

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

Microbiology
MLE – M3

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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-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	117	53.9%	Acceptable
Presump. Pos. Group A Strep	80	36.9%	Acceptable
Streptococcus pyogenes	13	6.0%	Acceptable
Gram positive cocci	2	0.9%	Acceptable

Organisms present in specimen TC-11: *Streptococcus pyogenes* and *Candida albicans*.

Specimen TC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	196	89.9%	Acceptable
Staphylococcus aureus	12	5.5%	Acceptable
Staphylococcus sp.	3	1.4%	Acceptable
Gram positive cocci	1	0.5%	Acceptable
No growth (sterile)	1	0.5%	Acceptable

Organism present in specimen TC-12: *Staphylococcus aureus*.

Specimen TC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	35	51.5%	Acceptable
Presump. Pos Group a Strep	30	44.1%	Acceptable

Organisms present in specimen TC-13: *Streptococcus pyogenes* and *Haemophilus influenzae*.

Specimen TC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	55	94.8%	Acceptable

Organisms present in specimen TC-14: *Neisseria mucosa* and *Staphylococcus epidermidis*.

Specimen TC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative For Group A Strep	56	96.6%	Acceptable

Organism present in specimen TC-15: *Streptococcus pneumoniae*.

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	744	737	7	563	122	14
Abbott Signify Strep A-waived	87	87	-	63	20	2
Applied Biotech Signify	9	8	1	5	2	1
Applied Biotech SureStep	4	4	-	-	3	1
Applied Biotech SureStep II	8	8	-	4	3	-
BD LINK 2	2	2	-	1	1	-
BD QTest	34	34	-	25	7	1
Beckman Coulter ICON DS	22	22	-	17	3	-
Beckman Coulter ICON Fx Strep A	6	6	-	5	1	-
Beckman Coulter ICON SC	29	29	-	16	11	-
Binax NOW Strep A	1	1	-	1	-	-
BioStar Acceava Strep A Test	81	81	-	66	9	1
BioStar Strep A MAX OIA	44	44	-	39	2	-
DE Healthcare TruView	10	10	-	9	-	-
Fisher HealthCare Sure-Vue	5	5	-	2	2	-
Fisher Sure-Vue Strep A-waived	1	1	-	-	1	-
Genzyme OSOM Ultra Strep A	38	38	-	29	4	1
Henry Schein One Step	3	3	-	1	1	-
LifeSign Status Strep A	1	1	-	1	-	-
Mainline Confirms	2	2	-	2	-	-
Mainline Confirms Strep A Dots	3	2	1	-	2	-
Polymedco Polystat Strep A (I)	30	30	-	18	10	1
Polymedco Polystat Strep A (II)	19	19	-	10	8	1
Quidel Cards QS	1	1	-	1	-	-
Quidel QuickVue Dipstick Strep	28	28	-	23	1	-
Quidel QuickVue In-Line	84	80	4	65	11	3
Quidel QuickVue+	133	133	-	126	5	-
Stanbio QuStick Strep A	1	1	-	1	-	-
Wampole Clearview	4	3	1	1	1	-
Wyntek OSOM	6	6	-	5	-	-
Wyntek OSOM Ultra Strep A	14	14	-	7	5	-

Specimen RS-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	710	1	709
Abbott Signify Strep A-waived	82	-	82
Applied Biotech Signify	7	1	6
Applied Biotech SureStep	4	-	4
Applied Biotech SureStep II	8	-	8
BD LINK 2	2	-	2
BD QTest	31	-	31
Beckman Coulter ICON DS	22	-	22
Beckman Coulter ICON Fx Strep A	6	-	6
Beckman Coulter ICON SC	28	-	28
Binax NOW Strep A	1	-	1
BioStar Acceava Strep A Test	81	-	81

STREP A ANTIGEN DETECTION

Specimen RS-12 (cont'd)

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
BioStar Strep A MAX OIA	43	-	43
DE Healthcare TruView	9	-	9
Fisher HealthCare Sure-Vue	3	-	3
Fisher Sure-Vue Strep A-waived	1	-	1
Genzyme OSOM Ultra Strep A	35	-	35
Henry Schein One Step	3	-	3
LifeSign Status Strep A	1	-	1
Mainline Confirms Strep A Dots	3	-	3
Polymedco Polystat Strep A (I)	30	-	30
Polymedco Polystat Strep A (II)	18	-	18
Quidel Cards QS	1	-	1
Quidel QuickVue Dipstick Strep	25	-	25
Quidel QuickVue In-Line	83	-	83
Quidel QuickVue+	128	-	128
Stanbio QuStick Strep A	1	-	1
Wampole Clearview	3	-	3
Wyntek OSOM	6	-	6
Wyntek OSOM Ultra Strep A	14	-	14

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	452	449	3	340	74	6
Abbott Signify Strep A-waived	44	44	-	34	8	1
Applied Biotech Signify	7	7	-	2	4	1
Applied Biotech SureStep	2	2	-	1	-	1
Applied Biotech SureStep II	6	6	-	2	4	-
BD LINK 2	1	1	-	-	1	-
BD QTest	29	29	-	19	8	-
Beckman Coulter ICON DS	11	11	-	6	3	1
Beckman Coulter ICON Fx Strep A	4	4	-	4	-	-
Beckman Coulter ICON SC	16	16	-	7	8	-
Binax NOW Strep A	1	1	-	1	-	-
BioStar Acceava Strep A Test	28	28	-	21	3	-
BioStar Strep A MAX OIA	42	42	-	38	-	-
DE Healthcare TruView	2	2	-	1	-	-
Fisher Sure-Vue Strep A-waived	1	1	-	1	-	-
Genzyme OSOM Ultra Strep A	19	19	-	14	4	-
Henry Schein One Step	2	2	-	1	-	-
Mainline Confirms Strep A Dots	3	2	1	-	2	-
Polymedco Polystat Strep A (I)	23	23	-	15	6	1
Polymedco Polystat Strep A (II)	8	8	-	-	5	3

STREP A ANTIGEN DETECTION

Specimen RS-13 (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	-	9	-	-
Quidel QuickVue In-Line	28	26	2	23	2	-
Quidel QuickVue+	125	125	-	114	9	-
Stanbio QuStick Strep A	1	1	-	1	-	-
Wampole Clearview	1	1	-	-	-	-
Wyntek OSOM	5	5	-	5	-	-
Wyntek OSOM Ultra Strep A	9	9	-	4	3	-

Specimen RS-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	381	2	379
Abbott Signify Strep A-waived	33	1	32
Applied Biotech Signify	7	-	7
Applied Biotech SureStep	2	-	2
Applied Biotech SureStep II	6	-	6
BD LINK 2	1	-	1
BD QTest	24	-	24
Beckman Coulter ICON DS	11	-	11
Beckman Coulter ICON Fx Strep A	4	-	4
Beckman Coulter ICON SC	12	-	12
Binax NOW Strep A	1	-	1
BioStar Acceava Strep A Test	23	-	23
BioStar Strep A MAX OIA	39	-	39
DE Healthcare TruView	2	-	2
Fisher Sure-Vue Strep A- waived	1	-	1
Genzyme OSOM Ultra Strep A	14	-	14
Henry Schein One Step	2	-	2
Mainline Confirms Strep A Dots	3	-	3
Polymedco Polystat Strep A (I)	21	-	21
Polymedco Polystat Strep A (II)	6	-	6
Quidel Cards QS	1	-	1
Quidel QuickVue Dipstick Strep	6	-	6
Quidel QuickVue In-Line	27	-	27
Quidel QuickVue+	109	1	108
Stanbio QuStick Strep A	1	-	1
Wampole Clearview	1	-	1
Wyntek OSOM	4	-	4
Wyntek OSOM Ultra Strep A	5	-	5

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	382	379	3	279	70	9
Abbott Signify Strep A-waived	33	33	-	23	8	1
Applied Biotech Signify	7	7	-	3	3	1
Applied Biotech SureStep	2	2	-	-	1	1
Applied Biotech SureStep II	6	6	-	3	2	1
BD LINK 2	1	1	-	-	1	-
BD QTest	24	24	-	12	10	-
Beckman Coulter ICON DS	11	11	-	5	5	-
Beckman Coulter ICON Fx Strep A	4	4	-	4	-	-
Beckman Coulter ICON SC	12	12	-	8	3	1
Binax NOW Strep A	1	1	-	1	-	-
BioStar Acceava Strep A Test	23	22	1	17	2	-
BioStar Strep A MAX OIA	40	40	-	33	2	-
DE Healthcare TruView	2	2	-	1	-	-
Fisher Sure-Vue Strep A-waived	1	1	-	1	-	-
Genzyme OSOM Ultra Strep A	14	14	-	12	1	-
Henry Schein One Step	2	2	-	-	1	-
Mainline Confirms Strep A Dots	3	2	1	-	2	-
Polymedco Polystat Strep A (I)	21	21	-	16	4	1
Polymedco Polystat Strep A (II)	6	6	-	2	4	-
Quidel Cards QS	1	1	-	1	-	-
Quidel QuickVue Dipstick Strep	6	6	-	6	-	-
Quidel QuickVue In-Line	27	26	1	19	4	1
Quidel QuickVue+	109	109	-	93	15	-
Stanbio QuStick Strep A	1	1	-	1	-	-
Wampole Clearview	1	1	-	-	-	-
Wyntek OSOM	4	4	-	4	-	-
Wyntek OSOM Ultra Strep A	5	5	-	3	1	-

GENERAL BACTERIOLOGY

Specimen UC-11 – Urine Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Escherichia coli	4	80.0%	Acceptable
Gram negative bacilli	1	20.0%	Acceptable

Gram Stain

Gram negative	3	100%	Acceptable
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Gram Stain Morphology

Rods/bacilli	3	100%
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Organism present in specimen UC-11: *Escherichia coli*.

GENERAL BACTERIOLOGY

Specimen TC-11 – Throat Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Streptococcus pyogenes	3	60.0%	Acceptable
Presump. Pos. Group A Strep	2	40.0%	Acceptable

Organisms present in specimen TC-11: *Streptococcus pyogenes* and *Candida albicans*.

Specimen BA-7 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Enterococcus (Strep) faecalis	3	75.0%	Acceptable
Enterococcus sp.	1	25.0%	Acceptable

Organism present in specimen BA-7: *Enterococcus faecalis*.

Specimen BA-8 – Ear Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pseudomonas aeruginosa	5	100%	Acceptable

Organisms present in specimen BA-8: *Pseudomonas aeruginosa* and *Staphylococcus epidermidis*.

Specimen BA-9 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus aureus	5	100%	Acceptable

Organism present in specimen BA-9: *Staphylococcus aureus*.

URINE CULTURE

Specimen UC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Escherichia coli	71	43.6%	Acceptable
Presump. Gram negative	29	17.8%	Acceptable
Growth, referred for identification	28	17.2%	Acceptable
Presump. Escherichia coli	18	11.0%	Acceptable
Gram negative bacilli	13	8.0%	Acceptable

Gram Stain

Gram negative	65	100%	Acceptable
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Gram Stain Morphology

Rods/bacilli	62	100%	
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Organism present in specimen UC-11: *Escherichia coli*.

URINE CULTURE

Specimen UC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Proteus mirabilis	55	32.7%	Acceptable
Presump. Gram negative	37	22.0%	Acceptable
Growth, referred for identification	29	17.3%	Acceptable
Gram negative bacilli	21	12.5%	Acceptable
Proteus sp.	9	5.4%	Acceptable
Presump. Proteus sp.	9	5.4%	Acceptable
Corynebacterium sp.	2	1.2%	Acceptable
Presump. Gram positive	2	1.2%	Acceptable

Organisms present in specimen UC-12: *Proteus mirabilis* and *Corynebacterium sp.*

Specimen UC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	34	32.1%	Acceptable
Presump. Gram positive	26	24.5%	Acceptable
Enterococcus sp.	14	13.2%	Acceptable
Gram positive cocci	9	8.5%	Acceptable
Enterococcus (Strep) faecium	3	2.8%	Acceptable
Staph – coagulase neg.	3	2.8%	Acceptable
Presump. Enterococcus sp.	3	2.8%	Acceptable
Staphylococcus epidermidis	2	1.9%	Acceptable
Strep. Grp. D – enterococcus	2	1.9%	Acceptable
Staphylococcus sp.	1	0.9%	Acceptable
Contaminated specimen	7	6.6%	

Organisms present in specimen UC-13: *Enterococcus faecium* and *Staphylococcus epidermidis*.

Specimen UC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	21	37.5%	Acceptable
Presump. Gram positive	17	30.4%	Acceptable
Staph – coagulase neg.	5	8.9%	Acceptable
Staphylococcus saprophyticus	5	8.9%	Acceptable
Staphylococcus sp.	2	3.6%	Acceptable
Gram positive cocci	2	3.6%	Acceptable
Presump. Staphylococcus sp.	2	3.6%	Acceptable

Organism present in specimen UC-14: *Staphylococcus saprophyticus*.

URINE CULTURE

Specimen UC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	25	44.6%	Acceptable
Growth, referred for identification	13	23.2%	Acceptable
Serratia marcescens	8	14.3%	Acceptable
Serratia sp.	3	5.4%	Acceptable
Gram negative bacilli	2	3.6%	Acceptable

Organism present in specimen UC-15: *Serratia marcescens*.

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Specimen UC-11, CC-11 (SUS-11)

<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	2	2	-	-	3	3	-	-	100%
Amoxicillin/Clavulanate	12	12	-	-	9	9	-	-	100%
Ampicillin	96	86	8	2	17	17	-	-	91.8%
Ampicillin/Sulbactam	-	-	-	-	4	4	-	-	100%
Aztreonam	-	-	-	-	2	2	-	-	100%
Carbenicillin	30	29	-	1	3	3	-	-	97.9%
Cefaclor	4	4	-	-	-	-	-	-	100%
Cefamandole	-	-	-	-	1	1	-	-	100%
Cefazolin	10	10	-	-	6	6	-	-	95.5%
Cefixime	4	4	-	-	-	-	-	-	100%
Cefotaxime	1	1	-	-	-	-	-	-	100%
Cefotetan	-	-	-	-	1	1	-	-	100%
Ceftazidime	2	2	-	-	1	1	-	-	100%
Ceftriaxone	7	7	-	-	7	7	-	-	100%
Cefuroxime	2	2	-	-	4	4	-	-	100%
Cephalexin	-	-	-	-	1	1	-	-	100%
Cephalothin	90	68	17	5	16	15	-	1	Not graded ¹
Chloramphenicol	1	1	-	-	-	-	-	-	100%
Cinoxacin	3	3	-	-	-	-	-	-	100%
Ciprofloxacin	84	83	1	-	20	20	-	-	99.3%
Doxycycline	8	8	-	-	1	1	-	-	100%
Fosfomycin	1	1	-	-	-	-	-	-	100%
Gatifloxacin	-	-	-	-	1	1	-	-	100%
Gentamicin	47	47	-	-	8	8	-	-	100%
Imipenem	1	1	-	-	4	4	-	-	100%
Levofloxacin	14	14	-	-	11	11	-	-	100%
Lomefloxacin	-	-	-	-	3	3	-	-	100%
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-11, CC-11 (SUS-11) (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>	
Mezlocillin	1	1	-	-	1	1	-	-	100%
Nalidixic Acid	2	2	-	-	1	1	-	-	100%
Nitrofurantoin	96	94	-	2	17	17	-	-	98.7%
Norfloxacin	31	31	-	-	6	6	-	-	98.0%
Ofloxacin	26	25	1	-	5	5	-	-	97.1%
Oxacillin	1	-	-	1	-	-	-	-	100%
Penicillin-G	1	-	-	1	-	-	-	-	100%
Piperacillin	-	-	-	-	5	5	-	-	100%
Peperacillin/Tazoactam	-	-	-	-	2	2	-	-	100%
Sulfamethoxazole	5	4	1	-	-	-	-	-	85.7
Sulfisoxazole	8	6	-	2	1	-	-	1	81.3
Sulfonamide	1	1	-	-	1	1	-	-	100%
Tetracycline	52	51	1	-	12	12	-	-	98.9%
Ticarillin	-	-	-	-	1	1	-	-	100%
Ticarillin/Clavulanate	-	-	-	-	1	1	-	-	100%
Tobramycin	4	4	-	-	3	3	-	-	100%
Trimethoprim	8	8	-	-	5	5	-	-	100%
Trimethoprim/Sulfamethoxazole	97	97	-	-	18	18	-	-	100%

Organism present in specimen UC-11, CC-11 (SUS-11): *Escherichia coli*.

GC CULTURE

Specimen GC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Neisseria gonorrhoeae	26	49.1%	Acceptable
Presump. GC, referred for ID	26	49.1%	Acceptable

Beta-lactamase Testing

Negative	6	85.7%
Positive	1	14.3%

Gram Stain

Gram negative	38	100%	Acceptable
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Gram Stain Morphology

Diplococci	38	100%
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Organism present in specimen GC-11: *Neisseria gonorrhoeae*.

GC CULTURE

Specimen GC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	19	82.6%	Acceptable
No growth (sterile)	2	8.7%	Acceptable
Gram positive cocci	1	4.4%	Acceptable
Growth select media, referred	1	4.4%	Acceptable

Organisms present in specimen GC-12: *Enterococcus faecalis* and *Lactobacillus* sp.

Specimen GC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	14	66.7%	Acceptable
Neisseria gonorrhoeae	5	23.8%	Acceptable

Beta-lactamase Testing

Negative	3	100%
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Organisms present in specimen GC-13: *Neisseria gonorrhoeae* and *Staphylococcus epidermidis*.

Specimen GC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	11	52.4%	Acceptable
No growth (sterile)	10	47.6%	Acceptable

Organism present in specimen GC-14: *Staphylococcus epidermidis*.

Specimen GC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	15	71.4%	Acceptable
Neisseria gonorrhoeae	5	23.8%	Acceptable

Beta-lactamase Testing

Negative	3	100%
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Organism present in specimen GC-15: *Neisseria gonorrhoeae*.

COLONY COUNT

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	114	2	21	73	18
Bactercult	2	-	-	-	2
Bacti-Star	1	-	-	-	1
Bulls Eye	7	-	-	6	1
Calibrated Loop	31	-	2	21	8
HealthLink	1	-	-	1	-
Henry Schein One Step	1	-	-	1	-
Uri-Check	15	-	4	10	1
Uri-Three	2	-	-	2	-
Uricult	49	2	14	28	5

This is an ungraded challenge due to lack of 80% participant consensus.

Identification—Specimen CC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Escherichia coli	26	50.0%	Acceptable
Presump. Gram negative	14	26.9%	Acceptable
Growth, referred for identification	6	11.5%	Acceptable
Escherichia coli	3	5.8%	Acceptable

Gram Stain

Gram negative	8	88.9%	Acceptable
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Gram Stain Morphology

Rods/bacilli	9	90.0%
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Organism present in specimen CC-11: *Escherichia coli*.

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	114	1	-	7	106
Bactercult	2	-	-	-	2
Bacti-Star	1	-	-	-	1
Bulls Eye	7	-	-	1	6
Calibrated Loop	31	-	-	-	31
HealthLink	1	-	-	-	1
Henry Schein One Step	1	-	-	-	1
Uri-Check	15	-	-	-	15
Uri-Three	2	-	-	-	2
Uricult	49	-	-	6	43

COLONY COUNT

Identification–Specimen CC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Proteus sp.	21	38.2%	Acceptable
Presump. Gram negative	19	34.6%	Acceptable
Growth, referred for identification	7	12.7%	Acceptable
Presump. Gram positive	4	7.3%	Acceptable
Proteus mirabilis	2	3.6%	Acceptable
Proteus sp.	1	1.8%	Acceptable

Organisms present in specimen CC-12: *Proteus mirabilis* and *Corynebacterium sp.*

Identification–Specimen CC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	18	39.1%	Acceptable
Presump. Enterococcus sp.	9	19.6%	Acceptable
Presump. Staphylococcus sp.	5	10.9%	Acceptable
Growth, referred for identificaton	4	8.7%	Acceptable
Presumptive Streptococcus sp.	2	4.4%	Acceptable
Staphylococcus epidermidis	1	2.2%	Acceptable
Streptococcus alpha-hemolytic	1	2.2%	Acceptable
Strep. Grp. D – enterococcus	1	2.2%	Acceptable

Organisms present in specimen CC-13: *Enterococcus faecium* and *Staphylococcus epidermidis*.

Identification–Specimen CC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Staphylococcus sp.	12	32.4%	Acceptable
Presump. Gram positive	11	29.7%	Acceptable
Growth, referred for identification	3	8.1%	Acceptable
Staphylococcus sp.	1	2.7%	Acceptable
Staphylococcus saprophyticus	1	2.7%	Acceptable
Bacturcult Group II	1	2.7%	Acceptable
Presump. Enterococcus sp.	5	13.5%	

Organism present in specimen CC-14: *Staphylococcus saprophyticus*.

Identification–Specimen CC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Klebsiella sp.	17	46.0%	Acceptable
Presump. Gram negative	12	32.4%	Acceptable
Growth, referred for identification	4	10.8%	Acceptable
Klebsiella pneumoniae	2	5.4%	Acceptable

Organism present in specimen CC-15: *Klebsiella pneumoniae*.

DERMATOPHYTE SCREEN

Specimen DM-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte present	14	63.6%	Not graded
Dermatophyte absent	8	36.4%	

Organism present in specimen DM-11: *Epidermophyton floccosum*. This is an ungraded challenge due to lack of 80% participant consensus.

Specimen DM-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte absent	19	86.4%	Acceptable

Organisms present in specimen DM-12: *Penicillium chrysogenum* and *Streptococcus gordonii*.

GRAM STAIN

Specimen GS-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	64	91.4%	Acceptable
Gram positive	6	8.6%	

Gram Stain Morphology

Rods/bacilli	66	100%
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Organism present in specimen GS-11: *Escherichia coli*.

Specimen GS-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	66	94.3%	Acceptable
Gram negative	4	5.7%	

Gram Stain Morphology

Cocci	49	75.4%
Cocci in pairs	14	21.5%
Cocci in chains	2	3.1%

Organism present in specimen GS-12: *Staphylococcus aureus*.

GRAM STAIN

Specimen GS-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	66	94.3%	Acceptable
Gram positive	4	5.7%	

Gram Stain Morphology

Rods/bacilli	26	40.0%
Cocco-bacilli	25	38.5%
Diplococci	11	16.9%
Cocci in pairs	2	3.1%
Cocci	1	1.5%

Organism present in specimen GS-13: *Klebsiella pneumoniae*.

Specimen GS-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	62	88.6%	Acceptable
Gram negative	8	11.4%	

Gram Stain Morphology

Cocci in chains	58	89.2%
Cocci	5	7.7%
Cocci in pairs	1	1.5%
Diplococci	1	1.5%

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

Specimen GS-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	64	91.4%	Acceptable
Gram negative	6	8.6%	

Gram Stain Morphology

Cocci	50	76.9%
Cocci in pairs	8	12.3%
Diplococci	6	9.2%
Cocci in chains	1	1.5%

Organism present in specimen GS-15: *Staphylococcus saprophyticus*.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	24	24	-
BD ProbeTec	3	3	-
Beckman (Sanofi) ACCESS	1	1	-
bioMerieux Vitek, Mini Vidas	1	1	-
BioStar OIA	5	5	-
Gen-Probe	3	3	-
Quidel QuickVue	10	10	-
Wampole Clearview	1	1	-

Organism present in specimen CY-11: *Chlamydia trachomatis*.

Specimen CY-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	24	1	23
BD ProbeTec	3	1	2
Beckman (Sanofi) ACCESS	1	-	1
bioMerieux Vitek, Mini Vidas	1	-	1
BioStar OIA	5	-	5
Gen-Probe	3	-	3
Quidel QuickVue	10	-	10
Wampole Clearview	1	-	1

Organism present in specimen CY-12: *Neisseria gonorrhoeae*.

Specimen CY-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	20	-	20
BD ProbeTec	3	-	3
Beckman (Sanofi) ACCESS	1	-	1
BioMerieux Vitek, Mini Vidas	1	-	1
BioStar OIA	5	-	5
Gen-Probe	3	-	3
Quidel Quick Vue	6	-	6
Wampole Clearview	1	-	1

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	20	19	1
BD ProbeTec	3	2	1
Beckman (Sanofi) ACCESS	1	1	-
bioMerieux Vitek, Mini Vidas	1	1	-
BioStar OIA	5	5	-
Gen-Probe	3	3	-
Quidel QuickVue	6	6	-
Wampole Clearview	1	1	-

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	20	-	20
BD ProbeTec	3	-	3
Beckman (Sanofi) ACCESS	1	-	1
bioMerieux Vitek, Mini Vidas	1	-	1
BioStar OIA	5	-	5
Gen-Probe	3	-	3
Quidel QuickVue	6	-	6
Wampole Clearview	1	-	1

Organism present in specimen CY-15: *Negative (sterile)*.

GC (ANTIGEN DETECTION)

Specimen CY-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	10	-	10
BD ProbeTec	3	-	3
BioStar OIA	4	-	4
Gen-Probe	3	-	3

Specimen CY-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	10	9	1
BD ProbeTec	3	2	1
BioStar OIA	4	4	-
Gen-Probe	3	3	-

GC (ANTIGEN DETECTION)

Specimen CY-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	10	10	-
BD ProbeTec	3	3	-
BioStar OIA	4	4	-
Gen-Probe	3	3	-

Specimen CY-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	10	1	9
BD ProbeTec	3	1	2
BioStar OIA	4	-	4
Gen-Probe	3	-	3

Specimen CY-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	10	-	10
BD ProbeTec	3	-	3
BioStar OIA	4	-	4
Gen-Probe	3	-	3

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	35	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>
Positive	24	68.6%	Not graded
Negative	11	31.4%	

Organisms present in specimen VP-12: *Trichomonas vaginalis* and *Gardnerella vaginalis*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen VP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	34	97.1%	Acceptable
Positive	1	2.9%	

Organism present in specimen VP-13: *Candida albicans*.

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	35	100%	Acceptable

Organism present in specimen VP-14: *Gardnerella vaginalis*.

Specimen VP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	32	88.9%	Acceptable
Negative	4	11.1%	

Organism present in specimen VP-15: *Trichomonas vaginalis*.

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	31	86.1%	Acceptable
Negative	5	13.9%	

Specimen VP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	32	88.9%	Acceptable
Negative	4	11.1%	

Specimen VP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	34	97.1%	Acceptable
Positive	1	2.9%	

Specimen VP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	33	91.7%	Acceptable
Negative	3	8.3%	

Specimen VP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	35	100%	Acceptable

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

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	35	100%	Acceptable

Specimen VP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	35	100%	Acceptable

Specimen VP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	36	100%	Acceptable

Specimen VP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	35	100%	Acceptable

Specimen VP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	34	97.1%	Acceptable
Positive	1	2.9%	

RSV ANTIGEN DETECTION**Specimen V-11**

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	35	34	1
Abbott TESTPACK	1	1	-
BD Directigen	11	11	-
Binax NOW – waived	8	8	-
BioStar OIA	13	13	-

Specimen V-11: Positive for RSV antigen.

Specimen V-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	35	2	33
Abbott TESTPACK	1	-	1
BD Directigen	11	1	10
Binax NOW – waived	8	-	8
BioStar OIA	13	-	13

Specimen V-12: Negative for RSV antigen.

RSV ANTIGEN DETECTION

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	35	2	33
Abbott TESTPACK	1	-	1
BD Directigen	11	-	11
Binax NOW – waived	8	-	8
BioStar OIA	13	1	12

Specimen V-13: Negative for RSV antigen.

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	35	33	2
Abbott TESTPACK	1	1	-
BD Directigen	11	11	-
Binax NOW – waived	8	8	-
BioStar OIA	13	12	1

Specimen V-14: Positive for RSV antigen.

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	35	1	34
Abbott TESTPACK	1	-	1
BD Directigen	11	-	11
Binax NOW – waived	8	-	8
BioStar OIA	13	-	13

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	4	91
BD Directigen	1	1	-
BioStar OIA	22	2	20
Quidel QuickVue Influenza	63	1	62
ZymeTx	3	-	3

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	94	77	17
BD Directigen	1	1	-
BioStar OIA	22	10	12
Quidel QuickVue Influenza	63	61	2
ZymeTx	3	-	3

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	51	47	4
BioStar OIA	19	17	2
Quidel QuickVue Influenza	27	27	-
ZymeTx	2	-	2

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

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	51	-	51
BioStar OIA	19	-	19
Quidel QuickVue Influenza	27	-	27
ZymeTx	2	-	2

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	51	46	5
BioStar OIA	19	16	3
Quidel QuickVue Influenza	27	27	-
ZymeTx	2	-	2

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	34	-	34
BD Directigen	9	-	9
Binax NOW – waived	10	-	10
BioStar Flu OIA A/B	5	-	5
Quidel QuickVue Influenza A+B	7	-	7

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	34	5	29
BD Directigen	9	-	9
Binax NOW – waived	10	-	10
BioStar Flu OIA A/B	4	-	4
Quidel QuickVue Influenza A+B	7	4	3

Specimen V-12: Negative for Influenza A antigen.

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	27	26	1
BD Directigen	9	9	-
Binax NOW – waived	7	7	-
BioStar Flu OIA A/B	5	4	1
Quidel QuickVue Influenza A+B	4	4	-

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	27	1	26
BD Directigen	9	-	9
Binax NOW – waived	7	-	7
BioStar Flu OIA A/B	5	1	4
Quidel QuickVue Influenza A+B	4	-	4

Specimen V-14: Negative for Influenza A antigen.

INFLUENZA A ANTIGEN DETECTION

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	26	2	24
BD Directigen	9	-	9
Binax NOW – waived	7	-	7
BioStar Flu OIA A/B	4	-	4
Quidel QuickVue Influenza A+B	4	2	2

Specimen V-15: Negative 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	27	1	26
BD Directigen	7	-	7
Binax NOW – waived	10	1	9
BioStar Flu OIA A/B	5	-	5
Quidel QuickVue Influenza A+B	3	-	3

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	28	26	2
BD Directigen	7	7	-
Binax NOW – waived	10	9	1
BioStar Flu OIA A/B	5	4	1
Quidel QuickVue Influenza A+B	3	3	-

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	23	-	23
BD Directigen	7	-	7
Binax NOW – waived	7	-	7
BioStar Flu OIA A/B	5	-	5
Quidel QuickVue Influenza A+B	2	-	2

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	23	-	23
BD Directigen	7	-	7
Binax NOW – waived	7	-	7
BioStar Flu OIA A/B	5	-	5
Quidel QuickVue Influenza A+B	2	-	2

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	23	21	2
BD Directigen	7	6	1
Binax NOW – waived	7	7	-
BioStar Flu OIA A/B	5	4	1
Quidel QuickVue Influenza A+B	2	2	-

Specimen V-15: Positive for Influenza B antigen.

LEGIONELLA ANTIGEN DETECTION

Specimen L-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	166	163	3

Specimen L-11: Positive for *Legionella* antigen.

Specimen L-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	166	165	1

Specimen L-12: Positive for *Legionella* antigen.

Specimen L-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	167	167	-

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	166	-	166

Specimen L-14: Negative for *Legionella* antigen.

Specimen L-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	166	-	166

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	20	-	20
Alexon (Hycor)	1	-	1
Becton Dickinson Toxin CD	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	6	-	6
BioStar OIA	7	-	7

Specimen AG-11: Negative for *Clostridium difficile* antigen.

Specimen AG-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	21	20	1
Alexon (Hycor)	1	1	-
Becton Dickinson Toxin CD	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	6	6	-
BioStar OIA	8	7	1

Specimen AG-12: Positive for *Clostridium difficile* antigen.

Specimen AG-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	21	-	21
Alexon (Hycor)	1	-	1
Becton Dickinson Toxin CD	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	6	-	6
BioStar OIA	8	-	8

Specimen AG-13: Negative for *Clostridium difficile* antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	21	20	1
Alexon (Hycor)	1	1	-
Becton Dickinson Toxin CD	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	6	6	-
BioStar OIA	8	7	1

Specimen AG-14: Positive for *Clostridium difficile* antigen.

Specimen AG-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	21	-	21
Alexon (Hycor)	1	-	1
Becton Dickinson Toxin CD	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	6	-	6
BioStar OIA	8	-	8

Specimen AG-15: Negative for *Clostridium difficile* antigen.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	10	-	10
Fisher HealthCare Sure-Vue	2	-	2
Meridian ImmunoCard	5	-	5

Specimen AG-11: Negative for Rotavirus antigen.

Specimen AG-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	12	-	12
Fisher HealthCare Sure-Vue	2	-	2
Meridian ImmunoCard	6	-	6

Specimen AG-12: Negative for Rotavirus antigen.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	12	12	-
Fisher HealthCare Sure-Vue	2	2	-
Meridian ImmunoCard	6	6	-

Specimen AG-13: Positive for Rotavirus antigen.

Specimen AG-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	12	-	12
Fisher HealthCare Sure-Vue	2	-	2
Meridian ImmunoCard	6	-	6

Specimen AG-14: Negative for Rotavirus antigen.

Specimen AG-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	12	12	-
Fisher HealthCare Sure-Vue	2	2	-
Meridian ImmunoCard	6	6	-

Specimen AG-15: Positive for Rotavirus antigen.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen AG-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	4	4	-
Meridian ImmunoCard STAT!	1	1	-
Remel Xpect	2	2	-

Specimen AG-11: Positive for *Cryptosporidium* antigen.

Specimen AG-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	4	-	4
Meridian ImmunoCard STAT!	1	-	1
Reme Xpect	2	-	2

Specimen AG-12: Negative for *Cryptosporidium* antigen.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen AG-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	9	9	-
Alexon (Hycor)	4	4	-
Meridian ImmunoCard STAT!	1	1	-
Remel RIM Immuno	1	1	-
Remel Xpect	2	2	-

Specimen AG-11: Positive for *Giardia lamblia* antigen.

Specimen AG-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	9	-	9
Alexon (Hycor)	4	-	4
Meridian ImmunoCard STAT!	1	-	1
Remel RIM Immuno	1	-	1
Remel Xpect	2	-	2

Specimen AG-12: Negative for *Giardia lamblia* antigen.

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	95	95	-

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

Specimen SP-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	95	-	95

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	94	94	-

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	94	94	-

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

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	94	-	94

Specimen SP-15: 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-11 – Entamoeba coli

PA-12 – Negative for parasites

Fecal Suspension

PA-13 – Ascaris lumbricoides eggs

PA-14 – Hookworm

PA-15 – Plasmodium falciparum

PARASITOLOGY – INTERNATIONAL (PA Specimens)

Specimen PA-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba histolytica	1	50.0%	Not acceptable
Enterobius vermicularis eggs	1	50.0%	Not acceptable

Parasite present in specimen PA-11: *Escherichia coli*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	1	100%	Not acceptable

Parasite present in specimen PA-12: Negative for parasites. This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	2	15.4%	Acceptable
Trichuris trichiura eggs	4	30.8%	Not acceptable
No parasite seen	3	23.1%	Not acceptable
Hookworm	2	15.4%	Not acceptable
Hymenolepis diminuta eggs	1	7.7%	Not acceptable
Hymenolepis nana eggs	1	7.7%	Not acceptable

Parasite present in specimen PA-13: *Ascaris lumbricoides* eggs. This is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY – INTERNATIONAL (PA Specimens)

Specimen PA-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	3	33.3%	Acceptable
No parasite seen	3	33.3%	Not acceptable
Ascaris lumbricoides eggs	2	22.2%	Not acceptable
Strongyloides sterco. Larvae	1	11.1%	Not acceptable

Parasite present in specimen PA-14: *Hookworm*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium falciparum	3	75.0%	Acceptable
Plasmodium vivax	1	25.0%	Not acceptable

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

PARASITOLOGY – INTERNATIONAL (FP Specimens)

Specimen FP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Balantidium coli	1	1.8%	Acceptable
Other parasite seen but no ID	1	1.8%	Acceptable
No parasite seen	26	47.3%	
Giardia lamblia	17	30.9%	
Endolimax nana	3	5.5%	
Blastocystis hominis	2	3.6%	
Fasciola hepatica eggs	2	3.6%	
Strongyloides sterco. larvae	2	3.6%	
Taenia sp. Eggs	1	1.8%	

Parasite present in specimen FP-11: *Balantidium coli*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen FP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. Eggs	34	65.4%	Acceptable
No parasite seen	14	26.9%	
Hymenolepis nana eggs	3	5.8%	
Hymenolepis diminuta eggs	1	1.9%	

Parasite present in specimen FP-12: *Taenia sp. eggs*. This is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY – INTERNATIONAL (FP Specimens)

Specimen FP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	37	54.4%	Acceptable
Parasite egg seen but no ID	1	1.5%	Acceptable
Trichuris trichiura eggs	21	30.9%	
No parasite seen	6	8.8%	
Entamoeba histolytica	1	1.5%	
Hymenolepis diminuta eggs	1	1.5%	
Hymenolepis nana eggs	1	1.5%	

Parasite present in specimen FP-13: *Ascaris lumbricoides* eggs. This is an ungraded challenge due to less than 80% participant consensus.

Specimen FP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	30	49.2%	Acceptable
Parasite egg seen but no ID	11	18.0%	Acceptable
Entamoeba coli	7	11.5%	
Blastocystis hominis	3	4.9%	
Trichostrongylus sp. eggs	3	4.9%	
Taenia sp. eggs	2	3.3%	
Entamoeba histolytica	1	1.6%	
Enterobius vermicularis eggs	1	1.6%	
Giardia lamblia	1	1.6%	
Strongyloides sterco. larvae	1	1.6%	
Trichuris trichiura eggs	1	1.6%	

Parasite present in specimen FP-14: *Hookworm* eggs. This is an ungraded challenge due to less than 80% participant consensus.

Specimen FP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium falciparum	36	72.0%	Acceptable
Plasmodium sp. NOS	3	6.0%	Acceptable
Plasmodium vivax	9	18.0%	
Babesia sp.	1	2.0%	
Plasmodium sp., not falciparum	1	2.0%	

Parasite present in specimen FP-15: *Plasmodium falciparum*.

ANTIMICROBIAL SUSCEPTIBILITY TESTING (FOR INTERNATIONAL LABS)

Specimen UC-11

<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	3	3	-	-	8	8	-	-	100%
Amoxicillin/Clavulanate	-	-	-	-	7	7	-	-	100%
Ampicillin	1	1	-	-	11	10	-	1	90.0%
Ampicillin/Sulbactam	2	2	-	-	8	8	-	-	100%
Aztreonam	2	2	-	-	4	4	-	-	100%
Carbenicillin	-	-	-	-	2	2	-	-	100%
Cefazolin	1	1	-	-	13	12	-	1	88.2%
Cefixime	1	1	-	-	-	-	-	-	100%
Cefoperazone	1	1	-	-	-	-	-	-	100%
Cefoperazone/Sulbactam	1	1	-	-	-	-	-	-	100%
Cefotaxime	1	1	-	-	3	3	-	-	100%
Cefotetan	-	-	-	-	1	1	-	-	100%
Cefoxitin	-	-	-	-	1	1	-	-	100%
Ceftazidime	1	1	-	-	3	3	-	-	100%
Ceftizoxime	-	-	-	-	1	1	-	-	100%
Ceftriaxone	-	-	-	-	6	6	-	-	100%
Cefuroxime	1	1	-	-	10	10	-	-	100%
Cephalothin	3	2	1	-	6	6	-	-	85.7%
Ciprofloxacin	4	4	-	-	12	12	-	-	100%
Gentamicin	3	3	-	-	13	13	-	-	100%
Imipenem	2	2	-	-	6	5	-	1	93.3%
Levofloxacin	1	1	-	-	4	4	-	-	100%
Meropenem	1	1	-	-	4	4	-	-	100%
Minocycline	-	-	-	-	1	1	-	-	100%
Nalidixic Acid	3	3	-	-	4	4	-	-	100%
Nitrofurantoin	5	5	-	-	10	9	-	1	96.0%
Norfloxacin	3	3	-	-	9	9	-	-	100%
Ofloxacin	3	3	-	-	2	2	-	-	100%
Piperacillin	-	-	-	-	5	4	-	1	87.5%
Piperacillin/Tazobactam	-	-	-	-	5	5	-	-	100%
Tetracycline	-	-	-	-	3	3	-	-	100%
Ticarcillin/Clavulanate	-	-	-	-	4	4	-	-	100%
Tobramycin	-	-	-	-	3	3	-	-	100%
Trimethoprim/Sulfamethoxazole	4	4	-	-	13	13	-	-	100%

SUMMARY OF ISOLATES FOUND IN THE 2004 MLE-M3 CULTURE SPECIMENS

Organism	ATCC Strain
<i>Enterococcus faecalis</i>	29212
<i>Pseudomonas aeruginosa</i>	27853
<i>Staphylococcus epidermidis</i>	14990
<i>Staphylococcus aureus</i>	25923
<i>Escherichia coli</i>	25922
<i>Proteus mirabilis</i>	12453
<i>Corynebacterium species</i>	49528
<i>Enterococcus faecium</i>	49032
<i>Staphylococcus saprophyticus</i>	35552
<i>Klebsiella pneumoniae</i>	13883
<i>Neisseria gonorrhoeae</i>	19424
<i>Lactobacillus species</i>	393
<i>Streptococcus pyogenes</i>	19615
<i>Candida albicans</i>	14053
<i>Haemophilus influenzae</i>	10211
<i>Neisseria mucosa</i>	19695
<i>Streptococcus pneumoniae</i>	6305
<i>Serratia marcescens</i>	8100

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