

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 0 • 7



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

Microbiology
MLE – M1

Table of Contents

2007 Evaluation Criteria 2

Microbiology

Throat Culture	3	Cryptosporidium Antigen Detection	24
Strep A Antigen Detection.....	4	Giardia lamblia Antigen Detection.....	25
General Bacteriology	8	RSV Antigen Detection.....	26
Urine Culture	10	Influenza A/B Antigen Detection.....	28
Gram Stain.....	10	Influenza A Antigen Detection	29
Antimicrobial Susceptibility Testing	12	Influenza B Antigen Detection	31
GC Culture	13	Legionella Antigen Detection.....	32
Gram Stain.....	13	Clostridium Difficile Toxin Antigen Detection	33
Colony Count	15	Rotavirus Antigen Detection.....	35
Gram Stain.....	15	Streptococcus pneumoniae Antigen Detection	36
Dermatophyte Screen	17	Parasitology	37
Gram Stain.....	18		
Affirm VP III			
Trichomonas vaginalis.....	19		
Gardnerella vaginalis	20		
Candida sp.	21		
Chlamydia (Antigen Detection).....	22		
GC (Antigen Detection).....	24		

2007 Evaluation Criteria

The evaluation criteria used in the 2007 MLE Program is in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) federal requirements for proficiency testing. The criteria are included below.

Qualitative

For qualitative procedures, evaluation is based on participant or referee consensus. If participant consensus is not reached, CMS requirements call for grading by referee consensus. A minimum percentage of participants or referee laboratories must receive a passing score or the challenge is not evaluated due to lack of consensus. These percentages are listed below.

Bacterial Identification	80% Consensus	Rotavirus Antigen Detection	80% Consensus
Urine Presumptive Identification	80% Consensus	RSV Antigen Detection	80% Consensus
Colony Count	80% Consensus	GC (EIA, DNA)	80% Consensus
Parasite Identification	80% Consensus	Antimicrobial Susceptibility Testing	80% Consensus
Strep A Antigen Detection	80% Consensus	Gram Stain	80% Consensus
Affirm VP III Gardnerella Ag Detection	80% Consensus	Gram Stain Morphology	Not Graded
Affirm VP III Candida Antigen Detection	80% Consensus	Beta-lactamase Testing	Not Graded
Affirm VP III Trichomonas Ag Detection	80% Consensus	C. Difficile Toxin/Antigen Detection	80% Consensus
Chlamydia (EIA, DNA)	80% Consensus	Dermatophyte Screen	80% Consensus
Cryptosporidium Antigen Detection	80% Consensus	Legionella Antigen Detection	80% Consensus
Giardia lamblia Antigen Detection	80% Consensus	Streptococcus pneumoniae Antigen Detection	80% Consensus
Influenza A/B Antigen Detection	80% Consensus		
Influenza A Antigen Detection	80% Consensus		
Influenza B Antigen Detection	80% Consensus		

THROAT CULTURE

Specimen TC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	106	48.1%	Acceptable
Presump. Pos. Group A Strep	88	40.0%	Acceptable
Streptococcus pyogenes	18	8.18%	Acceptable
Gram positive cocci	2	0.91%	Acceptable
Gram positive bacilli	1	0.45%	Acceptable

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

Specimen TC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	193	88.94%	Acceptable
Staphylococcus aureus	11	5.07%	Acceptable
Growth, referred for identification	3	1.38%	Acceptable
Gram positive cocci	2	0.92%	Acceptable

Organism present in specimen TC-2: *Staphylococcus aureus*.

Specimen TC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	93	98.94%	Acceptable

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

Specimen TC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	45	52.33%	Acceptable
Presump. Pos. Group A Strep	40	46.51%	Acceptable
Streptococcus pyogenes	1	1.16%	Acceptable

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

Specimen TC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	46	53.49%	Acceptable
Presump. Pos. Group A Strep	39	45.35%	Acceptable
Streptococcus pyogenes	1	1.16%	Acceptable

Organism present in specimen TC-5: *Streptococcus pyogenes*.

STREP A ANTIGEN DETECTION

Specimen RS-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	647	5	642
Abbott Signify Strep A-waived	23	-	23
Applied Biotech Signify	7	-	7
BD Directigen	5	-	5
BD Directigen EZ	6	-	6
BD QTest	2	-	2
Beckman Coulter ICON DS	9	-	9
Beckman Coulter ICON Fx Strep A	1	-	1
Beckman Coulter ICON SC	7	-	7
Binax NOW Strep A	2	-	2
BioStar Aceava Strep A Test	57	2	55
BioStar Strep A MAX OIA	27	-	27
Cardinal Health Strep A - moderate	8	-	8
Cardinal Health Strep A - waived	23	-	23
Fisher HealthCare Sure-Vue	5	-	5
Genzyme OSOM	26	-	26
Genzyme OSOM Ultra Strep A	63	-	63
Henry Schein One Step	7	-	7
Instant Technologies i Strep	10	-	10
Inverness Signify Strep A Dipstick	24	-	24
LifeSign Status Strep A	1	-	1
Mainline Confirms	2	-	2
Mainline Confirms Strep A Dots	1	-	1
McKesson Strep A Cassette	10	-	10
McKesson Strep A Dipstick	7	-	7
Polymedco Poly Stat Strep A - moderate	21	1	20
Polymedco Poly Stat Strep A - waived	20	-	20
Polymedco Strep A Liquid Test	2	-	2
Quidel QuickVue Dipstick Strep	74	1	73
Quidel QuickVue In-Line	71	1	70
Quidel QuickVue+	84	-	84
Stanbio QuStick Strep A	3	-	3
Wampole Clearview	1	-	1

STREP A ANTIGEN DETECTION

Specimen RS-2

<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	628	615	13	479	84	5
Abbott Signify Strep A-waived	23	23	-	14	7	-
Applied Biotech Signify	6	5	1	1	2	-
BD Directigen	5	5	-	4	-	-
BD Directigen EZ	6	6	-	5	1	-
BD QTest	2	2	-	1	-	-
Beckman Coulter ICON DS	9	9	-	7	-	-
Beckman Coulter ICON Fx Strep A	1	1	-	1	-	-
Beckman Coulter ICON SC	7	7	-	5	2	-
Binax NOW Strep A	2	2	-	1	-	-
BioStar Aceava Strep A Test	56	55	1	42	9	1
BioStar Strep A MAX OIA	27	27	-	24	2	-
Cardinal Health Strep A - moderate	8	8	-	8	-	-
Cardinal Health Strep A - waived	24	24	-	18	2	-
Fisher HealthCare Sure-Vue	2	2	-	1	1	-
Genzyme OSOM	25	25	-	24	-	-
Genzyme OSOM Ultra Strep A	62	62	-	53	5	-
Henry Schein One Step	6	6	-	3	1	-
Instant Technologies i Strep	10	10	-	6	3	-
Inverness Signify Strep A Dipstick	23	23	-	16	5	-
LifeSign Status Strep A	1	1	-	-	-	-
Mainline Confirms	1	1	-	1	-	-
Mainline Confirms Strep A Dots	1	1	-	-	1	-
McKesson Strep A Cassette	10	10	-	7	2	-
McKesson Strep A Dipstick	7	7	-	2	3	-
Polymedco Poly Stat Strep A - moderate	21	21	-	18	3	-
Polymedco Poly Stat Strep A - waived	20	20	-	12	7	-
Polymedco Strep A Liquid Test	2	2	-	1	1	-
Quidel QuickVue Dipstick Strep	74	71	3	55	9	-
Quidel QuickVue In-Line	70	62	8	52	5	4
Quidel QuickVue+	80	80	-	65	10	-
Stanbio QuStick Strep A	3	3	-	2	-	-
Wampole Clearview	1	1	-	1	-	-

STREP A ANTIGEN DETECTION

Specimen RS-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	352	3	349
Abbott Signify Strep A-waived	12	-	12
Applied Biotech Signify	6	-	6
BD Directigen	5	-	5
BD Directigen EZ	6	-	6
BD QTest	2	-	2
Beckman Coulter ICON DS	6	-	6
Beckman Coulter ICON Fx Strep A	1	-	1
Beckman Coulter ICON SC	4	-	4
Binax NOW Strep A	2	-	2
BioStar Aceava Strep A Test	21	1	20
BioStar Strep A MAX OIA	27	1	26
Cardinal Health Strep A - moderate	7	-	7
Cardinal Health Strep A - waived	10	-	10
Fisher HealthCare Sure-Vue	1	-	1
Genzyme OSOM	8	-	8
Genzyme OSOM Ultra Strep A	31	-	31
Henry Schein One Step	2	-	2
Instant Technologies i Strep	4	-	4
Inverness Signify Strep A Dipstick	5	-	5
Mainline Confirms	1	-	1
Mainline Confirms Strep A Dots	1	-	1
McKesson Strep A Cassette	8	-	8
McKesson Strep A Dipstick	4	-	4
Polymedco Poly Stat Strep A - moderate	21	1	20
Polymedco Poly Stat Strep A - waived	3	-	3
Quidel QuickVue Dipstick Strep	22	-	22
Quidel QuickVue In-Line	28	-	28
Quidel QuickVue+	75	-	75
Stanbio QuStick Strep A	2	-	2
Wampole Clearview	1	-	1

STREP A ANTIGEN DETECTION

Specimen RS-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	292	5	287
Abbott Signify Strep A-waived	11	-	11
Applied Biotech Signify	6	-	6
BD Directigen	5	-	5
BD Directigen EZ	6	-	6
BD QTest	1	-	1
Beckman Coulter ICON DS	6	-	6
Beckman Coulter ICON Fx Strep A	1	-	1
Beckman Coulter ICON SC	4	-	4
Binax NOW Strep A	1	-	1
BioStar Aceava Strep A Test	16	1	15
BioStar Strep A MAX OIA	27	-	27
Cardinal Health Strep A - moderate	6	1	5
Cardinal Health Strep A - waived	9	1	8
Fisher HealthCare Sure-Vue	1	-	1
Genzyme OSOM	5	-	5
Genzyme OSOM Ultra Strep A	27	-	27
Henry Schein One Step	1	-	1
Instant Technologies i Strep	2	-	2
Inverness Signify Strep A Dipstick	5	-	5
Mainline Confirms	1	-	1
Mainline Confirms Strep A Dots	1	-	1
McKesson Strep A Cassette	6	-	6
McKesson Strep A Dipstick	3	-	3
Polymedco Poly Stat Strep A - moderate	20	-	20
Polymedco Poly Stat Strep A - waived	2	-	2
Quidel QuickVue Dipstick Strep	14	-	14
Quidel QuickVue In-Line	23	1	22
Quidel QuickVue+	61	1	60
Stanbio QuStick Strep A	2	-	2
Wampole Clearview	1	-	1

STREP A ANTIGEN DETECTION

Specimen RS-5

<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	291	288	3	221	40	6
Abbott Signify Strep A-waived	11	11	-	8	2	-
Applied Biotech Signify	6	6	-	3	1	-
BD Directigen	5	5	-	4	-	-
BD Directigen EZ	6	6	-	6	-	-
BD QTest	1	1	-	-	-	-
Beckman Coulter ICON DS	6	6	-	4	-	-
Beckman Coulter ICON Fx Strep A	1	1	-	-	-	1
Beckman Coulter ICON SC	4	4	-	3	1	-
Binax NOW Strep A	1	1	-	1	-	-
BioStar Aceava Strep A Test	16	16	-	13	1	-
BioStar Strep A MAX OIA	27	27	-	22	4	-
Cardinal Health Strep A - moderate	6	5	1	4	-	-
Cardinal Health Strep A - waived	9	9	-	6	1	-
Fisher HealthCare Sure-Vue	1	1	-	1	-	-
Genzyme OSOM	5	5	-	4	-	-
Genzyme OSOM Ultra Strep A	27	27	-	22	3	-
Henry Schein One Step	1	1	-	1	-	-
Instant Technologies i Strep	2	2	-	1	1	-
Inverness Signify Strep A Dipstick	5	5	-	4	1	-
Mainline Confirms	1	1	-	1	-	-
Mainline Confirms Strep A Dots	1	1	-	1	-	-
McKesson Strep A Cassette	6	6	-	4	2	-
McKesson Strep A Dipstick	3	3	-	1	1	-
Polymedco Poly Stat Strep A - moderate	20	20	-	15	4	1
Polymedco Poly Stat Strep A - waived	2	2	-	2	-	-
Quidel QuickVue Dipstick Strep	14	14	-	10	2	1
Quidel QuickVue In-Line	22	20	2	15	3	2
Quidel QuickVue+	61	61	-	50	8	1
Stanbio QuStick Strep A	2	2	-	1	-	-
Wampole Clearview	1	1	-	1	-	-

GENERAL BACTERIOLOGY

Specimen UC-1 – Urine Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Enterococcus (Strep) faecalis	5	55.56%	Acceptable
Enterococcus sp.	3	33.33%	Acceptable
Gram positive cocci	1	11.11%	Acceptable

Gram Stain

Gram positive	7	100%	Acceptable
---------------	---	------	------------

Gram Stain Morphology

Cocci	4	57.14%
Cocci in pairs	3	42.86%

Organism present in specimen UC-1: *Enterococcus faecalis*.

GENERAL BACTERIOLOGY

Specimen TC-1 – Throat Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Streptococcus pyogenes	8	61.54%	Acceptable
Corynebacterium sp.	2	15.38%	Acceptable
Gram positive cocci	1	7.69%	Acceptable
Presump. Pos. Group A Strep	1	7.69%	Acceptable

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

Specimen BA-1 – Spinal Fluid Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Neisseria meningitidis	5	71.43%	Acceptable
Growth, referred for identification	2	28.57%	Acceptable

Organism present in specimen BA-1: *Neisseria meningitidis*.

Specimen BA-2 – Stool Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No enteric pathogens isolated	4	80.00%	Acceptable
Growth, referred for identification	1	20.00%	Acceptable

Organisms present in specimen BA-2: *Citrobacter freundii* and *Enterococcus faecalis*.

Specimen BA-3 – Respiratory Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Streptococcus pneumoniae	6	85.71%	Acceptable
Strep – alpha hemo: not Grp. D	1	14.29%	Acceptable

Organisms present in specimen BA-3: *Streptococcus pneumoniae* and *Streptococcus viridans*.

URINE CULTURE

Specimen UC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	40	29.20%	Acceptable
Enterococcus sp.	36	26.28%	Acceptable
Presump. Gram positive	24	17.52%	Acceptable
Gram positive cocci	13	9.49%	Acceptable
Enterococcus (Strep) faecalis	10	7.30%	Acceptable
Presump. Enterococcus sp.	8	5.84%	Acceptable
Streptococcus non-hemolytic	2	1.46%	Acceptable
Strep. Grp. D – enterococcus	1	0.73%	Acceptable

Gram Stain

Gram positive	64	100%	Acceptable
---------------	----	------	------------

Gram Stain Morphology

Cocci	49	79.03%
Cocci in chains	11	17.74%
Cocci in pairs	2	3.23%

Organism present in specimen UC-1: *Enterococcus faecalis*.

Specimen UC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	32	23.02%	Acceptable
Enterobacter cloacae	28	20.14%	Acceptable
Growth, referred for identification	25	17.99%	Acceptable
Gram negative bacilli	18	12.95%	Acceptable
Enterobacter sp.	16	11.51%	Acceptable
Gram positive bacilli	1	0.72%	Acceptable
Presump. Enterobacter sp.	1	0.72%	Acceptable
Presump. Klebsiella sp.	5	3.60%	

Organisms present in specimen UC-2: *Enterobacter cloacae* and *Lactobacillus casei*.

URINE CULTURE

Specimen UC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	31	32.63%	Acceptable
Presump. Gram positive	24	25.26%	Acceptable
Staphylococcus saprophyticus	13	13.68%	Acceptable
Gram positive cocci	6	6.32%	Acceptable
Staphylococcus sp.	6	6.32%	Acceptable
Staph – coagulase negative	6	6.32%	Acceptable
Presump. Staphylococcus sp.	4	4.21%	Acceptable
Gram positive bacilli	2	2.11%	Acceptable

Organisms present in specimen UC-3: *Staphylococcus saprophyticus* and *Corynebacterium sp.*

Specimen UC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	25	43.86%	Acceptable
Klebsiella oxytoca	11	19.30%	Acceptable
Growth, referred for identification	11	19.30%	Acceptable
Klebsiella sp.	4	7.02%	Acceptable
Gram negative bacilli	3	5.26%	Acceptable

Organism present in specimen UC-4: *Klebsiella oxytoca*.

Specimen UC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	17	29.82%	Acceptable
Growth, referred for identification	16	28.07%	Acceptable
Pseudomonas aeruginosa	9	15.79%	Acceptable
Presump. Pseudomonas sp.	8	14.04%	Acceptable
Pseudomonas sp.	5	8.77%	Acceptable
Gram negative bacilli	1	1.75%	Acceptable

Organisms present in specimen UC-5: *Pseudomonas aeruginosa* and *Staphylococcus epidermidis*.

ANTIMICROBIAL SUSCEPTIBILITY TESTING

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

<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	1	1	-	-	-	-	-	-	Inappropriate drug ¹
Amoxicillin/Clavulanate	3	3	-	-	-	-	-	-	100%
Ampicillin	44	42	-	2	6	6	-	-	95.83%
Ampicillin/Sulbactam	1	1	-	-	1	1	-	-	100%
Carbenicillin	1	1	-	-	-	-	-	-	100%
Cefazolin	1	-	-	1	-	-	-	-	Inappropriate drug ¹
Cephalothin	8	2	4	2	14	6	4	4	Inappropriate drug ¹
Ciprofloxacin	34	20	13	1	12	12	-	-	Not graded ²
Daptomycin	-	-	-	-	1	1	-	-	100%
Doxycycline	2	-	2	-	-	-	-	-	Not graded ²
Fosfomycin	2	2	-	-	-	-	-	-	100%
Gentamicin	8	4	-	4	1	1	-	-	Inappropriate drug ¹
Levofloxacin	13	12	1	-	9	9	-	-	96.88%
Linezolid	1	1	-	-	4	4	-	-	100%
Loracarbef	1	-	-	1	-	-	-	-	100%
Nitrofurantoin	55	54	1	-	13	13	-	-	98.95%
Norfloxacin	12	6	5	1	1	1	-	-	Not graded ²
Ofloxacin	6	3	2	1	-	-	-	-	Not graded ²
Penicillin	5	5	-	-	10	10	-	-	100%
Rifampin	-	-	-	-	4	4	-	-	100%
Sulfisoxazole	2	1	-	1	1	-	-	1	Inappropriate drug ¹
Tetracycline	18	3	2	13	9	2	3	4	Not graded ²
Tobramycin	1	-	-	1	-	-	-	-	Inappropriate drug ¹
Trimethoprim	2	2	-	-	2	2	-	-	Inappropriate drug ¹
Trimethoprim/Sulfamethoxazole	14	14	-	-	1	1	-	-	Inappropriate drug ¹
Vancomycin	13	13	-	-	10	10	-	-	100%

Organism present in specimen UC-1, CC-1 (SUS-1): *Enterococcus faecalis*.

For *Enterococcus* species, the following drugs may appear active *in vitro*, but are not effective clinically, and isolates should not be reported as susceptible:

cephalosporins (cefazolin, cephalothin), aminoglycosides (amikacin, gentamicin, tobramycin), clindamycin, and trimethoprim-sulfamethoxazole.

Reference:

Clinical and Laboratory Standards Institute. *Performance Standards for Antimicrobial Susceptibility Testing; Seventeenth Informational Supplement*. CLSI document M100-S17 [ISBN 1-56238-625-5]. Clinical and Laboratory Standards Institute, 940 West Valley Rd Ste 1400, Wayne, PA 19087 USA, 2007.

See the MLE website: <http://www.acponline.org/mle> for more information regarding the CLSI publication.

¹ This drug is an inappropriate drug for this organism and/or source.

² This is an ungraded challenge due to less than 80% participant consensus.

GC CULTURE

Specimen GC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	25	54.35%	Acceptable
Neisseria gonorrhoeae	20	43.48%	Acceptable

Beta-lactamase Testing

Negative	7	87.50%
Positive	1	12.50%

Gram Stain

Gram negative	40	100%	Acceptable
---------------	----	------	------------

Gram Stain Morphology

Diplococci	39	97.50%
Cocci in pairs	1	2.50%

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

Specimen GC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	14	58.33%	Acceptable
No growth (sterile)	9	37.50%	Acceptable

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

Specimen GC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	18	81.82%	Acceptable
Neisseria gonorrhoeae	4	18.18%	Acceptable

Beta-lactamase Testing

Negative	2	100%
----------	---	------

Organisms present in specimen GC-3: *Neisseria gonorrhoeae* and *Gardnerella vaginalis*.

GC CULTURE

Specimen GC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	14	63.64%	Acceptable
No growth (sterile)	8	36.36%	Acceptable

Organisms present in specimen GC-4: *Streptococcus agalactiae* and *Escherichsia coli*.

Specimen GC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	18	81.82%	Acceptable
Neisseria gonorrhoeae	4	18.18%	Acceptable

Beta-lactamase Testing

Negative	2	100%
----------	---	------

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

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	104	2	4	43	55
Bacti-Star	1	-	-	-	1
Bacturcult	1	-	-	-	1
Bulls Eye	6	-	-	2	4
Calibrated Loop	27	-	2	3	22
Uri-Check	14	1	1	5	7
Uricult	49	1	1	30	17
Uri-Three	1	-	-	1	-

Identification–Specimen CC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Enterococcus sp.	14	41.18%	Acceptable
Presump. Gram positive	9	26.47%	Acceptable
Growth, referred for identification	7	20.59%	Acceptable
Enterococcus (Strep) faecalis	2	5.88%	Acceptable
Enterococcus sp.	1	2.94%	Acceptable

Gram Stain

Gram positive	4	100%	Acceptable
---------------	---	------	------------

Gram Stain Morphology

Cocci in chains	3	60.00%
Cocci in pairs	2	40.00%

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

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	103	1	2	3	97
Bacti-Star	1	-	-	-	1
Bacturcult	1	1	-	-	-
Bulls Eye	5	-	-	2	3
Calibrated Loop	27	-	1	-	26
Uri-Check	14	-	1	-	13
Uricult	48	-	-	1	47
Uri-Three	1	-	-	-	1

Identification–Specimen CC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	11	30.56%	Acceptable
Presump. Enterobacter sp.	9	25.00%	Acceptable
Growth, referred for identification	5	13.89%	Acceptable
Enterobacter cloacae	2	5.56%	Acceptable

Organisms present in specimen CC-2: >100,000 CFU/mL *Enterobacter cloacae* and approximately 9,000 CFU/mL of *Lactobacillus casei*. This specimen is graded by 80% referee consensus.

Identification–Specimen CC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Staphylococcus sp.	11	39.29%	Acceptable
Presump. Gram positive	5	17.86%	Acceptable
Growth, referred for identification	5	17.86%	Acceptable
Staph – coagulase negative	2	7.14%	Acceptable
Staphylococcus saprophyticus	1	3.57%	Acceptable

Organisms present in specimen CC-3: >100,000 CFU/mL of *Staphylococcus saprophyticus* and approximately 10,000 CFU/mL of *Corynebacterium sp.*

Identification–Specimen CC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Klebsiella sp.	10	33.33%	Acceptable
Presump. Gram negative	8	26.67%	Acceptable
Growth, referred for identification	4	13.33%	Acceptable
Klebsiella oxytoca	2	6.67%	Acceptable
Presump. Escherichia coli	5	16.67%	

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

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Pseudomonas sp.	13	44.83%	Acceptable
Presump. Gram negative	7	24.14%	Acceptable
Pseudomonas aeruginosa	4	13.79%	Acceptable
Growth, referred for identification	4	13.79%	Acceptable
Bacturcult Group III	1	3.45%	Acceptable

Organisms present in specimen CC-5: >100,000 CFU/mL of *Pseudomonas aeruginosa* and approximately 25,500 CFU/mL of *Staphylococcus epidermidis*.

DERMATOPHYTE SCREEN

Specimen DM-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte absent	11	55.00%	Not graded
Dermatophyte present	9	45.00%	

Organisms present in specimen DM-1: *Candida albicans* and *Lactobacillus casei*. This specimen is ungraded due to the lack of 80% participant consensus. **Dermatophytes are absent** from this specimen. Dermatophytes are a group of fungi that commonly cause infections of the hair, skin and nails, including *Trichophyton*, *Microsporum* and *Epidermophyton*. On Dermatophyte Test Medium (DTM), dermatophytes produce typical morphology and a pink to red color in the medium around the colony within 10-14 days of incubation. Certain strains of *Candida albicans* are capable of converting the indicator to red, but the yeast can be recognized by their white bacteria-like colonial appearance. Presumptive identification of dermatophytes using DTM is based on both gross morphology and color change.

Reference:

www.bd.com/ds/technicalCenter/inserts/Dermatophyte_Test_Medium_Base.pdf

Specimen DM-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte present	20	100%	Acceptable

Organism present in specimen DM-2: *Microsporum nanum*.

GRAM STAIN

Specimen GS-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	50	94.34%	Acceptable
Gram negative	3	5.66%	

Gram Stain Morphology

Cocci	33	71.74%
Cocci in pairs	6	13.04%
Diplococci	4	8.70%
Cocci in chains	3	6.52%

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

Specimen GS-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	48	90.57%	Acceptable
Gram negative	5	9.43%	

Gram Stain Morphology

Cocco-bacilli	21	45.65%
Cocci in pairs	9	19.57%
Diplococci	6	13.04%
Cocci	6	13.04%
Cocci in chains	2	4.35%
Rods/bacilli	2	4.35%

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

Specimen GS-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	52	98.11%	Acceptable
Gram positive	1	1.89%	

Gram Stain Morphology

Rods/bacilli	40	86.96%
Diplococci	5	10.87%
Cocco-bacilli	1	2.17%

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

GRAM STAIN

Specimen GS-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	53	100%	Acceptable

Gram Stain Morphology

Cocci in chains	25	54.35%
Cocci	18	39.13%
Cocci in pairs	3	6.52%

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

Specimen GS-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	52	98.11%	Acceptable
Gram positive	1	1.89%	

Gram Stain Morphology

Rods/bacilli	45	97.83%
Cocco-bacilli	1	2.17%

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

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	27	100%	Acceptable

Organism present in specimen VP-1: *Candida albicans*.

Specimen VP-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	23	85.19%	Acceptable
Negative	4	14.81%	

Organisms present in specimen VP-2: *Gardnerella vaginalis* and *Trichomonas vaginalis*.

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	22	81.48%	Acceptable
Negative	5	18.52%	

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

Specimen VP-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	25	92.59%	Acceptable
Negative	2	7.41%	

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

Specimen VP-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	26	96.30%	Acceptable
Positive	1	3.70%	

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

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	27	100%	Acceptable

Specimen VP-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	23	85.19%	Acceptable
Negative	4	14.81%	

Specimen VP-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	27	100%	Acceptable

AFFIRM VP III–Gardnerella vaginalis**Specimen VP-4**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	25	92.59%	Acceptable
Positive	2	7.41%	

Specimen VP-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	23	85.19%	Acceptable
Negative	4	14.81%	

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

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	26	96.30%	Acceptable
Negative	1	3.70%	

Specimen VP-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	27	100%	Acceptable

Specimen VP-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	27	100%	Acceptable

Specimen VP-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	25	92.59%	Acceptable
Negative	2	7.41%	

Specimen VP-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	26	96.30%	Acceptable
Positive	1	3.70%	

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	20	20	-
BD ProbeTec	5	5	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	2	2	-
Gen-Probe	2	2	-
Quidel QuickVue	9	9	-

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	19	-	19
BD ProbeTec	4	-	4
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	2	-	2
Gen-Probe	2	-	2
Quidel QuickVue	9	-	9

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

Specimen CY-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	16	-
BD ProbeTec	5	5	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	2	2	-
Gen-Probe	2	2	-
Quidel QuickVue	5	5	-

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

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	15	-	15
BD ProbeTec	4	-	4
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	2	-	2
Gen-Probe	2	-	2
Quidel QuickVue	5	-	5

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	15	-	15
BD ProbeTec	4	-	4
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	2	-	2
Gen-Probe	2	-	2
Quidel QuickVue	5	-	5

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

GC (ANTIGEN DETECTION)

Specimen CY-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	8
BD ProbeTec	4	-	4
BioStar OIA	2	-	2
Gen-Probe	2	-	2

Specimen CY-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	9	-
BD ProbeTec	5	5	-
BioStar OIA	2	2	-
Gen-Probe	2	2	-

GC (ANTIGEN DETECTION)

Specimen CY-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	8
BD ProbeTec	4	-	4
BioStar OIA	2	-	2
Gen-Probe	2	-	2

Specimen CY-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	9	-
BD ProbeTec	5	5	-
BioStar OIA	2	2	-
Gen-Probe	2	2	-

Specimen CY-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	9	-
BD ProbeTec	5	5	-
BioStar OIA	2	2	-
Gen-Probe	2	2	-

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-1

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

Antigen present in specimen LC-1: *Cryptosporidium*.

Specimen LC-2

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

Antigen present in specimen LC-2: *Giardia lamblia*.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-3

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

Antigen present in specimen LC-3: *Giardia lamblia*.

Specimen LC-4

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

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	3	-
Remel Xpect	3	3	-

Antigens present in specimen LC-5: *Cryptosporidium*.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Alexon (Hycor)	1	-	1
Remel Xpect	3	-	3

Specimen LC-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Alexon (Hycor)	1	1	-
Remel Xpect	3	3	-

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Alexon (Hycor)	1	1	-
Remel Xpect	3	3	-

Specimen LC-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Alexon (Hycor)	1	-	1
Remel Xpect	3	-	3

Specimen LC-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Alexon (Hycor)	1	-	1
Remel Xpect	3	-	3

RSV ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	33	1	32
BD Directigen	1	-	1
BD Directigen EZ	1	-	1
Binax NOW - waived	13	-	13
BioStar OIA	5	1	4
Quidel QuickVue	4	-	4
Remel Xpect - waived	2	-	2
Wampole Clearview RSV - waived	3	-	3

Specimen V-1: Negative for RSV antigen.

RSV ANTIGEN DETECTION

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	33	33	-
BD Directigen	1	1	-
BD Directigen EZ	1	1	-
Binax NOW - waived	13	13	-
BioStar OIA	5	5	-
Quidel QuickVue	4	4	-
Remel Xpect - waived	2	2	-
Wampole Clearview RSV - waived	3	3	-

Specimen V-2: Positive for RSV antigen.

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	22	-	22
BD Directigen	1	-	1
BD Directigen EZ	1	-	1
Binax NOW - waived	7	-	7
BioStar OIA	4	-	4
Quidel QuickVue	2	-	2
Remel Xpect - waived	2	-	2
Wampole Clearview RSV - waived	2	-	2

Specimen V-3: Negative for RSV antigen.

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	22	-	22
BD Directigen	1	-	1
BD Directigen EZ	1	-	1
Binax NOW - waived	7	-	7
BioStar OIA	4	-	4
Quidel QuickVue	2	-	2
Remel Xpect - waived	2	-	2
Wampole Clearview RSV - waived	2	-	2

Specimen V-4: Negative for RSV antigen.

RSV ANTIGEN DETECTION

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	22	22	-
BD Directigen	1	1	-
BD Directigen EZ	1	1	-
Binax NOW - waived	7	7	-
BioStar OIA	4	4	-
Quidel QuickVue	2	2	-
Remel Xpect - waived	2	2	-
Wampole Clearview RSV - waived	2	2	-

Specimen V-5: Positive for RSV antigen.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	93	78	15
Binax NOW - waived	6	5	1
BioStar OIA	5	4	1
Quidel QuickVue Influenza	73	61	12

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

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	94	1	93
Binax NOW - waived	6	-	6
BioStar OIA	5	-	5
Quidel QuickVue Influenza	74	1	73

Specimen V-2: Negative for Influenza A/B antigen.

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	26	25	1
Binax NOW - waived	1	1	-
BioStar OIA	5	4	1
Quidel QuickVue Influenza	18	18	-

Specimen V-3: Positive for Influenza A/B antigen.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	26	26	-
Binax NOW - waived	1	1	-
BioStar OIA	5	5	-
Quidel QuickVue Influenza	18	18	-

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

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	26	-	26
Binax NOW - waived	1	-	1
BioStar OIA	5	-	5
Quidel QuickVue Influenza	18	-	18

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

INFLUENZA A ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	82	69	13
BD Directigen	3	3	-
Binax NOW - waived	23	20	3
BioStar Flu OIA A/B	4	3	1
Quidel QuickVue Influenza A+B	42	33	9
Remel Xpect	6	6	-

Specimen V-1: Positive for Influenza A antigen.

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	81	-	81
BD Directigen	3	-	3
Binax NOW - waived	23	-	23
BioStar Flu OIA A/B	4	-	4
Quidel QuickVue Influenza A+B	42	-	42
Remel Xpect	6	-	6

Specimen V-2: Negative for Influenza A antigen.

INFLUENZA A ANTIGEN DETECTION

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	43	36	7
BD Directigen	3	3	-
Binax NOW - waived	11	9	2
BioStar Flu OIA A/B	4	2	2
Quidel QuickVue Influenza A+B	17	14	3
Remel Xpect	6	6	-

Specimen V-3: Positive for Influenza A antigen.

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	43	1	42
BD Directigen	3	1	2
Binax NOW - waived	11	-	11
BioStar Flu OIA A/B	4	-	4
Quidel QuickVue Influenza A+B	17	-	17
Remel Xpect	6	-	6

Specimen V-4: Negative for Influenza A antigen.

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	43	-	43
BD Directigen	3	-	3
Binax NOW - waived	11	-	11
BioStar Flu OIA A/B	4	-	4
Quidel QuickVue Influenza A+B	17	-	17
Remel Xpect	6	-	6

Specimen V-5: Negative for Influenza A antigen.

INFLUENZA B ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	80	-	80
BD Directigen	3	-	3
Binax NOW - waived	23	-	23
BioStar Flu OIA A/B	4	-	4
Quidel QuickVue Influenza A+B	40	-	40
Remel Xpect	6	-	6

Specimen V-1: Negative for Influenza B antigen.

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	80	-	80
BD Directigen	3	-	3
Binax NOW - waived	23	-	23
BioStar Flu OIA A/B	4	-	4
Quidel QuickVue Influenza A+B	40	-	40
Remel Xpect	6	-	6

Specimen V-2: Negative for Influenza B antigen.

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	43	-	43
BD Directigen	3	-	3
Binax NOW - waived	11	-	11
BioStar Flu OIA A/B	4	-	4
Quidel QuickVue Influenza A+B	17	-	17
Remel Xpect	6	-	6

Specimen V-3: Negative for Influenza B antigen.

INFLUENZA B ANTIGEN DETECTION

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	43	43	-
BD Directigen	3	3	-
Binax NOW - waived	11	11	-
BioStar Flu OIA A/B	4	4	-
Quidel QuickVue Influenza A+B	17	17	-
Remel Xpect	6	6	-

Specimen V-4: Positive for Influenza B antigen.

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	43	-	43
BD Directigen	3	-	3
Binax NOW - waived	11	-	11
BioStar Flu OIA A/B	4	-	4
Quidel QuickVue Influenza A+B	17	-	17
Remel Xpect	6	-	6

Specimen V-5: Negative for Influenza B antigen.

LEGIONELLA ANTIGEN DETECTION

Specimen L-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	64	64	-

Specimen L-1: Positive for Legionella antigen.

Specimen L-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	64	-	64

Specimen L-2: Negative for Legionella antigen.

Specimen L-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	64	64	-

Specimen L-3: Positive for Legionella antigen.

LEGIONELLA ANTIGEN DETECTION

Specimen L-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	64	-	64

Specimen L-4: Negative for Legionella antigen.

Specimen L-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	64	-	64

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	16	15	1
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	4	3	1
BioStar OIA	4	4	-
Meridian ImmunoCard	1	1	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-

Antigen present in specimen AG-1: *Clostridium difficile*.

Specimen AG-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	15	-	15
Alexon (Hycor)	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	4	-	4
BioStar OIA	4	-	4
Meridian ImmunoCard	1	-	1
Meridian Premier	1	-	1
Remel Xpect	1	-	1

Antigen present in specimen AG-2: Rotavirus.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	15	1	14
Alexon (Hycor)	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	4	-	4
BioStar OIA	4	-	4
Meridian ImmunoCard	1	-	1
Meridian Premier	1	1	-
Remel Xpect	1	-	1

Antigen present in specimen AG-3: Rotavirus.

Specimen AG-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	16	-
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	4	4	-
BioStar OIA	4	4	-
Meridian ImmunoCard	1	1	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-

Antigen present in specimen AG-4: Clostridium difficile.

Specimen AG-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	16	-
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	4	4	-
BioStar OIA	4	4	-
Meridian ImmunoCard	1	1	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-

Antigens present in specimen AG-5: Rotavirus and *Clostridium difficile*.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	8
Fisher HealthCare Sure-Vue	3	-	3
Meridian ImmunoCard	4	-	4
Remel Xpect	1	-	1

Specimen AG-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	8	-
Fisher HealthCare Sure-Vue	3	3	-
Meridian ImmunoCard	4	4	-
Remel Xpect	1	1	-

Specimen AG-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	8	-
Fisher HealthCare Sure-Vue	3	3	-
Meridian ImmunoCard	4	4	-
Remel Xpect	1	1	-

Specimen AG-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	-	8
Fisher HealthCare Sure-Vue	3	-	3
Meridian ImmunoCard	4	-	4
Remel Xpect	1	-	1

Specimen AG-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	8	-
Fisher HealthCare Sure-Vue	3	3	-
Meridian ImmunoCard	4	4	-
Remel Xpect	1	1	-

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	63	63	-

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	63	-	63

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	63	-	63

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	63	63	-

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	63	63	-

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

PARASITOLOGY

Specimen PA-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	3	100%	Acceptable

Parasite present in specimen PA-1: *Giardia lamblia*.

PARASITOLOGY

Specimen PA-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Endolimax nana	3	100%	Acceptable

Parasite present in specimen PA-2: *Endolimax nana*.

Specimen PA-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	4	57.14%	Not graded
Blastocystis hominis	2	28.57%	
Entamoeba coli	1	14.29%	

Parasites present in specimen PA-3: *Hookworm*, *Giardia lamblia* and *Trichuris trichiura* eggs. This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	4	100%	Acceptable

Parasite present in specimen PA-4: No parasites present.

Specimen PA-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium malariae	2	50%	Acceptable
Plasodium sp., not falsiparun	1	25%	Acceptable
Plasmodium sp., NOS	1	25%	Acceptable

Parasite present in specimen PA-5: *Plasmodium malariae*.

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