	-	4

Specimen AG-8: Negative for Rotavirus antigen.

Specimen AG-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	11	11	-
Fisher HealthCare Sure-Vue	3	3	-
Meridian ImmunoCard	4	4	-

Specimen AG-9: Positive for Rotavirus antigen.

Specimen AG-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	11	-	11
Fisher HealthCare Sure-Vue	3	-	3
Meridian ImmunoCard	4	-	4

Specimen AG-10: Negative for Rotavirus antigen.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen AG-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	4	1
Becton Dickinson ColorPAC	2	2	-
Biosite Triage	1	-	1
Remel Xpect	1	1	-

Specimen AG-6: Positive for *Cryptosporidium* antigen.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen AG-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	-	5
Becton Dickinson ColorPAC	2	-	2
Biosite Triage	1	-	1
Reme Xpect	1	-	1

Specimen AG-7: Negative for *Cryptosporidium* antigen.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen AG-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	10	-	10
Alexon (Hycor)	3	-	3
Becton Dickinson ColorPAC	2	-	2
Biosite Triage	1	-	1
Remel RIM Immuno	1	-	1
Remel Xpect	1	-	1

Specimen AG-6: Negative for *Giardia lamblia* antigen.

Specimen AG-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	10	9	1
Alexon (Hycor)	3	3	-
Becton Dickinson ColorPAC	2	2	-
Biosite Triage	1	-	1
Remel RIM Immuno	1	1	-
Remel Xpect	1	1	-

Specimen AG-7: Positive for *Giardia lamblia* antigen.

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	83	83	-

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

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	83	82	1

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

Specimen SP-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	83	-	83

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	83	-	83

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	83	-	83

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

PARASITOLOGY - DOMESTIC

One participant reported parasitology. The parasites that are present in each parasitology specimen are as follows:

PVA Slide

PA-6 – *Dientamoeba fragilis*

PA-7 – *Giardia lamblia*

Fecal Suspension

PA-8 – Negative for parasites

PA-9 – *Ascaris lumbricoides* eggs and *Trichuris trichiura* eggs

PA-10 – *Strongyloides stercoralis* larvae

PARASITOLOGY – INTERNATIONAL

Specimen PA-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	3	60.0%	Not acceptable
Ascaris lumbricoides eggs	1	20.0%	Not acceptable
Entamoeba coli	1	20.0%	Not acceptable

Parasite present in specimen PA-6: *Dientamoeba fragilis*.

Specimen PA-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	1	16.7%	Acceptable
Parasite egg seen but no ID	1	16.7%	
Ascaris lumbricoides eggs	1	16.7%	
Cryptosporidium sp., oocysts	1	16.7%	
Entamoeba coli	1	16.7%	
Hookworm	1	16.7%	

Parasite present in specimen PA-7: *Giardia lamblia*.

Specimen PA-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	6	46.2%	Acceptable
Parasite larva seen but no ID	3	23.1%	
Ascaris lumbricoides eggs	1	7.7%	
Entamoeba hartmanni	1	7.7%	
Strongyloides sterco. larvae	1	7.7%	
Protozoan seen but no ID	1	7.7%	

Parasite present in specimen PA-8: Negative for parasites.

Specimen PA-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	12	44.4%	Acceptable
Trichuris trichiura eggs	10	37.0%	Acceptable
Parasite egg seen but no ID	1	3.7%	Acceptable
Hookworm	2	7.4%	
Schistosoma mansoni eggs	1	3.7%	
No parasite seen	1	3.7%	

Parasites present in specimen PA-9: *Ascaris lumbricoides* eggs and *Trichuris trichiura* eggs.

Specimen PA-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides sterco. larvae	11	73.3%	Acceptable
Parasite larva seen but no ID	1	6.7%	Acceptable
No parasite seen	3	20.0%	

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

PARASITOLOGY – INTERNATIONAL

Specimen FP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	48	80.0%	Acceptable
Entamoeba histolytica	3	5.0%	
Blastocystis hominis	2	3.3%	
Chilomastix mesnili	2	3.3%	
Entamoeba coli	2	3.3%	
Endolimax nana	1	1.7%	
Iodamoeba butschlii	1	1.7%	
No parasite seen	1	1.7%	

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

Specimen FP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba coli	44	39.6%	Not graded
Entamoeba histolytica	30	27.0%	
Iodamoeba butschlii	11	9.9%	
Endolimax nana	9	8.1%	
Chilomastix mesnili	5	4.5%	
Ascaris lumbricoides eggs	2	1.8%	
Entamoeba hartmanni	2	1.8%	
Fasciola hepatica eggs	2	1.8%	
Schistosoma mansoni eggs	2	1.8%	
Balantidium coli	1	0.9%	
Blastocystis hominis	1	0.9%	
Dientamoeba fragilis	1	0.9%	
Giardia lamblia	1	0.9%	

Parasite present in specimen FP-7: *Entamoeba histolytica*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen FP-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	37	82.2%	Acceptable
Strongyloides sterco. Larvae	5	11.1%	
Blastocystis hominis	2	4.4%	
Endolimax nana	1	2.2%	

Parasite present in specimen FP-8: Negative for parasites.

Specimen FP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	44	50.0%	Acceptable
Trichuris trichiura eggs	42	47.7%	Acceptable
Entamoeba histolytica	1	1.1%	
No parasite seen	1	1.1%	

Parasites present in specimen FP-9: *Ascaris lumbricoides* eggs and *Trichuris trichiura* eggs.

PARASITOLOGY – INTERNATIONAL

Specimen FP-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Trypanosoma cruzi	34	70.8%	Acceptable
Trypanosoma sp., NOS	8	16.7%	Acceptable
Leishmania sp.	2	4.2%	
Plasmodium falciparum	2	4.2%	
Plasmodium vivax	2	4.2%	

Parasite present in specimen FP-10: *Trypanosoma cruzi*.

SUMMARY OF ISOLATES FOUND IN THE 2004 MLE-M2 CULTURE SPECIMENS

Organism	ATCC Strain
<i>Streptococcus pneumoniae</i>	6305
<i>Listeria monocytogenes</i>	7644
<i>Bacteroides fragilis</i>	25285
<i>Staphylococcus epidermidis</i>	14990
<i>Staphylococcus saprophyticus</i>	35552
<i>Staphylococcus aureus</i>	25923
<i>Pseudomonas aeruginosa</i>	27853
<i>Streptococcus sp. Group B</i>	12386
<i>Lactobacillus casei</i>	393
<i>Serratia marcescens</i>	8100
<i>Enterococcus faecalis</i>	29212
<i>Corynebacterium species</i>	49528
<i>Neisseria gonorrhoeae</i>	19424
<i>Gardnerella vaginalis</i>	14018
<i>Escherichia coli</i>	25922
<i>Streptococcus pyogenes</i>	19615
<i>Staphylococcus aureus</i>	25923
<i>Moraxella catarrhalis</i>	25238
<i>Haemophilus influenzae</i>	10211
<i>Streptococcus gordonii</i>	35557
<i>Klebsiella pneumoniae</i>	13883

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