MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

Microbiology
MLE – A2

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2003 Evaluation Criteria

The evaluation criteria used in the 2003 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 Antigen Detection	80% Consensus		

THROAT CULTURE

Specimen TC-6

Identification	***Labs***	***Percent***	***Performance***
Neg. Group A Strep	233	98.7%	Acceptable
Pos. Group A Strep	3	1.3%	

Organism present in specimen TC-6: *Neisseria mucosa.*

Specimen TC-7

Identification	***Labs***	***Percent***	***Performance***
Pos. Group A Strep	144	60.5%	Acceptable
Presump. Pos. Group A Strep	85	35.7%	Acceptable
Neg. Group A Strep	9	3.8%	

Organisms present in specimen TC-7: *Streptococcus pyogenes* and *Staphylococcus epidermidis.*

Specimen TC-8

Identification	***Labs***	***Percent***	***Performance***
Neg. Group A Strep	76	96.2%	Acceptable
Pos. Group A Strep	2	2.5%	
Presump. Pos. Group A Strep	1	1.3%	

Organisms present in specimen TC-8: *Streptococcus pneumoniae* and *Staphylococcus epidermidis.*

Specimen TC-9

Identification	***Labs***	***Percent***	***Performance***
Neg. Group A Strep	64	95.5%	Acceptable
Presump. Pos. Group A Strep	2	3.0%	
Pos. Group A Strep	1	1.5%	

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

Specimen TC-10

Identification	***Labs***	***Percent***	***Performance***
Pos. Group A Strep	43	62.3%	Acceptable
Presump. Pos. Group A Strep	23	33.3%	Acceptable
Neg. Group A Strep	3	4.4%	

Organism present in specimen TC-10: *Streptococcus pyogenes* and *Corynebacterium sp.*

STREP A ANTIGEN DETECTION

Specimen RS-6

Method	*Labs*	*Positive*	*Negative*
All Methods	747	11	736
Abbott Signify Strep A-waived	100	1	99
Applied Biotech Signify	13	-	13
Applied Biotech SureStep	3	-	3
Applied Biotech SureStep II	5	-	5
BD Directigen 1-2-3	2	-	2
BD LINK 2	6	-	6
BD QTest	31	1	30
Beckman Coulter ICON DS	14	-	14
Beckman Coulter ICON Fx Strep A	52	-	52
BioStar Acceava Strep A Test	69	-	69
BioStar OIA	1	-	1
BioStar Strep A MAX OIA	62	4	58
DE Healthcare TruView	4	-	4
Fisher HealthCare Sure-Vue	2	-	2
Fisher Sure-Vue Strep A	6	-	6
Genzyme OSOM Ultra Strep A	23	-	23
Henry Schein One Step	3	-	3
LifeSign Status Strep A	3	-	3
Mainline Confirms	4	-	4
Mainline Confirms Strep A Dots	2	-	2
Meridian ImmunoCard	2	-	2
Polymedco Polystat Strep A (I)	29	1	28
Polymedco Polystat Strep A (II)	21	-	21
Quidel Cards QS	9	-	9
Quidel QuickVue	35	1	34
Quidel QuickVue Dipstick Strep	12	1	11
Quidel QuickVue Flex	4	-	4
Quidel QuickVue In-Line	89	2	87
Quidel QuickVue+	81	-	81
Stanbio QuStick Strep A	1	-	1
Wampole Clearview	2	-	2
Wyntek OSOM	6	-	6
Wyntek OSOM Ultra Strep A	17	-	17

Specimen RS-7

				Strength of Reaction		
Method	*Labs*	*Positive*	*Negative*	*Strong*	*Moderate*	*Weak*
All Methods	706	692	14	428	172	40
Abbott Signify Strep A-waived	92	90	2	68	16	2
Applied Biotech Signify	10	10	-	7	1	-
Applied Biotech SureStep	3	3	-	1	2	-
Applied Biotech SureStep II	5	5	-	1	3	1
BD Directigen 1-2-3	2	2	-	1	-	1
BD LINK 2	6	6	-	1	3	2
BD QTest	26	26	-	5	11	9
Beckman Coulter ICON DS	13	13	-	3	6	4
Beckman Coulter ICON Fx Strep A	52	52	-	30	17	2
BioStar Acceava Strep A Test	68	68	-	44	19	-

STREP A ANTIGEN DETECTION

Specimen RS-7 (cont'd)

Method	Labs	Positive	Negative	Strength of Reaction		
				Strong	Moderate	Weak
BioStar OIA	1	1	-	-	-	-
BioStar Strep A MAX OIA	61	60	1	48	11	-
DE Healthcare TruView	4	4	-	2	1	-
Fisher HealthCare Sure-Vue	2	2	-	1	1	-
Fisher Sure-Vue Strep A	4	4	-	1	1	1
Genzyme OSOM Ultra Strep A	20	20	-	11	5	-
Henry Schein One Step	3	3	-	2	-	-
LifeSign Status AccuStrep A	3	3	-	-	2	1
Mainline Confirms	2	2	-	-	1	-
Mainline Confirms Strep A Dots	2	2	-	-	1	1
Meridian ImmunoCard	2	2	-	-	2	-
Polymedco Polystat Strep A (I)	29	29	-	18	9	2
Polymedco Polystat Strep A (II)	19	19	-	3	8	7
Quidel Cards QS	8	8	-	6	1	-
Quidel QuickVue	33	32	1	26	2	1
Quidel QuickVue Dipstick Strep	12	12	-	7	3	-
Quidel QuickVue Flex	4	4	-	2	1	-
Quidel QuickVue In-Line	88	79	9	54	17	4
Quidel QuickVue+	80	80	-	58	17	-
Stanbio QuStick Strep A	1	1	-	-	-	1
Wampole Clearview	1	1	-	-	1	-
Wyntek OSOM	5	5	-	5	-	-
Wyntek OSOM Ultra Strep A	17	17	-	10	2	1

Specimen RS-8

Method	Labs	Positive	Negative	Strength of Reaction		
				Strong	Moderate	Weak
All Methods	462	455	7	280	113	30
Abbott Signify Strep A-waived	44	44	-	36	5	1
Applied Biotech Signify	10	10	-	4	5	-
Applied Biotech SureStep	2	2	-	2	-	-
Applied Biotech SureStep II	4	4	-	-	4	-
BD Directigen 1-2-3	2	2	-	1	-	1
BD LINK 2	1	1	-	-	-	1
BD Qtest	26	24	2	4	14	5
Beckman Coulter ICON DS	8	8	-	3	2	3
Beckman Coulter ICON Fx Strep A	21	20	1	11	9	1
BioStar Acceava Strep A Test	25	25	-	19	2	-
BioStar OIA	1	1	-	-	-	-
BioStar Strep A MAX OIA	60	60	-	44	13	2
DE Healthcare Sure-Vue	1	1	-	-	-	-
Fisher HealthCare Sure-Vue	2	2	-	1	-	1
Fisher Sure-Vue Strep A	1	1	-	-	-	1
Genzyme OSOM Ultra Strep A	11	11	-	7	1	-
Henry Schein One Step	3	3	-	1	1	-
LifeSign Status Strep A	3	3	-	1	1	1
Mainline Confirms	2	2	-	1	-	-
Mainline Confirms Strep A Dots	2	2	-	-	2	-
Meridian ImmunoCard	2	2	-	1	-	1
Polymedco Polystat Strep A (I)	22	22	-	15	5	2
Polymedco Polystat Strep A (II)	10	9	1	2	3	4

STREP A ANTIGEN DETECTION

Specimen RS-8 (cont'd)

Method	Labs	Positive	Negative	Strength of Reaction: Strong	Moderate	Weak
Quidel Cards QS	8	8	-	5	1	1
Quidel QuickVue	30	30	-	16	10	1
Quidel QuickVue Dipstick Strep	10	9	1	7	1	-
Quidel QuickVue Flex	3	3	-	2	-	-
Quidel QuickVue In-Line	37	35	2	25	9	1
Quidel QuickVue+	79	79	-	55	18	1
Stanbio QuStick Strep A	1	1	-	-	-	1
Wyntek OSOM	4	4	-	4	-	-
Wyntek OSOM Ultra Strep A	9	9	-	4	3	-

Specimen RS-9

Method	Labs	Positive	Negative
All Methods	388	3	385
Abbott Signify Strep A-waived	36	-	36
Applied Biotech Signify	7	-	7
Applied Biotech SureStep	1	-	1
Applied Biotech SureStep II	4	-	4
BD Directigen 1-2-3	2	-	2
BD LINK 2	1	-	1
BD Qtest	21	-	21
Beckman Coulter ICON DS	8	-	8
Beckman Coulter ICON Fx Strep A	17	-	17
BioStar Acceava Strep A Test	18	-	18
BioStar OIA	1	-	1
BioStar Strep A MAX OIA	58	1	57
DE Healthcare TruView	1	-	1
Fisher HealthCare Sure-Vue	1	-	1
Fisher Sure-Vue Strep A	1	-	1
Genzyme OSOM Ultra Strep A	7	-	7
Henry Schein One Step	3	-	3
LifeSign Status AccuStrep A	2	-	2
Mainline Confirms	1	-	1
Mainline ConfirmsStrep A Dots	2	-	2
Meridian ImmunoCard	2	-	2
Polymedco Polystat Strep A (I)	22	-	22
Polymedco Polystat Strep A (II)	6	-	6
Quidel Cards QS	7	-	7
Quidel QuickVue	25	1	24
Quidel QuickVue Dipstick Strep	9	-	9
Quidel QuickVue Flex	3	-	3
Quidel QuickVue In-Line	34	-	34
Quidel QuickVue+	66	-	66
Stanbio QuStick Strep A	1	-	1
Wyntek OSOM	3	-	3
Wyntek OSOM Ultra Strep A	6	-	6

STREP A ANTIGEN DETECTION

Specimen RS-10

				Strength of Reaction		
Method	***Labs***	***Positive***	***Negative***	***Strong***	***Moderate***	***Weak***
All Methods	388	385	3	216	127	18
Abbott Signify Strep A-waived	36	36	-	24	10	-
Applied Biotech Signify	7	7	-	3	1	2
Applied Biotech SureStep	1	1	-	-	1	-
Applied Biotech SureStep II	4	4	-	-	3	1
BD Directigen 1-2-3	2	2	-	-	2	-
BD LINK 2	1	1	-	-	-	1
BD Qtest	21	20	1	9	11	-
Beckman Coulter ICON DS	8	8	-	3	3	2
Beckman Coulter ICON Fx Strep A	17	17	-	6	11	-
BioStar Acceava Strep A Test	18	18	-	13	1	-
BioStar OIA	1	1	-	-	-	-
BioStar Strep A MAX OIA	58	58	-	45	11	1
DE Healthcare TruView	1	1	-	-	-	-
Fisher HealthCare Sure-Vue	1	1	-	-	1	-
Fisher Sure-Vue Strep A	1	1	-	-	-	1
Genzyme OSOM Ultra Strep A	7	7	-	3	2	-
Henry Schein One Step	3	3	-	1	1	-
LifeSign Status Strep A	2	2	-	1	-	1
Mainline Confirms	1	1	-	-	1	-
Mainline Confirms Strep A Dots	2	2	-	1	1	-
Meridian ImmunoCard	2	2	-	-	2	-
Polymedco Polystat Strep A (I)	22	22	-	12	10	-
Polymedco Polystat Strep A (II)	6	6	-	1	3	2
Quidel Cards QS	7	7	-	5	1	-
Quidel QuickVue	25	25	-	14	8	1
Quidel QuickVue Dipstick Strep	9	9	-	6	-	3
Quidel QuickVue Flex	3	3	-	2	-	-
Quidel QuickVue In-Line	34	32	2	18	13	1
Quidel QuickVue+	66	66	-	41	21	1
Stanbio QuStick Strep A	1	1	-	-	1	-
Wyntek OSOM	3	3	-	2	1	-
Wyntek OSOM Ultra Strep A	6	6	-	3	2	-

GENERAL BACTERIOLOGY

Specimen UC-6 – Urine Culture

Identification	***Labs***	***Percent***	***Performance***
Escherichia coli	4	100%	Acceptable
Gram Stain			
Gram negative	4	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	4	100%	

Organism present in specimen UC-6: *Escherichia coli.*

GENERAL BACTERIOLOGY

Specimen TC-6 – Throat Culture

Identification	***Labs***	***Percent***	***Performance***
Neisseria mucosa	1	33.3%	Not graded
Staphylococcus sp.	1	33.3%	
No enteric pathogens isolated	1	33.3%	

Organism present in specimen TC-6: *Neisseria mucosa.* This is an ungraded challenge due to less than 80% participant consensus.

Specimen BA-4 - Stool Culture

Identification	***Labs***	***Percent***	***Performance***
No enteric pathogens isolated	3	50.0%	Acceptable
Enterococcus (Strep) faecalis	1	16.7%	Acceptable
Klebsiella pneumoniae	1	16.7%	Acceptable
Staphylococcus aureus	1	16.7%	

Organisms present in specimen BA-4: *Enterococcus faecalis* and *Klebsiella pneumoniae.*

Specimen BA-5 – Wound Culture

Identification	***Labs***	***Percent***	***Performance***
Proteus mirabilis	3	60.0%	Acceptable
Proteus sp.	1	20.0%	Acceptable
Staphylococcus epidermidis	1	20.0%	Acceptable

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

Specimen BA-6 – Blood Culture

Identification	***Labs***	***Percent***	***Performance***
Pseudomonas aeruginosa	4	100%	Acceptable

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

URINE CULTURE

Specimen UC-6

Identification	***Labs***	***Percent***	***Performance***
Escherichia coli	78	44.3%	Acceptable
Growth, referred for identification	31	17.6%	Acceptable
Presump. Gram negative	26	14.8%	Acceptable
Presump. Escherichia coli	24	13.6%	Acceptable
Gram negative bacilli	16	9.1%	Acceptable
Gram Stain			
Gram negative	69	98.6%	Acceptable
Gram positive	1	1.4%	

URINE CULTURE

Specimen UC-6 (cont'd)

Gram Stain Morphology	***Labs***	***Percent***
Rods/bacilli	67	98.5%
Cocci	1	1.5%

Organism present in specimen UC-6: *Escherichia coli.*

Specimen UC-7

Identification	***Labs***	***Percent***	***Performance***
Enterococcus sp.	45	25.7%	Acceptable
Growth, referred for identification	44	25.1%	Acceptable
Presump. Gram positive	26	14.9%	Acceptable
Presump. Enterococcus sp.	11	6.3%	Acceptable
Gram positive cocci	20	11.4%	Acceptable
Enterococcus (Strep) faecalis	10	5.7%	Acceptable
Streptococcus non-hemolytic	2	1.1%	Acceptable
Presumptive Streptococcus sp.	2	1.1%	Acceptable
Strep. Grp. D – enterococcus	1	0.6%	Acceptable

Organisms present in specimen UC-7: *Enterococcus faecalis* and *Lactobacillus casei.*

Specimen UC-8

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	33	29.0%	Acceptable
Presump. Gram positive	26	22.8%	Acceptable
Streptococcus agalactiae	14	12.3%	Acceptable
Gram positive cocci	11	9.7%	Acceptable
Strep – beta hemo; not Grp A	4	3.5%	Acceptable
Presumptive Streptococcus sp.	3	2.6%	Acceptable
Corynebacterium sp.	2	1.8%	Acceptable
Contaminated specimen	7	6.1%	

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

Specimen UC-9

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram negative	20	31.8%	Acceptable
Growth, referred for identification	14	22.2%	Acceptable
Proteus vulgaris	10	15.9%	Acceptable
Gram negative bacilli	5	7.9%	Acceptable
Proteus sp.	3	4.8%	Acceptable
Presump. Gram positive	3	4.8%	Acceptable
Presump. Proteus sp.	2	3.2%	Acceptable

Organisms present in specimen UC-9: *Proteus vulgaris* and *Lactobacillus casei.*

URINE CULTURE

Specimen UC-10

Identification	*Labs*	*Percent*	*Performance*
Presump. Gram negative	17	27.0%	Acceptable
Growth, referred for identification	15	23.8%	Acceptable
Pseudomonas aeruginosa	11	17.5%	Acceptable
Pseudomonas sp.	8	12.7%	Acceptable
Presump. Pseudomonas sp.	7	11.1%	Acceptable
Gram negative bacilli	4	6.4%	Acceptable

Organism present in specimen UC-10: *Pseudomonas aeruginosa.*

ANTIMICROBIAL SUSCEPTIBILIY TESTING

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

	------Agar Diffusion------ *Interpretative category data*				*------MIC------* *Interpretative category data*				
Antimicrobial	*Labs*	*S*	*I*	*R*	*Labs*	*S*	*I*	*R*	*Acceptable (%)*
Amikacin	1	1	-	-	3	3	-	-	100%
Amoxicillin/Clavulanate	17	17	-	-	9	9	-	-	100%
Ampicillin	91	87	2	2	16	16	-	-	94.8%
Ampicillin/Sulbactam	1	1	-	-	2	2	-	-	100%
Carbenicillin	40	38	1	1	3	2	-	1	92.9%
Cefaclor	4	4	-	-	-	-	-	-	100%
Cefazolin	9	9	-	-	6	6	-	-	100%
Cefixime	10	10	-	-	1	1	-	-	100%
Ceftazidime	1	1	-	-	3	3	-	-	100%
Ceftriaxone	8	8	-	-	9	9	-	-	100%
Cefuroxime	2	2	-	-	4	4	-	-	100%
Cephalothin	90	69	19	2	16	11	4	1	Not graded[1]
Cinoxacin	3	3	-	-	-	-	-	-	100%
Ciprofloxacin	87	87	-	-	15	15	-	-	100%
Doxycycline	6	6	-	-	-	-	-	-	92.3%
Fosfomycin	1	1	-	-	-	-	-	-	100%
Gentamicin	49	49	-	-	8	8	-	-	100%
Imipenem	-	-	-	-	3	3	-	-	100%
Levofloxacin	12	12	-	-	11	11	-	-	100%
Lomefloxacin	1	1	-	-	3	3	-	-	100%
Nalidixic Acid	4	4	-	-	2	2	-	-	100%
Nitrofurantoin	100	100	-	-	19	18	-	1	99.4%
Norfloxacin	37	37	-	-	6	6	-	-	100%
Ofloxacin	21	21	-	-	3	3	-	-	100%
Piperacillin	-	-	-	-	1	1	-	-	100%
Sulfamethoxazole	4	4	-	-	-	-	-	-	100%
Sulfisoxazole	6	5	1	-	1	1	-	-	Not graded[1]
Tetracycline	47	46	1	-	8	8	-	-	97.7%
Ticarcillin	1	1	-	-	1	1	-	-	100%
Ticarcillin/Clavulanate	-	-	-	-	2	2	-	-	100%
Tobramycin	4	4	-	-	3	3	-	-	100%
Trimethoprim	12	12	-	-	5	5	-	-	100%

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

ANTIMICROBIAL SUSCEPTIBILIY TESTING

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

	------Agar Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Trimethoprim/Sulfamethoxazole	95	95	-	-	15	15	-	-	100%

Organism present in specimen UC-6, CC-6 (SUS-6): *Escherichia coli.*

GC CULTURE

Specimen GC-6

Identification	***Labs***	***Percent***	***Performance***
Neg. for N. gonorrhoeae	51	91.1%	Acceptable
Growth select. media, referred	2	3.6%	Acceptable
No growth	1	1.8%	Acceptable
Presp. N. gonorrhoeae, refer	2	3.6%	
Gram Stain			
Gram positive	24	77.4%	Not graded
Gram negative	7	22.6%	

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

Gram Stain Morphology		
Cocci	18	60.0%
Cocci in chains	5	16.7%
Cocci in pairs	2	6.7%
Cocco-bacilli	2	6.7%
Diplococci	2	6.7%
Rods/bacilli	1	3.3%

Organism present in specimen GC-6: *Enterococcus faecalis.*

Specimen GC-7

Identification	***Labs***	***Percent***	***Performance***
Presp. N. gonorrhoeae, refer	15	68.2%	Acceptable
Pos. for N. gonorrhoeae	6	27.3%	Acceptable
Neg. for N. gonorrhoeae	1	4.6%	
Beta-lactamase Testing			
Negative	2	66.7%	
Positive	1	33.3%	

Organisms present in specimen GC-7: *Neisseria gonorrhoeae* and *Corynebacterium sp.*

GC CULTURE

Specimen GC-8

Identification	***Labs***	***Percent***	***Performance***
No growth	15	75.0%	Acceptable
Neg. for N. gonorrhoeae	5	25.0%	Acceptable

Organisms present in specimen GC-8: *Gardnerella vaginalis* and *Staphylococcus epidermidis.*

Specimen GC-9

Identification	***Labs***	***Percent***	***Performance***
No growth	15	75.0%	Acceptable
Neg. for N. gonorrhoeae	5	25.0%	Acceptable

Organism present in specimen GC-9: *Streptococcus sp. Group B.*

Specimen GC-10

Identification	***Labs***	***Percent***	***Performance***
Presp. N. gonorrhoeae, refer	14	70.0%	Acceptable
Pos. for N. gonorrhoeae	5	25.0%	Acceptable
Neg. for N. gonorrhoeae	1	5.0%	
Beta-lactamase Testing			
Positive	2	50.0%	
Negative	2	50.0%	

Organisms present in specimen GC-10: *Neisseria gonorrhoeae* and *Lactobacillus casei.*

COLONY COUNT

Specimen CC-6

Method	***Labs***	***No growth***	***<10,000 organisms/mL***	***10,000-100,000 organisms/mL***	***>100,000 organisms/mL***
All Methods	136	3	1	9	123
Bactercult	2	-	-	-	2
Bacti-Star	1	-	-	-	1
Bulls Eye	6	-	1	1	4
Calibrated Loop	35	-	-	-	35
HealthLink	8	-	-	1	7
Med Ox Dip-Paddle/Slide	1	-	-	1	-
Troy Bacti- Urine, Plate	2	1	-	-	1
Uri-Check	18	1	-	-	17
Uri-Kit	1	-	-	-	1
Uri-Three	1	-	-	-	1
Uricult	55	1	-	5	49

COLONY COUNT

Identification - Specimen CC-6

Identification	***Labs***	***Percent***	***Performance***
Presump. Escherichia coli	25	42.4%	Acceptable
Presump. Gram negative	11	18.6%	Acceptable
Growth, referred for identification	8	13.6%	Acceptable
Escherichia coli	4	6.8%	Acceptable
Presump. Enterobacter sp.	7	11.9%	
Gram Stain			
Gram negative	6	85.7%	Acceptable
Gram positive	1	14.3%	
Gram Stain Morphology			
Rods/bacilli	8	88.9%	
Cocci in chains	1	11.1%	

Organism present in specimen CC-6: *Escherichia coli*.

Specimen CC-7

Method	***Labs***	***No growth***	***<10,000 organisms/mL***	***10,000-100,000 organisms/mL***	***>100,000 organisms/mL***
All Methods	136	4	15	52	65
Bactercult	2	-	-	-	2
Bacti-Star	1	-	-	-	1
Bulls Eye	6	-	1	4	1
Calibrated Loop	35	-	-	1	34
HealthLink	8	-	2	4	2
Med Ox Dip-Paddle/Slide	1	-	-	1	-
Troy Bacti- Urine, Plate	2	-	1	-	1
Uri-Check	18	-	3	11	4
Uri-Kit	1	-	-	1	-
Uri-Three	1	-	-	1	-
Uricult	55	4	8	27	16

Identification - Specimen CC-7

Identification	***Labs***	***Percent***	***Performance***
Presump. Enterococcus sp.	22	38.6%	Acceptable
Presump. Gram positive	18	31.6%	Acceptable
Growth, referred for identification	8	14.0%	Acceptable
Enterococcus sp.	2	3.5%	Acceptable
Enterococcus (Strep) faecalis	1	1.8%	Acceptable
Gram positive cocci	1	1.8%	Acceptable
Strep. Grp. D – enterococcus	1	1.8%	Acceptable

Organisms present in specimen CC-7: *Enterococcus faecalis* and *Lactobacillus casei.*

COLONY COUNT

Identification - Specimen CC-8

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram positive	10	25.0%	Not graded
Presumptive Streptococcus sp.	7	17.5%	
Growth, referred for identification	6	15.0%	
Streptococcus agalactiae	1	2.5%	
No growth (sterile)	12	30.0%	

Organisms present in specimen CC-8: *Streptococcus sp. Group B* and *Corynebacterium sp.* This is an ungraded challenge due to less than 80% participant consensus.

Identification - Specimen CC-9

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram negative	11	27.5%	Acceptable
Growth, referred for identification	9	22.5%	Acceptable
Presump. Proteus sp.	7	17.5%	Acceptable
Proteus vulgaris	2	5.0%	Acceptable
Presump. Gram positive	2	5.0%	Acceptable

Organisms present in specimen CC-9: *Proteus vulgaris* and *Lactobacillus casei.*

Identification - Specimen CC-10

Identification	***Labs***	***Percent***	***Performance***
Presump. Pseudomonas sp.	18	45.0%	Acceptable
Growth, referred for identification	7	17.5%	Acceptable
Presump. Gram negative	7	17.5%	Acceptable
Pseudomonas aeruginosa	4	10.0%	Acceptable
Pseudomonas sp.	1	2.5%	Acceptable
Bacturcult Group III	1	2.5%	Acceptable

Organism present in specimen CC-10: *Pseudomonas aeruginosa.*

DERMATOPHYTE SCREEN

Specimen DM-6

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte present	13	65.0%	Not Graded
Dermatophyte absent	7	35.0%	

Organisms present in specimen DM-6: *Epidermophyton bloccosum* and *Staphylococcys epidermidis.* This is ungraded challenge due to less than 80% participant consensus.

Specimen DM-7

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte present	20	100%	Acceptable
Dermatophyte absent	-	-	

Organisms present in specimen DM-7: *Microsporum gypseum* and *Staphylococcus epidermidis.*

GRAM STAIN

Specimen GS-6

Identification	***Labs***	***Percent***	***Performance***
Gram negative	67	91.8%	Acceptable
Gram positive	6	8.2%	

Gram Stain Morphology

Diplococci	55	79.7%
Cocci in pairs	8	11.6%
Cocci	6	8.7%

Organism present in specimen GS-6: *Branhamella catarrhalis.*

Specimen GS-7

Identification	***Labs***	***Percent***	***Performance***
Gram positive	66	90.4%	Acceptable
Gram negative	7	9.6%	

Gram Stain Morphology

Cocci in chains	67	95.7%
Rods/bacilli	2	2.9%
Cocci	1	1.4%

Organism present in specimen GS-7: *Streptococcus pneumoniae.*

Specimen GS-8

Identification	***Labs***	***Percent***	***Performance***
Gram positive	71	97.3%	Acceptable
Gram negative	2	2.7%	

Gram Stain Morphology

Cocci	57	85.1%
Cocci in pairs	8	11.9%
Cocci in chains	2	3.0%

Organism present in specimen GS-8: *Staphylococcus aureus*.

GRAM STAIN

Specimen GS-9

Identification	***Labs***	***Percent***	***Performance***
Gram positive	72	98.6%	Acceptable
Gram negative	1	1.4%	

Gram Stain Morphology

Rods/bacilli	65	92.9%
Cocco-bacilli	4	5.7%
Cocci in pairs	1	1.4%

Organism present in specimen GS-9: *Bacillus species.*

Specimen GS-10

Identification	***Labs***	***Percent***	***Performance***
Gram negative	72	98.6%	Acceptable
Gram positive	1	1.4%	

Gram Stain Morphology

Rods/bacilli	66	95.7%
Diplococci	2	2.9%
Cocci in chains	1	1.5%

Organism present in specimen GS-10: *Pseudomonas aeruginosa.*

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-6

Method	***Labs***	***Positive***	***Negative***
All Methods	31	29	2
Abbott LCx	2	2	-
BD ProbeTec	1	1	-
Beckman (Sanofi) ACCESS	1	1	-
bioMerieux Vitek, Mini Vidas	1	1	-
BioStar OIA	3	3	-
Gen-Probe	7	7	-
Quidel QuickVue	11	11	-
Syva Micro Trak II, XL	1	1	-
Wampole Clearview	2	-	2

Organism present in specimen CY-6: *Chlamydia trachomatis.*

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-7

Method	***Labs***	***Positive***	***Negative***
All Methods	31	3	28
Abbott LCx	2	2	-
BD ProbeTec	1	-	1
Beckman (Sanofi) ACCESS	1	-	1
bioMerieux Vitek, Mini Vidas	1	-	1
BioStar OIA	3	-	3
Gen-Probe	7	-	7
Quidel Quick Vue	11	-	11
Syva Micro Trak II, XL	1	-	1
Wampole Clearview	2	-	2

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

Specimen CY-8

Method	***Labs***	***Positive***	***Negative***
All Methods	25	1	24
Abbott LCx	2	-	2
BD ProbeTec	1	-	1
Beckman (Sanofi) ACCESS	1	-	1
BioMerieux Vitek, Mini Vidas	1	1	-
BioStar OIA	2	-	2
Gen-Probe	7	-	7
Quidel Quick Vue	8	-	8
Syva Micro Trak II, XL	1	-	1
Wampole Clearview	1	-	1

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

Specimen CY-9

Method	***Labs***	***Positive***	***Negative***
All Methods	25	24	1
Abbott LCx	2	2	-
BD ProbeTec	1	1	-
Beckman (Sanofi) ACCESS	1	1	-
bioMerieux Vitek, Mini Vidas	1	1	-
BioStar OIA	2	2	-
Gen-Probe	7	7	-
Quidel QuickVue	8	8	-
Syva Micro Trak II, XL	1	1	-
Wampole Clearview	1	-	1

Organism present in specimen CY-9: *Chlamydia trachomatis.*

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-10

Method	***Labs***	***Positive***	***Negative***
All Methods	25	23	2
Abbott LCx	2	2	-
BD ProbeTec	1	1	-
Beckman (Sanofi) ACCESS	1	1	-
bioMerieux Vitek, Mini Vidas	1	-	1
BioStar OIA	2	2	-
Gen-Probe	7	7	-
Quidel QuickVue	8	8	-
Syva Micro Trak II, XL	1	1	-
Wampole Clearview	1	-	1

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

GC (ANTIGEN DETECTION)

Specimen CY-6

Method	***Labs***	***Positive***	***Negative***
All Methods	10	-	10
Abbott LCx	2	-	2
BD ProbeTec	1	-	1
Gen-Probe	7	-	7

Specimen CY-7

Method	***Labs***	***Positive***	***Negative***
All Methods	10	10	-
Abbott LCx	2	2	-
BD ProbeTec	1	1	-
Gen-Probe	7	7	-

Specimen CY-8

Method	***Labs***	***Positive***	***Negative***
All Methods	10	10	-
Abbott LCx	2	2	-
BD ProbeTec	1	1	-
Gen-Probe	7	7	-

Specimen CY-9

Method	***Labs***	***Positive***	***Negative***
All Methods	10	-	10
Abbott LCx	2	-	2
BD ProbeTec	1	-	1
Gen-Probe	7	-	7

GC (ANTIGEN DETECTION)

Specimen CY-10

Method	***Labs***	***Positive***	***Negative***
All Methods	10	-	10
Abbott LCx	2	-	2
BD ProbeTec	1	-	1
Gen-Probe	7	-	7

AFFIRM VP III - Gardnerella vaginalis

Specimen VP-6

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

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

Specimen VP-7

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

Organism present in specimen VP-7: *Gardnerella vaginalis.*

Specimen VP-8

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

Organisms present in specimen VP-8: *Candida albicans* and *Trichomonas vaginalis.*

Specimen VP-9

Identification	***Labs***	***Percent***	***Performance***
Positive	34	100%	Acceptable

Organism present in specimen VP-9: *Gardnerella vaginalis.*

Specimen VP-10

Identification	***Labs***	***Percent***	***Performance***
Negative	34	100%	Acceptable

Organism present in specimen VP-10: Negative specimen (sterile).

AFFIRM VP III - Candida sp.

Specimen VP-6

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

Specimen VP-7

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

Specimen VP-8

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

Specimen VP-9

Identification	***Labs***	***Percent***	***Performance***
Negative	34	100%	Acceptable

Specimen VP-10

Identification	***Labs***	***Percent***	***Performance***
Negative	34	100%	Acceptable

AFFIRM VP III - Trichomonas vaginalis

Specimen VP-6

Identification	***Labs***	***Percent***	***Performance***
Positive	21	60.0%	Not graded
Negative	14	40.0%	

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

Specimen VP-7

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

Specimen VP-8

Identification	***Labs***	***Percent***	***Performance***
Positive	18	51.4%	Not graded
Negative	17	48.6%	

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

AFFIRM VP III - Trichomonas vaginalis

Specimen VP-9

Identification	***Labs***	***Percent***	***Performance***
Negative	34	100%	Acceptable

Specimen VP-10

Identification	***Labs***	***Percent***	***Performance***
Negative	34	100%	Acceptable

RSV ANTIGEN DETECTION

Specimen V-6

Method	***Labs***	***Positive***	***Negative***
All Methods	22	22	-
BD Directigen	16	16	-
Binax NOW	1	1	-
BioStar OIA	5	5	-

Specimen V-6: Positive for RSV antigen.

Specimen V-7

Method	***Labs***	***Positive***	***Negative***
All Methods	22	-	22
BD Directigen	16	-	16
Binax NOW	1	-	1
BioStar OIA	5	-	5

Specimen V-7: Negative for RSV antigen.

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
All Methods	22	21	1
BD Directigen	16	15	1
Binax NOW	1	1	-
BioStar OIA	5	5	-

Specimen V-8: Positive for RSV antigen.

RSV ANTIGEN DETECTION

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
All Methods	22	-	22
BD Directigen	16	-	16
Binax NOW	1	-	1
BioStar OIA	5	-	5

Specimen V-9: Negative for RSV antigen.

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
All Methods	22	22	-
BD Directigen	16	16	-
Binax NOW	1	1	-
BioStar OIA	5	5	-

Specimen V-10: Positive for RSV antigen.

INFLUENZA A ANTIGEN DETECTION

Specimen V-6

Method	***Labs***	***Positive***	***Negative***
All Methods	55	2	53
BD Directigen	5	1	4
Binax NOW	2	-	2
BioStar OIA	9	-	9
Quidel QuickVue Influenza	30	1	29
ZymeTx	8	-	8

Specimen V-6: Negative for Influenza A antigen.

Specimen V-7

Method	***Labs***	***Positive***	***Negative***
All Methods	55	54	1
BD Directigen	5	5	-
Binax NOW	2	2	-
BioStar OIA	9	9	-
Quidel QuickVue Influenza	30	29	1
ZymeTx	8	8	-

Specimen V-7: Positive for Influenza A antigen.

INFLUENZA A ANTIGEN DETECTION

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
All Methods	28	-	28
BD Directigen	4	-	4
Binax NOW	2	-	2
BioStar OIA	8	-	8
Quidel QuickVue Influenza	11	-	11
ZymeTx	2	-	2

Specimen V-8: Negative for Influenza A antigen.

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
All Methods	28	27	1
BD Directigen	4	4	-
Binax NOW	2	2	-
BioStar OIA	8	8	-
Quidel QuickVue Influenza	11	11	-
ZymeTx	2	1	1

Specimen V-9: Positive for Influenza A antigen.

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
All Methods	28	-	28
BD Directigen	4	-	4
Binax NOW	2	-	2
BioStar OIA	8	-	8
Quidel QuickVue Influenza	11	-	11
ZymeTx	2	-	2

Specimen V-10: Negative for Influenza A antigen.

LEGIONELLA ANTIGEN DETETION

Specimen L-6

Method	***Labs***	***Positive***	***Negative***
Binax NOW	188	-	188

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

Specimen L-7

Method	***Labs***	***Positive***	***Negative***
Binax NOW	187	187	-

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

LEGIONELLA ANTIGEN DETETION

Specimen L-8

Method	***Labs***	***Positive***	***Negative***
Binax NOW	188	188	-

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

Specimen L-9

Method	***Labs***	***Positive***	***Negative***
Binax NOW	188	1	187

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

Specimen L-10

Method	***Labs***	***Positive***	***Negative***
Binax NOW	188	187	1

Specimen L-10: Positive for *Legionella* antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-6

Method	***Labs***	***Positive***	***Negative***
All Methods	22	1	21
Alexon (Hycor)	1	-	1
Becton Dickinson Toxin CD	1	-	1
bioMerieux Vitek, Mini Vidas	1	-	1
Biosite Triage	7	-	7
BioStar OIA	9	-	9
Meridian Premier	1	-	1
Wampole	1	1	-

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

Specimen AG-7

Method	***Labs***	***Positive***	***Negative***
All Methods	22	22	-
Alexon (Hycor)	1	1	-
Becton Dickinson Toxin CD	1	1	-
bioMerieux Vitek, Mini Vidas	1	1	-
Biosite Triage	7	7	-
BioStar OIA	9	9	-
Meridian Premier	1	1	-
Wampole	1	1	-

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

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-8

Method	***Labs***	***Positive***	***Negative***
All Methods	22	-	22
Alexon (Hycor)	1	-	1
Becton Dickinson Toxin CD	1	-	1
bioMerieux Vitek, Mini Vidas	1	-	1
Biosite Triage	7	-	7
BioStar OIA	9	-	9
Meridian Premier	1	-	1
Wampole	1	-	1

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

Specimen AG-9

Method	***Labs***	***Positive***	***Negative***
All Methods	22	22	-
Alexon (Hycor)	1	1	-
Becton Dickinson Toxin CD	1	1	-
bioMerieux Vitek, Mini Vidas	1	1	-
Biosite Triage	7	7	-
BioStar OIA	9	9	-
Meridian Premier	1	1	-
Wampole	1	1	-

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

Specimen AG-10

Method	***Labs***	***Positive***	***Negative***
All Methods	22	-	22
Alexon (Hycor)	1	-	1
Becton Dickinson Toxin CD	1	-	1
bioMerieux Vitek, Mini Vidas	1	-	1
Biosite Triage	7	-	7
BioStar OIA	9	-	9
Meridian Premier	1	-	1
Wampole	1	-	1

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

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-6

Method	***Labs***	***Positive***	***Negative***
All Methods	8	-	8
Meridian ImmunoCard	5	-	5
Meridian Premier	1	-	1

Specimen AG-6: Neagtive for Rotavirus antigen.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-7

Method	***Labs***	***Positive***	***Negative***
All Methods	10	1	9
Meridian ImmunoCard	6	1	5
Meridian Premier	1	-	1

Specimen AG-7: Negative for Rotavirus antigen.

Specimen AG-8

Method	***Labs***	***Positive***	***Negative***
All Methods	10	10	-
Meridian ImmunoCard	6	6	-
Meridian Premier	1	1	-

Specimen AG-8: Positive for Rotavirus antigen.

Specimen AG-9

Method	***Labs***	***Positive***	***Negative***
All Methods	10	1	9
Meridian ImmunoCard	6	1	5
Meridian Premier	1	-	1

Specimen AG-9: Negative for Rotavirus antigen.

Specimen AG-10

Method	***Labs***	***Positive***	***Negative***
All Methods	10	10	-
Meridian ImmunoCard	6	6	-
Meridian Premier	1	1	-

Specimen AG-10: Positive for Rotavirus antigen.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen AG-6

Method	***Labs***	***Positive***	***Negative***
All Methods	5	4	1
Alexon (Hycor)	1	1	-
Becton Dickinson ColorPAC	2	2	-
Biostie Triage	1	-	1
Meridian Merifluor	1	1	-

Specimen AG 6: Positive for *Cryptosporidium* antigen.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen AG-7

Method	*Labs*	*Positive*	*Negative*
All Methods	5	-	5
Alexon (Hycor)	1	-	1
Becton Dickinson ColorPAC	2	-	2
Biosite Triage	1	-	1
Meridian Merifluor	1	-	1

Specimen AG 7: Negative for *Cryptosporidium* antigen.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen AG-6

Method	*Labs*	*Positive*	*Negative*
All Methods	9	8	1
Alexon (Hycor)	4	4	-
Becton Dickinson ColorPAC	2	2	-
Biosite Triage	1	-	1
Meridian Merifluor	1	1	-
Remel RIM Immuno	1	1	-

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

Specimen AG-7

Method	*Labs*	*Positive*	*Negative*
All Methods	9	-	9
Alexon (Hycor)	4	-	4
Becton Dickinson ColorPAC	2	-	2
Biosite Triage	1	-	1
Meridian Merifluor	1	-	1
Remel RIM Immuno	1	-	1

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

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-6

Method	*Labs*	*Positive*	*Negative*
Binax NOW	68	67	1

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

Specimen SP-7

Method	*Labs*	*Positive*	*Negative*
Binax NOW	68	-	68

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

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-8

Method	***Labs***	***Positive***	***Negative***
Binax NOW	68	1	67

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

Specimen SP-9

Method	***Labs***	***Positive***	***Negative***
Binax NOW	68	68	-

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

Specimen SP-10

Method	***Labs***	***Positive***	***Negative***
Binax NOW	68	68	-

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

PARASITOLOGY

One participant reported results for Parasitology. The parasites that are present in each specimen are as follows:

PVA Slide
PA-6 – Entamoeba coli
PA-7 – Dientamoeba fragilis

Fecal Suspension
PA-8 – Giardia lamblia
PA-9 – Hookworm
PA-10 – Strongyloides stercoralis larvae

SUMMARY OF ISOLATES FOUND IN THE 2003 MLE-A2 CULTURE SPECIMENS

Organism	ATCC Strain
Enterococcus faecalis	29212
Klebsiella pneumoniae	13883
Proteus mirabilis	12453
Staphylococcus epidermidis	14990
Pseudomonas aeruginosa	27853
Escherichia coli	25922
Lactobacillus casei	393
Streptococcus sp. Group B	12386
Corynebacterium sp.	49528
Proteus vulgaris	13315
Neisseria gonorrhoeae	19424
Gardnerella vaginalis	14018
Neisseria mucosa	19695
Streptococcus pyogenes	19615
Streptococcus pneumoniae	6305
Staphylococcus aureus	25923

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