MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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Microbiology
MLE-M3

ACP | Medical Laboratory Evaluation

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

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

THROAT CULTURE

Specimen TC-11

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	73	46.50%	Acceptable
Presump. Pos. Group A Strep	60	38.22%	Acceptable
Streptococcus pyogenes	15	9.55%	Acceptable
Neisseria sp.	3	1.91%	Acceptable
Neisseria sicca	1	0.64%	Acceptable
Negative for Group A Strep	5	3.18%	

Organisms present in specimen TC-11: *Streptococcus pyogenes* and *Neisseria sicca.*

Specimen TC-12

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	130	94.20%	Acceptable
No growth (sterile)	6	4.35%	Acceptable

Organisms present in specimen TC-12: *Haemophilus influenzae* and *Neisseria mucosa*.

Specimen TC-13

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	87	95.60%	Acceptable

Organism present in specimen TC-13: *Streptococcus pneumoniae.*

Specimen TC-14

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	41	53.25%	Acceptable
Presump. Pos. Group A Strep	35	45.45%	Acceptable

Organism present in specimen TC-14: *Streptococcus pyogenes*.

Specimen TC-15

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	75	97.40%	Acceptable

Organisms present in specimen TC-15: *Neisseria mucosa* and *Corynebacterium* species.

STREP A ANTIGEN DETECTION

Specimen RS-11

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	548	542	6
Abbott Signify Strep A-waived	3	3	-
BD Chek Strep A	4	4	-
BD Veritor - waived	1	1	-
Beckman Coulter ICON DS	3	3	-
Beckman Coulter ICON SC	3	3	-
Binax NOW Strep A	6	6	-
Cardinal Health Strep A - moderate	1	1	-
Cardinal Health Strep A - waived	16	16	-
Consult Diagnostic Strep A - Moderate	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	65	64	1
Fisher HealthCare Sure-Vue - waived	3	3	-
Henry Schein One Step+ - waived	40	40	-
Immunostics Detector Strep A Direct	8	8	-
Inverness Acceava Strep A Test	13	13	-
Inverness Signify Strep A Dipstick	1	1	-
McKesson Strep A Dipstick	34	33	1
Other Moderately Complex Method	2	2	-
Other Waived Method	11	11	-
Polymedco Poly Stat Strep A - moderate	1	1	-
Polymedco Poly Stat Strep A - waived	9	9	-
PSS Select Diag. Strep A Dipstick - waived	4	4	-
Quidel QuickVue Dipstick Strep	88	87	1
Quidel QuickVue In-Line	60	59	1
Quidel QuickVue+	30	29	1
Quidel Sofia - moderate	4	4	-
Sekisui OSOM	85	85	-
Sekisui OSOM Ultra Strep A	48	48	-

STREP A ANTIGEN DETECTION

Specimen RS-12

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	540	6	534
Abbott Signify Strep A-waived	3	-	3
BD Chek Strep A	4	-	4
BD Veritor - waived	1	-	1
Beckman Coulter ICON DS	3	-	3
Beckman Coulter ICON SC	3	-	3
Binax NOW Strep A	6	-	6
Cardinal Health Strep A - moderate	1	-	1
Cardinal Health Strep A - waived	16	-	16
Consult Diagnostic Strep A - Moderate	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	64	-	64
Fisher HealthCare Sure-Vue - waived	3	1	2
Henry Schein One Step+ - waived	40	-	40
Immunostics Detector Strep A Direct	8	-	8
Inverness Acceava Strep A Test	13	-	13
Inverness Signify Strep A Dipstick	1	-	1
McKesson Strep A Dipstick	33	1	32
Other Moderately Complex Method	2	-	2
Other Waived Method	10	-	10
Polymedco Poly Stat Strep A - moderate	1	-	1
Polymedco Poly Stat Strep A - waived	9	-	9
PSS Select Diag. Strep A Dipstick - waived	4	-	4
Quidel QuickVue Dipstick Strep	87	2	85
Quidel QuickVue In-Line	59	-	59
Quidel QuickVue+	27	1	26
Quidel Sofia - moderate	4	-	4
Sekisui OSOM	85	-	85
Sekisui OSOM Ultra Strep A	48	-	48

STREP A ANTIGEN DETECTION

Specimen RS-13

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	104	2	102
BD Chek Strep A	2	-	2
BD Veritor – waived	1	-	1
Beckman Coulter ICON DS	2	-	2
Binax NOW Strep A	1	-	1
Cardinal Health Strep A - waived	2	-	2
Consult Diagnostic Strep A Dipstick - Waived	6	-	6
Henry Schein One Step+ - waived	6	-	6
Inverness Acceava Strep A Test	2	-	2
McKesson Strep A Dipstick	9	1	8
Other Moderately Complex Method	1	-	1
Other Waived Method	2	-	2
Polymedco Poly Stat Strep A - moderate	1	-	1
Polymedco Poly Stat Strep A - waived	1	-	1
PSS Select Diag. Strep A Dipstick - waived	1	-	1
Quidel QuickVue Dipstick Strep	12	-	12
Quidel QuickVue In-Line	21	1	20
Quidel QuickVue+	17	-	17
Quidel Sofia - moderate	2	-	2
Sekisui OSOM	5	-	5
Sekisui OSOM Ultra Strep A	10	-	10

STREP A ANTIGEN DETECTION

Specimen RS-14

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	88	86	2
BD Chek Strep A	1	1	-
BD Veritor - waived	1	1	-
Beckman Coulter ICON DS	2	2	-
Binax NOW Strep A	1	1	-
Cardinal Health Strep A - waived	2	2	-
Consult Diagnostic Strep A Dipstick - Waived	6	6	-
Henry Schein One Step+ - waived	5	4	1
Inverness Acceava Strep A Test	2	2	-
McKesson Strep A Dipstick	8	8	-
Other Moderately Complex Method	1	1	-
Other Waived Method	2	1	1
PSS Select Diag. Strep A Dipstick - waived	1	1	-
Quidel QuickVue Dipstick Strep	11	11	-
Quidel QuickVue In-Line	20	20	-
Quidel QuickVue+	14	14	-
Quidel Sofia - moderate	2	2	-
Sekisui OSOM	3	3	-
Sekisui OSOM Ultra Strep A	6	6	-

Specimen RS-15

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	88	1	87
BD Chek Strep A	1	-	1
BD Veritor - waived	1	-	1
Beckman Coulter ICON DS	2	-	2
Binax NOW Strep A	1	-	1
Cardinal Health Strep A - waived	2	-	2
Consult Diagnostic Strep A Dipstick - Waived	6	-	6
Henry Schein One Step+ - waived	5	1	4
Inverness Acceava Strep A Test	2	-	2
McKesson Strep A Dipstick	8	-	8
Other Moderately Complex Method	1	-	1
Other Waived Method	2	-	2
PSS Select Diag. Strep A Dipstick - waived	1	-	1
Quidel QuickVue Dipstick Strep	11	-	11
Quidel QuickVue In-Line	20	-	20
Quidel QuickVue+	14	-	14
Quidel Sofia - moderate	2	-	2
Sekisui OSOM	3	-	3
Sekisui OSOM Ultra Strep A	6	-	6

GENERAL BACTERIOLOGY

Specimen BA-7 – Blood Culture

Identification	***Labs***	***Percent***	***Performance***
Enterococcus sp.	8	57.14%	Acceptable
Enterococcus (Strep) faecuim	5	35.71%	Acceptable

Organism present in specimen BA-7: *Enterococcus (Strep) faecium.*

Specimen BA-8 – Stool Culture

Identification	***Labs***	***Percent***	***Performance***
Escherichia coli	12	48.09%	Acceptable
Salmonella sp.	9	36.00%	Acceptable
Salmonella Group D	2	8.00%	Acceptable
Growth, referred for identification	1	4.00%	Acceptable

Organisms present in specimen BA-8: *Escherichia coli* and *Salmonella* Group D.

Specimen BA-9 – Wound Culture

Identification	***Labs***	***Percent***	***Performance***
Staphylococcus aureus	14	53.85%	Acceptable
Staph – coagulase negative	9	34.62%	Acceptable
Staphylococcus epidermidis	2	7.69%	Acceptable
Staphylococcus sp.	1	3.85%	Acceptable

Organisms present in specimen BA-9: *Staphylococcus aureus* and *Staphylococcus epidermidis.*

METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS SCREEN

Specimen MSA-11

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

Organisms present in specimen MSA-11: *Streptococcus pneumonia* and *Streptococcus viridans.*

Specimen MSA-12

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

Organisms present in specimen MSA-12: *Staphylococcus aureus* – Methicillin resistant and *Neisseria sicca.*

Specimen MSA-13

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

Organisms present in specimen MSA-13: *Staphylococcus aureus* – Methicillin resistant and *Staphylococcus epidermidis.*

Specimen MSA-14

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

Organisms present in specimen MSA-14: *Staphylococcus aureus* – Methicillin resistant and *Streptococcus viridans.*

Specimen MSA-15

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

Organisms present in specimen MSA-15: *Staphylococcus aureus* and *Corynebacterium* species.

URINE CULTURE

Specimen UC-11

Identification	***Labs***	***Percent***	***Performance***
Escherichia coli	43	59.72%	Acceptable
Growth, referred for identification	12	16.67%	Acceptable
Gram negative bacilli	8	11.11%	Acceptable
Presump. Escherichia coli	5	6.94%	Acceptable
Presump Gram negative	3	4.17%	Acceptable

Gram Stain

Gram negative	44	100%	Acceptable

Gram Stain Morphology

Rods/bacilli	43	100%	Acceptable

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

Specimen UC-12

Identification	***Labs***	***Percent***	***Performance***
Staphylococcus aureus	27	46.55%	Acceptable
Growth, referred for identification	16	27.59%	Acceptable
Gram positive cocci	9	15.52%	Acceptable
Presump. Staphylococcus sp.	3	5.17%	Acceptable
Presump. Gram positive	2	3.45%	Acceptable

Organisms present in specimen UC-12: *Staphylococcus aureus* and *Corynebacterium* species.

Specimen UC-13

Identification	***Labs***	***Percent***	***Performance***
Citrobacter freundii	12	33.33%	Acceptable
Growth, referred for identification	11	30.56%	Acceptable
Gram negative bacilli	5	13.89%	Acceptable
Citrobacter sp.	4	11.11%	Acceptable
Presump. Gram negative	2	5.56%	Acceptable

Organism present in specimen UC-13: *Citrobacter freundii.*

URINE CULTURE

Specimen UC-14

Identification	***Labs***	***Percent***	***Performance***
Staphylococcus saprophticus	6	40.00%	Acceptable
Growth, referred for identification	5	33.33%	Acceptable
Presump. Gram positive	1	6.67%	Acceptable
Presump. Staphylococcus sp.	1	6.67%	Acceptable
Gram positive cocci	1	6.67%	Acceptable
Staph – coagulase negative	1	6.67%	Acceptable

Organism present in specimen UC-14: *Staphylococcus saprophyticus*.

Specimen UC-15

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	4	26.67%	Acceptable
Enterococcus sp.	4	26.67%	Acceptable
Enterococcus (Strep) faecalis	3	20.00%	Acceptable
Gram positive cocci	1	6.67%	Acceptable
Presump. Gram positive	1	6.67%	Acceptable
Presump. Enterococcus sp.	1	6.67%	Acceptable

Organisms present in specimen UC-15: *Enterococcus (Strep) faecalis* and *Lactobacillus* species.

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen UC-11, CC-11 (SUS-11) The organism present is: *Escherichia coli.*

	------Disk Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Amikacin	-	-	-	-	3	3	-	-	100.00%
Amoxicillin/Clavulanate	12	11	1	-	6	6	-	-	96.55%
Ampicillin	32	-	-	32	11	-	-	11	100.00%
Ampicillin/Sulbactam	-	-	-	-	5	-	2	3	100.00%
Aztreonam	-	-	-	-	2	2	-	-	Not graded[1]
Carbenicillin	1	-	-	1	-	-	-	-	Inappropriate drug[2]
Cefamandole	1	1	-	-	-	-	-	-	Not graded[1]
Cefazolin	10	10	-	-	9	9	-	-	100.00%
Cefepime	-	-	-	-	4	4	-	-	100.00%
Cefixime	5	5	-	-	-	-	-	-	100.00%
Cefotaxime	-	-	-	-	2	2	-	-	Not graded[1]
Cefoxitin	1	1	-	-	4	4	-	-	100.00%
Cefpodoxime	1	1	-	-	-	-	-	-	Not graded[1]
Ceftazidime	2	2	-	-	5	5	-	-	100.00%
Ceftriaxone	8	8	-	-	7	7	-	-	100.00%
Cefuroxime	7	6	1	-	4	4	-	-	89.47%
Cephalothin	26	20	5	1	3	3	-	-	83.78%
Ciprofloxacin	34	34	-	-	10	10	-	-	100.00%
Doxycycline	2	2	-	-	-	-	-	-	Not graded[1]
Ertapenem	-	-	-	-	4	4	-	-	100.00%
Fosfomycin	3	3	-	-	-	-	-	-	Not graded[1]
Gentamicin	24	24	-	-	7	7	-	-	100.00%
Imipenem	-	-	-	-	5	5	-	-	100.00%
Levofloxacin	10	10	-	-	9	9	-	-	100.00%
Meropenem	-	-	-	-	1	1	-	-	Not graded[1]
Nalidixic Acid	2	2	-	-	-	-	-	-	Not graded[1]
Nitrofurantoin	34	34	-	-	11	11	-	-	100.00%
Norfloxacin	5	5	-	-	-	-	-	-	100.00%
Piperacillin/Tazobactam	1	1	-	-	5	5	-	-	100.00%
Sulfisoxazole	6	6	-	-	-	-	-	-	100.00%
Tetracycline	17	17	-	-	2	2	-	-	100.00%
Ticarcillin/Clavulanate	-	-	-	-	1	1	-	-	Not graded[1]
Tobramycin	3	3	-	-	8	8	-	-	100.00%
Trimethoprim	4	4	-	-	2	2	-	-	100.00%
Trimethoprim/Sulfamethoxazole	35	35	-	-	10	10	-	-	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-11

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhea	20	46.51%	Acceptable
Neisseria gonorrhoeae	17	39.53%	Acceptable
Growth, referred for identification	4	9.30%	Acceptable
Gram negative diplococci	1	2.33%	Acceptable
Gram Stain			
Gram negative	33	100%	Acceptable
Gram Stain Morphology			
Diplococci	32	94.12%	Acceptable

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

Specimen GC-12

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	12	80.00%	Acceptable
Gram positive cocci	2	13.33%	Acceptable
Growth, referred for identification	1	6.67%	Acceptable

Organisms present in specimen GC-12: *Enterococcus faecalis* and *Corynebacterium* species.

Specimen GC-13

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	13	92.86%	Acceptable

Organisms present in specimen GC-13: *Escherichia coli* and *Staphylococcus epidermidis.*

GENITAL CULTURE

Specimen GC-14

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	13	92.86%	Acceptable
No growth (sterile)	1	7.14%	Acceptable

Organism present in specimen GC-14: *Streptococcus agalactiae.*

Specimen GC-15

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhoeae	10	66.67%	Acceptable
Neisseria gonorrhoeae	3	20.00%	Acceptable
Gram negative diplococci	1	6.67%	Acceptable

Organisms present in specimen GC-15: *Neisseria gonorrhoeae* and *Lactobacillus casei.*

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-11

Method	***Labs***	***No growth***	***<10,000 organisms/mL***	***10,000-100,000 organisms/mL***	***>100,000 organisms/mL***
ALL METHODS	81	3	38	36	4
Bulls Eye	3	-	-	2	1
Calibrated Loop	24	1	9	13	1
HealthLink	2	-	-	2	-
Troy Bacti-Urine, Plate	1	-	-	1	-
Uri-Check	8	1	4	3	-
Uri-Kit	1	-	-	1	-
Uricult	36	-	23	11	2

Colony Count for CC-11 was graded to 80% referee consensus.

Identification–Specimen CC-11

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram negative	7	35%	Acceptable
Presump. Escherichia coli	5	25%	Acceptable
Growth, referred for identification	5	25%	Acceptable
Escherichia coli	2	10%	Acceptable
Gram Stain			
Gram negative	5	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	5	100%	Acceptable

Organism present in specimen CC-11: 72,000 CFU/mL of *Escherichia coli.*

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-12

Method	***Labs***	***No growth***	***<10,000 organisms/mL***	***10,000-100,000 organisms/mL***	***>100,000 organisms/mL***
ALL METHODS	81	1	-	7	73
Bulls Eye	3	-	-	-	3
Calibrated Loop	24	-	-	-	24
HealthLink	2	-	-	-	2
Troy Bacti-Urine, Plate	1	-	-	-	1
Uri-Check	8	-	-	-	8
Uri-Kit	1	-	-	-	1
Uricult	36	1	-	6	29

Identification–Specimen CC-12

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	8	40%	Acceptable
Presump. Gram positive	8	40%	Acceptable
Presump. Staphylococcus sp.	2	10%	Acceptable
Staphylococcus aureus	2	10%	Acceptable

Organisms present in specimen CC-12: >100,000 CFU/mL of *Staphylococcus aureus* and 1,200 CFU/mL of *Corynebacterium* species.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-13

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram negative	10	58.82%	Acceptable
Growth, referred for identification	4	23.53%	Acceptable
Citrobacter freundii	1	5.88%	Acceptable
Citrobacter sp.	1	5.88%	Acceptable

Organism present in specimen CC-13: 75,000 CFU/mL of *Citrobacter freundii*.

Identification–Specimen CC-14

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	7	41.18%	Acceptable
Presump. Gram positive	7	41.18%	Acceptable
Presump. Staphylococcus sp.	2	11.76%	Acceptable
Staphylococcus saprophyticus	1	5.88%	Acceptable

Organism present in specimen CC-14: >100,000 CFU/mL of *Staphylococcus saprophyticus.*

Identification–Specimen CC-15

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram positive	8	47.06%	Acceptable
Growth, referred for identification	5	29.41%	Acceptable
Presump. Enterococcus sp.	3	17.65%	Acceptable
Enterococcus (Strep) faecalis	1	5.88%	Acceptable

Organisms present in specimen CC-15: >100,000 CFU/mL of *Enterococcus (Strep) faecalis* and 10,000 CFU/mL *Lactobacillus* species.

DERMATOPHYTE SCREEN

Specimen DM-5

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte present	17	100%	Acceptable

Organism present in specimen DM-5: *Trichophyton tonsuraus*.

Specimen DM-6

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte present	10	58.82%	Acceptable
Dermatophyte absent	7	41.18%	

Organism present in specimen DM-6: *Microsporum canis.*

Specimen DM-6 was graded by 80% referee consensus.

GRAM STAIN

Specimen GS-11

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	19	95%	Acceptable
Gram positive	1	5%	

Gram Stain Morphology

Rods/bacilli	18	94.74%	Acceptable
Coccobacilli	1	5.26%	

Organism present in specimen GS-11: *Pseudomonae aeruginosa.*

Specimen GS-12

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	17	85%	Acceptable
Gram negative	3	15%	

Gram Stain Morphology

Cocci	16	84.21%	Acceptable
Coccobacilli	1	5.26%	
Diplococci	1	5.26%	
Rods/bacilli	1	5.26%	

Organism present in specimen GS-12: *Streptococcus agalactiae.*

GRAM STAIN

Specimen GS-13

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	18	90%	Acceptable
Gram positive	2	10%	

Gram Stain Morphology

Rods/bacilli	16	84.21%	Acceptable
Diplococci	2	10.53%	
Rods/bacilli	1	5.26%	

Organism present in specimen GS-13: *Proteus vulgaris.*

Specimen GS-14

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	17	89.47%	Acceptable
Gram negative	2	10.53%	

Gram Stain Morphology

Cocci	16	88.89%	Acceptable
Diplococci	1	5.56%	
Rods/bacilli	1	5.56%	

Organism present in specimen GS-14: *Staphlylococcus aureus.*

Specimen GS-15

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	18	90%	Acceptable
Gram positive	2	10%	

Gram Stain Morphology

Rods/bacilli	18	94.74%	Acceptable
Coccobacilli	1	5.26%	

Organism present in specimen GS-15: *Klebsiella pneumoniae.*

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-11

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

Organism present in specimen VP-11: *Trichomonas vaginalis*.

Specimen VP-12

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

Organism present in specimen VP-12: *Candida albicans.*

Specimen VP-13

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

Organisms present in specimen VP-13: *Gardnerella vaginalis* and *Candida albicans*.

Specimen VP-14

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

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

Specimen VP-15

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

Organism present in specimen VP-15: *Gardnerella vaginalis.*

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-11

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

Specimen VP-12

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

Specimen VP-13

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

Specimen VP-14

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

Specimen VP-15

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

AFFIRM VP III–Candida sp.

Specimen VP-11

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

Specimen VP-12

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

AFFIRM VP III–Candida sp.

Specimen VP-13

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

Specimen VP-14

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

Specimen VP-15

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

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-11

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	17	17	-
BD ProbeTec	6	6	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	7	7	-
Roche COBAS Amplicor	1	1	-
Wampole Clearview	2	2	-

Organism present in specimen CY-11: *Chlamydia trachomatis.*

Specimen CY-12

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	17	2	15
BD ProbeTec	6	1	5
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	7	-	7
Roche COBAS Amplicor	1	-	1
Wampole Clearview	2	1	1

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

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-13

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	15	-
BD ProbeTec	6	6	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	5	5	-
Roche COBAS Amplicor	1	1	-
Wampole Clearview	2	2	-

Organisms present in specimen CY-13: *Chlamydia trachomatis* and *Neisseria gonorrhea.*

Specimen CY-14

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	15	-
BD ProbeTec	6	6	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	5	5	-
Roche COBAS Amplicor	1	1	-
Wampole Clearview	2	2	-

Organism present in specimen CY-14: *Chlamydia trachomatis.*

Specimen CY-15

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	-	15
BD ProbeTec	6	-	6
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	5	-	5
Roche COBAS Amplicor	1	-	1
Wampole Clearview	2	-	2

Organism present in specimen CY-15: *Neisseria gonorrhea*.

GC (ANTIGEN DETECTION)

Specimen CY-11

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

Specimen CY-12

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	8	7	1
BD ProbeTec	6	5	1
Gen-Probe APTIMA	1	1	-
Roche COBAS Amplicor	1	1	-

Specimen CY-13

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	8	7	1
BD ProbeTec	6	5	1
Gen-Probe APTIMA	1	1	-
Roche COBAS Amplicor	1	1	-

Specimen CY-14

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

Specimen CY-15

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

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-11

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	1	-
Alere Giardia/Crypto Quik Chek	1	1	-

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

Specimen LC-12

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	-	1
Alere Giardia/Crypto Quik Chek	1	-	1

Antigen present in specimen LC-12: No antigens present.

Specimen LC-13

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	1	-
Alere Giardia/Crypto Quik Chek	1	1	-

Antigens present in specimen LC-13: *Cryptosporidium* and *Giardia lamblia.*

Specimen LC-14

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	-	1
Alere Giardia/Crypto Quik Chek	1	-	1

Antigen present in specimen LC-14: *Giardia lamblia*.

Specimen LC-15

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	1	-
Alere Giardia/Crypto Quik Chek	1	1	-

Antigen present in specimen LC-15: *Cryptosporidium.*

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-11

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	1	-	1
Alere Giardia/Crypto Quik Chek	1	-	1

Specimen LC-12

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	1	-	1
Alere Giardia/Crypto Quik Chek	1	-	1

Specimen LC-13

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	1	1	-
Alere Giardia/Crypto Quik Chek	1	1	-

Specimen LC-14

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	1	1	-
Alere Giardia/Crypto Quik Chek	1	1	-

Specimen LC-15

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	1	-	1
Alere Giardia/Crypto Quik Chek	1	-	1

RSV ANTIGEN DETECTION

Specimen V-11

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	69	-	69
Alere Clearview RSV - waived	7	-	7
Binax NOW - waived	45	-	45
Quidel QuickVue RSV - waived	7	-	7
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia - waived	6	-	6
Remel Xpect - waived	3	-	3

Antigen present in specimen V-11: Influenza A.

Specimen V-12

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	68	67	1
Alere Clearview RSV - waived	7	6	1
Binax NOW - waived	44	44	-
Quidel QuickVue RSV - waived	7	7	-
Quidel QuickVue RSV 10 Test	1	1	-
Quidel Sofia - waived	6	6	-
Remel Xpect - waived	3	3	-

Antigen present in specimen V-12: RSV.

Specimen V-13

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	16	-	16
Binax NOW - waived	8	-	8
Quidel QuickVue RSV - waived	2	-	2
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia - waived	3	-	3
Remel Xpect - waived	2	-	2

Antigen present in specimen V-13: No antigens present.

Specimen V-14

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	16	-	16
Binax NOW - waived	8	-	8
Quidel QuickVue RSV - waived	2	-	2
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia - waived	3	-	3
Remel Xpect - waived	2	-	2

Antigen present in specimen V-14: Influenza A.

RSV ANTIGEN DETECTION

Specimen V-15

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	16	-	16
Binax NOW – waived	8	-	8
Quidel QuickVue RSV - waived	2	-	2
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia - waived	3	-	3
Remel Xpect - waived	2	-	2

Antigen present in specimen V-15: Influenza B.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-11

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	40	36	4
Other Waived Method	1	-	1
Quidel QuickVue Influenza	32	31	1

Antigen present in specimen V-11: Influenza A.

Specimen V-12

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	42	-	42
Other Waived Method	1	-	1
Quidel QuickVue Influenza	32	-	32

Antigen present in specimen V-12: RSV.

Specimen V-13

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	11	-	11
Quidel QuickVue Influenza	11	-	11

Antigen present in specimen V-13: No antigens present.

Specimen V-14

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	11	11	-
Quidel QuickVue Influenza	11	11	-

Antigen present in specimen V-14: Influenza A.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-15

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	11	11	-
Quidel QuickVue Influenza	11	11	-

Antigen present in specimen V-15: Influenza B.

INFLUENZA A ANTIGEN DETECTION

Specimen V-11

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	332	329	3
BD Directigen	1	1	-
BD Veritor - waived	30	29	1
Binax NOW - waived	120	119	1
OraSure QuickFlu	2	2	-
Other Moderately Complex Method	1	1	-
Other Waived Method	2	2	-
Quidel QuickVue Influenza A+B	42	42	-
Quidel Sofia - waived	29	29	-
Remel Xpect	3	3	-
Sekisui OSOM Influenza A&B	81	80	1

Antigen present in specimen V-11: Influenza A.

Specimen V-12

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	330	1	329
BD Directigen	1	-	1
BD Veritor - waived	30	-	30
Binax NOW - waived	118	1	117
OraSure QuickFlu	2	-	2
Other Moderately Complex Method	1	-	1
Other Waived Method	2	-	2
Quidel QuickVue Influenza A+B	42	-	42
Quidel Sofia - waived	30	-	30
Remel Xpect	3	-	3
Sekisui OSOM Influenza A&B	81	-	81

Antigen present in specimen V-12: RSV.

INFLUENZA A ANTIGEN DETECTION

Specimen V-13

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	106	-	106
BD Directigen	1	-	1
BD Veritor - waived	2	-	2
Binax NOW - waived	15	-	15
Quidel QuickVue Influenza A+B	3	-	3
Quidel Sofia - waived	6	-	6
Remel Xpect	2	-	2
Sekisui OSOM Influenza A&B	72	-	72

Antigen present in specimen V-13: No antigens present.

Specimen V-14

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	106	105	1
BD Directigen	1	1	-
BD Veritor - waived	2	2	-
Binax NOW - waived	15	15	-
Quidel QuickVue Influenza A+B	3	3	-
Quidel Sofia - waived	6	6	-
Remel Xpect	2	2	-
Sekisui OSOM Influenza A&B	72	72	-

Antigen present in specimen V-14: Influenza A.

Specimen V-15

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	106	1	105
BD Directigen	1	-	1
BD Veritor - waived	2	-	2
Binax NOW - waived	15	1	14
Quidel QuickVue Influenza A+B	3	-	3
Quidel Sofia - waived	6	-	6
Remel Xpect	2	-	2
Sekisui OSOM Influenza A&B	72	-	72

Antigen present in specimen V-15: Influenza B.

INFLUENZA B ANTIGEN DETECTION

Specimen V-11

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	327	2	325
BD Directigen	1	-	1
BD Veritor - waived	28	-	28
Binax NOW - waived	118	1	117
OraSure QuickFlu	2	-	2
Other Moderately Complex Method	1	-	1
Other Waived Method	3	-	3
Quidel QuickVue Influenza A+B	43	-	43
Quidel Sofia - waived	27	1	26
Remel Xpect	4	-	4
Sekisui OSOM Influenza A&B	78	-	78

Antigen present in specimen V-11: Influenza A.

Specimen V-12

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	331	1	330
BD Directigen	1	-	1
BD Veritor - waived	28	-	28
Binax NOW - waived	120	-	120
OraSure QuickFlu	2	-	2
Other Moderately Complex Method	1	-	1
Other Waived Method	3	1	2
Quidel QuickVue Influenza A+B	43	-	43
Quidel Sofia - waived	28	-	28
Remel Xpect	4	-	4
Sekisui OSOM Influenza A&B	79	-	79

Antigen present in specimen V-12: RSV.

Specimen V-13

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	106	-	106
BD Directigen	1	-	1
BD Veritor - waived	2	-	2
Binax NOW - waived	15	-	15
Quidel QuickVue Influenza A+B	4	-	4
Quidel Sofia - waived	5	-	5
Remel Xpect	3	-	3
Sekisui OSOM Influenza A&B	71	-	71

Antigen present in specimen V-13: No antigens present.

INFLUENZA B ANTIGEN DETECTION

Specimen V-14

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	106	-	106
BD Directigen	1	-	1
BD Veritor - waived	2	-	2
Binax NOW - waived	15	-	15
Quidel QuickVue Influenza A+B	4	-	4
Quidel Sofia - waived	5	-	5
Remel Xpect	3	-	3
Sekisui OSOM Influenza A&B	71	-	71

Antigen present in specimen V-14: Influenza A.

Specimen V-15

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	106	105	1
BD Directigen	1	1	-
BD Veritor - waived	2	2	-
Binax NOW - waived	15	14	1
Quidel QuickVue Influenza A+B	4	4	-
Quidel Sofia - waived	5	5	-
Remel Xpect	3	3	-
Sekisui OSOM Influenza A&B	71	71	-

Antigen present in specimen V-15: Influenza B.

LEGIONELLA ANTIGEN DETETION

Specimen L-11

Method	***Labs***	***Positive***	***Negative***
Binax NOW	28	-	28

Specimen L-11: Negative for Legionella antigen.

Specimen L-12

Method	***Labs***	***Positive***	***Negative***
Binax NOW	28	-	28

Specimen L-12: Negative for Legionella antigen.

Specimen L-13

Method	***Labs***	***Positive***	***Negative***
Binax NOW	28	28	-

Specimen L-13: Positive for Legionella antigen.

Specimen L-14

Method	***Labs***	***Positive***	***Negative***
Binax NOW	28	28	-

Specimen L-14: Positive for Legionella antigen.

Specimen L-15

Method	***Labs***	***Positive***	***Negative***
Binax NOW	28	-	28

Specimen L-15: Negative for Legionella antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-11

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	9	9	-
Alere C. diff Quik Chek	6	6	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-

Antigens present in specimen AG-11: *Clostridium difficile* and Rotavirus.

Specimen AG-12

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	9	-	9
Alere C. diff Quik Chek	6	-	6
Meridian Premier	1	-	1
Remel Xpect	1	-	1

Antigen present in specimen AG-12: No antigens present.

Specimen AG-13

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	9	9	-
Alere C. diff Quik Chek	6	6	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-

Antigen present in specimen AG-13: *Clostridium difficile*.

Specimen AG-14

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	9	-	9
Alere C. diff Quik Chek	6	-	6
Meridian Premier	1	-	1
Remel Xpect	1	-	1

Antigen present in specimen AG-14: Rotavirus.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-15

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	9	9	-
Alere C. diff Quik Chek	6	6	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-

Antigen present in specimen AG-15: *Clostridium difficile.*

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-11

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Fisher HealthCare Sure-Vue	3	3	-
Meridian ImmunoCard	2	2	-

Specimen AG-12

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Fisher HealthCare Sure-Vue	3	-	3
Meridian ImmunoCard	2	-	2

Specimen AG-13

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Fisher HealthCare Sure-Vue	3	-	3
Meridian ImmunoCard	2	-	2

Specimen AG-14

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Fisher HealthCare Sure-Vue	3	3	-
Meridian ImmunoCard	2	2	-

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-15

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Fisher HealthCare Sure-Vue	3	-	3
Meridian ImmunoCard	2	-	2

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-11

Method	***Labs***	***Positive***	***Negative***
Binax NOW	25	25	-

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

Specimen SP-12

Method	***Labs***	***Positive***	***Negative***
Binax NOW	25	-	25

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

Specimen SP-13

Method	***Labs***	***Positive***	***Negative***
Binax NOW	25	25	-

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

Specimen SP-14

Method	***Labs***	***Positive***	***Negative***
Binax NOW	25	-	25

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

Specimen SP-15

Method	***Labs***	***Positive***	***Negative***
Binax NOW	25	25	-

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

PARASITOLOGY

Specimen PA-11

Identification	***Labs***	***Percent***	***Performance***
Giardia lamblia	2	100%	Acceptable

Parasite present in specimen PA-11: *Giardia lamblia.*

Specimen PA-12

Identification	***Labs***	***Percent***	***Performance***
No parasite seen	2	100%	Acceptable

Parasite present in specimen PA-12: No parasite present.

Specimen PA-13

Identification	***Labs***	***Percent***	***Performance***
Hookworm	2	100%	Acceptable

Parasite present in specimen PA-13: *Hookworm*.

Specimen PA-14

Identification	***Labs***	***Percent***	***Performance***
Taenia species eggs	2	100%	Acceptable

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

Specimen PA-15

Identification	***Labs***	***Percent***	***Performance***
Trypanosoma cruzi	1	50%	Ungraded
Trypanosoma brucei	1	50%	

Parasite present in specimen PA-15: *Trypanosoma brucei.*

Specimen PA-15 is an ungraded challenge due to less than 80% participant consensus.

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