MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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MLE
MedicalLaboratoryEvaluation

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

Microbiology
MLE-M2

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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.

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

THROAT CULTURE

Specimen TC-6

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	81	50.31%	Acceptable
Presump. Pos. Group A Strep	64	39.75%	Acceptable
Streptococcus pyogenes	9	5.59%	Acceptable
Neisseria sp.	1	0.62%	Acceptable
Neisseria sicca	1	0.62%	Acceptable
Negative for Group A Strep	5	3.11%	

Organisms present in specimen TC-6: *Streptococcus pyogenes* and *Neisseria sicca.*

Specimen TC-7

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	144	95.36%	Acceptable
No growth (sterile)	4	2.65%	Acceptable
Neisseria sp.	1	0.66%	Acceptable
Norma flora	1	0.66%	Acceptable

Organism present in specimen TC-7: *Neisseria mucosa*.

Specimen TC-8

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	46	48.42%	Acceptable
Presump. Pos. Group A Strep	46	48.42%	Acceptable

Organisms present in specimen TC-8: *Streptococcus pyogenes* and *Corynebacterium* species.

Specimen TC-9

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	77	95.06%	Acceptable
No growth (sterile)	1	1.23%	Acceptable

Organisms present in specimen TC-9: *Haemophilus influenzae* and *Neisseria sicca*.

Specimen TC-10

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	43	53.09%	Acceptable
Presump. Pos. Group A Strep	37	45.68%	Acceptable

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

STREP A ANTIGEN DETECTION

Specimen RS-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	545	479	66
Abbott Signify Strep A-waived	3	2	1
BD Chek Strep A	5	5	-
Beckman Coulter ICON DS	4	3	1
Beckman Coulter ICON SC	4	4	-
Binax NOW Strep A	2	2	-
Cardinal Health Strep A - waived	16	14	2
Consult Diagnostic Strep A - Moderate	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	69	60	9
Fisher HealthCare Sure-Vue - waived	5	3	2
Genzyme OSOM	87	82	5
Genzyme OSOM Ultra Strep A	48	42	6
Henry Schein One Step	1	1	-
Henry Schein One Step+ - waived	32	26	6
Immunostics Detector Strep A Direct	9	9	-
Inverness Acceava Strep A Test	15	14	1
Inverness Signify Strep A Dipstick	1	-	1
McKesson Strep A Cassette	1	1	-
McKesson Strep A Dipstick	33	26	7
Other Waived Method	7	7	-
Polymedco Poly Stat Strep A - moderate	1	1	-
Polymedco Poly Stat Strep A - waived	8	8	-
PSS Select Diag. Strep A Cassette	2	2	-
PSS Select Diag. Strep A Dipstick - waived	4	4	-
Quidel QuickVue Dipstick Strep	84	78	6
Quidel QuickVue In-Line	60	46	14
Quidel QuickVue+	34	30	4
Stanbio QuStick Strep A	2	2	-
Wampole Clearview	2	2	-

STREP A ANTIGEN DETECTION

Specimen RS-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	537	8	529
Abbott Signify Strep A-waived	3	-	3
BD Chek Strep A	5	-	5
Beckman Coulter ICON DS	4	-	4
Beckman Coulter ICON SC	4	-	4
Binax NOW Strep A	2	-	2
Cardinal Health Strep A - waived	16	-	16
Consult Diagnostic Strep A - Moderate	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	69	2	67
Fisher HealthCare Sure-Vue - waived	5	-	5
Genzyme OSOM	87	-	87
Genzyme OSOM Ultra Strep A	47	-	47
Henry Schein One Step	1	-	1
Henry Schein One Step+ - waived	32	-	32
Immunostics Detector Strep A Direct	9	-	9
Inverness Acceava Strep A Test	15	-	15
Inverness Signify Strep A Dipstick	1	-	1
McKesson Strep A Cassette	1	-	1
McKesson Strep A Dipstick	31	-	31
Other Waived Method	7	-	7
Polymedco Poly Stat Strep A - moderate	1	-	1
Polymedco Poly Stat Strep A - waived	8	-	8
PSS Select Diag. Strep A Cassette	2	-	2
PSS Select Diag. Strep A Dipstick - waived	4	-	4
Quidel QuickVue Dipstick Strep	82	2	80
Quidel QuickVue In-Line	59	1	58
Quidel QuickVue+	32	2	30
Stanbio QuStick Strep A	2	-	2
Wampole Clearview	2	-	2

STREP A ANTIGEN DETECTION

Specimen RS-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	167	164	3
BD Chek Strep A	2	2	-
Beckman Coulter ICON DS	1	1	-
Beckman Coulter ICON SC	1	1	-
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	7	7	-
Genzyme OSOM	52	52	-
Genzyme OSOM Ultra Strep A	13	13	-
Henry Schein One Step+ - waived	6	6	-
Inverness Acceava Strep A Test	3	3	-
McKesson Strep A Dipstick	8	8	-
Other Waived Method	3	3	-
Polymedco Poly Stat Strep A - moderate	1	1	-
PSS Select Diag. Strep A Dipstick - waived	1	1	-
Quidel QuickVue Dipstick Strep	14	13	1
Quidel QuickVue In-Line	21	20	1
Quidel QuickVue+	25	25	-
Stanbio QuStick Strep A	1	1	-

STREP A ANTIGEN DETECTION

Specimen RS-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	146	146	-
BD Chek Strep A	1	1	-
Beckman Coulter ICON DS	1	1	-
Beckman Coulter ICON SC	1	1	-
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	49	49	-
Genzyme OSOM Ultra Strep A	8	8	-
Henry Schein One Step+ - waived	5	5	-
Inverness Acceava Strep A Test	3	3	-
McKesson Strep A Dipstick	6	6	-
Other Waived Method	3	3	-
PSS Select Diag. Strep A Dipstick - waived	1	1	-
Quidel QuickVue Dipstick Strep	13	13	-
Quidel QuickVue In-Line	20	20	-
Quidel QuickVue+	21	21	-
Stanbio QuStick Strep A	1	1	-

Specimen RS-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	146	1	145
BD Chek Strep A	1	-	1
Beckman Coulter ICON DS	1	-	1
Beckman Coulter ICON SC	1	-	1
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	49	1	48
Genzyme OSOM Ultra Strep A	8	-	8
Henry Schein One Step+ - waived	5	-	5
Inverness Acceava Strep A Test	3	-	3
McKesson Strep A Dipstick	6	-	6
Other Waived Method	3	-	3
PSS Select Diag. Strep A Dipstick - waived	1	-	1
Quidel QuickVue Dipstick Strep	13	-	13
Quidel QuickVue In-Line	20	-	20
Quidel QuickVue+	21	-	21
Stanbio QuStick Strep A	1	-	1

GENERAL BACTERIOLOGY

Specimen BA-4 – Spinal Fluid Culture

Identification	***Labs***	***Percent***	***Performance***
Listeria monocytogenes	8	100%	Acceptable

Organism present in specimen BA-4: *Listeria monocytogenes.*

Specimen BA-5 – Respiratory Culture

Identification	***Labs***	***Percent***	***Performance***
Streptococcus pneumoniae	7	50.00%	Ungraded
Neisseria sp.	3	21.43%	
Gram positive cocci	1	7.14%	

Organisms present in specimen BA-5: *Streptococcus pneumoniae* and *Neisseria mucosa.* This is an ungraded challenge due to less than 80% consensus.

Specimen BA-6 – Wound Culture

Identification	***Labs***	***Percent***	***Performance***
Klebsiella pneumoniae	9	81.82%	Acceptable
Staphylococcus epidermidis	2	18.18%	Acceptable

Organisms present in specimen BA-6: *Klebsiella pneumoniae* and *Staphylococcus epidermidis*.

METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS SCREEN

Specimen MSA-6

Identification	***Labs***	***Percent***	***Performance***
Negative	5	100%	Acceptable

Organisms present in specimen MSA-6: *Streptococcus pneumoniae* and *Streptococcus sanguinis.*

Specimen MSA-7

Identification	***Labs***	***Percent***	***Performance***
Positive	5	100%	Acceptable

Organisms present in specimen MSA-7: *Staphylococcus aureus* – Methicillin resistant and *Staphylococcus epidermidis.*

Specimen MSA-8

Identification	***Labs***	***Percent***	***Performance***
Positive	5	100%	Acceptable

Organisms present in specimen MSA-8: *Staphylococcus aureus* – Methicillin resistant and *Neisseria sicca.*

Specimen MSA-9

Identification	***Labs***	***Percent***	***Performance***
Negative	5	100%	Acceptable

Organisms present in specimen MSA-9: *Staphylococcus aureus* – Methicillin sensitive and *Corynebacterium* species.

Specimen MSA-10

Identification	***Labs***	***Percent***	***Performance***
Negative	5	100%	Acceptable

Organism present in specimen MSA-10: *Staphylococcus aureus* – Methicillin sensitive.

URINE CULTURE

Specimen UC-6

Identification	***Labs***	***Percent***	***Performance***
Staphylococcus aureus	37	50.68%	Acceptable
Growth, referred for identification	19	26.03%	Acceptable
Gram positive cocci	7	9.59%	Acceptable
Presump. Gram positive	3	4.11%	Acceptable
Presump. Staphylococcus sp.	3	4.11%	Acceptable
Staphylococcus sp.	2	2.74%	Acceptable

Gram Stain

Gram positive	33	100%	Acceptable

Gram Stain Morphology

Cocci	32	100%	Acceptable

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

Specimen UC-7

Identification	***Labs***	***Percent***	***Performance***
Klebsiella pneumoniae	30	45.45%	Acceptable
Growth, referred for identification	16	24.24%	Acceptable
Gram negative bacilli	7	10.61%	Acceptable
Klebsiella sp.	5	7.58%	Acceptable
Presump. Klebsiella sp.	4	6.06%	Acceptable
Presump. Gram negative	3	4.55%	Acceptable
Lactobacillus sp.	1	1.52%	Acceptable

Organisms present in specimen UC-7: *Klebsiella pneumoniae* and *Lactobacillus* species.

Specimen UC-8

Identification	***Labs***	***Percent***	***Performance***
Pseudomonas aeruginosa	14	31.11%	Acceptable
Growth, referred for identification	13	28.89%	Acceptable
Pseudomonas sp.	6	13.33%	Acceptable
Gram negative bacilli	3	6.67%	Acceptable
Presump. Gram negative	3	6.67%	Acceptable
Presump. Pseudomonas sp.	3	6.67%	Acceptable
Corynebacterium sp.	1	2.22%	Acceptable

Organisms present in specimen UC-8: *Pseudomonas aeruginosa* and *Corynebacterium* species.

URINE CULTURE

Specimen UC-9

Identification	***Labs***	***Percent***	***Performance***
Staphylococcus saprophyticus	7	31.82%	Acceptable
Growth, referred for identification	7	31.82%	Acceptable
Staph – coagulase negative	3	13.64%	Acceptable
Presump. Staphylococcus sp.	2	9.09%	Acceptable
Presump. Gram positive	1	4.55%	Acceptable
Gram positive cocci	1	4.55%	Acceptable

Organisms present in specimen UC-9: *Staphylococcus saprophyticus* and *Staphylococcus epidermidis*.

Specimen UC-10

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	8	36.36%	Acceptable
Enterococcus sp.	7	31.82%	Acceptable
Enterococcus (Strep) faecium	3	13.64%	Acceptable
Gram positive cocci	1	4.55%	Acceptable
Presump. Gram positive	1	4.55%	Acceptable
Presump. Enterococcus sp.	1	4.55%	Acceptable
Presumptive Streptococcus sp.	1	4.55%	Acceptable

Organism present in specimen UC-10: *Enterococcus faecium.*

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen UC-6, CC-6 (SUS-6) The organism present is: *Staphylococcus aureus.*

	------Disk Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Amoxicillin/Clavulanate	4	3	-	1	4	4	-	-	90.91%
Ampicillin	16	2	-	14	1	1	-	-	80.00%
Ampicillin/Sulbactam	1	-	-	1	2	2	-	-	Not graded[1]
Cefazolin	2	2	-	-	2	2	-	-	100.00%
Cefepime	-	-	-	-	1	1	-	-	Not graded[1]
Cefotaxime	-	-	-	-	1	1	-	-	Not graded[1]
Cefoxitin	9	9	-	-	-	-	-	-	100.00%
Ceftriaxone	1	1	-	-	1	1	-	-	Not graded[1]
Cephalexin	1	1	-	-	-	-	-	-	Inappropriate drug[2]
Cephalothin	22	22	-	-	2	2	-	-	100.00%
Ciprofloxacin	29	29	-	-	10	10	-	-	100.00%
Clindamycin	-	-	-	-	1	1	-	-	Inappropriate drug[2]
Daptomycin	-	-	-	-	2	2	-	-	Not graded[1]
Doxycycline	1	1	-	-	1	1	-	-	Not graded[1]
Ertapenem	-	-	-	-	1	1	-	-	Not graded[1]
Erythromycin	-	-	-	-	1	1	-	-	Inappropriate drug[2]
Gatifloxacin	-	-	-	-	1	1	-	-	Not graded[1]
Gentamicin	7	7	-	-	6	6	-	-	100.00%
Imipenem	-	-	-	-	1	1	-	-	Not graded[1]
Levofloxacin	9	9	-	-	11	11	-	-	100.00%
Linezolid	1	1	-	-	4	4	-	-	100.00%
Moxifloxacin	-	-	-	-	3	3	-	-	Not graded[1]
Nitrofurantoin	26	26	-	-	12	12	-	-	100.00%
Norfloxacin	1	1	-	-	-	-	-	-	Not graded[1]
Oxacillin	14	14	-	-	9	9	-	-	100.00%
Penicillin	4	-	-	4	8	1	-	7	88.24%
Piperacillin/Tazobactam	-	-	-	-	1	1	-	-	Not graded[1]
Quinupristin/Dalfopristin	-	-	-	-	3	3	-	-	Not graded[1]
Rifampin	1	1	-	-	5	5	-	-	100.00%
Tetracycline	12	12	-	-	9	9	-	-	100.00%
Trimethoprim	5	4	1	-	1	1	-	-	83.33%
Trimethoprim/Sulfamethoxazole	32	32	-	-	11	11	-	-	100.00%
Vancomycin	-	-	-	-	9	9	-	-	100.00%

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.

GENITAL CULTURE

Specimen GC-6

Identification	***Labs***	***Percent***	***Performance***
Neisseria gonorrhoeae	16	45.71%	Acceptable
Presumptive for N. gonorrhoea	16	45.71%	Acceptable
Growth, referred for identification	2	5.71%	Acceptable
Gram Stain			
Gram negative	28	96.55%	Acceptable
Gram positive	1	3.45%	
Gram Stain Morphology			
Diplococci	28	96.55%	Acceptable
Cocci	1	3.45%	

Organism present in specimen GC-6: *Neisseria gonorrhoeae*.

Specimen GC-7

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	14	100%	Acceptable

Organisms present in specimen GC-7: *Enterococcus faecium* and *Lactobacillus casei.*

Specimen GC-8

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	9	69.23%	Acceptable

Organism present in specimen GC-8: *Lactobacillus casei.* This challenge was graded by 82% referee consensus.

GENITAL CULTURE

Specimen GC-9

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhoeae	10	76.92%	Acceptable
Neisseria gonorrhoeae	3	23.08%	Acceptable

Organisms present in specimen GC-9: *Neisseria gonorrhoeae* and *Corynebacterium* species.

Specimen GC-10

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	9	69.23%	Acceptable
No growth (sterile)	4	30.77%	Acceptable

Organism present in specimen GC-10: *Streptococcus* Group B.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-6

Method	***Labs***	***No growth***	***<10,000 organisms/mL***	***10,000-100,000 organisms/mL***	***>100,000 organisms/mL***
ALL METHODS	86	-	1	4	81
Bulls Eye	4	-	-	1	3
Calibrated Loop	25	-	-	1	24
HealthLink	4	-	-	-	4
Uri-Check	7	-	-	-	7
Uri-Three	1	-	-	-	1
Uricult	44	-	1	1	42

Identification–Specimen CC-6

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram positive	10	43.48%	Acceptable
Growth, referred for identification	7	30.43%	Acceptable
Presump. Staphylococcus sp.	3	13.04%	Acceptable
Staphylococcus aureus	3	13.04%	Acceptable
Gram Stain			
Gram positive	5	100%	Acceptable
Gram Stain Morphology			
Cocci	5	100%	Acceptable

Organism present in specimen CC-6: >100,000 CFU/mL of *Staphylococcus aureus.*

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-7

Method	***Labs***	***No growth***	***<10,000 organisms/mL***	***10,000-100,000 organisms/mL***	***>100,000 organisms/mL***
ALL METHODS	85	-	2	42	41
Bulls Eye	3	-	-	1	2
Calibrated Loop	25	-	1	14	10
HealthLink	4	-	-	2	2
Uri-Check	7	-	-	6	1
Uri-Three	1	-	-	-	1
Uricult	44	-	1	18	25

Identification–Specimen CC-7

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram negative	11	47.83%	Acceptable
Growth, referred for identification	5	21.74%	Acceptable
Presump. Klebsiella sp.	3	13.04%	Acceptable
Gram negative bacilli	2	8.70%	Acceptable
Klebsiella sp.	1	4.35%	Acceptable
Klebsiella pneumoniae	1	4.35%	Acceptable

Organisms present in specimen CC-7: 50,000 – 75,000 CFU/mL of *Klebsiella pneumoniae* and <10,000 CFU/mL of *Lactobacillus* species.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-8

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram negative	7	38.89%	Acceptable
Presump. Pseudomonas sp.	4	22.22%	Acceptable
Growth, referred for identification	4	22.22%	Acceptable
Pseudomonas aeruginosa	1	5.56%	Acceptable
Gram negative bacilli	1	5.56%	Acceptable

Organisms present in specimen CC-8: >100,000 CFU/mL of *Pseudomonas aeruginosa* and <10,000 CFU/mL of *Corynebacterium* species.

Identification–Specimen CC-9

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram positive	8	42.11%	Acceptable
Growth, referred for identification	4	21.05%	Acceptable
Staphylococcus saprophyticus	2	10.53%	Acceptable
Presump. Staphylococcus sp.	1	5.26%	Acceptable
Staphylococcus sp.	1	5.26%	Acceptable
Staph – coagulase negative	1	5.26%	Acceptable

Organisms present in specimen CC-9: >100,000 CFU/mL of *Staphylococcus saprophyticus* and <10,000 CFU/mL of *Staphylococcus epidermidis*.

Identification–Specimen CC-10

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram positive	7	38.89%	Acceptable
Growth, referred for identification	5	27.78%	Acceptable
Presump. Enterococcus sp.	3	16.67%	Acceptable
Enterococcus sp.	1	5.56%	Acceptable
Enterococcus (Strep) faecium	1	5.56%	Acceptable

Organism present in specimen CC-10: >100,000 CFU/mL of *Enterococcus faecium.*

DERMATOPHYTE SCREEN

Specimen DM-3

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte present	24	100%	Acceptable

Organism present in specimen DM-3: *Trichophyton tonsurans*.

Specimen DM-4

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte absent	22	91.67%	Acceptable
Dermatophyte positive	2	8.33%	

Organism present in specimen DM-4: *Aspergillus niger.*

GRAM STAIN

Specimen GS-6

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	27	100%	Acceptable

Gram Stain Morphology

Rods/bacilli	20	86.96%	Acceptable
Coccobacilli	3	13.14%	

Organism present in specimen GS-6: *Proteus vulgaris.*

Specimen GS-7

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	24	88.89%	Acceptable
Gram negative	3	11.11%	

Gram Stain Morphology

Cocci	19	82.61%	Acceptable
Diplococci	4	17.39%	

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

GRAM STAIN

Specimen GS-8

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	25	92.59%	Acceptable
Gram positive	2	7.41%	
Gram Stain Morphology			
Rods/bacilli	23	100%	Acceptable

Organism present in specimen GS-8: *Pseudomonas aeruginosa*

Specimen GS-9

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	27	100%	Acceptable
Gram Stain Morphology			
Cocci	21	91.30%	Acceptable
Coccibacilli	1	4.35%	
Diplococci	1	4.35%	

Organism present in specimen GS-9: *Staphylococcus pneumonia.*

Specimen GS-10

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	25	92.56%	Acceptable
Gram negative	2	7.41%	
Gram Stain Morphology			
Cocci	20	86.96%	Acceptable
Diplococci	2	8.70%	
Coccobacilli	1	4.35%	

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

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-6

Identification	***Labs***	***Percent***	***Performance***
Positive	32	96.97%	Acceptable
Negative	1	3.03%	

Organism present in specimen VP-6: *Trichomonas vaginalis*.

Specimen VP-7

Identification	***Labs***	***Percent***	***Performance***
Negative	33	100%	Acceptable

Organism present in specimen VP-7: *Escherichia coli.*

Specimen VP-8

Identification	***Labs***	***Percent***	***Performance***
Negative	33	100%	Acceptable

Organism present in specimen VP-8: *Gardnerella vaginalis*.

Specimen VP-9

Identification	***Labs***	***Percent***	***Performance***
Negative	32	96.97%	Acceptable
Positive	1	3.03%	

Organism present in specimen VP-9: *Candida albicans*.

Specimen VP-10

Identification	***Labs***	***Percent***	***Performance***
Negative	33	100%	Acceptable

Organisms present in specimen VP-10: *Gardnerella vaginalis.*

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-6

Identification	***Labs***	***Percent***	***Performance***
Negative	33	100%	Acceptable

Specimen VP-7

Identification	***Labs***	***Percent***	***Performance***
Negative	33	100%	Acceptable

Specimen VP-8

Identification	***Labs***	***Percent***	***Performance***
Positive	33	100%	Acceptable

Specimen VP-9

Identification	***Labs***	***Percent***	***Performance***
Negative	32	96.97%	Acceptable
Positive	1	3.03%	

Specimen VP-10

Identification	***Labs***	***Percent***	***Performance***
Positive	33	100%	Acceptable

AFFIRM VP III–Candida sp.

Specimen VP-6

Identification	***Labs***	***Percent***	***Performance***
Negative	32	96.97%	Acceptable
Positive	1	3.03%	

Specimen VP-7

Identification	***Labs***	***Percent***	***Performance***
Negative	33	100%	Acceptable

AFFIRM VP III–Candida sp.

Specimen VP-8

Identification	***Labs***	***Percent***	***Performance***
Negative	33	100%	Acceptable

Specimen VP-9

Identification	***Labs***	***Percent***	***Performance***
Positive	31	93.94%	Acceptable
Negative	2	6.06%	

Specimen VP-10

Identification	***Labs***	***Percent***	***Performance***
Negative	33	100%	Acceptable

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	14	14	-
BD ProbeTec	6	6	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	6	6	-

Organism present in specimen CY-6: *Chlamydia trachomatis.*

Specimen CY-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	14	-	14
BD ProbeTec	6	-	6
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	6	-	6

Organism present in specimen CY-7: *Neisseria gonorrheae*.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	13	13	-
BD ProbeTec	6	6	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	5	5	-

Organisms present in specimen CY-8: *Chlamydia trachomatis* and *Neisseria gonorrheae*

Specimen CY-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	13	13	-
BD ProbeTec	6	6	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	5	5	-

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

Specimen CY-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	13	-	13
BD ProbeTec	6	-	6
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	5	-	5

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

GC (ANTIGEN DETECTION)

Specimen CY-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	8	-	8
BD ProbeTec	6	-	6
Gen-Probe APTIMA	1	-	1

Specimen CY-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	8	8	-
BD ProbeTec	6	6	-
Gen-Probe APTIMA	1	1	-

Specimen CY-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	8	8	-
BD ProbeTec	6	6	-
Gen-Probe APTIMA	1	1	-

Specimen CY-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	8	-	8
BD ProbeTec	6	-	6
Gen-Probe APTIMA	1	-	1

Specimen CY-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	8	8	-
BD ProbeTec	6	6	-
Gen-Probe APTIMA	1	1	-

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	3	-	3
Remel Xpect	2	-	2

Antigen present in specimen LC-6: No antigen present.

Specimen LC-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	3	3	-
Remel Xpect	2	2	-

Antigens present in specimen LC-7: *Cryptosporidium* and *Giardia lamblia*.

Specimen LC-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	3	3	-
Remel Xpect	2	2	-

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

Specimen LC-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	3	-	3
Remel Xpect	2	-	2

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

Specimen LC-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	3	3	-
Remel Xpect	2	2	-

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

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-6

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	-	5
Remel Xpect	3	-	3

Specimen LC-7

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	5	-
Remel Xpect	3	3	-

Specimen LC-8

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	-	5
Remel Xpect	3	-	3

Specimen LC-9

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	5	-
Remel Xpect	3	3	-

Specimen LC-10

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	-	5
Remel Xpect	3	-	3

RSV ANTIGEN DETECTION

Specimen V-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	55	53	2
Binax NOW - waived	38	37	1
Quidel QuickVue RSV - waived	9	9	-
Quidel QuickVue RSV 10 Test	1	1	-
Remel Xpect - waived	4	4	-
Wampole Clearview RSV - waived	2	2	-

Antigen present in specimen V-6: RSV.

Specimen V-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	55	2	53
Binax NOW – waived	38	1	37
Quidel QuickVue RSV – waived	9	-	9
Quidel QuickVue RSV 10 Test	1	-	1
Remel Xpect – waived	4	-	4
Wampole Clearview RSV – waived	2	-	2

Antigen present in specimen V-7: Influenza B.

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	-	15
Binax NOW – waived	8	-	8
Quidel QuickVue RSV – waived	3	-	3
Quidel QuickVue RSV 10 Test	1	-	1
Remel Xpect – waived	2	-	2
Wampole Clearview RSV – waived	1	-	1

Antigen present in specimen V-8: Influenza A.

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	1	14
Binax NOW – waived	8	-	8
Quidel QuickVue RSV – waived	3	-	3
Quidel QuickVue RSV 10 Test	1	-	1
Remel Xpect – waived	2	-	2
Wampole Clearview RSV – waived	1	1	-

Antigen present in specimen V-9: No antigen present.

RSV ANTIGEN DETECTION

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	1	14
Binax NOW - waived	8	-	8
Quidel QuickVue RSV - waived	3	-	3
Quidel QuickVue RSV 10 Test	1	-	1
Remel Xpect - waived	2	-	2
Wampole Clearview RSV - waived	1	1	-

Antigen present in specimen V-10: Influenza A.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	51	1	50
Quidel QuickVue Influenza	46	1	45

Antigen present in specimen V-6: RSV.

Specimen V-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	51	51	-
Quidel QuickVue Influenza	46	46	-

Antigen present in specimen V-7: Influenza B.

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	15	-
Quidel QuickVue Influenza	15	15	-

Antigen present in specimen V-8: Influenza A.

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	-	15
Quidel QuickVue Influenza	15	-	15

Antigen present in specimen V-9: No antigen present.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	15	-
Quidel QuickVue Influenza	15	15	-

Antigen present in specimen V-10: Influenza A.

INFLUENZA A ANTIGEN DETECTION

Specimen V-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	268	1	267
BD Directigen	1	-	1
BD Veritor - waived	10	-	10
Binax NOW - waived	135	-	135
Genzyme OSOM	1	-	1
Genzyme OSOM Influenza A&B	59	-	59
Other Waived Method	1	-	1
Quidel QuickVue Influenza A+B	35	1	34
Quidel Sofia - waived	7	-	7
Remel Xpect	4	-	4

Antigen present in specimen V-6: RSV.

Specimen V-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	267	2	265
BD Directigen	1	-	1
BD Veritor - waived	10	-	10
Binax NOW - waived	134	2	132
Genzyme OSOM	1	-	1
Genzyme OSOM Influenza A&B	59	-	59
Other Waived Method	1	-	1
Quidel QuickVue Influenza A+B	35	-	35
Quidel Sofia - waived	7	-	7
Remel Xpect	4	-	4

Antigen present in specimen V-7: Influenza B.

INFLUENZA A ANTIGEN DETECTION

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	87	86	1
BD Directigen	1	1	-
Binax NOW - waived	20	20	-
Genzyme OSOM	1	1	-
Genzyme OSOM Influenza A&B	53	52	1
Quidel QuickVue Influenza A+B	4	4	-
Quidel Sofia - waived	4	4	-
Remel Xpect	3	3	-

Antigen present in specimen V-8: Influenza A.

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	87	-	87
BD Directigen	1	-	1
Binax NOW - waived	20	-	20
Genzyme OSOM	1	-	1
Genzyme OSOM Influenza A&B	53	-	53
Quidel QuickVue Influenza A+B	4	-	4
Quidel Sofia - waived	4	-	4
Remel Xpect	3	-	3

Antigen present in specimen V-9: No antigen present.

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	87	86	1
BD Directigen	1	1	-
Binax NOW - waived	20	20	-
Genzyme OSOM	1	1	-
Genzyme OSOM Influenza A&B	53	52	1
Quidel QuickVue Influenza A+B	4	4	-
Quidel Sofia - waived	4	4	-
Remel Xpect	3	3	-

Antigen present in specimen V-10: Influenza A.

INFLUENZA B ANTIGEN DETECTION

Specimen V-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	268	1	267
BD Directigen	1	-	1
BD Veritor - waived	9	-	9
Binax NOW - waived	130	1	129
Genzyme OSOM	1	-	1
Genzyme OSOM Influenza A&B	59	-	59
Other Waived Method	2	-	2
Quidel QuickVue Influenza A+B	36	-	36
Quidel Sofia - waived	7	-	7
Remel Xpect	4	-	4

Antigen present in specimen V-6: RSV.

Specimen V-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	268	263	5
BD Directigen	1	1	-
BD Veritor - waived	9	9	-
Binax NOW - waived	130	128	2
Genzyme OSOM	1	1	-
Genzyme OSOM Influenza A&B	59	56	3
Other Waived Method	2	2	-
Quidel QuickVue Influenza A+B	36	36	-
Quidel Sofia - waived	7	7	-
Remel Xpect	4	4	-

Antigen present in specimen V-7: Influenza B.

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	87	-	87
BD Directigen	1	-	1
Binax NOW - waived	19	-	19
Genzyme OSOM	1	-	1
Genzyme OSOM Influenza A&B	52	-	52
Quidel QuickVue Influenza A+B	5	-	5
Quidel Sofia - waived	4	-	4
Remel Xpect	3	-	3

Antigen present in specimen V-8: Influenza A.

INFLUENZA B ANTIGEN DETECTION

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	87	-	87
BD Directigen	1	-	1
Binax NOW - waived	19	-	19
Genzyme OSOM	1	-	1
Genzyme OSOM Influenza A&B	52	-	52
Quidel QuickVue Influenza A+B	5	-	5
Quidel Sofia - waived	4	-	4
Remel Xpect	3	-	3

Antigen present in specimen V-9: No antigen present.

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	87	-	87
BD Directigen	1	-	1
Binax NOW - waived	19	-	19
Genzyme OSOM	1	-	1
Genzyme OSOM Influenza A&B	52	-	52
Quidel QuickVue Influenza A+B	5	-	5
Quidel Sofia - waived	4	-	4
Remel Xpect	3	-	3

Antigen present in specimen V-10: Influenza A.

LEGIONELLA ANTIGEN DETETION

Specimen L-6

Method	***Labs***	***Positive***	***Negative***
Binax NOW	33	33	-

Specimen L-6: Positive for Legionella antigen.

Specimen L-7

Method	***Labs***	***Positive***	***Negative***
Binax NOW	33	-	33

Specimen L-7: Negative for Legionella antigen.

Specimen L-8

Method	***Labs***	***Positive***	***Negative***
Binax NOW	33	33	-

Specimen L-8: Positive for Legionella antigen.

Specimen L-9

Method	***Labs***	***Positive***	***Negative***
Binax NOW	33	-	33

Specimen L-9: Negative for Legionella antigen.

Specimen L-10

Method	***Labs***	***Positive***	***Negative***
Binax NOW	33	33	-

Specimen L-10: Negative for Legionella antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	12	12	-
Meridian ImmunoCard	2	2	-
Remel Xpect	1	1	-
Wampole C. diff Quik Chek	6	6	-

Antigen present in specimen AG-6: *Clostridium difficile*.

Specimen AG-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	12	12	-
Meridian ImmunoCard	2	2	-
Remel Xpect	1	1	-
Wampole C. diff Quik Chek	6	6	-

Antigen present in specimen AG-7: *Clostridium difficile*.

Specimen AG-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	12	-	12
Meridian ImmunoCard	2	-	2
Remel Xpect	1	-	1
Wampole C. diff Quik Chek	6	-	6

Antigen present in specimen AG-:8 Rotavirus.

Specimen AG-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	12	-	12
Meridian ImmunoCard	2	-	2
Remel Xpect	1	-	1
Wampole C. diff Quik Chek	6	-	6

Antigen present in specimen AG-9: No antigen present.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	12	-	12
Meridian ImmunoCard	2	-	2
Remel Xpect	1	-	1
Wampole C. diff Quik Chek	6	-	6

Antigen present in specimen AG-10: Rotavirus.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	-	6
bioMerieux Vidas, Mini Vidas	1	-	1
Fisher HealthCare Sure-Vue	1	-	1
Meridian ImmunoCard	4	-	4

Specimen AG-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	-	6
bioMerieux Vidas, Mini Vidas	1	-	1
Fisher HealthCare Sure-Vue	1	-	1
Meridian ImmunoCard	4	-	4

Specimen AG-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	6	-
bioMerieux Vidas, Mini Vidas	1	1	-
Fisher HealthCare Sure-Vue	1	1	-
Meridian ImmunoCard	4	4	-

Specimen AG-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	-	6
bioMerieux Vidas, Mini Vidas	1	-	1
Fisher HealthCare Sure-Vue	1	-	1
Meridian ImmunoCard	4	-	4

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	6	-
bioMerieux Vidas, Mini Vidas	1	1	-
Fisher HealthCare Sure-Vue	1	1	-
Meridian ImmunoCard	4	4	-

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-6

Method	***Labs***	***Positive***	***Negative***
Binax NOW	29	-	29

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

Specimen SP-7

Method	***Labs***	***Positive***	***Negative***
Binax NOW	29	28	1

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

Specimen SP-8

Method	***Labs***	***Positive***	***Negative***
Binax NOW	29	29	-

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

Specimen SP-9

Method	***Labs***	***Positive***	***Negative***
Binax NOW	29	-	29

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

Specimen SP-10

Method	***Labs***	***Positive***	***Negative***
Binax NOW	29	-	29

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

PARASITOLOGY

Specimen PA-6

Identification	***Labs***	***Percent***	***Performance***
Entamoeba histolytica	2	33.33%	Ungraded
Entamoeba hartmanni	1	33.33%	

Parasite present in specimen PA-6: *Entermoeba histolytica.* This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-7

Identification	***Labs***	***Percent***	***Performance***
Endolimax nana	2	100%	Acceptable

Parasite present in specimen PA-7: *Endolimax nana*

Specimen PA-8

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

Parasite present in specimen PA-8: No parasite present.

Specimen PA-9

Identification	***Labs***	***Percent***	***Performance***
Diphyllobothrium latum	1	100%	Acceptable

Parasite present in specimen PA-9: *Diphyllobothrium latum.*

Specimen PA-10

Identification	***Labs***	***Percent***	***Performance***
Schistosoma haematobium egg	1	100%	Acceptable

Parasite present in specimen PA-10: *Schistosoma haematobium.*

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