MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

Microbiology
MLE – M1

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2005 Evaluation Criteria

The evaluation criteria used in the 2005 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-1

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	99	47.1%	Acceptable
Presump. Pos. Group A Strep	82	39.1%	Acceptable
Streptococcus pyogenes	21	10.0%	Acceptable
Streptococcus alpha-hemolytic	1	0.5%	Acceptable
Negative for Group A Strep	5	2.4%	

Organisms present in specimens TC-1: *Streptococcus Pyogenes* and *Streptococcus gordonii.*

Specimen TC-2

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	188	90.0%	Acceptable
Streptococcus pneumoniae	15	7.2%	Acceptable
Streptococcus alpha-hemolytic	1	0.5%	Acceptable
Gram positive cocci	1	0.5%	Acceptable

Organism present in specimen TC-2: *Streptococcus pneumoniae.*

Specimen TC-3

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	63	92.7%	Acceptable
No growth (sterile)	4	5.9%	Acceptable

Organisms present in specimen TC-3: *Haemophilus influenzae* and *Corynebacterium species.*

Specimen TC-4

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	36	60.0%	Acceptable
Presump. Pos. Group A Strep	23	38.3%	Acceptable

Organism present in specimen TC-4: *Streptococcus pyogenes*.

Specimen TC-5

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	56	93.3%	Acceptable

Organisms present in specimen TC-5: *Staphylococcus aureus* and *Streptococcus gordonii.*

STREP A ANTIGEN DETECTION

Specimen RS-1

Method	*Labs*	*Positive*	*Negative*
All Methods	737	9	728
Abbott Signify Strep A-waived	90	1	89
Applied Biotech Signify	6	-	6
Applied Biotech SureStep	4	-	4
Applied Biotech SureStep II	3	-	3
BD Direction 1-2-3	1	-	1
BD LINK 2	2	-	2
BD QTest	28	-	28
Beckman Coulter ICON DS	19	-	19
Beckman Coulter ICON Fx Strep A	6	-	6
Beckman Coulter ICON SC	12	-	12
Binax NOW Strep A	1	-	1
BioStar Acceava Strep A Test	65	-	65
BioStar Strep A MAX OIA	41	1	40
DE Healthcare TruView	16	-	16
Fisher HealthCare Sure-Vue	5	-	5
Fisher Sure-Vue Strep A-waived	1	-	1
Genzyme OSOM	7	-	7
Genzyme OSOM Ultra Strep A	42	-	42
Henry Schein One Step	1	-	1
Instant Technologies i Strep	3	-	3
LifeSign Status AccuStrep A	1	-	1
LifeSign Status Strep A	2	-	2
Mainline Confirms	3	-	3
Mainline Confirms Strep A Dots	1	-	1
Polymedco Polystat Strep A (I)	31	1	30
Polymedco Polystat Strep A (II)	17	-	17
Quidel Cards QS	1	-	1
Quidel QuickVue Dipstick Strep	54	4	50
Quidel QuickVue In-Line	90	1	89
Quidel QuickVue+	127	1	126
Stanbio QuStick Strep A	1	-	1
Wampole Clearview	4	-	4
Wyntek OSOM Ultra Strep A	11	-	11

Specimen RS-2

				Strength of Reaction		
Method	*Labs*	*Positive*	*Negative*	*Strong*	*Moderate*	*Weak*
All Methods	703	692	11	508	130	10
Abbott Signify Strep A-waived	86	85	1	66	17	-
Applied Biotech Signify	4	2	2	-	1	1
Applied Biotech SureStep	4	4	-	1	3	-
Applied Biotech SureStep II	3	3	-	1	2	-
BD Directigen 1-2-3	1	1	-	1	-	-
BD LINK 2	2	2	-	-	2	-
BD QTest	25	25	-	21	3	-
Beckman Coulter ICON DS	19	19	-	9	10	-
Beckman Coulter ICON Fx Strep A	6	6	-	2	4	-
Beckman Coulter ICON SC	12	12	-	8	4	-
Binax NOW Strep A	1	1	-	1	-	-
BioStar Acceava Strep A Test	64	64	-	46	11	-

STREP A ANTIGEN DETECTION

Specimen RS-2 (cont'd)

Method	Labs	Positive	Negative	Strength of Reaction		
				Strong	Moderate	Weak
BioStar Strep A MAX OIA	40	40	-	34	1	-
DE Healthcare TruView	16	15	1	11	3	-
Fisher HealthCare Sure-Vue	4	4	-	2	1	-
Fisher Sure-Vue Strep A-waived	1	1	-	-	1	-
Genzyme OSOM	7	7	-	5	2	-
Genzyme OSOM Ultra Strep A	38	38	-	23	9	-
Henry Schein One Step	1	1	-	-	-	-
Instant Technologies i Strep	3	3	-	2	1	-
LifeSign Status Accustrep A	1	1	-	1	-	-
LifeSign Status Strep A	2	2	-	1	1	-
Mainline Confirms	1	1	-	-	1	-
Mainline Confirms Strep A Dots	1	1	-	-	1	-
Polymedco Polystat Strep A (I)	31	31	-	15	14	-
Polymedco Polystat Strep A (II)	16	16	-	9	6	-
Quidel Cards QS	1	1	-	1	-	-
Quidel QuickVue Dipstick Strep	52	50	2	44	3	-
Quidel QuickVue In-Line	88	84	4	60	11	7
Quidel QuickVue+	119	118	1	108	7	-
Stanbio QuStick Strep A	1	1	-	1	-	-
Wampole Clearview	4	4	-	1	2	-
Wyntek OSOM Ultra Strep A	11	11	-	8	1	1

Specimen RS-3

Method	Labs	Positive	Negative
All Methods	417	8	409
Abbott Signify Strep A-waived	42	1	41
Applied Biotech Signify	4	1	3
Applied Biotech SureStep	3	-	3
Applied Biotech SureStep II	3	-	3
BD Directigen 1-2-3	1	-	1
BD LINK 2	1	-	1
BD QTest	22	1	21
Beckman Coulter ICON DS	6	-	6
Beckman Coulter ICON Fx Strep A	5	-	5
Beckman Coulter ICON SC	8	-	8
Binax NOW Strep A	1	-	1
BioStar Acceava Strep A Test	21	-	21
BioStar Strep A MAX OIA	39	1	38
DE Healthcare TruView	3	-	3
Fisher HealthCare Sure-Vue	2	-	2
Genzyme OSOM	5	-	5
Genzyme OSOM Ultra Strep A	22	-	22
Henry Schein One Step	1	-	1
LifeSign Status AccuStrep A	1	-	1
LifeSign Status Strep A	1	-	1
Mainline Confirms	1	-	1
Mainline Confirms Strep A Dots	1	-	1
Polymedco Polystat Strep A (I)	24	1	23
Polymedco Polystat Strep A (II)	9	-	9

STREP A ANTIGEN DETECTION

Specimen RS-3 (cont'd)

Method	***Labs***	***Positive***	***Negative***
Quidel Cards QS	1	-	1
Quidel QuickVue Dipstick Strep	14	1	13
Quidel QuickVue In-Line	34	1	33
Quidel QuickVue+	113	-	113
Wampole Clearview	3	-	3
Wyntek OSOM Ultra Strep A	5	-	5

Specimen RS-4

Method	***Labs***	***Positive***	***Negative***
All Methods	351	1	350
Abbott Signify Strep A-waived	33	-	33
Applied Biotech Signify	4	-	4
Applied Biotech SureStep	1	-	1
Applied Biotech SureStep II	3	-	3
BD LINK 2	1	-	1
BD QTest	20	-	20
Beckman Coulter ICON DS	6	-	6
Beckman Coulter ICON Fx Strep A	4	-	4
Beckman Coulter ICON SC	8	-	8
Binax NOW Strep A	1	-	1
BioStar Acceava Strep A Test	16	-	16
BioStar Strep A MAX OIA	38	-	38
DE Healthcare TruView	3	-	3
Fisher HealthCare Sure-Vue	2	-	2
Genzyme OSOM	4	-	4
Genzyme OSOM Ultra Strep A	16	-	16
Henry Schein One Step	1	-	1
LifeSign Status AccuStrep A	1	-	1
LifeSign Status Strep A	1	-	1
Mainline Confirms	1	-	1
Mainline Confirms Strep A Dots	1	-	1
Polymedco Polystat Strep A (I)	22	-	22
Polymedco Polystat Strep A (II)	6	-	6
Quidel Cards QS	1	-	1
Quidel QuickVue Dipstick Strep	9	-	9
Quidel QuickVue In-Line	31	-	31
Quidel QuickVue+	95	1	94
Wampole Clearview	3	-	3
Wyntek OSOM Ultra Strep A	2	-	2

STREP A ANTIGEN DETECTION

Specimen RS-5

				Strength of Reaction		
Method	***Labs***	***Positive***	***Negative***	***Strong***	***Moderate***	***Weak***
All Methods	351	349	2	255	65	9
Abbott Signify Strep A-waived	33	33	-	25	6	1
Applied Biotech Signify	4	4	-	-	3	1
Applied Biotech SureStep	1	1	-	-	1	-
Applied Biotech SureStep II	3	3	-	1	1	1
BD LINK 2	1	1	-	1	-	-
BD QTest	20	20	-	16	3	-
Beckman Coulter ICON DS	6	6	-	3	2	1
Beckman Coulter ICON Fx Strep A	4	4	-	4	-	-
Beckman Coulter ICON SC	8	8	-	5	3	-
Binax NOW Strep A	1	1	-	1	-	-
BioStar Acceava Strep A Test	16	16	-	10	3	-
BioStar Strep A MAX OIA	38	38	-	33	1	-
DE Healthcare TruView	3	3	-	2	-	-
Fisher HealthCare Sure-Vue	2	2	-	-	-	1
Genzyme OSOM	4	4	-	3	1	-
Genzyme OSOM Ultra Strep A	16	16	-	9	3	1
Henry Schein One Step	1	1	-	-	-	-
LifeSign Status AccuStrep A	1	1	-	-	1	-
LifeSign Status Strep A	1	1	-	1	-	-
Mainline Confirms	1	1	-	-	1	-
Mainline Confirms Strep A Dots	1	1	-	-	-	1
Polymedco Polystat Strep A (I)	22	22	-	10	11	1
Polymedco Polystat Strep A (II)	6	6	-	2	4	-
Quidel Cards QS	1	1	-	1	-	-
Quidel QuickVue Dipstick Strep	9	9	-	7	2	-
Quidel QuickVue In-Line	31	30	1	22	6	-
Quidel QuickVue+	95	94	1	86	8	-
Wampole Clearview	3	3	-	1	1	-
Wyntek OSOM Ultra Strep A	2	2	-	1	1	-

GENERAL BACTERIOLOGY

Specimen UC-1 – Urine Culture

Identification	***Labs***	***Percent***	***Performance***
Klebsiella pneumoniae	10	90.9%	Acceptable
Presump. Klebsiella sp.	1	9.1%	Acceptable
Gram Stain			
Gram negative	8	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	8	100%	

Organism present in specimen UC-1: *Klebsiella pneumoniae*.

GENERAL BACTERIOLOGY

Specimen TC-1 – Throat Culture

Identification	***Labs***	***Percent***	***Performance***
Streptococcus pyogenes	6	75.0%	Acceptable
Positive for Group A Strep	1	12.5%	Acceptable
Presump. Pos. Group A Strep	1	12.5%	Acceptable

Organisms present in specimen TC-1: *Streptococcus pyogenes* and *Streptococcus gordonii.*

Specimen BA-1 – Blood Culture

Identification	***Labs***	***Percent***	***Performance***
Streptococcus pneumoniae	7	100%	Acceptable

Organism present in specimen BA-1: *Streptococcus pneumoniae*.

Specimen BA-2 – Respiratory Culture

Identification	***Labs***	***Percent***	***Performance***
Haemophilus influenzae	5	71.4%	Acceptable
Growth, referred for identification	1	14.3%	Acceptable

Organism present in specimen BA-2: *Haemophilus influenzae.*

Specimen BA-3 – Wound Culture

Identification	***Labs***	***Percent***	***Performance***
Enterococcus (Strep) faecalis	5	50.0%	Acceptable
Enterococcus sp.	2	20.0%	Acceptable
Staph – coagulase neg.	1	10.0%	Acceptable
Staphylococcus epidermidis	1	10.0%	Acceptable
Streptococcus Group D	1	10.0%	Acceptable

Organisms present in specimen BA-3: *Enterococcus faecalis* and *Staphylococcus epidermidis.*

URINE CULTURE

Specimen UC-1

Identification	***Labs***	***Percent***	***Performance***
Klebsiella pneumoniae	48	30.8%	Acceptable
Presump. Gram negative	33	21.2%	Acceptable
Growth, referred for identification	30	19.2%	Acceptable
Gram negative bacilli	19	12.2%	Acceptable
Presump. Klebsiella sp.	12	7.7%	Acceptable

Gram Stain

Gram negative	66	100%

Gram Stain Morphology

Rods/bacilli	60	98.4%
Cocco-bacilli	1	1.6%

Organism present in specimen UC-1: *Klebsiella pneumoniae*.

Specimen UC-2

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	41	25.2%	Acceptable
Enterococcus sp.	35	21.5%	Acceptable
Presump. Gram positive	29	17.8%	Acceptable
Gram positive cocci	18	11.0%	Acceptable
Enterococcus (Strep) faecalis	11	6.8%	Acceptable
Presump. Enterococcus sp.	11	6.8%	Acceptable
Staph – coagulase neg.	5	3.1%	Acceptable
Strep. Grp. D – enterococcus	4	2.5%	Acceptable
Stapyhlococcus sp.	1	0.6%	Acceptable
Staphylococcus epidermidis	1	0.6%	Acceptable
Streptococcus non-hemolytic	1	0.6%	Acceptable
Presump. Staphlyococcus sp.	1	0.6%	Acceptable
Presump. Streptococcus sp.	1	0.6%	Acceptable

Organisms present in specimen UC-2: *Enterococcus faecalis* and *Staphylococcus epidermidis*.

URINE CULTURE

Specimen UC-3

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram negative	32	34.4%	Acceptable
Growth, referred for identification	21	22.6%	Acceptable
Citrobacter freundii	20	21.5%	Acceptable
Gram negative bacilli	8	8.6%	Acceptable
Citrobacter sp.	4	4.3%	Acceptable

Organism present in specimen UC-3: *Citrobacter freundii*.

Specimen UC-4

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram positive	20	37.0%	Acceptable
Growth, referred for identification	18	33.3%	Acceptable
Staph – coagulase neg.	4	7.4%	Acceptable
Staphylococcus sp.	3	5.6%	Acceptable
Staphylococcus saprophyticus	3	5.6%	Acceptable
Gram positive cocci	2	3.7%	Acceptable
Presump. Staphlyococcus sp.	2	3.7%	Acceptable

Organism present in specimen UC-4: *Staphlyococcus saprophyticus*.

Specimen UC-5

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram negative	27	50.9%	Acceptable
Proteus mirabilis	12	22.6%	Acceptable
Growth, referred for identification	9	17.0%	Acceptable
Presump. Proteus sp.	3	5.7%	Acceptable
Proteus sp.	1	1.9%	Acceptable
Gram negative bacilli	1	1.9%	Acceptable

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

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen UC-1, CC-1 (SUS-1)

	------Agar Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Amikacin	2	2	-	-	6	6	-	-	100%
Amoxicillin/Clavulanate	19	18	-	1	13	13	-	-	97.1%
Ampicillin	90	2	-	88	21	-	-	21	98.5%
Ampicillin/Sulbactam	2	-	-	2	7	7	-	-	Not graded[1]
Aztreonam	-	-	-	-	3	3	-	-	100%
Carbenicillin	27	1	-	26	3	-	-	3	95.4%
Cefaclor	4	3	1	-	-	-	-	-	Not graded[1]
Cefamandole	1	1	-	-	1	1	-	-	100%
Cefazolin	14	14	-	-	11	11	-	-	100%
Cefixime	8	8	-	-	-	-	-	-	100%
Cefoperazone	-	-	-	-	1	1	-	-	100%
Cefotaxime	1	1	-	-	2	2	-	-	100%
Cefotetan	-	-	-	-	3	3	-	-	100%
Cefoxitin	1	1	-	-	1	1	-	-	100%
Cefprozil	4	4	-	-	-	-	-	-	100%
Ceftazidime	2	2	-	-	7	7	-	-	100%
Ceftizoxime	-	-	-	-	1	1	-	-	100%
Ceftriaxone	8	8	-	-	12	12	-	-	100%
Cefuroxime	4	4	-	-	7	7	-	-	100%
Cephalexin	2	2	-	-	1	1	-	-	100%
Cephalothin	93	85	6	2	17	17	-	-	91.8%
Cinoxacin	3	3	-	-	-	-	-	-	100%
Ciprofloxacin	93	93	-	-	22	22	-	-	100%
Doxycycline	9	8	-	1	-	-	-	-	83.3%
Fosfomycin	3	1	-	2	-	-	-	-	Not graded[1]
Gatifloxacin	1	1	-	-	2	2	-	-	100%
Gentamicin	51	51	-	-	11	11	-	-	100%
Imipenem	1	1	-	-	5	5	-	-	100%
Kanamycin	1	1	-	-	-	-	-	-	100%
Levofloxacin	25	25	-	-	12	12	-	-	100%
Lomefloxacin	1	1	-	-	2	2	-	-	100%
Loracarbef	1	1	-	-	-	-	-	-	100%
Meropenem	-	-	-	-	1	1	-	-	100%

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

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen UC-1, CC-1 (SUS-1) (cont'd)

	------Agar Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Mezlocillin	1	1	-	-	-	-	-	-	100%
Nalidixic Acid	5	5	-	-	1	1	-	-	100%
Nitrofurantoin	103	99	3	1	23	23	-	-	97.4%
Norfloxacin	29	29	-	-	7	7	-	-	100%
Ofloxacin	24	24	-	-	5	5	-	-	100%
Piperacillin	1	1	-	-	8	7	1	-	88.9%
Peperacillin/Tazoactam	-	-	-	-	6	6	-	-	100%
Sulfamethoxazole	10	10	-	-	1	1	-	-	100%
Sulfisoxazole	11	11	-	-	1	1	-	-	100%
Sulfonamide	1	1	-	-	-	-	-	-	100%
Tetracycline	62	59	2	1	15	15	-	-	96.5%
Ticarcillin	-	-	-	-	1	-	-	1	100%
Ticarcillin/Clavulanate	1	1	-	-	4	4	-	-	100%
Tobramycin	5	5	-	-	9	9	-	-	100%
Trimethoprim	14	14	-	-	7	7	-	-	100%
Trimethoprim/Sulfamethoxazole	95	95	-	-	22	22	-	-	100%

Organism present in specimen UC-1, CC-1 (SUS-1): *Klebsiella pneumoniae*.

GC CULTURE

Specimen GC-1

Identification	***Labs***	***Percent***	***Performance***
Presump. GC, referred for identification	26	50.0%	Acceptable
Neisseria gonorrhoeae	25	48.1%	Acceptable
Growth select media, referred	1	1.9%	Acceptable
Beta-lactamase Testing			
Negative	7	77.8%	
Positive	2	22.2%	
Gram Stain			
Gram negative	41	100%	Acceptable
Gram Stain Morphology			
Diplococci	39	90.7%	
Cocci in pairs	4	9.3%	

Organism present in specimen GC-1: *Neisseria gonorrhoeae*.

GC CULTURE

Specimen GC-2

Identification	***Labs***	***Percent***	***Performance***
Negative for Neisseria gonorrhoeae	19	79.2%	Acceptable
No growth (sterile)	3	12.5%	Acceptable
Gram positive cocci	1	4.2%	Acceptable
Growth select media, referred	1	4.2%	Acceptable

Organisms present in specimen GC-2: *Enterococcus faecalis* and *Lactobacillus casei*.

Specimen GC-3

Identification	***Labs***	***Percent***	***Performance***
No growth (sterile)	11	47.8%	Acceptable
Negative for Neisseria gonorrhoeae	11	47.8%	Acceptable
Growth, referred for identification	1	4.4%	Acceptable

Organisms present in specimen GC-3: *Streptococcus agalactiae* and *Lactobacillus casei*.

Specimen GC-4

Identification	***Labs***	***Percent***	***Performance***
No growth (sterile)	12	52.2%	Acceptable
Negative for Neisseria gonorrhoeae	10	43.5%	Acceptable
Growth, referred for identification	1	4.4%	Acceptable

Organism present in specimen GC-4: *Gardnerella vaginalis.*

Specimen GC-5

Identification	***Labs***	***Percent***	***Performance***
Presump. GC, referred for Identification	15	65.2%	Acceptable
Neisseria gonorrhoeae	6	26.1%	Acceptable
Growth, referred for indentification	1	4.4%	Acceptable
Growth select media, referred	1	4.4%	Accetpable

Beta-lactamase Testing

Negative	3	75.0%
Positive	1	25.0%

Organisms present in specimen GC-5: *Neisseria gonorrhoeae* and *Staphylococcus epidermidis*.

COLONY COUNT

Specimen CC-1

Method	***Labs***	***No growth***	***<10,000 organisms/mL***	***10,000-100,000 organisms/mL***	***>100,000 organisms/mL***
All Methods	111	-	1	45	65
Bactercult	3	-	-	-	3
Bacti-Star	1	-	-	-	1
Bulls Eye	7	-	-	2	5
Calibrated Loop	30	-	-	9	21
Dip-N-Count	1	-	-	-	1
HealthLink	1	-	-	-	1
Uri-Check	14	-	-	5	9
Uri-Three	2	-	-	1	1
Uricult	48	-	1	25	22

Identification–Specimen CC-1

Identification	***Labs***	***Percent***	***Performance***
Presump. Klebsiella sp.	21	42.0%	Acceptable
Presump. Gram negative	16	32.0%	Acceptable
Growth, referred for identification	7	14.0%	Acceptable
Klebsiella pneumoniae	3	6.0%	Acceptable
Klebsiella sp.	1	2.0%	Acceptable

Gram Stain

Gram negative	7	100%

Gram Stain Morphology

Rods/bacilli	8	100%

Organism present in specimen CC-1: approximately 63,000 CFU/mL of *Klebsiella pneumoniae*.

Specimen CC-2

Method	***Labs***	***No growth***	***<10,000 organisms/mL***	***10,000-100,000 organisms/mL***	***>100,000 organisms/mL***
All Methods	113	5	7	36	65
Bactercult	3	-	-	1	2
Bacti-Star	1	-	-	1	-
Bulls Eye	7	-	-	4	3
Calibrated Loop	30	1	2	3	24
Dip-N-Count	1	-	-	-	1
HealthLink	-	-	-	1	-
Uri-Check	15	1	1	6	7
Uri-Three	2	-	-	1	1
Uricult	49	3	4	17	25

COLONY COUNT

Identification–Specimen CC-2

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram positive	20	40.0%	Acceptable
Presump. Enterococcus sp.	16	32.0%	Acceptable
Growth, referred for identification	9	18.0%	Acceptable
Enterococcus (Strep) Faecalis	2	4.0%	Acceptable
Enterococcus sp.	1	2.0%	Acceptable
Staph – coagulase neg.	1	2.0%	Acceptable

Organisms present in specimen CC-2: > 100,000 CFU/mL of *Enterococcus faecalis* and approximately 2,500 CFU/mL *Staphylococcus epidermidis*.

Identification–Specimen CC-3

Identification	***Labs***	***Percent***	***Performance***
Presump. Escherichia coli	11	31.4%	Not graded
Presump. Gram negative	10	28.6%	
Growth, referred for identification	3	8.6%	
Citrobacter sp.	1	2.9%	
Bacturcult Group I	1	2.9%	
Citrobacter freundii	1	2.9%	

Organism present in specimen CC-3: > 100,000 CFU/mL of *Citrobacter freundii.* This is an ungraded challenge due to less than 80% referee consensus.

Identification–Specimen CC-4

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram positive	12	33.3%	Acceptable
Presump. Staphlyococcus sp.	11	30.6%	Acceptable
Growth, referred for identification	3	8.3%	Acceptable
Staphylococcus sp.	1	2.8%	Acceptable
Staph – coagulase neg.	1	2.8%	Acceptable
Staphylococcus saprophyticus	1	2.8%	Acceptable
Presump. Enterococcus sp.	5	13.9%	

Organism present in specimen CC-4: > 100,000 CFU/mL of *Staphylococcus saprophyticus.*

Identification–Specimen CC-5

Identification	***Labs***	***Percent***	***Performance***
Presump. Proteus sp.	19	52.8%	Acceptable
Presump. Gram negative	9	25.0%	Acceptable
Growth, referred for indentification	3	8.3%	Acceptable
Proteus sp.	1	2.8%	Acceptable
Proteus mirabilis	1	2.8%	Acceptable
Presump. Gram positive	1	2.8%	Acceptable

Organisms present in specimen CC-5: Approximately 91,500 CFU/mL of *Proteus mirabilis* and 1,000 CFU/mL of *Staphylococcus epidermidis*.

DERMATOPHYTE SCREEN

Specimen DM-1

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte present	22	91.7%	Acceptable
Dermatophyte absent	2	8.3%	

Organism present in specimen DM-1: *Trichophyton tonsurans.*

Specimen DM-2

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte absent	23	95.8%	Acceptable
Dermatophyte present	1	4.2%	

Organisms present in specimen DM-2: *Aspergillus niger* and *Lactobacillus casei*.

GRAM STAIN

Specimen GS-1

Identification	***Labs***	***Percent***	***Performance***
Gram positive	65	98.5%	Acceptable
Gram negative	1	1.5%	

Gram Stain Morphology

Cocci	41	67.2%
Cocci in chains	9	14.8%
Cocci in pairs	8	13.1%
Cocco-bacilli	1	1.6%
Diplococci	1	1.6%
Rods/bacilli	1	1.6%

Organism present in specimen GS-1: *Staphylococcus aureus*.

Specimen GS-2

Identification	***Labs***	***Percent***	***Performance***
Gram positive	55	83.3%	Acceptable
Gram negative	11	16.7%	

Gram Stain Morphology

Cocco-bacilli	19	31.7%
Cocci in pairs	14	23.3%
Diplococci	12	20.0%
Cocci	7	11.7%
Cocci in chains	4	6.7%
Rods/bacilli	4	6.7%

Organism present in specimen GS-2: *Streptococcus pneumoniae*.

GRAM STAIN

Specimen GS-3

Identification	***Labs***	***Percent***	***Performance***
Gram negative	63	95.5%	Acceptable
Gram positive	3	4.6%	

Gram Stain Morphology

Rods/bacilli	52	85.3%
Cocco-bacilli	5	8.2%
Cocci in chains	3	4.9%
Diplococci	1	1.6%

Organism present in specimen GS-3: *Escherichia coli*.

Specimen GS-4

Identification	***Labs***	***Percent***	***Performance***
Gram positive	63	95.5%	Acceptable
Gram negative	3	4.6%	

Gram Stain Morphology

Cocci in chains	47	77.1%
Cocci	11	18.0%
Cocco-bacilli	2	3.3%
Cocci in pairs	1	1.6%

Organism present in specimen GS-4: *Streptococcus agalactiae.*

Specimen GS-5

Identification	***Labs***	***Percent***	***Performance***
Gram negative	66	100%	Acceptable

Gram Stain Morphology

Rods/bacilli	55	91.7%
Cocci in chains	2	3.3%
Cocco-bacilli	2	3.3%
Cocci	1	1.7%

Organism present in specimen GS-5: *Proteus vulgaris.*

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-1

Identification	***Labs***	***Percent***	***Performance***
Positive	27	77.1%	Acceptable
Negative	8	22.9%	

Organism present in specimen VP-1: *Trichomonas vaginalis.*

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-2

Identification	***Labs***	***Percent***	***Performance***
Negative	34	97.1%	Acceptable
Positive	1	2.9%	

Organism present in specimen VP-2: *Candida albicans.*

Specimen VP-3

Identification	***Labs***	***Percent***	***Performance***
Negative	35	100%	Acceptable

Organism present in specimen VP-3: *Gardnerella vaginalis.*

Specimen VP-4

Identification	***Labs***	***Percent***	***Performance***
Positive	32	91.4%	Acceptable
Negative	3	8.6%	

Organisms present in specimen VP-4: *Candida albicans* and *Trichomonas vaginalis*.

Specimen VP-5

Identification	***Labs***	***Percent***	***Performance***
Negative	35	100%	Acceptable

Organism present in specimen VP-5: *Gardnerella vaginalis*.

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-1

Identification	***Labs***	***Percent***	***Performance***
Negative	35	100%	Acceptable

Specimen VP-2

Identification	***Labs***	***Percent***	***Performance***
Negative	35	100%	Acceptable

Specimen VP-3

Identification	***Labs***	***Percent***	***Performance***
Positive	32	91.4%	Acceptable
Negative	3	8.6%	

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-4

Identification	***Labs***	***Percent***	***Performance***
Negative	34	97.1%	Acceptable
Positive	1	2.9%	

Specimen VP-5

Identification	***Labs***	***Percent***	***Performance***
Positive	31	88.6%	Acceptable
Negative	4	11.4%	

AFFIRM VP III–Candida sp.

Specimen VP-1

Identification	***Labs***	***Percent***	***Performance***
Negative	35	100%	Acceptable

Specimen VP-2

Identification	***Labs***	***Percent***	***Performance***
Positive	35	100%	Acceptable

Specimen VP-3

Identification	***Labs***	***Percent***	***Performance***
Negative	35	100%	Acceptable

Specimen VP-4

Identification	***Labs***	***Percent***	***Performance***
Positive	32	91.4%	Acceptable
Negative	3	8.6%	

Specimen VP-5

Identification	***Labs***	***Percent***	***Performance***
Negative	35	100%	Acceptable

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-1

Method	***Labs***	***Positive***	***Negative***
All Methods	24	-	24
BD ProbeTec	4	-	4
Beckman (Sanofi) ACCESS	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	3	-	3
Fisher HealthCare Sure-Vue	1	-	1
Gen-Probe	3	-	3
Quidel QuickVue	9	-	9

Organism present in specimen CY-1: *Neisseria gonorrhoeae.*

Specimen CY-2

Method	***Labs***	***Positive***	***Negative***
All Methods	24	24	-
BD ProbeTec	4	4	-
Beckman (Sanofi) ACCESS	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	3	3	-
Fisher HealthCare Sure-Vue	1	1	-
Gen-Probe	3	3	-
Quidel QuickVue	9	9	-

Organism present in specimen CY-2: *Chlamydia trachomatis.*

Specimen CY-3

Method	***Labs***	***Positive***	***Negative***
All Methods	19	19	-
BD ProbeTec	4	4	-
Beckman (Sanofi) ACCESS	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	3	3	-
Fisher HealthCare Sure-Vue	1	1	-
Gen-Probe	3	3	-
Quidel QuickVue	4	4	-

Organism present in specimen CY-3: *Chlamydia trachomatis*.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-4

Method	***Labs***	***Positive***	***Negative***
All Methods	19	-	19
BD ProbeTec	4	-	4
Beckman (Sanofi) ACCESS	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	3	-	3
Fisher HealthCare Sure-Vue	1	-	1
Gen-Probe	3	-	3
Quidel QuickVue	4	-	4

Organism present in specimen CY-4: *Negative (sterile)*.

Specimen CY-5

Method	***Labs***	***Positive***	***Negative***
All Methods	19	-	19
BD ProbeTec	4	-	4
Beckman (Sanofi) ACCESS	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	3	-	3
Fisher HealthCare Sure-Vue	1	-	1
Gen-Probe	3	-	3
Quidel QuickVue	4	-	4

Organism present in specimen CY-5: *Neisseria gonorrhoeae.*

GC (ANTIGEN DETECTION)

Specimen CY-1

Method	***Labs***	***Positive***	***Negative***
All Methods	10	10	-
BD ProbeTec	4	4	-
BioStar OIA	3	3	-
Gen-Probe	3	3	-

Specimen CY-2

Method	***Labs***	***Positive***	***Negative***
All Methods	10	-	10
BD ProbeTec	4	-	4
BioStar OIA	3	-	3
Gen-Probe	3	-	3

GC (ANTIGEN DETECTION)

Specimen CY-3

Method	***Labs***	***Positive***	***Negative***
All Methods	10	-	10
BD ProbeTec	4	-	4
BioStar OIA	3	-	3
Gen-Probe	3	-	3

Specimen CY-4

Method	***Labs***	***Positive***	***Negative***
All Methods	10	-	10
BD ProbeTec	4	-	4
BioStar OIA	3	-	3
Gen-Probe	3	-	3

Specimen CY-5

Method	***Labs***	***Positive***	***Negative***
All Methods	10	10	-
BD ProbeTec	4	4	-
BioStar OIA	3	3	-
Gen-Probe	3	3	-

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-1

Method	***Labs***	***Positive***	***Negative***
All Methods	4	4	-
Meridian ImmunoCard STAT!	1	1	-
Remel Xpect	2	2	-

Specimen LC-1: Positive for *Cryptosporidium* antigen.

Specimen LC-2

Method	***Labs***	***Positive***	***Negative***
All Methods	4	-	4
Meridian ImmunoCard STAT!	1	-	1
Reme Xpect	2	-	2

Specimen LC-2: Negative for *Cryptosporidium* antigen.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-3

Method	***Labs***	***Positive***	***Negative***
All Methods	4	4	-
Meridian ImmunoCard STAT!	1	1	-
Reme Xpect	2	2	-

Specimen LC-3: Positive for *Cryptosporidium* antigen.

Specimen LC-4

Method	***Labs***	***Positive***	***Negative***
All Methods	4	4	-
Meridian ImmunoCard STAT!	1	1	-
Reme Xpect	2	2	-

Specimen LC-4: Positive for *Cryptosporidium* antigen.

Specimen LC-5

Method	***Labs***	***Positive***	***Negative***
All Methods	4	-	4
Meridian ImmunoCard STAT!	1	-	1
Reme Xpect	2	-	2

Specimen LC-5: Negative for *Cryptosporidium* antigen.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-1

Method	***Labs***	***Positive***	***Negative***
All Methods	9	9	-
Alexon (Hycor)	3	3	-
Meridian ImmunoCard STAT!	1	1	-
Meridian Merifluor	1	1	-
Remel RIM Immuno	1	1	-
Remel Xpect	2	2	-

Specimen LC-2

Method	***Labs***	***Positive***	***Negative***
All Methods	9	9	-
Alexon (Hycor)	3	3	-
Meridian ImmunoCard STAT!	1	1	-
Meridian Merifluor	1	1	-
Remel RIM Immuno	1	1	-
Remel Xpect	2	2	-

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-3

Method	***Labs***	***Positive***	***Negative***
All Methods	9	-	9
Alexon (Hycor)	3	-	3
Meridian ImmunoCard STAT!	1	-	1
Meridian Merifluor	1	-	1
Remel RIM Immuno	1	-	1
Reme Xpect	2	-	2

Specimen LC-4

Method	***Labs***	***Positive***	***Negative***
All Methods	9	-	9
Alexon (Hycor)	3	-	3
Meridian ImmunoCard STAT!	1	-	1
Meridian Merifiluor	1	-	1
Remel RIM Immuno	1	-	1
Reme Xpect	2	-	2

Specimen LC-5

Method	***Labs***	***Positive***	***Negative***
All Methods	9	9	-
Alexon (Hycor)	3	3	-
Meridian ImmunoCard STAT!	1	1	-
Meridian Merifluor	1	1	-
Remel RIM Immuno	1	1	-
Reme Xpect	2	2	-

RSV ANTIGEN DETECTION

Specimen V-1

Method	***Labs***	***Positive***	***Negative***
All Methods	34	-	34
BD Directigen	9	-	9
Binax NOW – waived	11	-	11
BioStar OIA	11	-	11

Specimen V-1: Negative for RSV antigen.

RSV ANTIGEN DETECTION

Specimen V-2

Method	***Labs***	***Positive***	***Negative***
All Methods	34	-	34
BD Directigen	9	-	9
Binax NOW – waived	11	-	11
BioStar OIA	11	-	11

Specimen V-12: Negative for RSV antigen.

Specimen V-3

Method	***Labs***	***Positive***	***Negative***
All Methods	34	33	1
BD Directigen	9	8	1
Binax NOW – waived	11	11	-
BioStar OIA	11	11	-

Specimen V-3: Positive for RSV antigen.

Specimen V-4

Method	***Labs***	***Positive***	***Negative***
All Methods	34	2	32
BD Directigen	9	-	9
Binax NOW – waived	11	-	11
BioStar OIA	11	2	9

Specimen V-4: Negative for RSV antigen.

Specimen V-5

Method	***Labs***	***Positive***	***Negative***
All Methods	34	33	1
BD Directigen	9	8	1
Binax NOW – waived	11	11	-
BioStar OIA	11	11	-

Specimen V-5: Positive for RSV antigen.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-1

Method	***Labs***	***Positive***	***Negative***
All Methods	100	78	22
BioStar OIA	19	12	7
Quidel QuickVue Influenza	71	61	10
ZymeTx	1	1	-

Specimen V-1: Positive for Influenza A/B antigen

Specimen V-2

Method	***Labs***	***Positive***	***Negative***
All Methods	95	95	5
BioStar OIA	19	17	2
Quidel QuickVue Influenza	71	70	1
ZymeTx	1	-	1

Specimen V-2: Positive for Influenza A/B antigen

Specimen V-3

Method	***Labs***	***Positive***	***Negative***
All Methods	42	1	41
BioStar OIA	16	1	15
Quidel QuickVue Influenza	23	-	23

Specimen V-3: Negative for Influenza A/B antigen

Specimen V-4

Method	***Labs***	***Positive***	***Negative***
All Methods	42	34	8
BioStar OIA	16	11	5
Quidel QuickVue Influenza	23	21	2

Specimen V-4: Positive for Influenza A/B antigen

Specimen V-5

Method	***Labs***	***Positive***	***Negative***
All Methods	42	1	41
BioStar OIA	16	1	15
Quidel QuickVue Influenza	23	-	23

Specimen V-5: Negative for Influenza A/B antigen

INFLUENZA A ANTIGEN DETECTION

Specimen V-1

Method	***Labs***	***Positive***	***Negative***
All Methods	67	63	4
BD Directigen	4	4	-
Binax NOW – waived	10	10	-
BioStar Flu OIA A/B	11	9	2
Quidel QuickVue Influenza A+B	30	30	-
Remel Xpect	7	5	2
Wampole Clearview	1	1	-

Specimen V-1: Positive for Influenza A antigen.

Specimen V-2

Method	***Labs***	***Positive***	***Negative***
All Methods	66	1	65
BD Directigen	4	-	4
Binax NOW – waived	10	-	10
BioStar Flu OIA A/B	11	-	11
Quidel QuickVue Influenza A+B	29	1	28
Remel Xpect	7	-	7
Wampole Clearview	1	-	1

Specimen V-2: Negative for Influenza A antigen.

Specimen V-3

Method	***Labs***	***Positive***	***Negative***
All Methods	37	-	37
BD Directigen	3	-	3
Binax NOW – waived	8	-	8
BioStar Flu OIA A/B	11	-	11
Quidel QuickVue Influenza A+B	7	-	7
Remel Xpect	4	-	4
Wampole Clearview	1	-	1

Specimen V-3: Negative for Influenza A antigen.

Specimen V-4

Method	***Labs***	***Positive***	***Negative***
All Methods	37	33	4
BD Directigen	3	3	-
Binax NOW – waived	8	8	-
BioStar Flu OIA A/B	11	8	3
Quidel QuickVue Influenza A+B	7	7	-
Remel Xpect	4	4	-
Wampole Clearview	1	-	1

Specimen V-4: Positive for Influenza A antigen.

INFLUENZA A ANTIGEN DETECTION

Specimen V-5

Method	***Labs***	***Positive***	***Negative***
All Methods	37	1	36
BD Directigen	3	1	2
Binax NOW – waived	8	-	8
BioStar Flu OIA A/B	11	-	11
Quidel QuickVue Influenza A+B	7	-	7
Remel Xpect	4	-	4
Wampole Clearview	1	-	1

Specimen V-5: Negative for Influenza A antigen.

INFLUENZA B ANTIGEN DETECTION

Specimen V-1

Method	***Labs***	***Positive***	***Negative***
All Methods	64	-	64
BD Directigen	3	-	3
Binax NOW – waived	10	-	10
BioStar Flu OIA A/B	11	-	11
Quidel QuickVue Influenza A+B	29	-	29
Remel Xpect	7	-	7
Wampole Clearview	1	-	1

Specimen V-1: Negative for Influenza B antigen.

Specimen V-2

Method	***Labs***	***Positive***	***Negative***
All Methods	66	65	1
BD Directigen	3	3	-
Binax NOW – waived	10	10	-
BioStar Flu OIA A/B	11	11	-
Quidel QuickVue Influenza A+B	30	29	1
Remel Xpect	7	7	-
Wampole Clearview	1	1	-

Specimen V-2: Positive for Influenza B antigen.

Specimen V-3

Method	***Labs***	***Positive***	***Negative***
All Methods	36	1	35
BD Directigen	2	-	2
Binax NOW – waived	8	-	8
BioStar Flu OIA A/B	11	-	11
Quidel QuickVue Influenza A+B	7	-	7
Remel Xpect	4	-	4
Wampole Clearview	1	-	1

Specimen V-3: Negative for Influenza B antigen.

INFLUENZA B ANTIGEN DETECTION

Specimen V-4

Method	***Labs***	***Positive***	***Negative***
All Methods	36	1	35
BD Directigen	2	-	2
Binax NOW – waived	8	-	8
BioStar Flu OIA A/B	11	-	11
Quidel QuickVue Influenza A+B	7	-	7
Remel Xpect	4	-	4
Wampole Clearview	1	-	1

Specimen V-4: Negative for Influenza B antigen.

Specimen V-5

Method	***Labs***	***Positive***	***Negative***
All Methods	36	-	36
BD Directigen	2	-	2
Binax NOW – waived	8	-	8
BioStar Flu OIA A/B	11	-	11
Quidel QuickVue Influenza A+B	7	-	7
Remel Xpect	4	-	4
Wampole Clearview	1	-	1

Specimen V-5: Negative for Influenza B antigen.

LEGIONELLA ANTIGEN DETETION

Specimen L-1

Method	***Labs***	***Positive***	***Negative***
All Methods	113	113	-

Specimen L-1: Positive for Legionella antigen.

Specimen L-2

Method	***Labs***	***Positive***	***Negative***
All Methods	113	-	113

Specimen L-2: Negative for Legionella antigen.

Specimen L-3

Method	***Labs***	***Positive***	***Negative***
All Methods	113	113	-

Specimen L-3: Positive for Legionella antigen.

LEGIONELLA ANTIGEN DETETION

Specimen L-4

Method	***Labs***	***Positive***	***Negative***
All Methods	113	-	113

Specimen L-4: Negative for Legionella antigen.

Specimen L-5

Method	***Labs***	***Positive***	***Negative***
All Methods	113	-	113

Specimen L-5: Negative for Legionella antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-1

Method	***Labs***	***Positive***	***Negative***
All Methods	20	20	-
Alexon	1	1	-
Becton Dickinson Toxin CD	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	7	7	-
BioStar OIA	6	6	-
Meridian ImmunoCard	2	2	-
Meridian Premier	1	1	-

Specimen AG-1: Positive for *Clostridium difficile* antigen.

Specimen AG-2

Method	***Labs***	***Positive***	***Negative***
All Methods	20	-	20
Alexon (Hycor)	1	-	1
Becton Dickinson Toxin CD	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	7	-	7
BioStar OIA	6	-	6
Meridian ImmunoCard	2	-	2
Meridian Premier	1	-	1

Specimen AG-2: Negative for *Clostridium difficile* antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-3

Method	***Labs***	***Positive***	***Negative***
All Methods	20	20	-
Alexon (Hycor)	1	1	-
Becton Dickinson Toxin CD	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	7	7	-
BioStar OIA	6	6	-
Meridian Immuno Card	2	2	-
Meridian Premier	1	1	-

Specimen AG-3: Positive for *Clostridium difficile* antigen.

Specimen AG-4

Method	***Labs***	***Positive***	***Negative***
All Methods	20	20	-
Alexon (Hycor)	1	1	-
Becton Dickinson Toxin CD	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	7	7	-
BioStar OIA	6	6	-
Meridian ImmunoCard	2	2	-
Meridian Premier	1	1	-

Specimen AG-4: Positive for *Clostridium difficile* antigen.

Specimen AG-5

Method	***Labs***	***Positive***	***Negative***
All Methods	20	1	19
Alexon (Hycor)	1	-	1
Becton Dickinson Toxin CD	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	6	-	6
BioStar OIA	6	-	6
Meridian ImmunoCard	2	-	2
Meridian Premier	1	-	1

Specimen AG-5: Negative for *Clostridium difficile* antigen

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-1

Method	***Labs***	***Positive***	***Negative***
All Methods	11	-	11
Fisher HealthCare Sure-Vue	3	-	3
Meridian ImmunoCard	6	-	6

Specimen AG-1: Negative for *Rotavirus* antigen.

Specimen AG-2

Method	***Labs***	***Positive***	***Negative***
All Methods	11	-	11
Fisher HealthCare Sure-Vue	3	-	3
Meridian ImmunoCard	6	-	6

Specimen AG-2: Negative for *Rotavirus* antigen.

Specimen AG-3

Method	***Labs***	***Positive***	***Negative***
All Methods	11	11	-
Fisher HealthCare Sure-Vue	3	3	-
Meridian ImmunoCard	6	6	-

Specimen AG-3: Positive for *Rotavirus* antigen.

Specimen AG-4

Method	***Labs***	***Positive***	***Negative***
All Methods	11	-	11
Fisher HealthCare Sure-Vue	3	-	3
Meridian ImmunoCard	6	-	6

Specimen AG-4: Negative for *Rotavirus* antigen.

Specimen AG-5

Method	***Labs***	***Positive***	***Negative***
All Methods	11	11	-
Fisher HealthCare Sure-Vue	3	3	-
Meridian ImmunoCard	6	6	-

Specimen AG-5: Positive for *Rotavirus* antigen.

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-1

Method	*Labs*	*Positive*	*Negative*
Binax NOW	99	99	-

Specimen SP-1: Positive for *Streptococcus pneumoniae* antigen.

Specimen SP-2

Method	*Labs*	*Positive*	*Negative*
Binax NOW	99	99	-

Specimen SP-2: Positive for *Streptococcus pneumoniae* antigen.

Specimen SP-3

Method	*Labs*	*Positive*	*Negative*
Binax NOW	98	98	-

Specimen SP-3: Positive for *Streptococcus pneumoniae* antigen.

Specimen SP-4

Method	*Labs*	*Positive*	*Negative*
Binax NOW	99	-	99

Specimen SP-4: Negative for *Streptococcus pneumoniae* antigen.

Specimen SP-5

Method	*Labs*	*Positive*	*Negative*
Binax NOW	99	-	99

Specimen SP-5: Negative for *Streptococcus pneumoniae* antigen.

PARASITOLOGY – DOMESTIC

Specimen PA-1

Identification	*Labs*	*Percent*	*Performance*
Giardia lamblia	2	66.7%	Not graded
Blastocystis hominis	1	33.3%	

Parasite present in specimen PA-1: *Giardia lamblia.* This is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY – DOMESTIC

Specimen PA-2

Identification	***Labs***	***Percent***	***Performance***
No parasite seen	3	100%	Acceptable

Parasite present in specimen PA-2: Negative (sterile)

Specimen PA-3

Identification	***Labs***	***Percent***	***Performance***
Strongyloides sterco. larvae	2	66.7%	Acceptable
Parasite larva seen but no ID	1	33.3%	Acceptable

Parasite present in specimen PA-3: *Strongyloides stercoralis.*

Specimen PA-4

Identification	***Labs***	***Percent***	***Performance***
No parasite seen	3	100%	Acceptable

Parasite present in specimen PA-4: *Schistosoma mansoni.* **Technical Assistance**: The low concentration of *Schistosoma mansoni* in this specimen, an average of three organisms per 22mm x 22mm coverslip, made the discovery of this parasite challenging. If you would like additional information on the identification of Schistosoma *mansoni*, click on the following internet link: http://www.dpd.cdc.gov/DPDx/HTML/Schistosomiasis.asp?body=Frames/S-Z/Schistosomiasis/body_Schistosomiasis_mic1.htm . If you do not have internet access, a copy of this information will be included in the printed materials included with your evaluation report.

Specimen PA-5

Identification	***Labs***	***Percent***	***Performance***
Trypanosoma cruzi	1	33.3%	Not graded
Parasite larva seen but no ID	1	33.3%	
No parasite seen	1	33.3%	

Parasite present in specimen PA-5: *Trypanosoma cruzi*. This is an ungraded challenge due to less than 80% participant consensus.

INTERNATIONAL LABS

PARASITOLOGY – INTERNATIONAL (PA Specimens)

Specimen PA-1

Identification	***Labs***	***Percent***	***Performance***
Ascaris lumbricoides eggs	1	33.3%	Not graded
Endolimax nana	1	33.3%	
Giardia lamblia	1	33.3%	

Parasite present in specimen PA-1: *Giardia lamblia.* This is an ungrade challenge due to less than 80% participant consensus.

PARASITOLOGY – INTERNATIONAL (PA Specimens)

Specimen PA-2

Identification	***Labs***	***Percent***	***Performance***
No parasite seen	2	100%	Acceptable

Parasite present in specimen PA-2: Negative (sterile).

Specimen PA-3

Identification	***Labs***	***Percent***	***Performance***
Strongyloides sterco. Larvae	7	70.0%	Acceptable
Parasite larva seen but no ID	1	10.0%	Acceptable
Schistosoma mansoni eggs	1	10.0%	
No parasite seen	1	10.0%	

Parasite present in specimen PA-3: *Strongyloides stercoralis.*

Specimen PA-4

Identification	***Labs***	***Percent***	***Performance***
No parasite seen	3	33.3%	Acceptable
Schistosoma mansoni eggs	2	22.2%	Acceptable
Blastocystis hominis	2	22.2%	
Strongyloides sterco. Larvae	1	11.1%	
Parasite larva seen but no ID	1	11.1%	

Parasite present in specimen PA-4: *Schistosoma mansoni.*

Specimen PA-5

Identification	***Labs***	***Percent***	***Performance***
Trypanosoma cruzi	6	75.0%	
Trypanosoma gambiense	2	25.0%	

Parasite present in specimen PA-5: *Trypanosoma cruzi.* This is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY – INTERNATIONAL (FP Specimens)

Specimen FP-1

Identification	***Labs***	***Percent***	***Performance***
Taenia sp. Eggs	31	70.5%	Not graded
No parasite seen	5	11.4%	
Hymenolepis diminuta eggs	2	4.6%	
Strongyloides sterco. larvae	2	4.6%	
Endolimax nana	1	2.3%	
Giardia lamblia	1	2.3%	
Hymenolepis nana eggs	1	2.3%	
Parasite larva seen but no ID	1	2.3%	

Parasite present in specimen FP-1: *Taenia sp. eggs.* This is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY – INTERNATIONAL (FP Specimens)

Specimen FP-2

Identification	***Labs***	***Percent***	***Performance***
Hookworm	30	51.7%	Not graded
Ascaris lumbricoides eggs	5	8.6%	
Balstocystis hominis	5	8.6%	
Parasote egg seen but no ID	5	8.6%	
Endolimax nana	3	5.2%	
Entamoeba coli	3	5.2%	
Taenia sp. eggs	2	3.5%	
Trichostrongylus sp. eggs	2	3.5%	
Enterobius vermicularis eggs	1	1.7%	
Strongyloides sterco. larvae	1	1.7%	
No parasite seen	1	1.7%	

Parasite present in specimen FP-2: Hookworm eggs. This is an ungraded challenge due to less than 80% participant consensus.

Specimen FP-3

Identification	***Labs***	***Percent***	***Performance***
Strongyloides sterco. larvae	23	54.8%	Not graded
No parasite seen	12	28.6%	
Parasite larva seen but no ID	3	7.1%	
Ascaris lumbricoides eggs	2	4.8%	
Enterobius vermicularis eggs	1	2.4%	
Taenia sp. eggs	1	2.4%	

Parasite present in specimen FP-3: Negative (sterile). This is an ungraded challenge due to less than 80% participant consensus.

Specimen FP-4

Identification	***Labs***	***Percent***	***Performance***
Trichuris trichiura eggs	37	55.2%	Not graded
Ascaris lumbricoides eggs	22	32.8%	
Endolimax nana	1	1.5%	
Hookworm	1	1.5%	
Schistosoma sp. eggs, NOS	1	1.5%	
Schistosoma mansoni eggs	1	1.5%	
Taenia sp. eggs	1	1.5%	
Trichostrongylus sp. eggs	1	1.5%	
Protozoan seen but no ID	1	1.5%	
No parasite seen	1	1.5%	

Parasite present in specimen FP-4: *Trichuris trichiura.* This is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY – INTERNATIONAL (FP Specimens)

Specimen FP-5

Identification	***Labs***	***Percent***	***Performance***
Plasmodium falciparum	30	75.0%	Acceptable
Plasmodium sp., NOS	2	5.0%	Acceptable
Plasmodium vivax	6	15.0%	
Plasmodium sp., not falciparum	2	5.0%	

Parasite present in specimen FP-5: *Plasmodium falciparum.*

ANTIMICROBIAL SUSCEPTIBILIY TESTING (FOR INTERNATIONAL LABS)

Specimen UC-11

	------Agar Diffusion------				***------MIC------***				
	Interpretative category data				***Interpretative category data***				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Amikacin	5	5	-	-	16	16	-	-	100%
Amoxicillin/Clavulanate	-	-	-	-	10	10	-	-	93.3%
Ampicillin	5	-	-	5	16	-	-	16	100%
Ampicillin/Sulbactam	1	-	-	1	13	6	5	2	Not graded[1]
Aztreonam	3	3	-	-	5	5	-	-	100%
Carbenicillin	1	-	-	1	1	-	-	1	100%
Cefazolin	-	-	-	-	14	14	-	-	90.9%
Cefepime	-	-	-	-	2	2	-	-	100%
Cefixime	-	-	-	-	1	1	-	-	100%
Cefotaxime	2	2	-	-	13	12	-	1	90.0%
Cefotetan	-	-	-	-	7	7	-	-	100%
Cefoxitin	-	-	-	-	1	-	-	1	Not graded[2]
Ceftazidime	2	2	-	-	13	12	-	1	90.9%
Ceftriaxone	2	2	-	-	15	15	-	-	100%
Cefuroxime	-	-	-	-	14	13	-	1	85.0%
Cephalexin	2	1	-	1	-	-	-	-	Not graded[2]
Cephalothin	5	5	-	-	10	8	-	1	83.3%
Ciprofloxacin	5	5	-	-	20	20	-	-	100%
Fosfomycin	-	-	-	-	1	1	-	-	100%
Gentamicin	5	5	-	-	18	18	-	-	100%
Imipenem	-	-	-	-	14	14	-	-	100%
Levofloxacin	-	-	-	-	9	9	-	-	100%
Meropenem	-	-	-	-	6	6	-	-	100%
Moxifloxacin	-	-	-	-	2	2	-	-	100%
Naldixic Acid	4	4	-	-	6	6	-	-	100%
Nitrofuantoin	5	5	-	-	13	13	-	-	96.0%
Norfloxacin	8	8	-	-	8	8	-	-	100%
Ofloxacin	1	1	-	-	3	3	-	-	100%
Penicillin-G	-	-	-	-	1	1	-	-	100%
Piperacillin	-	-	-	-	11	9	-	2	Not graded[2]
Piperacillin/Tazobactam	-	-	-	-	12	12	-	-	100%
Tetracycline	-	-	-	-	2	2	-	-	100%
Ticarcillin	-	-	-	-	1	-	-	-	Not graded[2]

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

ANTIMICROBIAL SUSCEPTIBILIY TESTING (FOR INTERNATIONAL LABS) (cont'd)

Specimen UC-11

	------Agar Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Ticarcillin/Clavulanate	-	-	-	-	6	6	-	-	100%
Tobramycin	-	-	-	-	10	10	-	-	100%
Trimethoprim/Sulfamethoxazole	7	7	-	-	18	18	-	-	100%

SUMMARY OF ISOLATES FOUND IN THE 2005 MLE-M1 CULTURE SPECIMENS

Organism	ATCC Strain
Streptococcus pneumoniae	6305
Haemophilus influenzae	10211
Enterococcus faecalis	29212
Staphylococcus epidermidis	14990
Klebsiella pneumoniae	13883
Citrobacter freundii	8090
Staphylococcus saprophyticus	35552
Proteus mirabilis	12453
Neisseria gonorrhoeae	19424
Lactobacillus casei	393
Streptococcus agalactiae	12386
Gardnerella vaginalis	14018
Streptococcus pyogenes	19615
Streptococcus gordonii	35557
Corynebacterium sp.	49528
Staphylococcus aureus	25923

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