

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 1 • 3



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

Microbiology
MLE-M1

Table of Contents

Evaluation Criteria.....	2
---------------------------------	----------

Microbiology

Throat Culture	3	GC (Antigen Detection)	25
Strep A Antigen Detection.....	4	Cryptosporidium Antigen Detection	26
General Bacteriology	8	Giardia lamblia Antigen Detection.....	27
MRSA Screening	9	RSV Antigen Detection.....	28
Urine Culture	10	Influenza A/B Antigen Detection.....	29
Gram Stain.....	10	Influenza A Antigen Detection	30
Antimicrobial Susceptibility Testing	12	Influenza B Antigen Detection	31
Genital Culture	14	Legionella Antigen Detection.....	33
Gram Stain.....	14	Clostridium Difficile Toxin Antigen Detection	34
Colony Count/Presumptive ID	16	Rotavirus Antigen Detection.....	35
Gram Stain.....	16	Streptococcus pneumoniae Antigen Detection	36
Dermatophyte Screen	19	Parasitology	37
Gram Stain.....	19		
Affirm VP III			
Trichomonas vaginalis.....	21		
Gardnerella vaginalis	22		
Candida sp.	22		
Chlamydia (Antigen Detection).....	23		

Evaluation Criteria

The evaluation criteria used in the 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	80% Consensus
Affirm VP III Candida Antigen Detection	80% Consensus	C. Difficile Toxin/Antigen Detection	80% Consensus
Affirm VP III Trichomonas Ag Detection	80% Consensus	Dermatophyte Screen	80% Consensus
Chlamydia (EIA, DNA)	80% Consensus	Legionella Antigen Detection	80% Consensus
Cryptosporidium Antigen Detection	80% Consensus	Streptococcus pneumoniae Antigen Detection	80% Consensus
Giardia lamblia Antigen Detection	80% Consensus		
Influenza A/B Antigen Detection	80% Consensus		
Influenza A Antigen Detection	80% Consensus		
Influenza B Antigen Detection	80% Consensus		

THROAT CULTURE

Specimen TC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	77	49.04%	Acceptable
Presump. Pos. Group A Strep	68	43.31%	Acceptable
Streptococcus pyogenes	8	5.10%	Acceptable

Organism present in specimen TC-1: *Streptococcus pyogenes*.

Specimen TC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	141	93.38%	Acceptable
No growth (sterile)	6	3.97%	Acceptable
Moraxella catarrhalis	3	1.99%	Acceptable

Organisms present in specimen TC-2: *Moraxella catarrhalis* and *Neisseria sicca*.

Specimen TC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Pos. Group A Strep	48	51.61%	Acceptable
Positive for Group A Strep	45	48.39%	Acceptable

Organism present in specimen TC-3: *Streptococcus pyogenes* and *Streptococcus viridans*.

Specimen TC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	39	49.37%	Acceptable
Presump. Pos. Group A Strep	38	48.10%	Acceptable

Organisms present in specimen TC-4: *Streptococcus pyogenes* and *Neisseria mucosa*.

Specimen TC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	76	97.44%	Acceptable

Organism present in specimen TC-5: *Neisseria mucosa*.

STREP A ANTIGEN DETECTION

Specimen RS-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	550	535	15
Abbott Signify Strep A-waived	3	2	1
BD Chek Strep A	5	5	-
BD Directigen	1	1	-
Beckman Coulter ICON DS	6	5	1
Beckman Coulter ICON SC	3	3	-
Binax NOW Strep A	2	2	-
Cardinal Health Strep A - waived	19	19	-
Consult Diagnostic Strep A - Moderate	3	3	-
Consult Diagnostic Strep A Dipstick - Waived	60	60	-
Fisher HealthCare Sure-Vue	1	1	-
Fisher HealthCare Sure-Vue - waived	4	4	-
Genzyme OSOM	81	74	7
Genzyme OSOM Ultra Strep A	51	51	-
Henry Schein One Step+ - waived	32	32	-
Immunostics Detector Strep A Direct	12	11	1
Inverness Acceava Strep A Test	15	15	-
Inverness Signify Strep A Dipstick	1	1	-
McKesson Strep A Dipstick	37	37	-
Other Waived Method	8	8	-
Polymedco Poly Stat Strep A - moderate	1	1	-
Polymedco Poly Stat Strep A - waived	9	9	-
PSS Select Diag. Strep A Dipstick - waived	6	6	-
Quidel QuickVue Dipstick Strep	82	81	1
Quidel QuickVue In-Line	64	62	2
Quidel QuickVue+	34	33	1
Stanbio QuStick Strep A	2	2	-
Wampole Clearview	3	3	-

STREP A ANTIGEN DETECTION

Specimen RS-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	539	3	536
Abbott Signify Strep A-waived	3	1	2
BD Chek Strep A	5	-	5
BD Directigen	1	-	1
Beckman Coulter ICON DS	6	1	5
Beckman Coulter ICON SC	3	-	3
Binax NOW Strep A	2	-	2
Cardinal Health Strep A - waived	19	-	19
Consult Diagnostic Strep A - Moderate	3	-	3
Consult Diagnostic Strep A Dipstick - Waived	59	-	59
Fisher HealthCare Sure-Vue	1	-	1
Fisher HealthCare Sure-Vue - waived	4	-	4
Genzyme OSOM	81	-	81
Genzyme OSOM Ultra Strep A	49	-	49
Henry Schein One Step+ - waived	32	-	32
Immunostics Detector Strep A Direct	12	-	12
Inverness Acceava Strep A Test	14	-	14
Inverness Signify Strep A Dipstick	1	-	1
McKesson Strep A Dipstick	35	-	35
Other Waived Method	8	-	8
Polymedco Poly Stat Strep A - moderate	1	-	1
Polymedco Poly Stat Strep A - waived	9	-	9
PSS Select Diag. Strep A Dipstick - waived	6	-	6
Quidel QuickVue Dipstick Strep	81	1	80
Quidel QuickVue In-Line	63	-	63
Quidel QuickVue+	31	-	31
Stanbio QuStick Strep A	2	-	2
Wampole Clearview	3	-	3

STREP A ANTIGEN DETECTION

Specimen RS-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	170	-	170
BD Chek Strep A	2	-	2
Beckman Coulter ICON DS	3	-	3
Binax NOW Strep A	1	-	1
Cardinal Health Strep A - waived	3	-	3
Consult Diagnostic Strep A - Moderate	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	6	-	6
Genzyme OSOM	51	-	51
Genzyme OSOM Ultra Strep A	15	-	15
Henry Schein One Step+ - waived	6	-	6
Immunostics Detector Strep A Direct	1	-	1
Inverness Acceava Strep A Test	2	-	2
McKesson Strep A Dipstick	9	-	9
Other Waived Method	4	-	4
Polymedco Poly Stat Strep A - moderate	1	-	1
Polymedco Poly Stat Strep A - waived	1	-	1
PSS Select Diag. Strep A Dipstick - waived	2	-	2
Quidel QuickVue Dipstick Strep	12	-	12
Quidel QuickVue In-Line	23	-	23
Quidel QuickVue+	25	-	25
Stanbio QuStick Strep A	1	-	1

STREP A ANTIGEN DETECTION

Specimen RS-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	148	144	4
BD Chek Strep A	1	1	-
Beckman Coulter ICON DS	3	3	-
Binax NOW Strep A	1	1	-
Cardinal Health Strep A - waived	3	3	-
Consult Diagnostic Strep A - Moderate	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	5	5	-
Genzyme OSOM	49	47	2
Genzyme OSOM Ultra Strep A	9	9	-
Henry Schein One Step+ - waived	5	4	1
Immunostics Detector Strep A Direct	1	1	-
Inverness Acceava Strep A Test	2	2	-
McKesson Strep A Dipstick	7	7	-
Other Waived Method	4	4	-
PSS Select Diag. Strep A Dipstick - waived	2	2	-
Quidel QuickVue Dipstick Strep	11	11	-
Quidel QuickVue In-Line	22	21	1
Quidel QuickVue+	21	21	-
Stanbio QuStick Strep A	1	1	-

Specimen RS-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	148	-	148
BD Chek Strep A	1	-	1
Beckman Coulter ICON DS	3	-	3
Binax NOW Strep A	1	-	1
Cardinal Health Strep A - waived	3	-	3
Consult Diagnostic Strep A - Moderate	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	5	-	5
Genzyme OSOM	49	-	49
Genzyme OSOM Ultra Strep A	9	-	9
Henry Schein One Step+ - waived	5	-	5
Immunostics Detector Strep A Direct	1	-	1
Inverness Acceava Strep A Test	2	-	2
McKesson Strep A Dipstick	7	-	7
Other Waived Method	4	-	4
PSS Select Diag. Strep A Dipstick - waived	2	-	2
Quidel QuickVue Dipstick Strep	11	-	11
Quidel QuickVue In-Line	22	-	22
Quidel QuickVue+	21	-	21
Stanbio QuStick Strep A	1	-	1

GENERAL BACTERIOLOGY

Specimen BA-1 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Serratia marcescens	8	100%	Acceptable

Organism present in specimen BA-1: *Serratia marcescens*.

Specimen BA-2 – Respiratory Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Morganella morganii	8	100%	Acceptable

Organisms present in specimen BA-2: *Morganella morganii* and *Corynebacterium* species.

Specimen BA-3 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pseudomonas aeruginosa	9	90%	Acceptable
Staphylococcus epidermidis	1	10%	Acceptable

Organisms present in specimen BA-3: *Pseudomonas aeruginosa* and *Staphylococcus epidermidis*.

METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS SCREEN

Specimen MSA-1

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

Organisms present in specimen MSA-1: *Staphylococcus aureus* – Methicillin resistant and *Moraxella catarrhalis*.

Specimen MSA-2

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

Organisms present in specimen MSA-2: *Staphylococcus aureus* – Methicillin sensitive and *Corynebacterium* species.

Specimen MSA-3

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

Organism present in specimen MSA-3: *Staphylococcus aureus* – Methicillin sensitive.

Specimen MSA-4

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

Organisms present in specimen MSA-4: *Staphylococcus aureus* – Methicillin resistant and *Corynebacterium* species.

Specimen MSA-5

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

Organisms present in specimen MSA-5: *Staphylococcus aureus* – Methicillin resistant and *Streptococcus viridans*.

URINE CULTURE

Specimen UC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Proteus mirabilis	35	45.45%	Acceptable
Growth, referred for identification	18	23.38%	Acceptable
Proteus sp.	9	11.69%	Acceptable
Gram negative bacilli	7	9.09%	Acceptable
Presump. Proteus sp.	4	5.19%	Acceptable
Presump. Gram negative	2	2.60%	Acceptable
Bacturcult Group III	1	1.30%	Acceptable

Gram Stain

Gram negative	36	100%	Acceptable
---------------	----	------	------------

Gram Stain Morphology

Rods/bacilli	35	100%	Acceptable
--------------	----	------	------------

Organism present in specimen UC-1: *Proteus mirabilis*.

Specimen UC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus saprophyticus	26	37.14%	Acceptable
Growth, referred for identification	23	32.86%	Acceptable
Gram positive cocci	8	11.43%	Acceptable
Presump. Staphylococcus species	4	5.71%	Acceptable
Staph – coagulase negative	4	5.71%	Acceptable
Staphylococcus sp.	2	2.86%	Acceptable
Presump. Gram positive	2	2.86%	Acceptable
Corynebacterium species	1	1.43%	Acceptable

Organisms present in specimen UC-2: *Staphylococcus saprophyticus* and *Corynebacterium* species.

Specimen UC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No growth (sterile)	43	95.56%	Acceptable

Organism present in specimen UC-3: No organism present

URINE CULTURE

Specimen UC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	9	39.13%	Acceptable
Enterococcus species	7	30.43%	Acceptable
Enterococcus (Strep) faecalis	3	13.04%	Acceptable
Presumptive Streptococcus species	1	4.35%	Acceptable
Gram positive cocci	1	4.35%	Acceptable
Presumptive Gram positive	1	4.35%	Acceptable
Presumptive Enterococcus species	1	4.35%	Acceptable

Organism present in specimen UC-4: Enterococcus (Strep) faecalis.

Specimen UC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Escherichia coli	11	45.83%	Acceptable
Growth, referred for identification	9	37.50%	Acceptable
Presumptive Escherichia coli	1	4.17%	Acceptable
Presumptive Gram negative	1	4.17%	Acceptable
Lactobacillus species	1	4.17%	Acceptable
Gram negative bacilli	1	4.17%	Acceptable

Organisms present in specimen UC-5: *Escherichia coli* and *Lactobacillus* species.

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Specimen UC-1, CC-1 (SUS-1) The organism present is: *Proteus mirabilis*.

<u>Antimicrobial</u>	-----Disk 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	-	-	-	-	4	4	-	-	Not graded ¹
Amoxicillin/Clavulanate	9	9	-	-	8	8	-	-	100.00%
Ampicillin	32	31	-	1	15	15	-	-	96.55%
Ampicillin/Sulbactam	-	-	-	-	7	7	-	-	100.00%
Aztreonam	-	-	-	-	2	2	-	-	Not graded ¹
Carbenicillin	2	2	-	-	-	-	-	-	Not graded ¹
Cefamandole	1	1	-	-	-	-	-	-	Not graded ¹
Cefazolin	1	-	-	1	9	9	-	-	84.62%
Cefepime	-	-	-	-	6	6	-	-	100.00%
Cefixime	4	4	-	-	-	-	-	-	100.00%
Cefotaxime	-	-	-	-	2	2	-	-	Not graded ¹
Cefoxitin	-	-	-	-	4	4	-	-	100.00%
Cefpodoxime	1	1	-	-	-	-	-	-	Not graded ¹
Ceftazidime	1	1	-	-	5	5	-	-	100.00%
Ceftriaxone	5	4	1	-	9	9	-	-	94.44%
Cefuroxime	4	4	-	-	6	6	-	-	100.00%
Cephalothin	28	27	1	-	11	11	-	-	97.87%
Ciprofloxacin	33	33	-	-	13	13	-	-	100.00%
Doxycycline	2	-	-	2	1	-	-	1	Not graded ¹
Ertapenem	-	-	-	-	4	4	-	-	Not graded ¹
Gatifloxacin	-	-	-	-	1	1	-	-	Not graded ¹
Gentamicin	23	23	-	-	9	9	-	-	100.00%
Imipenem	-	-	-	-	3	3	-	-	Not graded ¹
Levofloxacin	14	14	-	-	13	13	-	-	100.00%
Lomefloxacin	1	1	-	-	-	-	-	-	Not graded ¹
Meropenem	-	-	-	-	2	2	-	-	Not graded ¹
Nalidixic Acid	2	-	2	-	-	-	-	-	Not graded ¹
Nitrofurantoin	38	-	-	38	16	-	-	16	100.00%
Norfloxacin	13	13	-	-	-	-	-	-	100.00%
Ofloxacin	2	2	-	-	-	-	-	-	Not graded ¹
Oxacillin	-	-	-	-	1	1	-	-	Inappropriate drug ²

NOTE: Please be aware that CLSI may issue a new edition of the supplement to the standards used by all proficiency testing programs for grading of susceptibilities as often as annually. Please contact CLSI to ensure that you are using the most recent version of these standards when reporting your susceptibilities. MLE has observed significant changes to which drugs are considered appropriate for various organisms with each subsequent supplement editions.

¹ This is an ungraded challenge due to lack of comparison group.

² This is an inappropriate drug for organism and/or source.

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Specimen UC-1, CC-1 (SUS-1) The organism present is: *Proteus mirabilis*.

<u>Antimicrobial</u>	-----Disk 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>	
Piperacillin	-	-	-	-	2	2	-	-	Not graded ¹
Piperacillin/Tazobactam	1	1	-	-	4	4	-	-	100.00%
Sulfisoxazole	5	4	1	-	-	-	-	-	83.33%
Tetracycline	9	-	-	9	4	-	-	4	95.00%
Ticarcillin/Clavulanate	-	-	-	-	1	1	-	-	Not graded ¹
Tobramycin	3	3	-	-	9	9	-	-	100.00%
Trimethoprim	4	4	-	-	6	6	-	-	84.62%
Trimethoprim/Sulfamethoxazole	39	38	-	1	14	14	-	-	95.52%

NOTE: Please be aware that CLSI may issue a new edition of the supplement to the standards used by all proficiency testing programs for grading of susceptibilities as often as annually. Please contact CLSI to ensure that you are using the most recent version of these standards when reporting your susceptibilities. MLE has observed significant changes to which drugs are considered appropriate for various organisms with each subsequent supplement editions.

GENITAL CULTURE

Specimen GC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	22	61.11%	Acceptable
Streptococcus agalactiae	7	19.44%	Acceptable
No growth (sterile)	7	19.44%	Acceptable

Gram Stain

Gram positive	17	100%	Acceptable
---------------	----	------	------------

Gram Stain Morphology

Cocci	17	100%	Acceptable
-------	----	------	------------

Organisms present in specimen GC-1: *Streptococcus agalactiae* and *Staphylococcus epidermidis*.

Specimen GC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive for N. gonorrhoeae	10	71.43%	Acceptable
Neisseria gonorrhoeae	3	21.43%	Acceptable
Growth, referred for identification	1	7.14%	Acceptable

Organism present in specimen GC-2: *Neisseria gonorrhoeae*.

Specimen GC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive for N. gonorrhoeae	11	84.62%	Acceptable
Neisseria gonorrhoeae	2	15.38%	Acceptable

Organisms present in specimen GC-3: *Neisseria gonorrhoeae* and *Staphylococcus epidermidis*.

GENITAL CULTURE

Specimen GC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive for <i>N. gonorrhoeae</i>	9	69.23%	Acceptable
<i>Neisseria gonorrhoeae</i>	3	23.08%	Acceptable

Organisms present in specimen GC-4: *Neisseria gonorrhoeae*.

Specimen GC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for <i>N. gonorrhoeae</i>	9	69.23%	Acceptable

Organisms present in specimen GC-5: *Staphylococcus epidermidis* and *Lactobacillus casei*. This challenge was graded by 82% referee consensus.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-1

<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	85	-	-	21	64
Bacturcult	1	-	-	-	1
Bulls Eye	5	-	-	-	5
Calibrated Loop	23	-	-	8	15
HealthLink	3	-	-	1	2
Uri-Check	7	-	-	-	7
Uri-Three	1	-	-	-	1
Uricult	44	-	-	12	32

Identification–Specimen CC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive Gram negative	9	40.91%	Acceptable
Growth, referred for identification	6	27.27%	Acceptable
Presumptive Proteus species	4	18.18%	Acceptable
Proteus mirabilis	2	9.09%	Acceptable
Gram negative bacilli	1	4.55%	Acceptable

Gram Stain

Gram negative	5	100%	Acceptable
---------------	---	------	------------

Gram Stain Morphology

Rods/bacilli	5	100%	Acceptable
--------------	---	------	------------

Organism present in specimen CC-1: >100,000 CFU/mL of *Proteus mirabilis*.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-2

<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	85	2	-	10	73
Bacturcult	1	-	-	-	1
Bulls Eye	5	-	-	1	4
Calibrated Loop	23	-	-	-	23
HealthLink	3	-	-	-	3
Uri-Check	7	-	-	2	5
Uri-Three	1	-	-	1	-
Uricult	44	2	-	6	36

Identification–Specimen CC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	7	31.82%	Acceptable
Presumptive Gram positive	7	31.82%	Acceptable
Presumptive Staphylococcus species	3	13.64%	Acceptable
Staphylococcus saprophyticus	2	9.09%	Acceptable
Staph-coagulase negative	1	4.55%	Acceptable

Organisms present in specimen CC-2: >100,000 CFU/mL of *Staphylococcus saprophyticus* and <10,000 CFU/mL of *Corynebacterium* species.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No growth (sterile)	18	100%	Acceptable

Organism present in specimen CC-3: No organism present.

Identification–Specimen CC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive Gram positive	8	44.44%	Acceptable
Growth, referred for identification	5	27.78%	Acceptable
Presumptive Enterococcus species	2	11.11%	Acceptable
Enterococcus (Strep) faecalis	1	5.56%	Acceptable
Enterococcus species	1	5.56%	Acceptable

Organism present in specimen CC-4: >100,000 CFU/mL of *Enterococcus (Strep) faecalis*.

Identification–Specimen CC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive Gram negative	9	50.00%	Acceptable
Presumptive Escherichia coli	3	16.67%	Acceptable
Growth, referred for identification	2	11.11%	Acceptable
Escherichia coli	2	11.11%	Acceptable
Gram negative bacilli	1	5.56%	Acceptable

Organisms present in specimen CC-5: 50,000 – 75,000 CFU/mL of *Escherichia coli* and <10,000 CFU/mL of *Lactobacillus* species.

DERMATOPHYTE SCREEN

Specimen DM-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte absent	24	100%	Acceptable

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

Specimen DM-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte present	23	95.83%	Acceptable
Dermatophyte absent	1	4.17%	

Organism present in specimen DM-3: *Microsporum gypseum*.

GRAM STAIN

Specimen GS-1

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	26	100%	Acceptable

Gram Stain Morphology

Cocci	19	86.18%	Acceptable
Diplococci	3	13.64%	

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

Specimen GS-2

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	23	88.46%	Acceptable
Gram positive	3	11.54%	

Gram Stain Morphology

Diplococci	15	68.18%	Acceptable
Cocci	7	31.82%	Acceptable

Organism present in specimen GS-2: *Neisseria mucosa*.

GRAM STAIN

Specimen GS-3

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	23	88.46%	Acceptable
Gram negative	3	11.54%	

Gram Stain Morphology

Cocci	17	77.27%	Acceptable
Diplococci	5	22.73%	

This challenge was graded by 82% referee consensus.

Organism present in specimen GS-3: *Staphylococcus aureus*

Specimen GS-4

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	26	100%	Acceptable

Gram Stain Morphology

Rods/bacilli	22	100%	Acceptable
--------------	----	------	------------

Organism present in specimen GS-4: *Pseudomonas aeruginosa*.

Specimen GS-5

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	24	92.31%	Acceptable
Gram positive	2	7.69%	

Gram Stain Morphology

Rods/bacilli	16	76.19%	Acceptable
Coccobacilli	5	23.81%	

This challenge was graded by 82% referee consensus.

Organism present in specimen GS-5: *Klebsiella pneumoniae*

AFFIRM VP III–*Trichomonas vaginalis*

Specimen VP-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
-----------------------	-------------	----------------	--------------------

Negative	36	100%	Acceptable
----------	----	------	------------

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

Specimen VP-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
-----------------------	-------------	----------------	--------------------

Positive	36	100%	Acceptable
----------	----	------	------------

Organism present in specimen VP-2: *Trichomonas vaginalis*.

Specimen VP-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
-----------------------	-------------	----------------	--------------------

Negative	36	100%	Acceptable
----------	----	------	------------

Organism present in specimen VP-3: *Candida* species.

Specimen VP-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
-----------------------	-------------	----------------	--------------------

Positive	36	100%	Acceptable
----------	----	------	------------

Organism present in specimen VP-4: *Trichomonas vaginalis*.

Specimen VP-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
-----------------------	-------------	----------------	--------------------

Negative	36	100%	Acceptable
----------	----	------	------------

Organisms present in specimen VP-5: *Gardnerella vaginalis* and *Candida* species.

AFFIRM VP III–Gardnerella vaginalis**Specimen VP-1**

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

Specimen VP-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	35	97.22%	Acceptable
Positive	1	2.78%	

Specimen VP-3

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

Specimen VP-4

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

Specimen VP-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	35	97.22%	Acceptable
Negative	1	2.78%	

AFFIRM VP III–Candida sp.**Specimen VP-1**

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

Specimen VP-2

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

AFFIRM VP III–Candida sp.**Specimen VP-3**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	35	97.22%	Acceptable
Negative	1	2.78%	

Specimen VP-4

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

Specimen VP-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	35	97.22%	Acceptable
Negative	1	2.78%	

CHLAMYDIA (ANTIGEN DETECTION)**Specimen CY-1**

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	13	-
BD ProbeTec	5	5	-
Gen-Probe	1	1	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	5	5	-

Organism present in specimen CY-1: *Chlamydia trachomatis*.

Specimen CY-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	-	13
BD ProbeTec	5	-	5
Gen-Probe	1	-	1
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	5	-	5

Organism present in specimen CY-2: *Neisseria gonorrhoeae*.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	-	12
BD ProbeTec	5	-	5
Gen-Probe	1	-	1
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	4	-	4

Organism present in specimen CY-3: No antigens present.

Specimen CY-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	-	12
BD ProbeTec	5	-	5
Gen-Probe	1	-	1
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	4	-	4

Organism present in specimen CY-4: *Neisseria gonorrhoeae*..

Specimen CY-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	12	-
BD ProbeTec	5	5	-
Gen-Probe	1	1	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	4	4	-

Organism present in specimen CY-5: *Chlamydia trachomatis*.

GC (ANTIGEN DETECTION)

Specimen CY-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	8
BD ProbeTec	5	-	5
Gen-Probe	1	-	1
Gen-Probe APTIMA	1	-	1

Specimen CY-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	8	-
BD ProbeTec	5	5	-
Gen-Probe	1	1	-
Gen-Probe APTIMA	1	1	-

Specimen CY-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	8
BD ProbeTec	5	-	5
Gen-Probe	1	-	1
Gen-Probe APTIMA	1	-	1

Specimen CY-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	8	-
BD ProbeTec	5	5	-
Gen-Probe	1	1	-
Gen-Probe APTIMA	1	1	-

Specimen CY-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	8
BD ProbeTec	5	-	5
Gen-Probe	1	-	1
Gen-Probe APTIMA	1	-	1

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	-	3
Remel Xpect	2	-	2

Antigen present in specimen LC-1: *Giardia lamblia*.

Specimen LC-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	-	3
Remel Xpect	2	-	2

Antigen present in specimen LC-2: No antigen present.

Specimen LC-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	3	-
Remel Xpect	2	2	-

Antigen present in specimen LC-3: *Cryptosporidium*.

Specimen LC-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	3	-
Remel Xpect	2	2	-

Antigen present in specimen LC-4: *Cryptosporidium*.

Specimen LC-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	1	2
Remel Xpect	2	-	2

Antigens present in specimen LC-5: *Giardia lamblia* and *Cryptosporidium*. This is an ungraded challenge due to less than 80% participant consensus.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	4	1
Remel Xpect	4	3	1

Specimen LC-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Remel Xpect	4	-	4

Specimen LC-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Remel Xpect	4	-	4

Specimen LC-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Remel Xpect	4	-	4

Specimen LC-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Remel Xpect	4	4	-

RSV ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	56	-	56
Binax NOW - waived	37	-	37
Quidel QuickVue RSV - waived	10	-	10
Quidel QuickVue RSV 10 Test	1	-	1
Remel Xpect - waived	4	-	4
Wampole Clearview RSV - waived	2	-	2

Antigen present in specimen V-1: Influenza A.

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	57	57	-
Binax NOW - waived	38	38	-
Quidel QuickVue RSV - waived	10	10	-
Quidel QuickVue RSV 10 Test	1	1	-
Remel Xpect - waived	4	4	-
Wampole Clearview RSV - waived	2	2	-

Antigen present in specimen V-2: RSV.

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	-	14
Binax NOW - waived	5	-	5
Quidel QuickVue RSV - waived	4	-	4
Quidel QuickVue RSV 10 Test	1	-	1
Remel Xpect - waived	2	-	2
Wampole Clearview RSV - waived	1	-	1

Antigen present in specimen V-3: No antigen present.

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	-	14
Binax NOW - waived	5	-	5
Quidel QuickVue RSV - waived	4	-	4
Quidel QuickVue RSV 10 Test	1	-	1
Remel Xpect - waived	2	-	2
Wampole Clearview RSV - waived	1	-	1

Antigen present in specimen V-4: Influenza B.

RSV ANTIGEN DETECTION

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	14	-
Binax NOW - waived	5	5	-
Quidel QuickVue RSV - waived	4	4	-
Quidel QuickVue RSV 10 Test	1	1	-
Remel Xpect - waived	2	2	-
Wampole Clearview RSV - waived	1	1	-

Antigen present in specimen V-5: RSV.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	50	49	1
Genzyme OSOM Influenza A&B	2	2	-
Quidel QuickVue Influenza	44	43	1

Antigen present in specimen V-1: Influenza A.

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	50	-	50
Genzyme OSOM Influenza A&B	2	-	2
Quidel QuickVue Influenza	44	-	44

Antigen present in specimen V-2: RSV.

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	15	-	15
Genzyme OSOM Influenza A&B	1	-	1
Quidel QuickVue Influenza	13	-	13

Antigen present in specimen V-3: No antigen present.

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	15	15	-
Genzyme OSOM Influenza A&B	1	1	-
Quidel QuickVue Influenza	13	13	-

Antigen present in specimen V-4: Influenza B.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	15	-	15
Genzyme OSOM Influenza A&B	1	-	1
Quidel QuickVue Influenza	13	-	13

Antigen present in specimen V-5: RSV.

INFLUENZA A ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	248	243	5
BD Directigen	1	1	-
BD Veritor - waived	4	4	-
Binax NOW - waived	131	128	3
Genzyme OSOM Influenza A&B	56	54	2
Quidel QuickVue Influenza A+B	32	32	-
Quidel Sofia - waived	7	7	-
Remel Xpect	4	4	-

Antigen present in specimen V-1: Influenza A.

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	248	1	247
BD Directigen	1	-	1
BD Veritor - waived	4	-	4
Binax NOW - waived	131	-	131
Genzyme OSOM Influenza A&B	56	1	55
Quidel QuickVue Influenza A+B	32	-	32
Quidel Sofia - waived	7	-	7
Remel Xpect	4	-	4

Antigen present in specimen V-2: RSV.

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	85	1	84
BD Directigen	1	-	1
Binax NOW - waived	19	-	19
Genzyme OSOM Influenza A&B	53	1	52
Quidel QuickVue Influenza A+B	4	-	4
Quidel Sofia - waived	5	-	5
Remel Xpect	3	-	3

Antigen present in specimen V-3: No antigen present.

INFLUENZA A ANTIGEN DETECTION

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	84	1	83
BD Directigen	1	-	1
Binax NOW - waived	19	-	19
Genzyme OSOM Influenza A&B	52	1	51
Quidel QuickVue Influenza A+B	4	-	4
Quidel Sofia - waived	5	-	5
Remel Xpect	3	-	3

Antigen present in specimen V-4: Influenza B.

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	85	-	85
BD Directigen	1	-	1
Binax NOW - waived	19	-	19
Genzyme OSOM Influenza A&B	53	-	53
Quidel QuickVue Influenza A+B	4	-	4
Quidel Sofia - waived	5	-	5
Remel Xpect	3	-	3

Antigen present in specimen V-5: RSV.

INFLUENZA B ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	247	3	244
BD Directigen	1	-	1
BD Veritor - waived	3	-	3
Binax NOW - waived	128	1	127
Genzyme OSOM Influenza A&B	54	2	52
Other Waived Method	1	-	1
Quidel QuickVue Influenza A+B	30	-	30
Quidel Sofia - waived	7	-	7
Remel Xpect	4	-	4

Antigen present in specimen V-1: Influenza A.

INFLUENZA B ANTIGEN DETECTION

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	248	-	248
BD Directigen	1	-	1
BD Veritor - waived	3	-	3
Binax NOW - waived	128	-	128
Genzyme OSOM Influenza A&B	54	-	54
Other Waived Method	1	-	1
Quidel QuickVue Influenza A+B	30	-	30
Quidel Sofia - waived	7	-	7
Remel Xpect	4	-	4

Antigen present in specimen V-2: RSV.

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	85	-	85
BD Directigen	1	-	1
Binax NOW - waived	18	-	18
Genzyme OSOM Influenza A&B	51	-	51
Quidel QuickVue Influenza A+B	5	-	5
Quidel Sofia - waived	5	-	5
Remel Xpect	3	-	3

Antigen present in specimen V-3: No antigen present.

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	85	83	2
BD Directigen	1	1	-
Binax NOW - waived	18	18	-
Genzyme OSOM Influenza A&B	51	49	2
Quidel QuickVue Influenza A+B	5	5	-
Quidel Sofia - waived	5	5	-
Remel Xpect	3	3	-

Antigen present in specimen V-4: Influenza B.

INFLUENZA B ANTIGEN DETECTION

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	85	-	85
BD Directigen	1	-	1
Binax NOW - waived	18	-	18
Genzyme OSOM Influenza A&B	51	-	51
Quidel QuickVue Influenza A+B	5	-	5
Quidel Sofia - waived	5	-	5
Remel Xpect	3	-	3

Antigen present in specimen V-5: RSV.

LEGIONELLA ANTIGEN DETECTION

Specimen L-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	32	-	32

Specimen L-1: Negative for Legionella antigen.

Specimen L-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	32	31	1

Specimen L-2: Positive for Legionella antigen.

Specimen L-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	32	32	-

Specimen L-3: Positive for Legionella antigen.

Specimen L-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	32	-	32

Specimen L-4: Negative for Legionella antigen.

Specimen L-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	32	-	32

Specimen L-5: Negative for Legionella antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	1	11
Meridian ImmunoCard	2	-	2
Meridian Premier	1	-	1
Remel Xpect	1	-	1
Wampole	1	-	1
Wampole C. diff Quik Chek	5	1	4

Antigen present in specimen AG-1: Rotavirus.

Specimen AG-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	11	1
Meridian ImmunoCard	2	2	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-
Wampole	1	1	-
Wampole C. diff Quik Chek	5	4	1

Antigen present in specimen AG-2: *Clostridium difficile*.

Specimen AG-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	11	1
Meridian ImmunoCard	2	2	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-
Wampole	1	1	-
Wampole C. diff Quik Chek	5	4	1

Antigens present in specimen AG-3: Rotavirus and *Clostridium difficile*.

Specimen AG-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	11	1
Meridian ImmunoCard	2	2	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-
Wampole	1	1	-
Wampole C. diff Quik Chek	5	4	1

Antigen present in specimen AG-4: *Clostridium difficile*.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	1	11
Meridian ImmunoCard	2	-	2
Meridian Premier	1	-	1
Remel Xpect	1	-	1
Wampole	1	-	1
Wampole C. diff Quik Chek	5	1	4

Antigen present in specimen AG-5: Rotavirus.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	7	-
bioMerieux Vidas, Mini Vidas	1	1	-
Fisher HealthCare Sure-Vue	1	1	-
Meridian ImmunoCard	4	4	-

Specimen AG-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	7
bioMerieux Vidas, Mini Vidas	1	-	1
Fisher HealthCare Sure-Vue	1	-	1
Meridian ImmunoCard	4	-	4

Specimen AG-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	7	-
bioMerieux Vidas, Mini Vidas	1	1	-
Fisher HealthCare Sure-Vue	1	1	-
Meridian ImmunoCard	4	4	-

Specimen AG-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	7
bioMerieux Vidas, Mini Vidas	1	-	1
Fisher HealthCare Sure-Vue	1	-	1
Meridian ImmunoCard	4	-	4

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	7	-
bioMerieux Vidas, Mini Vidas	1	1	-
Fisher HealthCare Sure-View	1	1	-
Meridian ImmunoCard	4	4	-

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	28	28	-

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

Specimen SP-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	28	-	28

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

Specimen SP-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	28	-	28

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

Specimen SP-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	28	28	-

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

Specimen SP-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	28	28	-

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

PARASITOLOGY

Specimen PA-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dientamoeba fragilis	2	66.6%	Ungraded
Entamoeba coli	1	33.3%	Ungraded

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

Specimen PA-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	2	100%	Acceptable

Parasite present in specimen PA-2: No parasite present.

Specimen PA-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. eggs	2	100%	Acceptable

Parasite present in specimen PA-3: *Taenia* species.

Specimen PA-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis larvae	2	100%	Acceptable

Parasite present in specimen PA-4: *Strongyloides stercoralis*.

Specimen PA-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	1	50%	Ungraded
Microfilaria Loa Loa	1	50%	Ungraded

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

Technical note: The specimen manufacturer's certificate of analysis showed only one parasite per 100 oil immersion fields. *Loa loa*, often referred to as the "eye worm," is a filarial tissue and blood parasite endemic in West and Central Africa. Adult worms measure up to 300 µm in length. They are sheathed, and contain nuclei that extend to the end of the tail.

Reference:

Orihel, T.C., Ash, L.R. "Tissue Helminths." *Manual of Clinical Microbiology*. 6th ed. Ed. P.R. Murray. Washington, D.C.: ASM Press, 1995. 1246.

Medical Laboratory Evaluation
25 Massachusetts Ave NW Ste 700
Washington, DC 20001-7401
800-338-2746 • 202-261-4500 • Fax: 202-835-0440