

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

Microbiology
MLE – M3

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2005 Evaluation Criteria 2

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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-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	188	88.7%	Acceptable
No growth (sterile)	9	4.3%	Acceptable
Growth, referred for identification	5	2.4%	Acceptable
Moraxella sp.	1	0.5%	Acceptable
Moraxella catarrhalis	1	0.5%	Acceptable
Presump. Pos. Group A Strep	5	2.4%	

Organisms present in specimen TC-11: *Moraxella catarrhalis* and *Corynebacterium species*.

Specimen TC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	117	55.7%	Acceptable
Presump. Pos. Group A Strep	76	36.2%	Acceptable
Streptococcus pyogenes	11	5.2%	Acceptable
Negative for Group A Strep	6	2.9%	

Organism present in specimen TC-12: *Streptococcus pyogenes*.

Specimen TC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	46	54.1%	Acceptable
Presump. Pos. Group A Strep	36	42.4%	Acceptable

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

Specimen TC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	70	95.9%	Acceptable
No growth (sterile)	3	4.1%	Acceptable

Organism present in specimen TC-14: *Haemophilus influenzae*.

Specimen TC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	70	95.9%	Acceptable

Organisms present in specimen TC-15: *Streptococcus species Group B* and *Neisseria sicca*.

STREP A ANTIGEN DETECTION

Specimen RS-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>	<u>Strength of Reaction</u>		
				<u>Strong</u>	<u>Moderate</u>	<u>Weak</u>
All Methods	722	717	5	527	120	13
Abbott Signify Strep A-waived	45	44	1	29	14	-
Applied Biotech Signify	7	6	1	1	3	1
Applied Biotech SureStep	1	1	-	-	1	-
Applied Biotech SureStep II	3	3	-	2	-	1
BD LINK 2	2	2	-	1	1	-
BD QTest	30	30	-	26	-	1
Beckman Coulter ICON DS	17	17	-	12	4	1
Beckman Coulter ICON Fx Strep A	1	1	-	1	-	-
Beckman Coulter ICON SC	8	8	-	5	3	-
Binax NOW Strep A	3	3	-	1	-	1
BioStar Acceava Strep A Test	62	62	-	41	15	2
BioStar Strep A MAX OIA	38	38	-	34	-	-
Cardinal Hlth Step A Dipstick	4	4	-	3	1	-
DE Healthcare TruView	5	5	-	1	2	-
Fisher HealthCare Sure-Vue	7	7	-	1	3	1
Fisher Sure-Vue Strep A-waived	3	3	-	2	1	-
Genzyme OSOM	6	6	-	2	3	-
Genzyme OSOM Ultra Strep A	63	63	-	38	20	-
Henry Schein One Step	4	4	-	4	-	-
Instant Technologies i Strep	3	3	-	2	1	-
Inverness Signify Strep A Dipstick	17	17	-	10	5	-
Mainline Confirms	3	3	-	1	2	-
Mainline Confirms Strep A Dots	1	1	-	1	-	-
McKesson Strep A Cassette	9	9	-	5	3	-
McKesson Strep A Dipstick	8	8	-	7	-	-
Polymedco Polystat Strep A (I)	19	19	-	13	6	-
Polymedco Polystat Strep A (II)	7	7	-	5	-	-
Polymedco Strep A Liquid Test	27	27	-	14	11	1
Quidel QuickVue Dipstick Strep	75	74	1	66	4	-
Quidel QuickVue In-Line	80	78	2	64	6	4
Quidel QuickVue+	118	118	-	108	2	-
Wampole Clearview	6	6	-	3	2	-
Wyntek OSOM Ultra Strep A	7	7	-	6	1	-

Specimen RS-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	689	4	685
Abbott Signify Strep A-waived	42	-	42
Applied Biotech Signify	6	-	6
Applied Biotech SureStep	1	-	1
Applied Biotech SureStep II	3	-	3
BD LINK 2	2	-	2
BD QTest	27	-	27
Beckman Coulter ICON DS	17	-	17
Beckman Coulter ICON Fx Strep A	1	-	1
Beckman Coulter ICON SC	8	-	8
Binax NOW Strep A	3	-	3

STREP A ANTIGEN DETECTION

Specimen RS-12 (cont'd)

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
BioStar Acceava Strep A Test	61	-	61
BioStar Strep A MAX OIA	37	2	35
Cardinal Hlth Strep A Dipstick	4	-	4
DE Healthcare TruView	4	-	4
Fisher HealthCare Sure-Vue	4	-	4
Fisher Sure-Vue Strep A-waived	3	-	3
Genzyme OSOM	6	-	6
Genzyme OSOM Ultra Strep A	61	-	61
Henry Schein One Step	4	-	4
Instant Technologies i Strep	3	-	3
Inverness Signify Strep A Dipstick	16	-	16
Mainline Confirms	1	-	1
Mainline Confirms Strep A Dots	1	-	1
McKesson Strep A Cassette	8	-	8
McKesson Strep A Dipstick	7	-	7
Polymedco Polystat Strep A (I)	19	-	19
Polymedco Polystat Strep A (II)	6	-	6
Polymedco Strep A Liquid Test	27	-	27
Quidel QuickVue Dipstick Strep	71	1	70
Quidel QuickVue In-Line	79	-	79
Quidel QuickVue+	113	1	112
Wampole Clearview	6	-	6
Wyntek OSOM Ultra Strep A	6	-	6

Specimen RS-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>	<u>Strength of Reaction</u>		
				<u>Strong</u>	<u>Moderate</u>	<u>Weak</u>
All Methods	399	396	3	273	80	10
Abbott Signify Strep A-waived	20	20	-	14	6	-
Applied Biotech Signify	6	6	-	-	2	3
Applied Biotech SureStep II	2	2	-	1	-	1
BD LINK 2	1	1	-	1	-	-
BD QTest	25	25	-	16	6	-
Beckman Coulter ICON DS	5	5	-	4	1	-
Beckman Coulter ICON Fx Strep A	1	1	-	-	1	-
Beckman Coulter ICON SC	4	4	-	2	2	-
Binax NOW Strep A	3	3	-	-	2	-
BioStar Acceava Strep A Test	22	22	-	14	6	1
BioStar Strep A MAX OIA	36	35	1	31	-	-
Cardinal Hlth Strep A Dipstick	3	3	-	3	-	-
DE Healthcare TruView	2	2	-	-	1	-
Fisher HealthCare Sure-Vue	3	3	-	1	1	-
Genzyme OSOM	5	5	-	4	1	-
Genzyme OSOM Ultra Strep A	33	33	-	21	10	-
Henry Schein One Step	1	1	-	1	-	-
Instant Technologies i Strep	2	2	-	2	-	-
Inverness Signify Strep A Dipstick	4	4	-	1	3	-
Mainline Confirms	1	1	-	-	1	-
Mainline Confirms Strep A Dots	1	1	-	-	1	-
McKesson Strep A Cassette	4	4	-	1	2	-
McKesson Strep A Dipstick	6	6	-	4	1	-
Polymedco Polystat Strep A (I)	19	19	-	12	7	-

STREP A ANTIGEN DETECTION

Specimen RS-13 (cont'd)

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>	<u>Strength of Reaction</u>		
				<u>Strong</u>	<u>Moderate</u>	<u>Weak</u>
Polymedco Polystat Strep A(II)	1	1	-	-	-	-
Polymedco Strep A Liquid Test	11	11	-	3	7	-
Quidel QuickVue Dipstick Strep	22	22	-	16	-	2
Quidel QuickVue In-Line	28	27	1	21	4	1
Quidel QuickVue+	106	106	-	89	10	-
Wampole Clearview	5	5	-	3	1	-
Wyntek OSOM Ultra Strep A	2	2	-	1	1	-

Specimen RS-14

<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	347	340	7	240	66	8
Abbott Signify Strep A-waived	17	17	-	11	5	-
Applied Biotech Signify	6	5	1	-	3	1
Applied Biotech SureStep II	2	2	-	1	1	-
BD LINK 2	1	1	-	1	-	-
BD QTest	22	22	-	15	2	3
Beckman Coulter ICON DS	5	5	-	4	1	-
Beckman Coulter ICON Fx Strep A	1	1	-	-	-	1
Beckman Coulter ICON SC	4	4	-	3	1	-
Binax NOW Strep A	2	2	-	1	1	-
BioStar Acceava Strep A Test	19	18	1	12	4	1
BioStar Strep A MAX OIA	35	34	1	29	1	-
Cardinal Hlth Strep A Dipstick	3	3	-	3	-	-
DE Healthcare TruView	2	2	-	-	1	-
Fisher HealthCare Sure-Vue	3	3	-	-	1	1
Genzyme OSOM	5	5	-	5	-	-
Genzyme OSOM Ultra Strep A	26	26	-	17	8	-
Henry Schein One Step	1	1	-	1	-	-
Instant Technologies i Strep	1	1	-	1	-	-
Inverness Signify Strep A Dipstick	4	4	-	2	2	-
Mainline Confirms	1	1	-	-	1	-
Mainline Confirms Strep A Dots	1	1	-	-	1	-
McKesson Strep A Cassette	4	4	-	1	2	-
McKesson Strep A Dipstick	5	5	-	3	1	-
Polymedco Polystat Strep A (I)	19	19	-	13	6	-
Polymedco Polystat Strep A (II)	1	1	-	-	-	-
Polymedco Strep A Liquid Test	7	7	-	-	7	-
Quidel QuickVue Dipstick Strep	13	13	-	11	1	-
Quidel QuickVue In-Line	26	26	-	20	4	1
Quidel QuickVue+	94	90	4	78	7	-
Wampole Clearview	5	5	-	3	1	-

STREP A ANTIGEN DETECTION

Specimen RS-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	346	7	339
Abbott Signify Strep A-waived	17	-	17
Applied Biotech Signify	6	-	6
Applied Biotech SureStep II	2	-	2
BD LINK 2	1	-	1
BD QTest	22	-	22
Beckman Coulter ICON DS	5	-	5
Beckman Coulter ICON Fx Strep A	1	-	1
Beckman Coulter ICON SC	4	-	4
Binax NOW Strep A	1	-	1
BioStar Acceava Strep A Test	19	1	18
BioStar Strep A MAX OIA	35	1	34
Cardinal Hlth Strep A Dipstick	3	-	3
DE Healthcare TruView	2	-	2
Fisher HealthCare Sure-Vue	3	-	3
Genzyme OSOM	5	-	5
Genzyme OSOM Ultra Strep A	26	-	26
Henry Schein One Step	1	-	1
Instant Technologies i Strep	1	-	1
Inverness Signify Strep A Dipstick	4	-	4
Mainline Confirms	1	-	1
Mainline Confirms Strep A Dots	1	-	1
Mckesson strep A Cassette	4	-	4
Mckesson strep A Dipstick	5	-	5
Polymedco Polystat Strep A (I)	19	-	19
Polymedco Polystat Strep A (II)	1	-	1
Polymedco Strep A Liquid Test	7	-	7
Quidel QuickVue Dipstick Strep	13	-	13
Quidel QuickVue in-Line	26	-	26
Quidel QuickVue+	94	4	90
Wampole Clearview	5	-	5

GENERAL BACTERIOLOGY

Specimen UC-11 – Urine Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Escherichia coli	6	100%	Acceptable
<u>Gram Stain</u>			
Gram negative	4	100%	Acceptable
<u>Gram Stain Morphology</u>			
Rods/bacilli	4	100%	

Organism present in specimen UC-11: *Escherichia coli*.

GENERAL BACTERIOLOGY

Specimen TC-11 – Throat Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Moraxella sp.	3	37.5%	Acceptable
Negative for Group A Strep	3	37.5%	Acceptable
Corynebacterium sp.	1	12.5%	Acceptable
Moraxella catarrhalis	1	12.5%	Acceptable

Organisms present in specimen TC-11: *Moraxella catarrhalis* and *Corynebacterium species*.

Specimen BA-7 – Respiratory Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	4	50.0%	Not graded
Streptococcus alpha-hemolytic	1	12.5%	
Strep – alpha hemo; not Group D	1	12.5%	

Organisms present in specimen BA-7: *Neisseria sicca* and *Streptococcus gordonii*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen BA-8 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Proteus vulgaris	7	100%	Acceptable

Organism present in specimen BA-8: *Proteus vulgaris*.

Specimen BA-9 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Salmonella sp.	6	100%	Acceptable

Organism present in specimen BA-9: *Salmonella choleraesuis*.

URINE CULTURE

Specimen UC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Escherichia coli	61	42.7%	Acceptable
Growth, referred for identification	25	17.5%	Acceptable
Presump. Gram negative	25	17.5%	Acceptable
Presump. Escherichia coli	18	12.6%	Acceptable
Gram negative bacilli	14	9.8%	Acceptable

Gram Stain

Gram negative	65	98.5%	Acceptable
Gram positive	1	1.5%	

Gram Stain Morphology

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

Specimen UC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus aureus	47	32.6%	Acceptable
Growth, referred for identification	34	23.6%	Acceptable
Presump. Gram positive	28	19.4%	Acceptable
Gram positive cocci	15	10.4%	Acceptable
Staphylococcus sp.	10	6.9%	Acceptable
Presump. Staphylococcus sp.	5	3.5%	Acceptable

Organisms present in specimen UC-12: *Staphylococcus aureus* and *Lactobacillus casei*.

URINE CULTURE

Specimen UC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	30	33.0%	Acceptable
Growth, referred for identification	20	22.0%	Acceptable
Klebsiella pneumoniae	14	15.4%	Acceptable
Klebsiella sp.	10	11.0%	Acceptable
Gram negative bacilli	9	9.9%	Acceptable
Presump. Klebsiella sp.	5	5.5%	Acceptable
Presump. Gram positive	2	2.2%	Acceptable

Organisms present in specimen UC-13: *Klebsiella pneumoniae* and *Corynebacterium* species.

Specimen UC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	25	45.5%	Acceptable
Growth, referred for identification	14	25.5%	Acceptable
Enterobacter cloacae	7	12.7%	Acceptable
Enterobacter sp.	2	3.6%	Acceptable
Gram negative bacilli	2	3.6%	Acceptable

Organisms present in specimen UC-14: *Enterobacter cloacae* and *Staphylococcus epidermidis*.

Specimen UC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	21	38.9%	Acceptable
Growth, referred for identification	20	37.0%	Acceptable
Enterococcus sp.	6	11.1%	Acceptable
Enterococcus (Strep) faecalis	2	3.7%	Acceptable
Gram positive cocci	2	3.7%	Acceptable
Streptococcus non-hemolytic	1	1.9%	Acceptable
Strep. Group D – enterococcus	1	1.9%	Acceptable
Presumptive Streptococcus sp.	1	1.9%	Acceptable

Organism present in specimen UC-15: *Enterococcus (Strep) faecalis*.

ANTIMICROBIAL SUSCEPTIBILITY TESTING
Specimen UC-11, CC-11 (SUS-11)

<u>Antimicrobial</u>	-----Agar Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Amikacin	3	3	-	-	7	7	-	-	100%
Amoxicillin/Clavulanate	17	17	-	-	14	13	1	-	97.1%
Ampicillin	80	75	4	1	17	17	-	-	96.2%
Ampicillin/Sulbactam	-	-	-	-	6	6	-	-	100%
Aztreonam	-	-	-	-	3	3	-	-	100%
Carbenicillin	25	23	2	-	3	3	-	-	95.4%
Cefaclor	2	2	-	-	-	-	-	-	100%
Cefazolin	14	13	1	-	9	9	-	-	96.4%
Cefixime	5	5	-	-	1	1	-	-	100%
Cefotaxime	2	2	-	-	3	3	-	-	100%
Cefotetan	-	-	-	-	1	1	-	-	100%
Cefoxitin	1	1	-	-	1	1	-	-	100%
Cefpodoxime	-	-	-	-	1	1	-	-	100%
Cefprozil	3	3	-	-	-	-	-	-	100%
Ceftazidime	3	3	-	-	7	7	-	-	100%
Ceftriaxone	5	5	-	-	9	9	-	-	100%
Cefuroxime	5	5	-	-	8	8	-	-	100%
Cephalexin	1	-	1	-	-	-	-	-	Not graded ¹
Cephalothin	73	51	16	6	17	16	1	-	Not graded ¹
Cinoxacin	3	3	-	-	-	-	-	-	100%
Ciprofloxacin	78	78	-	-	18	18	-	-	100%
Doxycycline	5	5	-	-	2	2	-	-	100%
Fosfomycin	3	3	-	-	-	-	-	-	100%
Gatifloxacin	1	1	-	-	1	1	-	-	100%
Gentamicin	44	44	-	-	11	11	-	-	100%
Imipenem	1	1	-	-	4	4	-	-	100%
Kanamycin	1	1	-	-	-	-	-	-	100%
Levofloxacin	21	21	-	-	11	11	-	-	100%
Lomefloxacin	1	1	-	-	3	3	-	-	100%
Loracarbef	1	1	-	-	-	-	-	-	100%
Mezlocillin	1	1	-	-	-	-	-	-	100%
Nalidixic Acid	3	3	-	-	2	2	-	-	100%
Nitrofurantoin	86	86	-	-	18	18	-	-	99.3%
Norfloxacin	28	28	-	-	6	6	-	-	100%
Ofloxacin	26	26	-	-	4	4	-	-	100%
Oxacillin	3	1	2	-	-	-	-	-	Not graded ¹
Piperacillin	1	1	-	-	8	8	-	-	100%
Piperacillin/Tazobactam	-	-	-	-	2	2	-	-	100%
Sulfamethoxazole	6	6	-	-	1	1	-	-	100%
Sulfisoxazole	10	10	-	-	1	1	-	-	93.8%
Sulfonamide	1	1	-	-	-	-	-	-	100%
Tetracycline	55	54	1	-	12	12	-	-	98.8%
Ticarcillin	-	-	-	-	1	1	-	-	100%
Ticarcillin/Clavulanate	1	1	-	-	4	4	-	-	100%
Tobramycin	4	4	-	-	9	9	-	-	100%
Trimethoprim	13	13	-	-	8	8	-	-	100%
Trimethoprim/Sulfamethoxazole	82	82	-	-	16	16	-	-	100%

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

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

GC CULTURE

Specimen GC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Neisseria gonorrhoeae	25	50.0%	Acceptable
Presump. GC, referred for ID	25	50.0%	Acceptable

Beta-lactamase Testing

Negative	11	91.7%
Positive	1	8.3%

Gram Stain

Gram negative	43	100%	Acceptable
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Gram Stain Morphology

Diplococci	43	91.5%
Cocci	2	4.3%
Cocci in pairs	2	4.3%

Organism present in specimen GC-11: *Neisseria gonorrhoeae*.

Specimen GC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No growth (sterile)	14	58.3%	Acceptable
Negative for N. gonorrhoeae	9	37.5%	Acceptable

Organisms present in specimen GC-12: *Gardnerella vaginalis* and *Lactobacillus casei*.

Specimen GC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No growth (sterile)	13	56.5%	Acceptable
Negative for N. gonorrhoeae	9	39.1%	Acceptable

Organism present in specimen GC-13: *Escherichia coli*.

Specimen GC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No growth (sterile)	13	56.5%	Acceptable
Negative for N. gonorrhoeae	10	43.5%	Acceptable

Organisms present in specimen GC-14: *Streptococcus species Group B* and *Lactobacillus casei*.

GC CULTURE

Specimen GC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	15	65.2%	Acceptable
Neisseria gonorrhoeae	7	30.4%	Acceptable
Growth select media, referred	1	4.4%	Acceptable

Beta-lactamase Testing

Negative	4	100%
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Organisms present in specimen GC-15: *Neisseria gonorrhoeae* and *Staphylococcus epidermidis*.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-11

<u>Method</u>	<u>Labs</u>	<u>No growth</u>	<u><10,000 organisms/mL</u>	<u>10,000-100,000 organisms/mL</u>	<u>>100,000 organisms/mL</u>
All Methods	113	1	-	9	103
Bactercult	3	-	-	-	3
Bacti-Star	1	-	-	-	1
Bulls Eye	7	-	-	2	5
Calibrated Loop	33	-	-	4	29
HealthLink	1	-	-	-	1
Uri-Check	14	-	-	-	14
Uri-Three	2	-	-	-	2
Uricult	47	-	-	3	43

Identification–Specimen CC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Escherichia coli	23	48.9%	Acceptable
Presump. Gram negative	15	31.9%	Acceptable
Growth, referred for identification	5	10.6%	Acceptable
Escherichia coli	4	8.5%	Acceptable

Gram Stain

Gram negative	6	100%	Acceptable
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Gram Stain Morphology

Rods/bacilli	6	100%
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Organism present in specimen CC-11: >100,000 CFU/mL of *Escherichia coli*.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-12

<u>Method</u>	<u>Labs</u>	<u>No growth</u>	<u><10,000 organisms/mL</u>	<u>10,000-100,000 organisms/mL</u>	<u>>100,000 organisms/mL</u>
All Methods	112	6	3	14	89
Bactercult	3	-	-	-	3
Bacti-Star	1	-	-	-	1
Bulls Eye	6	-	-	1	5
Calibrated Loop	33	-	-	7	26
HealthLink	1	-	-	-	1
Uri-Check	14	4	-	-	10
Uri-Three	2	-	-	-	2
Uricult	47	2	3	5	37

Identification—Specimen CC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	17	37.0%	Acceptable
Presump. Staphylococcus sp.	15	32.6%	Acceptable
Growth, referred for identification	6	13.0%	Acceptable
Staphylococcus aureus	3	6.5%	Acceptable
Staphylococcus sp.	2	4.4%	Acceptable
Bacturcult Group II	1	2.2%	Acceptable

Organisms present in specimen CC-12: >100,000 CFU/mL of *Staphylococcus aureus* and approximately 3,500 CFU/mL of *Lactobacillus casei*.

Identification—Specimen CC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Klebsiella sp.	17	42.5%	Acceptable
Presump. Gram negative	10	25.0%	Acceptable
Presump. Gram positive	4	10.0%	Acceptable
Klebsiella pneumoniae	3	7.5%	Acceptable
Growth, referred for identification	3	7.5%	Acceptable

Organisms present in specimen CC-13: approximately 68,000 CFU/mL of *Klebsiella pneumoniae* and approximately 19,000 CFU/mL of *Corynebacterium species*.

Identification—Specimen CC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	13	34.2%	Not graded
Presump. Enterobacter sp.	6	15.8%	
Growth, referred for identification	4	10.5%	
Presump. Gram positive	2	5.3%	
Enterobacter sp.	1	2.6%	
Enterobacter cloacae	1	2.6%	

Organisms present in specimen CC-14: approximately 86,000 CFU/mL of *Enterobacter cloacae* and approximately 21,000 CFU/mL of *Staphylococcus epidermidis*. This is an ungraded challenge due to less than 80% referee consensus.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	12	34.3%	Acceptable
Presump. Enterococcus sp.	12	34.3%	Acceptable
Growth, referred for identification	4	11.4%	Acceptable
Enterococcus sp.	2	5.7%	Acceptable
Enterococcus (Strep) faecalis	1	2.9%	Acceptable
Streptococcus Group D	1	2.9%	Acceptable
Presumptive Streptococcus sp.	1	2.9%	Acceptable

Organism present in specimen CC-15: >100,000 CFU/mL of *Enterococcus (Strep) faecalis*.

DERMATOPHYTE SCREEN

Specimen DM-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte present	19	82.6%	Acceptable
Dermatophyte absent	4	17.4%	

Organism present in specimen DM-11: *Epidermophyton floccosum*.

Specimen DM-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte absent	23	100%	Acceptable

Organisms present in specimen DM-12: *Escherichia coli* and *Lactobacillus casei*.

GRAM STAIN

Specimen GS-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	70	100%	Acceptable

Gram Stain Morphology

Cocci	53	81.5%
Cocci in pairs	8	12.3%
Cocci in chains	2	3.1%
Cocco-bacilli	1	1.5%
Diplococci	1	1.5%

Organism present in specimen GS-11: *Staphylococcus epidermidis*.

Specimen GS-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	65	92.9%	Acceptable
Gram positive	5	7.1%	

Gram Stain Morphology

Diplococci	27	41.5%
Cocci	23	35.4%
Cocci in pairs	7	10.8%
Cocco-bacilli	5	7.7%
Cocci in chains	2	3.1%
Rods/bacilli	1	1.5%

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

GRAM STAIN

Specimen GS-13

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

Gram Stain Morphology

Cocc in chains	41	63.1%
Cocci	16	24.6%
Cocci in pairs	6	9.2%
Rods/bacilli	2	3.1%

Organism present in specimen GS-13: *Streptococcus pyogenes*.

Specimen GS-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	69	98.6%	Acceptable
Gram positive	1	1.4%	

Gram Stain Morphology

Rods/bacilli	62	95.4%
Cocci	1	1.5%
Cocci in chains	1	1.5%
Diplococci	1	1.5%

Organism present in specimen GS-14: *Pseudomonas aeruginosa*.

Specimen GS-15

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

Gram Stain Morphology

Rods/bacilli	50	76.9%
Cocco-bacilli	14	21.5%
Diplococci	1	1.5%

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

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	29	90.6%	Acceptable
Negative	3	9.4%	

Organisms present in specimen VP-11: *Candida albicans* and *Trichomonas vaginalis*.

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	31	31	Acceptable

Organism present in specimen VP-12: *Gardnerella vaginalis*.

Specimen VP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	31	96.9%	Acceptable
Negative	1	3.1%	

Organism present in specimen VP-13: *Trichomonas vaginalis*.

Specimen VP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	31	100%	Acceptable

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

Specimen VP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	31	100%	Acceptable

Organisms present in specimen VP-15: *Candida albicans* and *Gardnerella vaginalis*.

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	31	100%	Acceptable

Specimen VP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	29	90.6%	Acceptable
Negative	3	9.4%	

Specimen VP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	31	100%	Acceptable

AFFIRM VP III–Gardnerella vaginalis**Specimen VP-14**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	26	81.3%	Acceptable
Negative	6	18.8%	

Specimen VP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	23	74.2%	Acceptable by Referee Grading
Negative	8	25.8%	

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

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	32	100%	Acceptable

Specimen VP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	31	100%	Acceptable

Specimen VP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	31	100%	Acceptable

Specimen VP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	31	100%	Acceptable

Specimen VP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	32	100%	Acceptable

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	21	-	21
BD ProbeTec	2	-	2
Beckman (Sanofi) ACCESS	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	2	-	2
Gen-Probe	3	-	3
Quidel QuickVue	10	-	10

Organism present in specimen CY-11: *Neisseria gonorrhoeae*.

Specimen CY-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	21	21	-
BD ProbeTec	2	2	-
Beckman (Sanofi) ACCESS	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	2	2	-
Gen-Probe	3	3	-
Quidel QuickVue	10	10	-

Organisms present in specimen CY-12: *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

Specimen CY-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	16	16	-
BD ProbeTec	2	2	-
Beckman (Sanofi) ACCESS	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	2	2	-
Gen-Probe	3	3	-
Quidel QuickVue	5	5	-

Organism present in specimen CY-13: *Chlamydia trachomatis*.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	16	-	16
BD ProbeTec	2	-	2
Beckman (Sanofi) ACCESS	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	2	-	2
Gen-Probe	3	-	3
Quidel QuickVue	5	-	5

Organism present in specimen CY-14: *Neisseria gonorrhoeae*.

Specimen CY-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	16	16	-
BD Probe	2	2	-
Beckman (Sanofi) ACCESS	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	2	2	-
Gen-Probe	3	3	-
Quidel QuickVue	5	5	-

Organisms present in specimen CY-15: *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

GC (ANTIGEN DETECTION)

Specimen CY-11

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

Specimen CY-12

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

GC (ANTIGEN DETECTION)

Specimen CY-13

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

Specimen CY-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	9	9	-
BD ProdeTec	2	2	-
BioStar OIA	3	3	-
Gen-Probe	3	3	-

Specimen CY-15

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

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	5	-
Meridian ImmunoCard STAT!	2	2	-
Remel Xpect	3	3	-

Antigen present in specimen LC-11: *Cryptosporidium*.

Specimen LC-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	-	5
Meridian ImmunoCard STAT!	2	-	2
Remel Xpect	3	-	3

Antigen present in specimen LC-12: *Giardia lamblia*.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	-	5
Meridian ImunoCard STAT!	2	-	2
Remel Xpect	3	-	3

Antigen present in specimen LC-13: Neither *Cryptosporidium* or *Giardia lamblia* antigens present.

Specimen LC-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	4	1
Meridian ImmunoCard STAT!	2	1	1
Remel Xpect	3	3	-

Antigen present in specimen LC-14: *Cryptosporidium*.

Specimen LC-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	-	5
Meridian ImmunoCard STAT!	2	-	2
Remel Xpect	3	-	3

Antigen present in specimen LC-15: *Giardia lamblia*.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	9	-	9
Alexcon (Hycor)	3	-	3
Meridian ImmunoCard STAT!	2	-	2
Meridian Merifluor	1	-	1
Remel Xpect	3	-	3

Specimen LC-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	9	9	-
Alexcon (Hycor)	3	3	-
Meridian ImmunoCard STAT!	2	2	-
Meridian Merifluor	1	1	-
Remel Xpect	3	3	-

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	8	-	8
Alexon (Hycor)	2	-	2
Meridian ImmunoCard STAT!	2	-	2
Meridian Merifluor	1	-	1
Remel Xpect	3	-	3

Specimen LC-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	8	8	-
Alexon (Hycor)	2	2	-
Meridian ImmunoCard STAT!	2	2	-
Meridian Merifluor	1	1	-
Remel Xpect	3	3	-

Specimen LC-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	8	8	-
Alexon (Hycor)	2	2	-
Meridian ImmunoCard STAT!	2	2	-
Meridian Merifluor	1	1	-
Remel Xpect	3	3	-

RSV ANTIGEN DETECTION

Specimen V-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	31	-	31
BD Directigen	5	-	5
Binax NOW – waived	11	-	11
BioStar OIA	7	-	7
Fisher HealthCare Sure-Vue	1	-	1
Wampole Clearview RSV – waived	3	-	3

Specimen V-11: Negative for RSV antigen.

RSV ANTIGEN DETECTION

Specimen V-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	31	23	8
BD Directigen	5	5	-
Binax NOW – waived	11	10	1
BioStar OIA	7	1	6
Fisher HealthCare Sure-Vue	1	1	-
Wampole Clearview RSV – waived	3	3	-

Specimen V-12: Positive for RSV antigen.

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	31	-	31
BD Directigen	5	-	5
Binax NOW – waived	11	-	11
BioStar OIA	7	-	7
Fisher HealthCare Sure-Vue	1	-	1
Wampole Clearview RSV – waived	3	-	3

Specimen V-13: Negative for RSV antigen.

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	31	28	3
BD Directigen	5	5	-
Binax NOW – waived	11	11	-
BioStar OIA	7	5	2
Fisher HealthCare Sure-Vue	1	1	-
Wampole Clearview RSV – waived	3	3	-

Specimen V-14: Positive for RSV antigen.

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	31	1	30
BD Directigen	5	-	5
Binax NOW – waived	11	-	11
BioStar OIA	7	1	6
Fisher HealthCare Sure-Vue	1	-	1
Wampole Clearview RSV – waived	3	-	3

Specimen V-15: Negative for RSV antigen.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	87	73	14
Biostar OIA	10	3	7
Quidel QuickVue Influenza	70	65	5

Specimen V-11: Positive for Influenza A/B antigen.

Specimen V-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	87	2	85
BioStar OIA	10	-	10
Quidel QuickVue Influenza	70	2	68

Specimen V-12: Negative for Influenza A/B antigen.

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	33	31	2
BioStar OIA	8	8	-
Quidel QuickVue Influenza	22	21	1

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

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	33	-	33
BioStar OIA	8	-	8
Quidel QuickVue Influenza	22	-	22

Specimen V-14: Negative for Influenza A/B antigen.

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	33	28	5
BioStar OIA	8	5	3
Quidel QuickVue Influenza	22	21	1

Specimen V-15: Positive for Influenza A/B antigen.

INFLUENZA A ANTIGEN DETECTION

Specimen V-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	70	3	67
BD Directigen	3	-	3
Binax NOW – waived	13	-	13
BioStar Flu OIA A/B	7	-	7
Quidel QuickVue Influenza A+B	35	2	33
Remel Xpect	5	-	5
Wampole Clearview	2	-	2

Specimen V-11: Negative for Influenza A antigen.

Specimen V-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	70	-	70
BD Directigen	3	-	3
Binax NOW – waived	13	-	13
BioStar Flu OIA A/B	7	-	7
Quidel QuickVue Influenza A+B	35	-	35
Remel Xpect	5	-	5
Wampole Clearview	2	-	2

Specimen V-12: Negative for Influenza A antigen.

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	47	47	-
BD Directigen	2	2	-
Binax Now – waived	8	8	-
BioStar Flu OIA A/B	7	7	-
Quidel QuickVue Influenza A+B	18	18	-
Remel Xpect	5	5	-
Wampole Clearview	2	2	-

Specimen V-13: Positive for Influenza A antigen.

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	47	-	47
BD Directigen	2	-	2
Binax NOW – waived	8	-	8
BioStar Flu OIA A/B	7	-	7
Quidel QuickVue Influenza A+B	18	-	18
Remel Xpect	5	-	5
Wampole Clearview	2	-	2

Specimen V-14: Negative for Influenza A antigen.

INFLUENZA A ANTIGEN DETECTION

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	47	47	-
BD Directigen	2	2	-
Binax NOW – waived	8	8	-
BioStar Flu OIA A/B	7	7	-
Quidel QuickVue Influenza A+B	18	18	-
Remel Xpect	5	5	-
Wampole Clearview	2	2	-

Specimen V-15: Positive for Influenza A antigen.

INFLUENZA B ANTIGEN DETECTION

Specimen V-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	69	60	9
BD Directigen	3	3	-
Binax NOW – waived	13	11	2
BioStar Flu OIA A/B	7	5	2
Quidel QuickVue Influenza A+B	35	31	4
Remel Xpect	5	5	-
Wampole Clearview	2	1	1

Specimen V-11: Positive for Influenza B antigen.

Specimen V-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	69	-	69
BD Directigen	3	-	3
Binax NOW – waived	13	-	13
BioStar Flu OIA A/B	7	-	7
Quidel QuickVue Influenza A+B	35	-	35
Remel Xpect	5	-	5
Wampole Clearview	2	-	2

Specimen V-12: Negative for Influenza B antigen.

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	46	-	46
BD Directigen	2	-	2
Binax NOW – waived	8	-	8
BioStar Flu OIA A/B	7	-	7
Quidel QuickVue Influenza A+B	18	-	18
Remel Xpect	5	-	5
Wampole Clearview	2	-	2

Specimen V-13: Negative for Influenza B antigen.

INFLUENZA B ANTIGEN DETECTION

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	46	-	46
BD Directigen	2	-	2
Binax NOW – waived	8	-	8
BioStar Flu OIA A/B	7	-	7
Quidel QuickVue Influenza A+B	18	-	18
Remel Xpect	5	-	5
Wampole Clearview	2	-	2

Specimen V-14: Negative for Influenza B antigen.

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	46	-	46
BD Directigen	2	-	2
Binax NOW – waived	8	-	8
BioStar Flu OIA A/B	7	-	7
Quidel QuickVue Influenza A+B	18	-	18
Remel Xpect	5	-	5
Wampole Clearview	2	-	2

Specimen V-15: Negative for Influenza B antigen.

LEGIONELLA ANTIGEN DETECTION

Specimen L-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	118	-	118

Specimen L-11: Negative for Legionella antigen.

Specimen L-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	118	117	1

Specimen L-12: Positive for Legionella antigen.

Specimen L-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	118	118	-

Specimen L-13: Positive for Legionella antigen.

LEGIONELLA ANTIGEN DETECTION

Specimen L-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	118	118	-

Specimen L-14: Positive for Legionella antigen.

Specimen L-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	118	1	117

Specimen L-15: Negative for Legionella antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	21	21	-
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	7	7	-
BioStar OIA	6	6	-
Meridian ImmunoCard	3	3	-
Meridian Premier	1	1	-

Antigen present in specimen AG-11: *Clostridium difficile*.

Specimen AG-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	21	21	-
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	7	7	-
BioStar OIA	6	6	-
Meridian ImmunoCard	3	3	-
Meridian Premier	1	1	-

Antigens present in specimen AG-12: *Clostridium difficile* and Rotavirus.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	21	-	21
Alexon (Hycor)	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	7	-	7
BioStar OIA	6	-	6
Meridian ImmunoCard	3	-	3
Meridian Premier	1	-	1

Antigen present in specimen AG-13: Rotavirus.

Specimen AG-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	21	21	-
Alexcon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	7	7	-
BioStar OIA	6	6	-
Meridian ImmunoCard	3	3	-
Meridan Premier	1	1	-

Antigen present in specimen AG-14: *Clostridium difficile*.

Specimen AG-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	21	-	21
Alexon (Hycor)	1	-	1
Biomerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	7	-	7
BioStar OIA	6	-	6
Meridian ImmunoCard	3	-	3
Meridian Premier	1	-	1

Antigen present in specimen AG-15: Rotavirus.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-11

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

Specimen AG-12

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

Specimen AG-13

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

Specimen AG-14

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

Specimen AG-15

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

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	111	111	-

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

Specimen SP-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	112	-	112

Specimen SP-12: Negative for *Streptococcus pneumoniae* antigen.

Specimen SP-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	112	-	112

Specimen SP-13: Negative for *Streptococcus pneumoniae* antigen.

Specimen SP-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	112	112	-

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

Specimen SP-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	112	112	-

Specimen SP-15: Positive for *Streptococcus pneumoniae* antigen.

PARASITOLOGY – DOMESTIC

Specimen PA-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba histolytica	1	50.0%	Acceptable
Blastocystis hominis	1	50.0%	Acceptable

Parasite present in specimen PA-11: *Entamoeba histolytica*.

PARASITOLOGY – DOMESTIC

Specimen PA-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	1	100%	Acceptable

Parasite present in specimen PA-12: *Giardia lamblia*.

Specimen PA-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	1	50.0%	Not graded
Parasite egg seen but no ID	1	50.0%	

Parasite present in specimen PA-13: Negative for parasites. This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. eggs	1	50.0%	Acceptable
Other parasite seen but no ID	1	50.0%	Acceptable

Parasite present in specimen PA-14: *Taenia sp. eggs*.

Specimen PA-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium sp., not falciparum	1	50.0%	Not graded
No parasite seen	1	50.0%	

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

INTERNATIONAL LABS

PARASITOLOGY – INTERNATIONAL (PA Specimens)

Specimen PA-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba histolytica	1	50.0%	Acceptable
Blastocystis hominis	1	50.0%	Acceptable

Parasite present in specimen PA-11: *Entamoeba histolytica*.

PARASITOLOGY – INTERNATIONAL (PA Specimens)

Specimen PA-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
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Parasite present in specimen PA-12: *Giardia lamblia*. No labs reported results for PA-12.

Specimen PA-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
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No parasite seen	1	25.0%	Not graded
Diphyllobothrium sp. eggs	1	25.0%	
Strongyloides sterco. larvae	1	25.0%	
Taenia sp. eggs	1	25.0%	

Parasite present in specimen PA-13: Negative for parasites. This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
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Taenia sp. eggs	1	25.0%	Acceptable
Paragonimus westermani eggs	1	25.0%	
Schistosoma japonicum eggs	1	25.0%	
No parasite seen	1	25.0%	

Parasite present in specimen PA-14: *Taenia sp. eggs*.

Specimen PA-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
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Plasmodium sp., NOS	2	66.7%	Not graded
Plasmodium vivax	1	33.3%	

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

PARASITOLOGY – INTERNATIONAL (FP Specimens)

Specimen FP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. Eggs	27	45.0%	Not graded
No parasite seen	20	33.3%	
Ascaris lumbricoides eggs	5	8.3%	
Endolimax nana	3	5.0%	
Blastocystis hominis	1	1.7%	
Diphyllobothrium sp. eggs	1	1.7%	
Hookworm	1	1.7%	
Strongyloides sterco. larvae	1	1.7%	
Trichuris trichiura eggs	1	1.7%	

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

Specimen FP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba coli	46	66.7%	Not graded
Entamoeba histolytica	16	23.2%	
Blastocystis hominis	2	2.9%	
Strongyloides sterco. larvae	2	2.9%	
Ascaris lumbricoides eggs	1	1.5%	
Endolimax	1	1.5%	
Giardia lamblia	1	1.5%	

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

Specimen FP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	38	47.5%	Not graded
Blastocystis hominis	9	11.3%	
Entamoeba coli	6	7.5%	
Strongyloides sterco. larvae	5	6.3%	
Parasite egg seen but no ID	4	5.0%	
Ascaris lumbricoides eggs	3	3.8%	
Endolimax nana	3	3.8%	
Entamoeba histolytica	3	3.8%	
Trichostrongylus sp. eggs	3	3.8%	
Enterobius vermicularis eggs	2	2.5%	
Fasciola hepatica eggs	1	1.3%	
Taenia sp. eggs	1	1.3%	
Other parasite seen but no ID	1	1.3%	
No parasite seen	1	1.3%	

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

PARASITOLOGY – INTERNATIONAL (FP Specimens)

Specimen FP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	50	87.7%	Acceptable
Endolimax nana	4	7.0%	
Entamoeba coli	1	1.8%	
Entamoeba histolytica	1	1.8%	
No parasite seen	1	1.8%	

Parasite present in specimen FP-14: *Giardia lamblia*.

Specimen FP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium falciparum	34	64.2%	Not graded
Plasmodium vivax	12	22.6%	
Plasmodium sp., NOS	2	3.8%	
Plasmodium sp., not falciparum	2	3.8%	
Babesia sp.	1	1.9%	
Plasmodium malariae	1	1.9%	
Hookworm	1	1.9%	

Parasite present in specimen FP-15: *Babesia sp.* This is an ungraded challenge due to less than 80% participant consensus.

ANTIMICROBIAL SUSCEPTIBILITY TESTING (FOR INTERNATIONAL LABS)

Specimen UC-11

<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	8	8	-	-	21	21	-	-	100%
Amoxicillin/Clavulanate	3	3	-	-	12	12	-	-	95.2%
Ampicillin	6	6	-	-	15	14	-	1	96.7%
Ampicillin/Sulbactam	4	4	-	-	15	15	-	-	100%
Azteronam	4	4	-	-	5	5	-	-	100%
Cefaclor	1	1	-	-	-	-	-	-	100%
Cefazolin	3	3	-	-	12	12	-	-	100%
Cefepime	-	-	-	-	2	2	-	-	100%
Cefoperazone	-	-	-	-	1	1	-	-	100%
Cefoperazone/Sulbactam	-	-	-	-	2	2	-	-	100%
Cefotaxime	-	-	-	-	13	13	-	-	100%
Cefotetan	-	-	-	-	2	2	-	-	100%
Cefoxitin	2	2	-	-	5	4	-	1	85.7%
Ceftazidime	5	5	-	-	18	17	-	1	96.4%
Ceftriaxone	5	5	-	-	11	11	-	-	100%
Cefuroxime	1	1	-	-	14	12	-	2	85.7%
Cephalexin	2	1	1	-	2	2	-	-	Not graded ¹
Cephalothin	5	4	1	-	10	10	-	-	87.0%
Ciprofloxacin	7	7	-	-	23	23	-	-	100%
Clindamycin	1	1	-	-	-	-	-	-	100%
Fosfomycin	-	-	-	-	3	3	-	-	100%
Gentamicin	8	8	-	-	22	22	-	-	100%
Imipenem	4	4	-	-	15	15	-	-	100%
Levofloxacin	2	2	-	-	9	9	-	-	100%
Meropenem	-	-	-	-	10	10	-	-	100%
Naldixic Acid	5	5	-	-	4	4	-	-	100%
Nitrofurantoin	8	8	-	-	20	20	-	-	100%
Norfloxacin	3	3	-	-	11	11	-	-	100%
Ofloxacin	2	2	-	-	4	4	-	-	100%
Oxacillin	2	-	-	2	2	1	-	1	Not graded ¹
Penicillin-G	2	-	-	2	2	1	-	1	Not graded ¹
Piperacillin	-	-	-	-	13	13	-	-	100%
Piperacillin/Tazobactam	2	2	-	-	13	13	-	-	100%
Tetracycline	-	-	-	-	1	1	-	-	100%
Ticarcillin	-	-	-	-	1	1	-	-	100%
Ticarcillin/Clavulanate	-	-	-	-	5	5	-	-	100%
Tobramycin	-	-	-	-	10	10	-	-	100%
Trimethoprim	-	-	-	-	1	1	-	-	100%
Trimethoprim/Sulfamethoxazole	6	6	-	-	19	19	-	-	100%

Organism present in specimen UC-11: *Escherichia coli*.

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

SUMMARY OF ISOLATES FOUND IN THE 2005 MLE-M3 CULTURE SPECIMENS

Organism	ATCC Strain
<i>Moraxella catarrhalis</i>	25238
<i>Streptococcus pyogenes</i>	19615
<i>Streptococcus gordonii</i>	35557
<i>Haemophilus influenzae</i>	10211
<i>Streptococcus agalactiae</i>	12386
<i>Corynebacterium species</i>	49528
<i>Neisseria sicca</i>	29256
<i>Proteus vulgaris</i>	8427
<i>Salmonella choleraesuis subspecies choleraesuis serotype enteritidis</i>	13076
<i>Escherichia coli</i>	25922
<i>Lactobacillus casei</i>	393
<i>Staphylococcus aureus</i>	25923
<i>Klebsiella pneumoniae</i>	13883
<i>Enterobacter cloacae</i>	13047
<i>Staphylococcus epidermidis</i>	14990
<i>Enterococcus faecalis</i>	29212
<i>Neisseria gonorrhoeae</i>	19424
<i>Gardnerella vaginalis</i>	14018

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