

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

Microbiology
MLE – M2

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2005 Evaluation Criteria 2

Microbiology

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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-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	186	89.0%	Acceptable
Streptococcus pneumoniae	13	6.2%	Acceptable
Streptococcus alpha-hemolytic	2	1.0%	Acceptable
Gram positive cocci	2	1.0%	Acceptable
Growth, referred for identification	1	0.5%	Acceptable
No growth(sterile)	1	0.5%	Acceptable

Organism present in specimens TC-6: *Streptococcus pneumoniae*.

Specimen TC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	108	50.7%	Acceptable
Presump. Pos. Group A Strep	79	37.1%	Acceptable
Streptococcus pyogenes	11	5.2%	Acceptable
Staphylococcus epidermidis	3	1.4%	Acceptable
Staphylococcus sp.	1	0.5%	Acceptable
Staph – coagulase neg.	1	0.5%	Acceptable
Gram positive cocci	1	0.5%	Acceptable
Negative for Group A Strep	7	3.3%	

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

Specimen TC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	72	96.0%	Acceptable
Staphylococcus aureus	1	1.3%	Acceptable

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

Specimen TC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	57	89.1%	Acceptable
No growth (sterile)	4	6.3%	Acceptable

Organisms present in specimen TC-9: *Moraxella catarrhalis* and *Corynebacterium species*.

Specimen TC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	36	56.3%	Acceptable
Presump. Pos. Group A Strep	22	34.4%	Acceptable
Negative for Group A Strep	6	9.4%	

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

STREP A ANTIGEN DETECTION

Specimen RS-6

<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	746	742	4	556	119	15
Abbott Signify Strep A-waived	73	72	1	58	11	-
Applied Biotech Signify	7	6	1	2	2	-
Applied Biotech SureStep	3	3	-	1	2	-
Applied Biotech SureStep II	3	3	-	2	-	1
BD Direction 1-2-3	1	1	-	1	-	-
BD LINK 2	2	2	-	1	1	-
BD QTest	29	29	-	27	1	1
Beckman Coulter ICON DS	16	16	-	12	3	1
Beckman Coulter ICON Fx Strep A	5	5	-	2	1	-
Beckman Coulter ICON SC	7	7	-	3	3	1
Binax NOW Strep A	2	2	-	2	-	-
BioStar Acceava Strep A Test	60	60	-	31	21	1
BioStar Strep A MAX OIA	37	37	-	33	3	-
DE Healthcare TruView	11	11	-	6	2	-
Fisher HealthCare Sure-Vue	5	5	-	1	2	-
Fisher Sure-Vue Strep A-waived	1	1	-	1	-	-
Genzyme OSOM	6	6	-	4	2	-
Genzyme OSOM Ultra Strep A	61	61	-	44	10	1
Henry Schein One Step	9	9	-	9	-	-
Instant Technologies i Strep	2	2	-	1	1	-
Inverness Signify Strep A Dip	6	6	-	2	2	-
LifeSign Status AccuStrep A	1	1	-	1	-	-
Mainline Confirms	3	3	-	-	2	1
Mainline Confirms Strep A Dots	1	1	-	1	-	-
McKesson Strep A Cassette	7	7	-	6	-	-
McKesson Strep A Dipstick	9	9	-	5	4	-
Polymedco Polystat Strep A (I)	30	30	-	17	9	3
Polymedco Polystat Strep A (II)	21	21	-	14	5	-
Quidel QuickVue Dipstick Strep	58	58	-	49	4	-
Quidel QuickVue In-Line	98	97	1	73	14	5
Quidel QuickVue+	128	127	1	118	5	-
Wampole Clearview	6	6	-	3	1	-
Wampole PreVue	1	1	-	1	-	-
Wyntek OSOM Ultra Strep A	11	11	-	7	2	-

Specimen RS-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>	<u>Strength of Reaction</u>		
				<u>Strong</u>	<u>Moderate</u>	<u>Weak</u>
All Methods	711	697	14	489	141	19
Abbott Signify Strep A-waived	69	68	1	45	20	2
Applied Biotech Signify	5	5	-	2	-	1
Applied Biotech SureStep	3	3	-	1	2	-
Applied Biotech SureStep II	3	3	-	1	1	1
BD Directigen 1-2-3	1	1	-	1	-	-
BD LINK 2	2	2	-	2	-	-
BD QTest	27	27	-	23	2	2
Beckman Coulter ICON DS	16	15	1	9	6	-
Beckman Coulter ICON Fx Strep A	5	5	-	2	1	-
Beckman Coulter ICON SC	7	7	-	3	4	-
Binax NOW Strep A	2	2	-	1	1	-

STREP A ANTIGEN DETECTION

Specimen RS-7 (cont'd)

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>	<u>Strength of Reaction</u>		
				<u>Strong</u>	<u>Moderate</u>	<u>Weak</u>
BioStar Acceava Strep A Test	58	57	1	31	19	-
BioStar Strep A MAX OIA	36	36	-	34	1	-
DE Healthcare TruView	10	10	-	5	2	-
Fisher HealthCare Sure-Vue	4	4	-	-	2	1
Genzyme OSOM	6	6	-	4	2	-
Genzyme OSOM Ultra Strep A	56	56	-	36	14	-
Henry Schein One Step	9	9	-	9	-	-
Instant Technologies i Strep	2	2	-	2	-	-
Inverness Signify Strep A Dip.	6	6	-	2	2	-
LifeSign Status Strep A	1	1	-	1	-	-
Mainline Confirms	1	1	-	-	1	-
Mainline Confirms Strep A Dots	1	1	-	1	-	-
McKesson Strep A Cassette	7	7	-	4	2	-
McKesson Strep A Dipstick	9	9	-	6	3	-
Polymedco Polystat Strep A (I)	30	30	-	12	13	4
Polymedco Polystat Strep A (II)	20	20	-	10	8	-
Quidel QuickVue Dipstick Strep	56	56	-	46	5	-
Quidel QuickVue In-Line	96	86	10	64	12	7
Quidel QuickVue+	120	120	-	108	7	-
Wampole Clearview	6	6	-	3	1	-
Wampole PreVue	1	1	-	1	-	-
Wyntek OSOM Ultra Strep A	11	11	-	8	1	-

Specimen RS-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	413	4	409
Abbott Signify Strep A-waived	35	1	34
Applied Biotech Signify	5	-	5
Applied Biotech SureStep	2	-	2
Applied Biotech SureStep II	3	-	3
BD Directigen 1-2-3	1	-	1
BD LINK 2	1	-	1
BD QTest	26	1	25
Beckman Coulter ICON DS	7	-	7
Beckman Coulter ICON Fx Strep A	3	-	3
Beckman Coulter ICON SC	4	-	4
Binax NOW Strep A	2	-	2
BioStar Acceava Strep A Test	21	-	21
BioStar Strep A MAX OIA	35	-	35
DE Healthcare TruView	4	-	4
Fisher HealthCare Sure-Vue	2	-	2
Genzyme OSOM	3	-	3
Genzyme OSOM Ultra Strep A	32	-	32
Mainline Confirms	1	-	1
Mainline Confirms Strep A Dots	1	-	1
McKesson Strep A Cassette	5	-	5
McKesson Strep A Dipstick	5	-	5
Polymedco Polystat Strep A (I)	23	-	23
Polymedco Polystat Strep A (II)	6	-	6

STREP A ANTIGEN DETECTION

Specimen RS-8 (cont'd)

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Quidel QuickVue Dipstick Strep	15	-	15
Quidel QuickVue In-Line	38	1	37
Quidel QuickVue+	114	1	113
Wampole Clearview	4	-	4
Wyntek OSOM Ultra Strep A	5	-	5

Specimen RS-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>	<u>Strength of Reaction</u>		
				<u>Strong</u>	<u>Moderate</u>	<u>Weak</u>
All Methods	354	350	4	239	70	16
Abbott Signify Strep A-waived	30	29	1	21	8	-
Applied Biotech Signify	5	4	1	1	1	1
Applied Biotech SureStep II	3	3	-	1	-	2
BD LINK 2	1	1	-	-	1	-
BD QTest	22	22	-	17	3	2
Beckman Coulter ICON DS	7	7	-	2	5	-
Beckman Coulter ICON Fx Strep A	2	2	-	-	1	-
Beckman Coulter ICON SC	4	4	-	1	3	-
Binax NOW Strep A	2	2	-	2	-	-
BioStar Acceava Strep A Test	18	18	-	6	7	1
BioStar Strep A MAX OIA	34	34	-	29	3	-
DE Healthcare TruView	4	4	-	1	2	1
Fisher HealthCare Sure-Vue	2	2	-	-	1	-
Genzyme OSOM	3	3	-	2	1	-
Genzyme OSOM Ultra Strep A	23	23	-	15	4	1
Mainline Confirms	1	1	-	-	-	1
Mainline Confirms Strep A Dots	1	1	-	-	1	-
McKesson Strep A Cassette	5	5	-	3	1	-
McKesson Strep A Dipstick	3	3	-	2	-	1
Polymedco Polystat Strep A (I)	22	22	-	14	6	2
Polymedco Polystat Strep A (II)	5	5	-	1	3	-
Quidel QuickVue Dipstick Strep	11	11	-	9	1	-
Quidel QuickVue In-Line	35	34	1	22	7	3
Quidel QuickVue+	97	96	1	84	7	1
Wampole Clearview	4	4	-	-	2	-
Wyntek OSOM Ultra Strep A	1	1	-	1	-	-

STREP A ANTIGEN DETECTION

Specimen RS-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	353	1	352
Abbott Signify Strep A-waived	30	1	29
Applied Biotech Signify	5	-	5
Applied Biotech SureStep II	3	-	3
BD LINK 2	1	-	1
BD QTest	22	-	22
Beckman Coulter ICON DS	7	-	7
Beckman Coulter ICON Fx Strep A	2	-	2
Beckman Coulter ICON SC	4	-	4
Binax NOW Strep A	2	-	2
BioStar Acceava Strep A Test	18	-	18
BioStar Strep A MAX OIA	34	-	34
DE Healthcare TruView	4	-	4
Fisher HealthCare Sure-Vue	2	-	2
Genzyme OSOM	3	-	3
Genzyme OSOM Ultra Strep A	23	-	23
Mainline Confirms	1	-	1
Mainline Confirms Strep A Dots	1	-	1
Mckesson strep A Cassette	5	-	5
Mckesson strep A Dipstick	3	-	3
Polymedco Polystat Strep A (I)	21	-	21
Polymedco Polystat Strep A (II)	5	-	5
Quidel QuickVue Dipstick Strep	11	-	11
Quidel QuickVue in-Line	35	-	35
Quidel QuickVue+	97	-	97
Wampole Clearview	4	-	4
Wyntek OSOM Ultra Strep A	1	-	1

GENERAL BACTERIOLOGY

Specimen UC-6 – Urine Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus saprophyticus	5	55.6%	Acceptable
Staph – coagulase neg.	3	33.3%	Acceptable
Staphylococcus sp.	1	11.1%	Acceptable

Gram Stain

Gram positive	6	100%	Acceptable
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Gram Stain Morphology

Cocci	6	100%	
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Organism present in specimen UC-6: *Staphylococcus saprophyticus*.

GENERAL BACTERIOLOGY

Specimen GC-6 – GC Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Streptococcus agalactiae	6	54.6%	Acceptable
Staphylococcus sp.	1	9.1%	Acceptable
Staph – coagulase neg.	1	9.1%	Acceptable
Staphylococcus epidermidis	1	9.1%	Acceptable
No growth (sterile)	1	9.1%	Acceptable

Organisms present in specimen GC-6: *Streptococcus agalactiae* and *Staphylococcus epidermidis*.

Specimen BA-4 – Stool Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Shigella sp.	6	75.0%	Acceptable
Escherichia coli	1	12.5%	Acceptable

Organisms present in specimen BA-4: *Shigella sonnei* and *Escherichia coli*.

Specimen BA-5 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus aureus	9	50.0%	Acceptable
Streptococcus pyogenes	8	44.4%	Acceptable
Presump. Pos. Group A Strep	1	5.6%	Acceptable

Organisms present in specimen BA-5: *Staphylococcus aureus* and *Streptococcus pyogenes*.

Specimen BA-6 – Spinal Fluid Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Neisseria meningitidis	7	87.5%	Acceptable
Growth, referred for identification	1	12.5%	Acceptable

Organism present in specimen BA-6: *Neisseria meningitidis*.

URINE CULTURE

Specimen UC-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	38	24.7%	Acceptable
Staphylococcus saprophyticus	34	22.1%	Acceptable
Presump. Gram positive	24	15.6%	Acceptable
Staph – coagulase neg.	17	11.0%	Acceptable
Gram positive cocci	14	9.1%	Acceptable
Presump. Staphylococcus sp.	12	7.8%	Acceptable
Staphylococcus sp.	9	5.8%	Acceptable
No growth (sterile)	1	0.7%	Acceptable

Gram Stain

Gram positive	68	98.6%	Acceptable
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Gram Stain Morphology

Cocci	64	97.0%	
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Organism present in specimen UC-6: *Staphylococcus saprophyticus*.

Specimen UC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pseudomonas aeruginosa	41	26.0%	Acceptable
Growth, referred for identification	32	20.3%	Acceptable
Presump. Gram negative	23	14.6%	Acceptable
Presump. Pseudomonas sp.	19	12.0%	Acceptable
Pseudomonas sp.	17	10.8%	Acceptable
Gram negative bacilli	16	10.1%	Acceptable
Staphylococcus epidermidis	3	1.9%	Acceptable
Staph – coagulase neg.	2	1.3%	Acceptable

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

URINE CULTURE

Specimen UC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	31	33.3%	Acceptable
Presump. Gram positive	24	25.8%	Acceptable
Streptococcus agalactiae	13	14.0%	Acceptable
Gram positive cocci	9	9.7%	Acceptable
Strep – beat hemo; not Group A	6	6.5%	Acceptable
No Growth (sterile)	4	4.3%	Acceptable
Presumptive Streptococcus sp.	4	4.3%	Acceptable

Organisms present in specimen UC-8: *Streptococcus agalactiae* and *Lactobacillus casei*.

Specimen UC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	20	36.4%	Acceptable
Growth, referred for identification	19	34.6%	Acceptable
Staphylococcus aureus	8	14.6%	Acceptable
Gram positive cocci	3	5.5%	Acceptable
Presump. Staphylococcus sp.	3	5.5%	Acceptable
Staphylococcus sp.	1	1.8%	Acceptable

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

Specimen UC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	22	38.6%	Acceptable
Escherichia coli	15	26.3%	Acceptable
Growth, referred for identification	10	17.5%	Acceptable
Presump. Escherichia coli	6	10.5%	Acceptable
Gram negative bacilli	2	3.5%	Acceptable
Presump. Gram positive	2	3.5%	Acceptable

Organisms present in specimen UC-10: *Escherichia coli* and *Corynebacterium sp.*

ANTIMICROBIAL SUSCEPTIBILITY TESTING

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

<u>Antimicrobial</u>	<u>-----Agar Diffusion-----</u>				<u>-----MIC-----</u>				<u>Acceptable (%)</u>
	<u>Interpretative category data</u>				<u>Interpretative category data</u>				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Amoxicillin/Clavulanate	15	10	-	5	14	7	-	7	Not graded ¹
Ampicillin	57	48	-	9	9	5	-	4	Not graded ¹
Ampicillin/Sulbactam	-	-	-	-	7	-	-	7	80%
Cefaclor	3	3	-	-	-	-	-	-	100%
Cefamandole	1	1	-	-	-	-	-	-	100%
Cefazolin	6	6	-	-	8	-	-	8	Not graded ¹
Cefixime	6	-	-	6	-	-	-	-	100%
Cefotaxime	-	-	-	-	2	-	-	2	100%
Ceftazidime	1	-	1	-	-	-	-	-	100%
Ceftizoxime	1	-	1	-	-	-	-	-	100%
Ceftriaxone	6	1	3	2	4	-	-	4	Not graded ¹
Cefuroxime	3	3	-	-	-	-	-	-	100%
Cephalexin	1	1	-	-	-	-	-	-	100%
Cephalothin	56	47	-	9	11	7	-	4	Not graded ¹
Cinoxacin	1	-	-	1	-	-	-	-	100%
Ciprofloxacin	56	55	1	-	16	16	-	-	99%
Clindamycin	3	3	-	-	2	2	-	-	87.5%
Doxycycline	5	5	-	-	-	-	-	-	100%
Fosfomycin	2	2	-	-	-	-	-	-	100%
Gatifloxacin	1	1	-	-	1	1	-	-	100%
Gentamicin	26	26	-	-	12	12	-	-	100%
Imipenem	-	-	-	-	4	-	-	4	100%
Levofloxacin	15	15	-	-	12	12	-	-	100%
Linezolid	-	-	-	-	2	2	-	-	100%
Lomefloxacin	1	-	-	1	1	1	-	-	Not graded ¹
Loracarbef	1	1	-	-	-	-	-	-	100%
Methicillin	2	-	-	2	-	-	-	-	100%
Nitrofurantoin	67	65	-	2	17	17	-	-	98.3%
Norfloxacin	15	15	-	-	5	-	-	-	100%
Ofloxacin	8	8	-	-	4	4	-	-	100%
Oxacillin	13	1	2	10	13	2	-	11	Not graded ¹
Penicillin-G	7	5	1	1	9	2	-	7	Not graded ¹
Rifampin	-	-	-	-	1	1	-	-	100%
Sulfamethoxazole	6	6	-	-	1	1	-	-	100%
Sulfisoxazole	6	4	-	2	1	1	-	-	Not graded ¹
Sulfonamide	1	1	-	-	-	-	-	-	100%
Tetracycline	36	35	-	1	14	14	-	-	98.5%
Tobramycin	3	3	-	-	-	-	-	-	100%
Trimethoprim	9	9	-	-	2	2	-	-	100%
Trimethoprim/Sulfamethoxazole	65	63	-	2	17	17	-	-	98.2%
Vancomycin	8	8	-	-	12	12	-	-	100%

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

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

GC CULTURE

Specimen GC-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	34	58.6%	Acceptable
No growth (sterile)	16	27.6%	Acceptable
Streptococcus agalactiae	4	6.9%	Acceptable
Staph – coagulase negative	1	1.7%	Acceptable
Staphylococcus epidermidis	1	1.7%	Acceptable
Strep – beta hemo; not Group A	1	1.7%	Acceptable

Beta-lactamase Testing

Negative	3	75.0%
Positive	1	25.0%

Gram Stain

Gram positive	23	95.8%	Acceptable
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Gram Stain Morphology

Cocci	13	54.2%
Cocci in chains	9	37.5%
Cocci in pairs	1	4.2%
Cocco-bacilli	1	4.2%

Organisms present in specimen GC-6: *Streptococcus agalactiae* and *Staphylococcus epidermidis*.

Specimen GC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	17	73.9%	Acceptable
Neisseria gonorrhoeae	5	21.7%	Acceptable

Organisms present in specimen GC-7: *Neisseria gonorrhoeae* and *Staphylococcus epidermidis*.

Specimen GC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	12	54.6%	Acceptable
No growth (sterile)	10	45.5%	Acceptable

Organism present in specimen GC-8: *Staphylococcus epidermidis*.

Specimen GC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	12	54.6%	Acceptable
No growth (sterile)	10	45.5%	Acceptable

Organisms present in specimen GC-9: *Gardnerella vaginalis* and *Lactobacillus casei*.

GC CULTURE

Specimen GC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	16	72.7%	Acceptable
Growth select media, referred	3	13.6%	Acceptable
No growth (sterile)	2	9.1%	Acceptable
Presump. GC, referred for ID	1	4.6%	Acceptable

Organism present in specimen GC-10: *Enterococcus faecalis*.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-6

<u>Method</u>	<u>Labs</u>	<u>No growth</u>	<u><10,000 organisms/mL</u>	<u>10,000-100,000 organisms/mL</u>	<u>>100,000 organisms/mL</u>
All Methods	113	7	2	22	82
Bactercult	3	-	-	-	3
Bacti-Star	1	-	-	-	1
Bulls Eye	7	1	-	2	4
Calibrated Loop	29	-	1	5	23
HealthLink	1	-	-	-	1
Henry Schein One Step	1	-	-	-	1
Uri-Check	14	5	1	2	6
Uri-Kit	1	-	-	-	1
Uri-Three	2	-	-	-	2
Uricult	47	1	-	13	33

Identification–Specimen CC-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	12	25.0%	Acceptable
Presump. Staphylococcus sp.	12	25.05	Acceptable
Growth, referred for identification	8	16.7%	Acceptable
Staphylococcus sp.	1	2.1%	Acceptable
Staph – coagulase negative	1	2.1%	Acceptable
Staphylococcus saprophyticus	1	2.1%	Acceptable

Gram Stain

Gram positive	6	100%
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Gram Stain Morphology

Cocci	7	100%
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Organism present in specimen CC-6: >100,000 CFU/mL of *Staphylococcus saprophyticus*.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-7

<u>Method</u>	<u>Labs</u>	<u>No growth</u>	<u><10,000 organisms/mL</u>	<u>10,000-100,000 organisms/mL</u>	<u>>100,000 organisms/mL</u>
All Methods	111	3	9	47	52
Bactercult	3	-	-	-	3
Bacti-Star	1	-	-	-	1
Bulls Eye	6	-	-	2	4
Calibrated Loop	29	1	3	13	12
HealthLink	1	-	-	-	1
Henry Schein One Step	1	-	-	1	-
Uri-Check	14	1	-	8	5
Uri-Kit	1	1	-	-	-
Uri-Three	2	-	-	2	-
Uricult	46	-	6	18	22

Identification–Specimen CC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Pseudomonas sp.	19	39.6%	Acceptable
Presump. Gram negative	12	25.0%	Acceptable
Growth, referred for identification	8	16.7%	Acceptable
Pseudomonas aeruginosa	4	8.3%	Acceptable
Pseudomonas sp.	2	4.2%	Acceptable
Presump. Gram positive	1	2.1%	Acceptable
Bacturcult Group III	1	2.1%	Acceptable

Organisms present in specimen CC-7: approximately 80,000 CFU/mL of *Pseudomonas aeruginosa* and approximately 2,000 CFU/mL *Staphylococcus epidermidis*.

Identification–Specimen CC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	15	42.9%	Acceptable
Presumptive Streptococcus sp.	6	17.1%	Acceptable
Growth, referred for identification	4	11.4%	Acceptable
Streptococcus agalactiae	2	5.7%	Acceptable

Organisms present in specimen CC-8: >100,000 CFU/mL of *Streptococcus agalactiae* and approximately 20,000 CFU/mL of *Lactobacillus casei*.

Identification–Specimen CC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	14	38.9%	Acceptable
Presump. Staphylococcus	12	33.3%	Acceptable
Growth, referred for identification	4	11.1%	Acceptable
Staphylococcus aureus	3	8.3%	Acceptable
Staphylococcus sp.	1	2.8%	Acceptable

Organism present in specimen CC-9: >100,000 CFU/mL of *Staphylococcus aureus*.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Escherichia coli	19	51.4%	Acceptable
Presump. Gram negative	8	21.6%	Acceptable
Growth, referred for identification	4	10.8%	Acceptable
Escherichia coli	3	8.1%	Acceptable
Presump. Gram positive	2	5.4%	Acceptable

Organisms present in specimen CC-10: Approximately 85,500 CFU/mL of *Escherichia coli* and approximately 12,000 CFU/mL of *Corynebacterium sp.*

DERMATOPHYTE SCREEN

Specimen DM-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte absent	14	53.9%	Not graded
Deratophye present	12	46.2%	

Organisms present in specimen DM-6: *Candida albicans* and *Lactobacillus casei*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen DM-6 contained *Candida albicans* and *Lactobacillus casei* without any dermatophytes. However, since almost one half of the participants in this challenge reported this specimen as “Dermatophytes present,” we saw an opportunity to review the interpretation of growth on dermatophyte media. While selective and differential media are very good at restricting growth of organisms with different nutritional needs, the organisms do not know that the media is selective and differential. Thus, depending upon the media formulation being used for dermatophyte testing, some yeast, non-dermatophyte molds, and rare bacteria can grow.

The manufacturers of dermatophyte test agar provide specific instructions for determining if colony growth is a dermatophyte or not. These interpretive guidelines will address the color change of the media and the appearance of the colony. We encourage you to review the manufacturer’s interpretation guidelines for your media, and, if necessary, contact the manufacturer for specific assistance in how you should interpret the growth.

Specimen DM-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte present	24	92.3%	Acceptable
Dermatophyte absent	2	7.7%	

Organism present in specimen DM-7: *Microsporum canis*.

GRAM STAIN

Specimen GS-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	64	95.5%	Acceptable
Gram positive	3	4.5%	

Gram Stain Morphology

Rods/bacilli	22	36.1%
Cocco-bacilli	21	34.4%
Diplococci	10	16.4%
Cocci	5	8.2%
Cocci in pairs	3	4.9%

Organism present in specimen GS-6: *Haemophilus influenzae*.

Specimen GS-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	67	100%	Acceptable

Gram Stain Morphology

Cocci	46	74.2%
Cocci in chains	10	16.1%
Cocci in pairs	6	9.7%

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

GRAM STAIN

Specimen GS-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	64	95.5%	Acceptable
Gram positive	3	4.5%	

Gram Stain Morphology

Rods/bacilli	56	91.8%
Cocco-bacilli	3	4.9%
Diplococci	2	3.3%

Organism present in specimen GS-8: *Klebsiella pneumoniae*.

Specimen GS-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	62	92.5%	Acceptable
Gram positive	5	7.5%	

Gram Stain Morphology

Rods/bacilli	56	91.8%
Cocco-bacilli	3	4.9%
Cocci in chains	1	1.6%
Cocci in pairs	1	1.6%

Organism present in specimen GS-9: *Escherichia coli*.

Specimen GS-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	62	92.5%	Acceptable
Gram negative	5	7.5%	

Gram Stain Morphology

Cocci in pairs	23	37.1%
Cocci	19	30.7%
Diplococci	11	17.7%
Cocco-bacilli	8	12.9%
Cocci in chains	1	1.6%

Organism present in specimen GS-10: *Streptococcus pneumoniae*.

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	32	86.5%	Acceptable
Negative	5	13.5%	

Organisms present in specimen VP-6: *Gardnerella vaginalis* and *Trichomonas vaginalis*.

AFFIRM VP III–*Trichomonas vaginalis*

Specimen VP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	23	62.2%	Not graded
Negative	14	37.8%	

Organism present in specimen VP-7: *Trichomonas vaginalis*. This is an ungraded challenge due to excessive variability in data.

Specimen VP-8

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

Organism present in specimen VP-8: *Candida albicans*.

Specimen VP-9

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

Organisms present in specimen VP-9: *Candida albicans* and *Gardnerella vaginalis*.

Specimen VP-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	27	73.0%	Not graded
Negative	10	27.0%	

Organism present in specimen VP-10: *Trichomonas vaginalis*. This is an ungraded challenge due to excessive variability in data.

AFFIRM VP III–*Gardnerella vaginalis*

Specimen VP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	35	94.6%	Acceptable
Negative	2	5.4%	

Specimen VP-7

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

Specimen VP-8

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

AFFIRM VP III–Gardnerella vaginalis**Specimen VP-9**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	23	62.2%	Not graded
Negative	14	37.8%	

This is an ungraded challenge due to excessive variability in data.

Specimen VP-10

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

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

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

Specimen VP-7

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

Specimen VP-8

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

Specimen VP-9

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

Specimen VP-10

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

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	23	23	-
BD ProbeTec	4	4	-
Beckman (Sanofi) ACCESS	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	2	2	-
Gen-Probe	3	3	-
Quidel QuickVue	11	11	-

Organisms present in specimen CY-6: *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

Specimen CY-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	23	23	-
BD ProbeTec	4	4	-
Beckman (Sanofi) ACCESS	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	2	2	-
Gen-Probe	3	3	-
Quidel QuickVue	11	11	-

Organism present in specimen CY-7: *Chlamydia trachomatis*.

Specimen CY-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	18	-	18
BD ProbeTec	4	-	4
Beckman (Sanofi) ACCESS	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	2	-	2
Gen-Probe	3	-	3
Quidel QuickVue	6	-	6

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

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	18	18	-
BD ProbeTec	4	4	-
Beckman (Sanofi) ACCESS	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	2	2	-
Gen-Probe	3	3	-
Quidel QuickVue	6	6	-

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

Specimen CY-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	18	-	18
BD Probe	4	-	4
Beckman (Sanofi) ACCESS	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	2	-	2
Gen-Probe	3	-	3
Quidel QuickVue	6	-	6

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

GC (ANTIGEN DETECTION)

Specimen CY-6

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

Specimen CY-7

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

GC (ANTIGEN DETECTION)

Specimen CY-8

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

Specimen CY-9

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

Specimen CY-10

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

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-6

<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

Antigen present in specimen LC-6: *Giardia lamblia*.

Specimen LC-7

<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

Antigen present in specimen LC-7: *Giardia lamblia*.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-8

<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	-

Antigen present in specimen LC-8: *Cryptosporidium*.

Specimen LC-9

<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

Antigen present in specimen LC-9: *Giardia lamblia*.

Specimen LC-10

<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	-

Antigen present in specimen LC-10: *Cryptosporidium*.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-6

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

Specimen LC-7

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

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-8

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

Specimen LC-9

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

Specimen LC-10

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

RSV ANTIGEN DETECTION

Specimen V-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	32	32	-
BD Directigen	8	8	-
Binax NOW – waived	11	11	-
BioStar OIA	8	8	-
Wampole Clearview RSV – waived	3	3	-

Specimen V-6: Positive for RSV antigen.

RSV ANTIGEN DETECTION

Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	32	-	32
BD Directigen	8	-	8
Binax NOW – waived	11	-	11
BioStar OIA	8	-	8
Wampole Clearview RSV – waived	3	-	3

Specimen V-7: Negative for RSV antigen.

Specimen V-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	32	32	-
BD Directigen	8	8	-
Binax NOW – waived	11	11	-
BioStar OIA	8	8	-
Wampole Clearview RSV – waived	3	3	-

Specimen V-8: Positive for RSV antigen.

Specimen V-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	32	1	32
BD Directigen	8	-	8
Binax NOW – waived	11	-	11
BioStar OIA	8	1	7
Wampole Clearview RSV – waived	3	-	3

Specimen V-9: Negative for RSV antigen.

Specimen V-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	32	-	32
BD Directigen	8	-	8
Binax NOW – waived	11	-	11
BioStar OIA	8	-	8
Wampole Clearview RSV – waived	3	-	3

Specimen V-10: Negative for RSV antigen.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	91	-	91
Biostar OIA	15	-	15
Quidel QuickVue Influenza	69	-	69

Specimen V-6: Negative for Influenza A/B antigen

Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	91	-	91
BioStar OIA	15	-	15
Quidel QuickVue Influenza	69	-	69

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

Specimen V-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	38	-	38
BioStar OIA	13	-	13
Quidel QuickVue Influenza	21	-	21

Specimen V-8: Negative for Influenza A/B antigen

Specimen V-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	38	37	1
BioStar OIA	13	12	1
Quidel QuickVue Influenza	21	21	-

Specimen V-9: Positive for Influenza A/B antigen

Specimen V-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	38	3	35
BioStar OIA	13	3	10
Quidel QuickVue Influenza	21	-	21

Specimen V-10: Negative for Influenza A/B antigen

INFLUENZA A ANTIGEN DETECTION

Specimen V-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	68	1	67
BD Directigen	3	-	3
Binax NOW – waived	11	-	11
BioStar Flu OIA A/B	11	1	10
Quidel QuickVue Influenza A+B	32	-	32
Remel Xpect	6	-	6
Wampole Clearview	2	-	2

Specimen V-6: Negative for Influenza A antigen.

Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	68	3	65
BD Directigen	3	-	3
Binax NOW – waived	11	-	11
BioStar Flu OIA A/B	11	2	9
Quidel QuickVue Influenza A+B	32	1	31
Remel Xpect	6	-	6
Wampole Clearview	2	-	2

Specimen V-7: Negative for Influenza A antigen.

Specimen V-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	45	1	44
BD Directigen	2	-	2
Binax Now – waived	7	-	7
BioStar Flu OIA A/B	11	1	10
Quidel QuickVue Influenza A+B	15	-	15
Remel Xpect	5	-	5
Wampole Clearview	2	-	2

Specimen V-8: Negative for Influenza A antigen.

Specimen V-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	45	4	41
BD Directigen	2	-	2
Binax NOW – waived	7	-	7
BioStar Flu OIA A/B	11	4	7
Quidel QuickVue Influenza A+B	15	-	15
Remel Xpect	5	-	5
Wampole Clearview	2	-	2

Specimen V-9: Negative for Influenza A antigen.

INFLUENZA A ANTIGEN DETECTION

Specimen V-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	45	1	44
BD Directigen	2	-	2
Binax NOW – waived	7	-	7
BioStar Flu OIA A/B	11	1	10
Quidel QuickVue Influenza A+B	15	-	15
Remel Xpect	5	-	5
Wampole Clearview	2	-	2

Specimen V-10: Negative for Influenza A antigen.

INFLUENZA B ANTIGEN DETECTION

Specimen V-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	67	2	65
BD Directigen	2	-	2
Binax NOW – waived	11	-	11
BioStar Flu OIA A/B	11	2	9
Quidel QuickVue Influenza A+B	31	-	31
Remel Xpect	6	-	6
Wampole Clearview	2	-	2

Specimen V-6: Negative for Influenza B antigen.

Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	67	3	64
BD Directigen	2	-	2
Binax NOW – waived	11	-	11
BioStar Flu OIA A/B	11	2	9
Quidel QuickVue Influenza A+B	31	1	30
Remel Xpect	6	-	6
Wampole Clearview	2	-	2

Specimen V-7: Negative for Influenza B antigen.

Specimen V-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	44	1	43
BD Directigen	1	-	1
Binax NOW – waived	7	-	7
BioStar Flu OIA A/B	11	1	10
Quidel QuickVue Influenza A+B	15	-	15
Remel Xpect	5	-	5
Wampole Clearview	2	-	2

Specimen V-8: Negative for Influenza B antigen.

INFLUENZA B ANTIGEN DETECTION

Specimen V-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	44	44	-
BD Directigen	1	1	-
Binax NOW – waived	7	7	-
BioStar Flu OIA A/B	11	11	-
Quidel QuickVue Influenza A+B	15	15	-
Remel Xpect	5	5	-
Wampole Clearview	2	2	-

Specimen V-9: Positive for Influenza B antigen.

Specimen V-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	44	-	44
BD Directigen	1	-	1
Binax NOW – waived	7	-	7
BioStar Flu OIA A/B	11	-	11
Quidel QuickVue Influenza A+B	15	-	15
Remel Xpect	5	-	5
Wampole Clearview	2	-	2

Specimen V-10: Negative for Influenza B antigen.

LEGIONELLA ANTIGEN DETECTION

Specimen L-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	115	114	1

Specimen L-6: Positive for Legionella antigen.

Specimen L-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	115	115	-

Specimen L-7: Positive for Legionella antigen.

Specimen L-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	115	1	114

Specimen L-8: Negative for Legionella antigen.

LEGIONELLA ANTIGEN DETECTION

Specimen L-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	115	114	1

Specimen L-9: Positive for Legionella antigen.

Specimen L-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	115	-	115

Specimen L-10: Negative for Legionella antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	22	21	1
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	3	3	-
Biosite Triage	8	7	1
BioStar OIA	6	6	-
Meridian ImmunoCard	3	3	-
Meridian Premier	1	1	-

Antigens present in specimen AG-6: *Clostridium difficile* and *Rotavirus*.

Specimen AG-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	22	-	22
Alexon (Hycor)	1	-	1
bioMerieux Vitek, Mini Vidas	3	-	3
Biosite Triage	8	-	8
BioStar OIA	6	-	6
Meridian ImmunoCard	3	-	3
Meridian Premier	1	-	1

Antigen present in specimen AG-7: *Rotavirus*.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	22	22	-
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	3	3	-
Biosite Triage	8	8	-
BioStar OIA	6	6	-
Meridian ImmunoCard	3	3	-
Meridian Premier	1	1	-

Antigen present in specimen AG-8: *Clostridium difficile*.

Specimen AG-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	22	21	1
Alexcon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	3	3	-
Biosite Triage	8	7	1
BioStar OIA	6	6	-
Meridian ImmunoCard	3	3	-
Meridan Premier	1	1	-

Antigen present in specimen AG-9: *Clostridium difficile*.

Specimen AG-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	22	2	20
Alexon (Hycor)	1	-	1
Biomerieux Vitek, Mini Vidas	3	-	3
Biosite Triage	8	2	6
BioStar OIA	6	-	6
Meridian ImmunoCard	3	-	3
Meridian Premier	1	-	1

Antigen present in specimen AG-10: *Rotavirus*.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	11	11	-
Fisher HealthCare Sure-Vue	2	2	-
Meridian ImmunoCard	5	5	-
SA Scientific Rota Test	3	3	-

Specimen AG-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	11	11	-
Fisher HealthCare Sure-Vue	2	2	-
Meridian ImmunoCard	5	5	-
SA Scientific Rota Test	3	3	-

Specimen AG-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	11	-	11
Fisher HealthCare Sure-Vue	2	-	2
Meridian ImmunoCard	5	-	5
SA Scientific Rota Test	3	-	3

Specimen AG-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	11	-	11
Fisher HealthCare Sure-Vue	2	-	2
Meridian ImmunoCard	5	-	5
SA Scientific Rota Test	3	-	3

Specimen AG-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	11	11	-
Fisher HealthCare Sure-Vue	2	2	-
Meridian ImmunoCard	5	5	-
SA Scientific Rota Test	3	3	-

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	107	1	106

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

Specimen SP-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	107	1	106

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

Specimen SP-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	107	105	2

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

Specimen SP-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	107	106	1

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

Specimen SP-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	107	-	107

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

PARASITOLOGY – DOMESTIC

Specimen PA-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dientamoeba fragilis	2	100%	Acceptable

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

PARASITOLOGY – DOMESTIC

Specimen PA-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba coli	2	100%	Acceptable

Parasite present in specimen PA-7: *Entamoeba coli*.

Specimen PA-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	2	66.7%	Acceptable
Parasite egg seen but no ID	1	33.3%	Acceptable

Parasite present in specimen PA-8: Hookworm eggs.

Specimen PA-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	2	66.7%	Not graded
Parasite larva seen but no ID	1	33.3%	

Parasite present in specimen PA-9: Negative for parasites. Plant root hairs present. This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	2	66.7%	Not graded
No parasite seen	1	33.3%	

Parasite present in specimen PA-10: *Ascaris lumbricoides* eggs. This is an ungraded challenge due to less than 80% participant consensus.

INTERNATIONAL LABS

PARASITOLOGY – INTERNATIONAL (PA Specimens)

Specimen PA-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	4	66.7%	
Endolimax nana	1	16.7%	
Iodamoeba butschlii	1	16.7%	

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

PARASITOLOGY – INTERNATIONAL (PA Specimens)

Specimen PA-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	4	57.1%	
Blastocystis hominis	1	14.3%	
Endolimax nana	1	14.3%	
Entamoeba histolytica	1	14.3%	

Parasite present in specimen PA-7: *Entamoeba coli*.

Specimen PA-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	7	50.0%	Acceptable
Parasite egg seen but no ID	1	7.1%	Acceptable
No parasite seen	2	14.3%	
Ascaris lumbricoides eggs	1	7.1%	
Blastocystis hominis	1	7.1%	
Entamoeba coli	1	7.1%	
Trichostrongylus sp. eggs	1	7.1%	

Parasite present in specimen PA-8: Hookworm eggs.

Specimen PA-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides sterco. larvae	7	63.6%	Not graded
No parasite seen	4	36.4%	

Parasite present in specimen PA-9: Negative for parasites. Plant root hairs present. This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	8	50.0%	Not graded
Entamoeba coli	3	18.8%	
No parasite seen	3	18.8%	
Endolimax nana	1	6.3%	
Schistosoma mansoni eggs	1	6.3%	

Parasite present in specimen PA-10: *Ascaris lumbricoides* eggs. This is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY – INTERNATIONAL (FP Specimens)

Specimen FP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Blastocystis hominis	22	39.3%	Not graded
No parasite seen	19	33.9%	
Schistosoma mansoni eggs	7	12.5%	
Endolimax nana	4	7.1%	
Trypanosoma cruzi	1	1.8%	
Schistosoma sp. Eggs, NOS	1	1.8%	
Strongyloides sterco. larvae	1	1.8%	
Parasite larva seen but no ID	1	1.8%	

Parasite present in specimen FP-6: *Schistosoma mansoni*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen FP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	25	41.7%	Not graded
Trichuris trichiura eggs	14	23.3%	
No parasite seen	13	21.7%	
Hookworm	2	3.3%	
Hymenolepis nana eggs	2	3.3%	
Blastocystis hominis	1	1.7%	
Endolimax nana	1	1.7%	
Taenia sp. eggs	1	1.7%	
Parasite egg seen but no ID	1	1.7%	

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

Specimen FP-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	43	63.2%	Not graded
Entamoeba coli	7	10.3%	
Ascaris lumbricoides eggs	3	4.4%	
Diphyllobothrium sp. eggs	3	4.4%	
Hymenolepis nana eggs	3	4.4%	
Trichuris trichiura eggs	3	4.4%	
Blastocystis hominis	2	2.9%	
No parasite seen	2	2.9%	
Strongyloides sterco. larvae	1	1.5%	
Taenia sp. eggs	1	1.5%	

Parasite present in specimen FP-8: *Giardia lamblia*. This is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY – INTERNATIONAL (FP Specimens)

Specimen FP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba histolytica	35	58.3%	Not graded
Entamoeba coli	14	23.3%	
Blastocystis hominis	2	3.3%	
Endolimax nana	2	3.3%	
Hookworm	2	3.3%	
No parasite seen	2	3.3%	
Giardia lamblia	1	1.7%	
Iodamoeba butschlii	1	1.7%	
Schistosoma mansoni eggs	1	1.7%	

Parasite present in specimen FP-9: *Entamoeba histolytica*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen FP-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	33	78.6%	Not graded
Plasmodium falciparum	2	4.8%	
Plasmodium vivax	2	4.8%	
Babesia sp.	1	2.4%	
Plasmodium sp. NOS	1	2.4%	
Plasmodium malariae	1	2.4%	
Trypanosoma cruzi	1	2.4%	
Protozoan seen but no ID	1	2.4%	

Parasite present in specimen FP-10: No parasites present. This is an ungraded challenge due to less than 80% participant consensus.

ANTIMICROBIAL SUSCEPTIBILITY TESTING (FOR INTERNATIONAL LABS)

Specimen UC-6

<u>Antimicrobial</u>	-----Agar Diffusion-----				-----MIC-----				<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	-	-	1	1	-	-	100%
Amoxicillin/Clavulanate	2	2	-	-	8	2	-	6	Not graded ¹
Ampicillin	1	-	-	1	9	1	-	8	Not graded ¹
Ampicillin/Sulbactam	2	2	-	-	4	-	-	4	Not graded ¹
Cefazolin	1	1	-	-	10	2	-	8	Not graded ¹
Cefotaxime	1	1	-	-	6	2	-	4	Not graded ¹
Cefoxitin	-	-	-	-	1	-	-	1	Not graded ¹
Ceftazidime	-	-	-	-	1	1	-	-	Not graded ¹
Ceftriaxone	-	-	-	-	1	-	-	1	Not graded ¹
Cefuroxime	-	-	-	-	6	2	-	4	Not graded ¹
Cephalexin	3	3	-	-	1	-	-	1	Not graded ¹
Cephalothin	1	1	-	-	5	1	-	4	Not graded ¹
Ciprofloxacin	3	3	-	-	14	14	-	-	100%
Clindamycin	3	3	-	-	10	10	-	-	100%
Gentamicin	5	5	-	-	12	12	-	-	100%
Imipenem	1	1	-	-	7	3	-	4	Not graded ¹
Levofloxacin	-	-	-	-	1	1	-	-	100%
Linezolid	-	-	-	-	1	1	-	-	100%
Meropenem	-	-	-	-	6	3	-	3	Not graded ¹
Methicillin	1	1	-	-	-	-	-	-	100%
Nitrofurantoin	3	3	-	-	9	9	-	-	95.2%
Norfloxacin	-	-	-	-	6	6	-	-	91.7%
Ofloxacin	-	-	-	-	8	8	-	-	100%
Oxacillin	6	2	2	2	11	2	-	9	Not graded ¹
Penicillin-G	2	2	-	-	7	1	-	6	Not graded ¹
Piperacillin/Tazobactam	-	-	-	-	1	1	-	-	100%
Rifampin	2	2	-	-	2	2	-	-	100%
Tetracycline	2	1	-	1	10	10	-	-	89.5%
Ticarcillin/Clavulanate	-	-	-	-	7	2	-	5	Not graded ¹
Tobramycin	-	-	-	-	1	1	-	-	100%
Trimethoprim	1	1	-	-	1	1	-	-	Not graded ¹
Trimethoprim/Sulfamethoxazole	5	3	-	2	12	12	-	-	90.3%
Vancomycin	2	2	-	-	12	12	-	-	100%

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

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

SUMMARY OF ISOLATES FOUND IN THE 2005 MLE-M2 CULTURE SPECIMENS

Organism	ATCC Strain
<i>Streptococcus pneumoniae</i>	6305
<i>Streptococcus pyogenes</i>	19615
<i>Staphylococcus epidermidis</i>	14990
<i>Staphylococcus aureus</i>	25923
<i>Moraxella catarrhalis</i>	25238
<i>Corynebacterium species</i>	49528
<i>Staphylococcus saprophyticus</i>	35552
<i>Pseudomonas aeruginosa</i>	27853
<i>Streptococcus agalactiae</i>	12386
<i>Lactobacillus casei</i>	393
<i>Escherichia coli</i>	25922
<i>Neisseria gonorrhoeae</i>	19424
<i>Gardnerella vaginalis</i>	14018
<i>Enterococcus faecalis</i>	29212
<i>Shigella sonnei</i>	25931
<i>Neisseria meningitidis</i>	13090

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