MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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Microbiology
2017 MLE-M1

ACP | Medical Laboratory Evaluation

Total Commitment to Education and Service
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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.

Affirm VP III Candida Antigen Detection	80% Consensus	Influenza A Antigen Detection	80% Consensus
Affirm VP III Gardnerella Ag Detection	80% Consensus	Influenza A/B Antigen Detection	80% Consensus
Affirm VP III Trichomonas Ag Detection	80% Consensus	Influenza B Antigen Detection	80% Consensus
Antimicrobial Susceptibility Testing	80% Consensus	Legionella Antigen Detection	80% Consensus
Bacterial Identification	80% Consensus	Parasite Identification	80% Consensus
C. difficile Antigen Detection	80% Consensus	Rotavirus Antigen Detection	80% Consensus
Chlamydia (EIA, DNA)	80% Consensus	RSV Antigen Detection	80% Consensus
Colony Count	80% Consensus	Strep A Antigen Detection	80% Consensus
Cryptosporidium Antigen Detection	80% Consensus	Streptococcus pneumoniae Antigen Detection	80% Consensus
Dermatophyte Screen	80% Consensus	Urine Presumptive Identification	80% Consensus
GC (EIA, DNA)	80% Consensus		
Giardia lamblia Antigen Detection	80% Consensus		
Gram Stain	80% Consensus		
Gram Stain Morphology	80% Consensus		

THROAT CULTURE

Specimen TC-1

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A. Strep	116	88.55%	Acceptable
Neisseria sp.	4	3.05%	Acceptable
Staph – coagulase negative	4	3.05%	Acceptable
Staphylococcus epidermidis	2	1.53%	Acceptable
Normal flora	1	0.76%	Acceptable

Organism(s) present: *Neisseria sicca* and *Staphylococcus epidermidis.*

Specimen TC-2

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	71	62.28%	Acceptable
Presump. Pos. Group A Strep	38	33.33%	Acceptable
Streptococcus pyogenes	1	0.88%	Acceptable

Organism(s) present: *Streptococcus pyogenes.*

Specimen TC-3

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	34	48.57%	Acceptable
Presump. Pos. Group A Strep	33	47.14%	Acceptable

Organism(s) present: *Streptococcus pyogenes.*

Specimen TC-4

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	35	52.24%	Acceptable
Presump. Pos. Group A Strep	32	47.76%	Acceptable

Organism(s) present: *Streptococcus pyogenes*.

Specimen TC-5

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	66	98.51%	Acceptable

Organism(s) present: *Moraxella catarrhalis* and *Staphylococcus aureus.*

STREP A ANTIGEN DETECTION

Specimen RS-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	537	507	30
Abbott Signify Strep A-waived	2	2	-
Alere Acceava Strep A Test	10	10	-
Alere i Instrument - waived	4	4	-
Alere Signify Strep A Dipstick	3	3	-
BD Chek Strep A	2	1	1
BD Veritor - waived	9	9	-
Beckman Coulter ICON DS	6	6	-
Beckman Coulter ICON SC	1	1	-
Binax NOW Strep A	1	1	-
Cardinal Health Strep A - moderate	2	1	1
Cardinal Health Strep A - waived	6	6	-
Consult Diagnostic Strep A Dipstick - Waived	83	73	10
Fisher HealthCare Sure-Vue - waived	1	1	-
Germaine Laboratories StrepAim	3	2	1
Henry Schein One Step	2	1	1
Henry Schein One Step+ - waived	51	46	5
McKesson Strep A Dipstick	15	15	-
Medline Strep A Test Strip	1	1	-
Moore Medical Strep A Rapid Test	1	1	-
Other Waived Method	27	25	2
Polymedco Poly Stat Strep A - waived	5	4	1
Quidel QuickVue Dipstick Strep	65	64	1
Quidel QuickVue In-Line	51	45	6
Quidel QuickVue+	15	15	-
Quidel Sofia - waived	1	1	-
Quidel Sofia Strep A - moderate	3	3	-
Quidel Sofia Strep A+ - waived	12	12	-
Sekisui OSOM	98	97	1
Sekisui OSOM Ultra Strep A	55	55	-

STREP A ANTIGEN DETECTION

Specimen RS-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	533	5	528
Abbott Signify Strep A-waived	2	-	2
Alere Acceava Strep A Test	9	-	9
Alere i Instrument - waived	4	-	4
Alere Signify Strep A Dipstick	3	-	3
BD Chek Strep A	2	-	2
BD Veritor - waived	8	-	8
Beckman Coulter ICON DS	6	-	6
Beckman Coulter ICON SC	1	-	1
Binax NOW Strep A	1	-	1
Cardinal Health Strep A - moderate	2	-	2
Cardinal Health Strep A - waived	6	-	6
Consult Diagnostic Strep A Dipstick - Waived	83	-	83
Fisher HealthCare Sure-Vue - waived	1	-	1
Germaine Laboratories StrepAim	3	-	3
Henry Schein One Step	2	-	2
Henry Schein One Step+ - waived	51	1	50
McKesson Strep A Dipstick	14	-	14
Medline Strep A Test Strip	1	-	1
Moore Medical Strep A Rapid Test	1	-	1
Other Waived Method	27	-	27
Polymedco Poly Stat Strep A - waived	6	1	5
Quidel QuickVue Dipstick Strep	64	-	64
Quidel QuickVue In-Line	51	2	49
Quidel QuickVue+	14	-	14
Quidel Sofia - waived	1	-	1
Quidel Sofia Strep A - moderate	3	-	3
Quidel Sofia Strep A+ - waived	12	-	12
Sekisui OSOM	98	1	97
Sekisui OSOM Ultra Strep A	55	-	55

STREP A ANTIGEN DETECTION

Specimen RS-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	77	77	-
Alere Acceava Strep A Test	2	2	-
Alere Signify Strep A Dipstick	1	1	-
BD Chek Strep A	2	2	-
BD Veritor - waived	1	1	-
Beckman Coulter ICON DS	1	1	-
Binax NOW Strep A	1	1	-
Cardinal Health Strep A - moderate	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	12	12	-
Henry Schein One Step+ - waived	4	4	-
McKesson Strep A Dipstick	3	3	-
Other Waived Method	2	2	-
Quidel QuickVue Dipstick Strep	9	9	-
Quidel QuickVue In-Line	18	18	-
Quidel QuickVue+	6	6	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	3	3	-
Sekisui OSOM	1	1	-
Sekisui OSOM Ultra Strep A	8	8	-

STREP A ANTIGEN DETECTION

Specimen RS-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	73	1	72
Alere Acceava Strep A Test	2	-	2
Alere Signify Strep A Dipstick	1	-	1
BD Chek Strep A	2	-	2
BD Veritor - waived	1	-	1
Beckman Coulter ICON DS	1	-	1
Binax NOW Strep A	1	-	1
Cardinal Health Strep A - moderate	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	11	-	11
Henry Schein One Step+ - waived	3	-	3
McKesson Strep A Dipstick	3	-	3
Other Waived Method	2	-	2
Quidel QuickVue Dipstick Strep	9	-	9
Quidel QuickVue In-Line	18	1	17
Quidel QuickVue+	6	-	6
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	3	-	3
Sekisui OSOM	1	-	1
Sekisui OSOM Ultra Strep A	6	-	6

Specimen RS-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	73	71	2
Alere Acceava Strep A Test	2	2	-
Alere Signify Strep A Dipstick	1	1	-
BD Chek Strep A	2	2	-
BD Veritor - waived	1	1	-
Beckman Coulter ICON DS	1	1	-
Binax NOW Strep A	1	1	-
Cardinal Health Strep A - moderate	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	11	10	1
Henry Schein One Step+ - waived	3	3	-
McKesson Strep A Dipstick	3	3	-
Other Waived Method	2	2	-
Quidel QuickVue Dipstick Strep	9	9	-
Quidel QuickVue In-Line	18	17	1
Quidel QuickVue+	6	6	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	3	3	-
Sekisui OSOM	1	1	-
Sekisui OSOM Ultra Strep A	6	6	-

GENERAL BACTERIOLOGY

Specimen BA-1 – Blood Culture

Identification	***Labs***	***Percent***	***Performance***
No growth (sterile)	5	62.50%	Ungraded
Anaerobic culture not performed	3	37.50%	

Organism(s) present: *Fusobacterium necrophorum.* This is an ungraded challenge due to lack of participant consensus. Since this is a Blood Culture, the specimen should be plated both aerobically and anaerobically.

Specimen BA-2 – Sputum Culture

Identification	***Labs***	***Percent***	***Performance***
Streptococcus pneumoniae	4	33.33%	Acceptable
Staphylococcus epidermidis	3	25.00%	Acceptable
Streptococcus alpha-hemolytic	2	16.67%	Acceptable
Staph – coagulase negative	2	16.67%	Acceptable
Staphylococcus sp.	1	8.33%	Acceptable

Organism(s) present: *Streptococcus pneumoniae* and *Staphylococcus epidermidis.*

Specimen BA-3 – Wound Culture

Identification	***Labs***	***Percent***	***Performance***
Aeromonas sp.	4	22.22%	Acceptable
Aeromonas hydrophila	3	16.67%	Acceptable
Streptococcus alpha-hemolytic	3	16.67%	Acceptable
Streptococcus salivarius	3	16.67%	Acceptable
Anaerobic cultures not perform	2	11.11%	Acceptable
Growth, referred for identification	1	5.56%	Acceptable
Streptococcus sanguinis	1	5.56%	Acceptable

Organism(s) present: *Aeromonas hydrophila* and *Streptococcus salivarius.*

METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS SCREEN

Specimen MSA-1

Identification	***Labs***	***Percent***	***Performance***
Negative	7	100%	Acceptable

Organism(s) present: *Staphylococcus aureus* – Methicillin susceptible and *Staphylococcus epidermidis.*

Specimen MSA-2

Identification	***Labs***	***Percent***	***Performance***
Positive	7	100%	Acceptable

Organism(s) present: *Staphylococcus aureus* – Methicillin resistant.

Specimen MSA-3

Identification	***Labs***	***Percent***	***Performance***
Positive	7	100%	Acceptable

Organism(s) present: *Staphylococcus aureus* – Methicillin resistant and *Corynebacterium sp.*

Specimen MSA-4

Identification	***Labs***	***Percent***	***Performance***
Positive	7	100%	Acceptable

Organism(s) present: *Staphylococcus aureus* – Methicillin resistant and *Streptococcus viridans.*

Specimen MSA-5

Identification	***Labs***	***Percent***	***Performance***
Negative	7	100%	Acceptable

Organism(s) present: *Neisseria sicca.*

URINE CULTURE

Specimen UC-1

Identification	***Labs***	***Percent***	***Performance***
Streptococcus agalactiae	44	67.69%	Acceptable
Growth, referred for identification	8	12.31%	Acceptable
Gram positive cocci	5	7.69%	Acceptable
Presump. Gram positive	3	4.62%	Acceptable
Strep – beta hemo, not Grp A	2	3.08%	Acceptable
Presump. Streptococcus sp.	1	1.54%	Acceptable

Gram Stain

Gram positive	37	100%	Acceptable

Gram Stain Morphology

Cocci	36	100%	Acceptable

Organism(s) present: *Streptococcus agalactiae.*

Specimen UC-2

Identification	***Labs***	***Percent***	***Performance***
Citrobacter sp.	27	47.37%	Acceptable
Citrobacter koseri	13	22.81%	Acceptable
Growth, referred for identification	8	14.04%	Acceptable
Gram negative bacilli	5	8.77%	Acceptable
Presump. Gram negative	3	5.26%	Acceptable

Organism(s) present: *Citrobacter koseri* and *Lactobacillus sp*.

Specimen UC-3

Identification	***Labs***	***Percent***	***Performance***
Moraxella catarrhalis	15	38.46%	Acceptable
Growth, referred for identification	10	25.64%	Acceptable
Moraxella sp.	3	7.69%	Acceptable
Gram negative diplococci	2	5.13%	Acceptable

Organism(s) present: *Moraxella catarrhalis*. Specimen UC-3 was graded by 85% referee consensus.

URINE CULTURE

Specimen UC-4

Identification	***Labs***	***Percent***	***Performance***
No growth (sterile)	13	72.22%	Ungraded
Growth, referred for identification	3	16.67%	
Gram positive bacilli	2	11.11%	

Organism(s) present: *Lactobacillus sp.* This is an ungraded challenge due to less than 80% referee consensus.

Specimen UC-5

Identification	***Labs***	***Percent***	***Performance***
Enterococcus sp.	6	28.57%	Acceptable
Enterococcus (Strep) faecalis	3	14.29%	Acceptable
Presump. Enterococcus sp.	3	14.29%	Acceptable
Growth, referred for identification	2	9.52%	Acceptable
Corynebacterium sp.	2	9.52%	Acceptable
Presump. Gram positive	1	4.76%	Acceptable
Gram positive cocci	1	4.76%	Acceptable
Gram positive bacilli	1	4.76%	Acceptable

Organism(s) present: *Enterococcus (Strep) faecalis* and *Corynebacterium sp.*

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen UC-1, CC-1 (SUS-1) Organism(s) present: *Streptococcus agalactiae.*

	------Disk Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Amoxicillin/Clavulanate	1	1	-	-	-	-	-	-	Ungraded[1]
Ampicillin	33	33	-	-	6	6	-	-	100.00%
Cefotaxime	-	-	-	-	1	1	-	-	Ungraded[1]
Ceftriaxone	15	15	-	-	2	2	-	-	100.00%
Cephalothin	14	14	-	-	-	-	-	-	100.00%
Ciprofloxacin	14	12	2	-	-	-	-	-	Inappropriate drug[2]
Clindamycin	-	-	-	-	2	2	-	-	Inappropriate drug[2]
Daptomycin	-	-	-	-	1	1	-	-	Ungraded[1]
Erythromycin	-	-	-	-	1	1	-	-	Inappropriate drug[2]
Levofloxacin	21	21	-	-	5	5	-	-	100.00%
Linezolid	1	1	-	-	4	4	-	-	100.00%
Penicillin	18	18	-	-	6	6	-	-	100.00%
Quinupristin/Dalfopristin	-	-	-	-	1	1	-	-	Inappropriate drug[2]
Tetracycline	15	-	-	15	4	-	-	4	100.00%
Trimethoprim/Sulfamethoxazole	-	-	-	-	2	2	-	-	Inappropriate drug[2]
Vancomycin	31	31	-	-	5	5	-	-	100.00%

NOTE: Please be aware that CLSI issues annual editions of M100, the supplement to the standards used by all proficiency testing programs for grading of susceptibilities. MLE has observed significant changes to which drugs are considered appropriate for various organisms with subsequent supplement editions. The current CLSI M100 document is accessible online at CLSI.org/m100.

[1] This is an ungraded challenge due to lack of comparison group.
[2] This is an inappropriate drug for organism and/or source.

GENITAL CULTURE

Specimen GC-1

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhoeae	21	63.64%	Acceptable
Neisseria gonorrhoeae	11	33.33%	Acceptable
Gram negative diplococci	1	3.03%	Acceptable

Gram Stain

Gram negative	23	100%	Acceptable

Gram Stain Morphology

Diplococci	23	100%	Acceptable

Organism(s) present: *Neisseria gonorrhoeae*.

Specimen GC-2

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	9	75.00%	Acceptable
Listeria monocytogenes	2	16.67%	Acceptable
Staphylococcus sp.	1	8.33%	Acceptable

Organism(s) present: *Listeria monocytogenes* and *Staphylococcus epidermidis.*

Specimen GC-3

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhoeae	8	72.73%	Acceptable
Neisseria gonorrhoeae	3	27.27%	Acceptable

Organism(s) present: *Neisseria gonorrhoeae.*

Specimen GC-4

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhoeae	8	88.89%	Acceptable
Neisseria gonorrhoeae	1	11.11%	Acceptable

Organism(s) present: *Neisseria gonorrhoeae* and *Streptococcus viridans.*

Specimen GC-5

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	8	88.89%	Acceptable
Gram positive cocci	1	11.11%	Acceptable

Organism(s) present: *Enterococcus faecalis.*

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-1

Method	***Labs***	***No growth***	***<10,000 organisms/mL***	***10,000-100,000 organisms/mL***	***>100,000 organisms/mL***
ALL METHODS	63	20	12	25	6
Calibrated Loop	23	-	2	16	5
HealthLink	1	-	-	1	-
Uri-Check	7	-	3	4	-
Uricult	30	20	7	3	-

Note: Uricult method was not graded due to lack of consensus.

Identification–Specimen CC-1

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	5	45.45%	Acceptable
Presump. Gram positive	2	18.18%	Acceptable
Presump. Streptococcus sp.	1	9.09%	Acceptable
Streptococcus agalactiae	1	9.09%	Acceptable

Organism(s) present: 50,000 – 75,000 CFU/mL of *Streptococcus agalactiae.*

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-2

Method	***Labs***	***No growth***	***<10,000 organisms/mL***	***10,000-100,000 organisms/mL***	***>100,000 organisms/mL***
ALL METHODS	63	-	2	29	32
Calibrated Loop	23	-	1	14	8
HealthLink	1	-	-	-	1
Uri-Check	7	-	-	2	5
Uricult	30	-	1	12	17

Identification–Specimen CC-2

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	5	41.67%	Acceptable
Presump. Gram negative	5	41.67%	Acceptable
Citrobacter koseri	1	8.33%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Citrobacter koseri* and <10,000 CFU/mL of *Lactobacillus sp.*

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-3

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	4	40.00%	Acceptable
Presump. Pseudomonas sp.	2	20.00%	Acceptable
Presump. Gram negative	1	10.00%	Acceptable
Pseudomonas aeruginosa	1	10.00%	Acceptable

Organism(s) present: 50,000 – 75,000 CFU/mL of *Pseudomonas aeruginosa*.

Identification–Specimen CC-4

Identification	***Labs***	***Percent***	***Performance***
No growth (sterile)	8	80.00%	Acceptable
Growth referred for identification	1	10.00%	Acceptable
Streptococcus pyogenes	1	10.00%	

Organism(s) present: >100,000 CFU/mL of *Lactobacillus* species. No growth was accepted because *Lactobacillus* did not grow on most media. This challenge was graded by participant consensus.

Identification–Specimen CC-5

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	4	40.00%	Acceptable
Presump. Gram positive	3	30.00%	Acceptable
Presump. Enterococcus sp.	2	20.00%	Acceptable
Enterococcus (Strep) faecalis	1	10.00%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Enterococcus faecalis* and *50,000 – 75,000 CFU/mL of Corynebacterium sp.*

DERMATOPHYTE SCREEN

Specimen DM-1

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte absent	10	90.91%	Acceptable
Dermatophyte present	1	9.09%	

Organism(s) present: *Staphylococcus epidermidis.*

Specimen DM-2

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte present	6	54.55%	Not graded
Dermatophyte absent	5	45.55%	

Organism(s) present: *Microsporum canis.* Specimen DM-2 was ungraded due to lack of participant consensus.

GRAM STAIN

Specimen GS-1

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	16	88.89%	Acceptable
Gram negative	2	11.11%	

Gram Stain Morphology

Cocci	13	81.25%	Acceptable
Diplococci	3	18.75%	

Organism(s) present: *Staphylococcus aureus.*

Specimen GS-2

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	18	100%	Acceptable

Gram Stain Morphology

Cocci	15	93.75%	Acceptable
Coccobacilli	1	6.25%	

Organism(s) present: *Streptococcus pneumoniae*

GRAM STAIN

Specimen GS-3

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	17	94.44%	Acceptable
Gram positive	1	5.56%	
Gram Stain Morphology			
Diplococci	11	68.75%	Acceptable
Cocci	3	18.75%	Acceptable
Coccobacilli	1	6.25%	
Rods/bacilli	1	6.25%	

Organism(s) present: *Neisseria mucosa.*

Specimen GS-4

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	17	94.44%	Acceptable
Gram positive	1	5.56%	
Gram Stain Morphology			
Rods/bacilli	14	87.50%	Acceptable
Coccobacilli	1	6.25%	
Diplococci	1	6.25%	

Organism(s) present: *Citrobacter freundii*.

Specimen GS-5

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	17	94.44%	Acceptable
Gram positive	1	5.56%	
Gram Stain Morphology			
Rods/bacilli	15	93.75%	Acceptable
Coccobacilli	1	6.25%	

Organism(s) present: *Pseudomonas aeruginosa.*

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-1

Identification	***Labs***	***Percent***	***Performance***
Negative	28	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*.

Specimen VP-2

Identification	***Labs***	***Percent***	***Performance***
Positive	28	100%	Acceptable

Organism(s) present: *Candida* species and *Trichomonas vaginalis*

Specimen VP-3

Identification	***Labs***	***Percent***	***Performance***
Negative	28	100%	Acceptable

Organism(s) present: *Escherichia coli*.

Specimen VP-4

Identification	***Labs***	***Percent***	***Performance***
Negative	29	100%	Acceptable

Organism(s) present: *Candida* species.

Specimen VP-5

Identification	***Labs***	***Percent***	***Performance***
Positive	28	100%	Acceptable

Organism(s) present: *Trichomonas vaginalis*

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-1

Identification	***Labs***	***Percent***	***Performance***
Positive	28	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*.

Specimen VP-2

Identification	***Labs***	***Percent***	***Performance***
Negative	24	85.71%	Acceptable
Positive	4	14.29%	

Organism(s) present: *Candida* species and *Trichomonas vaginalis*

Specimen VP-3

Identification	***Labs***	***Percent***	***Performance***
Negative	28	100%	Acceptable

Organism(s) present: *Escherichia coli*.

Specimen VP-4

Identification	***Labs***	***Percent***	***Performance***
Negative	28	100%	Acceptable

Organism(s) present: *Candida* species.

Specimen VP-5

Identification	***Labs***	***Percent***	***Performance***
Negative	22	78.57%	Acceptable
Positive	6	21.43%	

Organism(s) present: *Trichomonas vaginalis.* Specimen VP-5 was graded by 87% referee consensus.

AFFIRM VP III–Candida sp.

Specimen VP-1

Identification	***Labs***	***Percent***	***Performance***
Negative	28	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*.

Specimen VP-2

Identification	***Labs***	***Percent***	***Performance***
Positive	27	96.43%	Acceptable
Negative	1	3.57%	

Organism(s) present: *Candida* species and *Trichomonas vaginalis*

Specimen VP-3

Identification	***Labs***	***Percent***	***Performance***
Negative	28	100%	Acceptable

Organism(s) present: *Escherichia coli*.

Specimen VP-4

Identification	***Labs***	***Percent***	***Performance***
Positive	27	96.43%	Acceptable
Negative	1	3.57%	

Organism(s) present: *Candida* species.

Specimen VP-5

Identification	***Labs***	***Percent***	***Performance***
Negative	28	100%	Acceptable

Organism(s) present: *Trichomonas vaginalis.*

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-1

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	14	14	-
BD ProbeTec	3	3	-
BD Viper	1	1	-
Cepheid GeneXpert	2	2	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	4	4	-
Roche COBAS Amplicor	2	2	-

Antigen(s) present: *Chlamydia trachomatis*.

Specimen CY-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	14	14	-
BD ProbeTec	3	3	-
BD Viper	1	1	-
Cepheid GeneXpert	2	2	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	4	4	-
Roche COBAS Amplicor	2	2	-

Antigen(s) present: *Chlamydia trachomatis* and *Neisseria gonorrhoeae.*

Specimen CY-3

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	12	-	12
BD ProbeTec	3	-	3
BD Viper	1	-	1
Cepheid GeneXpert	2	-	2
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	2	-	2
Roche COBAS Amplicor	2	-	2

Antigen(s) present: *Neisseria gonorrhoeae.*

Specimen CY-4

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	12	-	12
BD ProbeTec	3	-	3
BD Viper	1	-	1
Cepheid GeneXpert	2	-	2
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	2	-	2
Roche COBAS Amplicor	2	-	2

Antigen(s) present: *Neisseria gonorrhoeae.*

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	12	-	12
BD ProbeTec	3	-	3
BD Viper	1	-	1
Cepheid GeneXpert	2	-	2
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	2	-	2
Roche COBAS Amplicor	2	-	2

Antigen(s) present: *Neisseria gonorrhoeae*.

GC (ANTIGEN DETECTION)

Specimen CY-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	10	1	9
BD ProbeTec	3	-	3
BD Viper	1	-	1
Cepheid GeneXpert	2	-	2
Gen-Probe APTIMA	1	-	1
Roche COBAS Amplicor	2	-	2

Antigen(s) present: *Chlamydia trachomatis*.

Specimen CY-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	10	9	1
BD ProbeTec	3	3	-
BD Viper	1	1	-
Cepheid GeneXpert	2	2	-
Gen-Probe APTIMA	1	-	1
Roche COBAS Amplicor	2	2	-

Antigen(s) present: *Chlamydia trachomatis* and *Neisseria gonorrhoeae.*

Specimen CY-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	10	9	1
BD ProbeTec	3	3	-
BD Viper	1	1	-
Cepheid GeneXpert	2	2	-
Gen-Probe APTIMA	1	1	-
Roche COBAS Amplicor	2	2	-

Antigen(s) present: *Neisseria gonorrhoeae.*

GC (ANTIGEN DETECTION)

Specimen CY-4

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	10	8	2
BD ProbeTec	3	3	-
BD Viper	1	1	-
Cepheid GeneXpert	2	2	-
Gen-Probe APTIMA	1	-	1
Roche COBAS Amplicor	2	2	-

Antigen(s) present: *Neisseria gonorrhoeae*.

Specimen CY-5

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	10	9	1
BD ProbeTec	3	3	-
BD Viper	1	1	-
Cepheid GeneXpert	2	2	-
Gen-Probe APTIMA	1	-	1
Roche COBAS Amplicor	2	2	-

Antigen(s) present: *Neisseria gonorrhoeae*.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	1	1	-
Alere CRYPTOSPORIDIUM II	1	1	-

Antigen(s) present: *Cryptosporidium* and *Giardia lamblia.*

Specimen LC-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	1	-	1
Alere CRYPTOSPORIDIUM II	1	-	1

Antigen(s) present: *Giardia lamblia.*

Specimen LC-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	1	1	-
Alere CRYPTOSPORIDIUM II	1	1	-

Antigen(s) present: *Cryptosporidium* and *Giardia lamblia.*

Specimen LC-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	1	1	-
Alere CRYPTOSPORIDIUM II	1	1	-

Antigen(s) present: *Cryptosporidium*.

Specimen LC-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	1	-	1
Alere CRYPTOSPORIDIUM II	1	-	1

Antigen(s) present: No antigen present.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-1

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	1	-
Alere GIARDIA II	1	1	-

Antigen(s) present: *Cryptosporidium* and *Giardia lamblia.*

Specimen LC-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	1	-
Alere GIARDIA II	1	1	-

Antigen(s) present: *Giardia lamblia*.

Specimen LC-3

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	1	-
Alere GIARDIA II	1	1	-

Antigen(s) present: *Cryptosporidium* and *Giardia lamblia.*

Specimen LC-4

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	-	1
Alere GIARDIA II	1	-	1

Antigen(s) present: *Cryptosporidium*.

Specimen LC-5

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	-	1
Alere GIARDIA II	1	-	1

Antigen(s) present: No antigen present.

RSV ANTIGEN DETECTION

Specimen V-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	70	68	2
Alere Binax NOW - waived	40	39	1
Alere Clearview RSV - waived	5	5	-
BD Veritor - waived	1	1	-
Quidel QuickVue RSV - waived	11	11	-
Quidel QuickVue RSV 10 Test	2	2	-
Quidel Sofia - waived	11	10	1

Antigen(s) present: RSV.

Specimen V-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	69	2	67
Alere Binax NOW - waived	40	2	38
Alere Clearview RSV - waived	5	-	5
BD Veritor - waived	1	-	1
Quidel QuickVue RSV - waived	10	-	10
Quidel QuickVue RSV 10 Test	2	-	2
Quidel Sofia - waived	11	-	11

Antigen(s) present: Influenza A.

Specimen V-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	16	-	16
Alere Binax NOW - waived	4	-	4
Quidel QuickVue RSV - waived	5	-	5
Quidel QuickVue RSV 10 Test	2	-	2
Quidel Sofia - waived	5	-	5

Antigen(s) present: Influenza B.

Specimen V-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	16	-	16
Alere Binax NOW - waived	4	-	4
Quidel QuickVue RSV - waived	5	-	5
Quidel QuickVue RSV 10 Test	2	-	2
Quidel Sofia - waived	5	-	5

Antigen(s) present: No antigen present.

RSV ANTIGEN DETECTION

Specimen V-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	16	-	16
Alere Binax NOW - waived	4	-	4
Quidel QuickVue RSV - waived	5	-	5
Quidel QuickVue RSV 10 Test	2	-	2
Quidel Sofia - waived	5	-	5

Antigen(s) present: Influenza B.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	48	1	47
BD Veritor - waived	3	-	3
Quidel QuickVue Influenza	31	-	31

Antigen(s) present: RSV.

Specimen V-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	46	46	-
Alere Binax NOW - waived	2	2	-
Other Waived Method	3	3	-
Quidel QuickVue Influenza	30	30	-

Antigen(s) present: Influenza A.

Specimen V-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	9	9	-
Quidel QuickVue Influenza	9	9	-

Antigen(s) present: Influenza B.

Specimen V-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	9	-	9
Quidel QuickVue Influenza	9	-	9

Antigen(s) present: No antigen present.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	9	9	-
Quidel QuickVue Influenza	9	9	-

Antigen(s) present: Influenza B.

INFLUENZA A ANTIGEN DETECTION

Specimen V-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	294	2	292
Alere Binax NOW - waived	65	1	64
Alere i Instrument - moderate	8	-	8
Alere Influenza A&B	10	-	10
BD Veritor - waived	39	-	39
Henry Schein OneStep+ Flu A&B	8	-	8
Medline Influenza A&B	3	-	3
Other Waived Method	1	-	1
Quidel QuickVue Influenza	3	-	3
Quidel QuickVue Influenza A+B	30	1	29
Quidel Sofia - waived	119	-	119
Sekisui OSOM Influenza A&B	7	-	7

Antigen(s) present: RSV.

Specimen V-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	295	289	6
Alere Binax NOW - waived	65	63	2
Alere i Instrument - moderate	8	8	-
Alere Influenza A&B	10	10	-
BD Veritor - waived	39	37	2
Henry Schein OneStep+ Flu A&B	8	8	-
Medline Influenza A&B	3	3	-
Other Waived Method	1	1	-
Quidel QuickVue Influenza	4	4	-
Quidel QuickVue Influenza A+B	30	29	1
Quidel Sofia - waived	119	118	1
Sekisui OSOM Influenza A&B	7	7	-

Antigen(s) present: Influenza A.

INFLUENZA A ANTIGEN DETECTION

Specimen V-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	95	1	94
Alere Binax NOW - waived	7	-	7
Alere Influenza A&B	3	-	3
BD Veritor - waived	2	-	2
Henry Schein OneStep+ Flu A&B	1	-	1
Quidel QuickVue Influenza A+B	4	-	4
Quidel Sofia - waived	74	1	73
Sekisui OSOM Influenza A&B	4	-	4

Antigen(s) present: Influenza B.

Specimen V-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	95	1	94
Alere Binax NOW - waived	7	-	7
Alere Influenza A&B	3	-	3
BD Veritor - waived	2	-	2
Henry Schein OneStep+ Flu A&B	1	-	1
Quidel QuickVue Influenza A+B	4	-	4
Quidel Sofia - waived	74	1	73
Sekisui OSOM Influenza A&B	4	-	4

Antigen(s) present: No antigen present.

Specimen V-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	95	-	95
Alere Binax NOW - waived	7	-	7
Alere Influenza A&B	3	-	3
BD Veritor - waived	2	-	2
Henry Schein OneStep+ Flu A&B	1	-	1
Quidel QuickVue Influenza A+B	4	-	4
Quidel Sofia - waived	74	-	74
Sekisui OSOM Influenza A&B	4	-	4

Antigen(s) present: Influenza B.

INFLUENZA B ANTIGEN DETECTION

Specimen V-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	294	9	285
Alere Binax NOW - waived	64	2	62
Alere i Instrument - moderate	8	-	8
Alere Influenza A&B	10	-	10
BD Veritor - waived	39	2	37
Henry Schein OneStep+ Flu A&B	8	-	8
Medline Influenza A&B	3	-	3
Other Waived Method	1	-	1
Quidel QuickVue Influenza	3	-	3
Quidel QuickVue Influenza A+B	31	-	31
Quidel Sofia - waived	119	3	116
Sekisui OSOM Influenza A&B	7	2	5

Antigen(s) present: RSV.

Specimen V-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	293	1	292
Alere Binax NOW - waived	63	-	63
Alere i Instrument - moderate	8	-	8
Alere Influenza A&B	10	-	10
BD Veritor - waived	39	-	39
Henry Schein OneStep+ Flu A&B	8	1	7
Medline Influenza A&B	3	-	3
Other Waived Method	1	-	1
Quidel QuickVue Influenza	3	-	3
Quidel QuickVue Influenza A+B	31	-	31
Quidel Sofia - waived	119	-	119
Sekisui OSOM Influenza A&B	7	-	7

Antigen(s) present: Influenza A.

INFLUENZA B ANTIGEN DETECTION

Specimen V-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	95	95	-
Alere Binax NOW - waived	7	7	-
Alere Influenza A&B	3	3	-
BD Veritor - waived	2	2	-
Henry Schein OneStep+ Flu A&B	1	1	-
Quidel QuickVue Influenza A+B	4	4	-
Quidel Sofia - waived	74	74	-
Sekisui OSOM Influenza A&B	4	4	-

Antigen(s) present: Influenza B.

Specimen V-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	95	1	94
Alere Binax NOW - waived	7	-	7
Alere Influenza A&B	3	-	3
BD Veritor - waived	2	-	2
Henry Schein OneStep+ Flu A&B	1	1	-
Quidel QuickVue Influenza A+B	4	-	4
Quidel Sofia - waived	74	-	74
Sekisui OSOM Influenza A&B	4	-	4

Antigen(s) present: No antigen present.

Specimen V-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	95	94	1
Alere Binax NOW - waived	7	7	-
Alere Influenza A&B	3	3	-
BD Veritor - waived	2	2	-
Henry Schein OneStep+ Flu A&B	1	-	1
Quidel QuickVue Influenza A+B	4	4	-
Quidel Sofia - waived	74	74	-
Sekisui OSOM Influenza A&B	4	4	-

Antigen(s) present: Influenza B.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-1

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	6	-
Alere C. diff Quik Chek	6	6	-

Antigen(s) present: *Clostridium difficile* and Rotavirus.

Specimen AG-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	6	-
Alere C. diff Quik Chek	6	6	-

Antigen(s) present: *Clostridium difficile* and Rotavirus.

Specimen AG-3

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	-	6
Alere C. diff Quik Chek	6	-	6

Antigen(s) present: Rotavirus.

Specimen AG-4

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	6	-
Alere C. diff Quik Chek	6	6	-

Antigen(s) present: *Clostridium difficile* and Rotavirus.

Specimen AG-5

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	-	6
Alere C. diff Quik Chek	6	-	6

Antigen(s) present: No antigen present.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-1

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Fisher HealthCare Sure-Vue	5	5	-

Antigen(s) present: *Clostridium difficile* and Rotavirus.

Specimen AG-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Fisher HealthCare Sure-Vue	5	5	-

Antigen(s) present: *Clostridium difficile* and Rotavirus.

Specimen AG-3

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Fisher HealthCare Sure-Vue	5	5	-

Antigen(s) present: Rotavirus.

Specimen AG-4

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Fisher HealthCare Sure-Vue	5	5	-

Antigen(s) present: *Clostridium difficile* and Rotavirus.

Specimen AG-5

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Fisher HealthCare Sure-Vue	5	-	5

Antigen(s) present: No antigen present.

LEGIONELLA ANTIGEN DETETION

Specimen L-1

Method	***Labs***	***Positive***	***Negative***
Binax NOW	18	18	-

Specimen L-2

Method	***Labs***	***Positive***	***Negative***
Binax NOW	18	-	18

Specimen L-3

Method	***Labs***	***Positive***	***Negative***
Binax NOW	18	-	18

Specimen L-4

Method	***Labs***	***Positive***	***Negative***
Binax NOW	18	-	18

Specimen L-5

Method	***Labs***	***Positive***	***Negative***
Binax NOW	18	18	-

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-1

Method	***Labs***	***Positive***	***Negative***
Binax NOW	16	-	16

Specimen SP-2

Method	***Labs***	***Positive***	***Negative***
Binax NOW	16	16	-

Specimen SP-3

Method	***Labs***	***Positive***	***Negative***
Binax NOW	16	-	16

Specimen SP-4

Method	***Labs***	***Positive***	***Negative***
Binax NOW	16	16	-

Specimen SP-5

Method	***Labs***	***Positive***	***Negative***
Binax NOW	16	16	-

PARASITOLOGY

Specimen PA-1

Identification	***Labs***	***Percent***	***Performance***
Giardia lamblia	1	100%	Acceptable

Parasite(s) present: *Giardia lamblia.*

Specimen PA-2

Identification	***Labs***	***Percent***	***Performance***
Dientamoeba fragilis	1	100%	Acceptable

Parasite(s) present: Dientamoeba fragilis.

Specimen PA-3

Identification	***Labs***	***Percent***	***Performance***
No parasite seen	1	100%	Acceptable

Parasite(s) present: *Pollen artifact*.

Specimen PA-4

Identification	***Labs***	***Percent***	***Performance***
Clonorchis sinensis	1	100%	Acceptable

Parasite(s) present: *Clonorchis sinensis.*

Specimen PA-5

Identification	***Labs***	***Percent***	***Performance***
Plasmodium malariae	1	100%	Ungraded

Parasite(s) present: *Plasmodium falciparum.* This is an ungraded challenge due to less than 80% participant consensus.

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