MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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Microbiology
MLE-M2

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 Toxin/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-6

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	128	82.58%	Acceptable
Staphylococcus aureus	15	9.68%	Acceptable
Staphylococcus sp.	5	3.23%	Acceptable

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

Specimen TC-7

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	74	53.62%	Acceptable
Presump. Pos. Group A Strep	60	43.48%	Acceptable
Streptococcus pyogenes	2	1.45%	Acceptable

Organism present in specimen TC-7: *Streptococcus pyogenes.*

Specimen TC-8

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	84	96.55%	Acceptable

Organisms present in specimen TC-8: *Moraxella catarrhalis* and *Staphylococcus epidermidis.*

Specimen TC-9

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	70	97.22%	Acceptable

Organism present in specimen TC-9: *Neisseria mucosa*.

Specimen TC-10

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	36	50.00%	Acceptable
Presump. Pos. Group A Strep	34	47.22%	Acceptable

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

STREP A ANTIGEN DETECTION

Specimen RS-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	531	526	5
Abbott Signify Strep A-waived	3	3	-
Alere Acceava Strep A Test	12	12	-
Alere Signify Strep A Dipstick	1	1	-
BD Chek Strep A	3	3	-
BD Veritor - waived	3	3	-
Beckman Coulter ICON DS	2	2	-
Beckman Coulter ICON SC	3	3	-
Binax NOW Strep A	7	7	-
Cardinal Health Strep A - waived	16	15	1
Consult Diagnostic Strep A Dipstick - Waived	80	80	-
Fisher HealthCare Sure-Vue	1	1	-
Fisher HealthCare Sure-Vue - waived	1	1	-
Henry Schein One Step+ - waived	40	40	-
Immunostics Detector Strep A Direct	7	7	-
McKesson Strep A Dipstick	19	19	-
Other Moderately Complex Method	1	1	-
Other Waived Method	13	13	-
Polymedco Poly Stat Strep A - moderate	1	1	-
Polymedco Poly Stat Strep A - waived	8	8	-
PSS Select Diag. Strep A Dipstick - waived	3	3	-
Quidel QuickVue Dipstick Strep	76	74	2
Quidel QuickVue In-Line	66	65	1
Quidel QuickVue+	21	21	-
Quidel Sofia Strep A - moderate	6	6	-
Quidel Sofia Strep A+ - waived	1	1	-
Sekisui OSOM	87	86	1
Sekisui OSOM Ultra Strep A	46	46	-

STREP A ANTIGEN DETECTION

Specimen RS-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	523	5	518
Abbott Signify Strep A-waived	3	-	3
Alere Acceava Strep A Test	12	-	12
Alere Signify Strep A Dipstick	1	-	1
BD Chek Strep A	3	-	3
BD Veritor - waived	2	-	2
Beckman Coulter ICON DS	2	-	2
Beckman Coulter ICON SC	3	-	3
Binax NOW Strep A	7	-	7
Cardinal Health Strep A - waived	16	1	15
Consult Diagnostic Strep A Dipstick - Waived	78	-	78
Fisher HealthCare Sure-Vue	1	-	1
Fisher HealthCare Sure-Vue - waived	1	-	1
Henry Schein One Step+ - waived	40	-	40
Immunostics Detector Strep A Direct	7	-	7
McKesson Strep A Dipstick	19	-	19
Other Moderately Complex Method	1	-	1
Other Waived Method	13	-	13
Polymedco Poly Stat Strep A - moderate	1	-	1
Polymedco Poly Stat Strep A - waived	8	-	8
PSS Select Diag. Strep A Dipstick - waived	3	-	3
Quidel QuickVue Dipstick Strep	75	2	73
Quidel QuickVue In-Line	66	1	65
Quidel QuickVue+	18	-	18
Quidel Sofia Strep A - moderate	6	-	6
Sekisui OSOM	87	1	86
Sekisui OSOM Ultra Strep A	46	-	46

STREP A ANTIGEN DETECTION

Specimen RS-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	105	1	104
Alere Acceava Strep A Test	2	-	2
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 - waived	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	2	-	2
Henry Schein One Step+ - waived	1	-	1
McKesson Strep A Dipstick	6	-	6
Other Waived Method	6	-	6
Polymedco Poly Stat Strep A - moderate	12	-	12
PSS Select Diag. Strep A Dipstick - waived	2	-	2
Quidel QuickVue Dipstick Strep	1	-	1
Quidel QuickVue In-Line	12	-	12
Quidel QuickVue+	23	1	22
Quidel Sofia Strep A - moderate	15	-	15
Sekisui OSOM	4	-	4
Sekisui OSOM Ultra Strep A	3	-	3

STREP A ANTIGEN DETECTION

Specimen RS-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	89	1	88
Alere Acceava Strep A Test	2	-	2
BD Chek Strep A	1	-	1
BD Veritor - waived	1	-	1
Beckman Coulter ICON DS	1	-	1
Binax NOW Strep A	1	-	1
Cardinal Health Strep A - waived	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	13	-	13
Henry Schein One Step+ - waived	6	-	6
McKesson Strep A Dipstick	4	-	4
Other Waived Method	2	-	2
PSS Select Diag. Strep A Dipstick - waived	1	-	1
Quidel QuickVue Dipstick Strep	12	-	12
Quidel QuickVue In-Line	20	1	19
Quidel QuickVue+	10	-	10
Quidel Sofia Strep A - moderate	5	-	5
Sekisui OSOM	2	-	2
Sekisui OSOM Ultra Strep A	7	-	7

Specimen RS-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	90	89	1
Alere Acceava Strep A Test	2	2	-
BD Chek Strep A	1	1	-
BD Veritor - waived	1	1	-
Beckman Coulter ICON DS	1	1	-
Binax NOW Strep A	1	1	-
Cardinal Health Strep A - waived	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	13	13	-
Henry Schein One Step+ - waived	6	6	-
McKesson Strep A Dipstick	4	4	-
Other Waived Method	2	1	1
PSS Select Diag. Strep A Dipstick - waived	1	1	-
Quidel QuickVue Dipstick Strep	12	12	-
Quidel QuickVue In-Line	20	20	-
Quidel QuickVue+	11	11	-
Quidel Sofia Strep A - moderate	5	5	-
Sekisui OSOM	2	2	-
Sekisui OSOM Ultra Strep A	7	7	-

GENERAL BACTERIOLOGY

Specimen BA-4 – Spinal Fluid Culture

Identification	***Labs***	***Percent***	***Performance***
Listeria monocytogenes	12	85.71%	Acceptable

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

Specimen BA-5 – Respiratory Culture

Identification	***Labs***	***Percent***	***Performance***
Haemophilus influenzae	13	48.15%	Acceptable
Corynebacterium species	11	40.74%	Acceptable

Organisms present in specimen BA-5: *Haemophilus influenzae* and *Corynebacterium* species.

Specimen BA-6 – Wound Culture

Identification	***Labs***	***Percent***	***Performance***
Pseudomonas aeruginosa	12	48.00%	Acceptable
Staph – coagulase negative	5	20.00%	Acceptable
Staphylococcus species	4	16.00%	Acceptable
Staphylococcus epidermidis	2	8.00%	Acceptable

Organisms present in specimen BA-6: *Pseudomonas aeruginosa* and *Staphylococcus epidermidis.*

METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS SCREEN

Specimen MSA-6

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

Organisms present in specimen MSA-6 *Staphylococcus aureus* – Methicillin resistant and *Pseudomonas aeruginosa.*

Specimen MSA-7

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

Organism present in specimen MSA-7: *Staphylococcus aureus* – Methicillin resistant.

Specimen MSA-8

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

Organisms present in specimen MSA-8: *Klebsielle pneumoniae* and *Staphylococcus epidermidis.*

Specimen MSA-9

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

Organisms present in specimen MSA-9: *Corynebacterium* species and *Neisseria meningitidis.*

Specimen MSA-10

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

Organisms present in specimen MSA-10: *Staphylococcus aureus* – Methicillin resistant and *Streptococcus pyogenes.*

URINE CULTURE

Specimen UC-6

Identification	***Labs***	***Percent***	***Performance***
Citrobacter freundii	45	60.81%	Acceptable
Growth, referred for identification	12	16.22%	Acceptable
Citrobacter sp.	7	9.46%	Acceptable
Gran negative bacilli	6	8.11%	Acceptable
Presump. Gram negative	4	5.41%	Acceptable
Gram Stain			
Gram negative	48	97.96%	Acceptable
Gram positive	1	2.04%	
Gram Stain Morphology			
Rods/bacilli	50	100%	Acceptable

Organism present in specimen UC-6: *Citrobacter freundii.*

Specimen UC-7

Identification	***Labs***	***Percent***	***Performance***
Enterococcus sp.	29	48.33%	Acceptable
Growth, referred for identification	15	25.00%	Acceptable
Gram positive cocci	7	11.67%	Acceptable
Enterococcus (Strep) faecalis	4	6.67%	Acceptable
Presump. Gram positive	3	5.00%	Acceptable
Presump. Enterococcus sp.	2	3.33%	Acceptable

Organisms present in specimen UC-7: *Enterococcus (Strep) faecalis* and *Lactobacillus* species.

Specimen UC-8

Identification	***Labs***	***Percent***	***Performance***
No growth (sterile)	32	82.05%	Acceptable
Growth, referred for identification	7	17.95%	

Organism present in specimen UC-8: No growth (sterile).

URINE CULTURE

Specimen UC-9

Identification	***Labs***	***Percent***	***Performance***
Klebsiella pneumoniae	8	50.00%	Acceptable
Growth, referred for identification	3	18.75%	Acceptable
Presump. Gram negative	1	6.25%	Acceptable
Gram negative bacilli	1	6.25%	Acceptable
Corynebacterium sp.	1	6.25%	Acceptable
Klebsiella sp.	1	6.25%	Acceptable

Organisms present in specimen UC-9: *Klebsiella pneumoniae* and *Corynebacterium* species.

Specimen UC-10

Identification	***Labs***	***Percent***	***Performance***
Staphylococcus saprophyticus	7	46.67%	Acceptable
Growth, referred for identification	3	20.00%	Acceptable
Presump. Gram	1	6.67%	Acceptable
Gram positive cocci	1	6.67%	Acceptable
Staphylococcus sp.	1	6.67%	Acceptable
Staph = coagulase negative	1	6.67%	Acceptable

Organism present in specimen UC-10: *Staphylococcus saprophyticus.*

ANTIMICROBIAL SUSCEPTIBILIY TESTING

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

	------Disk Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Amikacin	-	-	-	-	4	4	-	-	Not graded[1]
Amoxicillin/Clavulanate	12	1	-	11	7	-	-	7	96.55%
Ampicillin	36	8	1	27	5	1	-	4	76.92%[2]
Ampicillin/Sulbactam	-	-	-	-	2	1	-	1	Not graded[1]
Aztreonam	-	-	-	-	2	2	-	-	Not graded[1]
Carbenicillin	1	1	-	-	-	-	-	-	Inappropriate drug[3]
Cefamandole	1	1	-	-	-	-	-	-	Not graded[1]
Cefazolin	11	-	1	10	9	-	-	9	93.33%
Cefepime	-	-	-	-	6	6	-	-	100.00%
Cefixime	5	5	-	-	-	-	-	-	100.00%
Cefotaxime	-	-	-	-	3	3	-	-	Not graded[1]
Cefoxitin	1	-	-	1	4	-	-	4	100.00%
Cefpodoxime	3	3	-	-	-	-	-	-	Not graded[1]
Ceftazidime	3	3	-	-	5	5	-	-	100.00%
Ceftriaxone	10	10	-	-	7	7	-	-	100.00%
Cefuroxime	7	6	-	1	4	1	-	3	Not graded[4]
Cephalothin	24	-	-	24	5	-	-	5	100.00%
Ciprofloxacin	40	40	-	-	10	10	-	-	100.00%
Doxycycline	2	1	1	-	-	-	-	-	Not graded[1]
Ertapenem	-	-	-	-	6	6	-	-	100.00%
Gentamicin	31	31	-	-	9	9	-	-	100.00%
Imipenem	-	-	-	-	6	6	-	-	100.00%
Levofloxacin	12	12	-	-	9	9	-	-	100.00%
Meropenem	-	-	-	-	3	3	-	-	Not graded[1]
Nalidixic Acid	2	2	-	-	-	-	-	-	Not graded[1]
Nitrofurantoin	40	40	-	-	11	11	-	-	100.00%
Norfloxacin	6	6	-	-	-	-	-	-	100.00%
Piperacillin	-	-	-	-	1	1	-	-	Not graded[1]
Piperacillin/Tazobactam	2	2	-	-	7	7	-	-	100.00%
Sulfisoxazole	5	5	-	-	-	-	-	-	100.00%
Tetracycline	21	21	-	-	2	2	-	-	100.00%
Tobramycin	2	2	-	-	5	5	-	-	100.00%
Trimethoprim	4	4	-	-	2	2	-	-	100.00%
Trimethoprim/Sulfamethoxazole	41	41	-	-	11	11	-	-	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 specimen was graded by 90% referee consensus.
[3] This is an inappropriate drug for organism and/or source.
[4] Ungraded challenge due to less than 80% referee consensus.

GENITAL CULTURE

Specimen GC-6

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhoeae	17	41.46%	Acceptable
Neisseria gonorrhoeae	16	39.02%	Acceptable
Growth, referred for identification	5	12.20%	Acceptable
Gram negative diplococci	3	7.32%	Acceptable
Gram Stain			
Gram negative	31	96.88%	Acceptable
Gram positive	1	3.13%	
Gram Stain Morphology			
Diplococci	32	96.97%	Acceptable
Cocci	1	3.03%	

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

Specimen GC-7

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	11	91.67%	Acceptable

Organisms present in specimen GC-7: *Streptococcus agalactiae* and *Corynebacterium* species.

Specimen GC-8

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhea	8	72.73%	Acceptable
Neisseria gonorrhoeae	2	18.18%	Acceptable

Organisms present in specimen GC-8: *Neisseria gonorrhoeae* and *Lactobacillus* species.

GENITAL CULTURE

Specimen GC-9

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	10	83.33%	Acceptable
Gram positive cocci	1	8.33%	Acceptable
Growth, referred for identification	1	8.33%	Acceptable

Organism present in specimen GC-9: *Staphylococcus aureus.*

Specimen GC-10

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	11	91.67%	Acceptable

Organism present in specimen GC-10: *Escherichia coli.*

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	78	5	21	47	5
Bulls Eye	1	-	-	1	-
Calibrated Loop	26	-	6	19	1
HealthLink	3	-	-	3	-
Troy Bacti-Urine, Plate	1	-	-	1	-
Uri-Check	7	-	2	5	-
Uricult	36	4	12	17	3

This specimen was graded by 87% referee consensus.

Identification–Specimen CC-6

Identification	*Labs*	*Percent*	*Performance*
Presump. Gram negative	11	52.38%	Acceptable
Growth, referred for identification	5	23.81%	Acceptable
Citrobacter freundii	1	4.76%	Acceptable
Gram negative bacilli	1	4.76%	Acceptable

Organism present in specimen CC-6: 10,000 - 100,000 CFU/mL of *Citrobacter freundii.*

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	78	5	2	7	64
Bulls Eye	1	-	-	-	1
Calibrated Loop	26	-	-	2	24
HealthLink	3	-	-	-	3
Troy Bacti-Urine, Plate	1	-	-	-	1
Uri-Check	7	1	-	-	6
Uricult	36	4	2	4	26

Identification–Specimen CC-7

Identification	*Labs*	*Percent*	*Performance*
Presump. Gram positive	10	47.62%	Acceptable
Growth, referred for identification	7	33.33%	Acceptable
Presump. Enterococcus sp.	2	9.52%	Acceptable
Enterococcus (Strep) faecalis	1	4.76%	Acceptable
Gram positive cocci	1	4.76%	Acceptable

Organisms present in specimen CC-7: >100,000 CFU/mL of *Enterococcus (Strep) faecalis* and <10,000 CFU/mL of *Lactobacillus* species.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-8

Identification	***Labs***	***Percent***	***Performance***
No growth (sterile)	16	88.89%	Acceptable

Organism present in specimen CC-8: No growth (sterile).

Identification–Specimen CC-9

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram negative	10	55.56%	Acceptable
Growth, referred for identification	4	22.22%	Acceptable
Presump. Klebsiella sp.	1	5.56%	Acceptable
Klebsiella sp.	1	5.56%	Acceptable
Klebsiella pneumoniae	1	5.56%	Acceptable

Organisms present in specimen CC-9: 10,000 - 100,000 CFU/mL of *Klebsiella pneumoniae* and <10,000 CFU/mL of *Corynebacterium* species.

Identification–Specimen CC-10

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram positive	9	50.00%	Acceptable
Growth, referred for identification	5	27.78%	Acceptable
Presump. Staphylococcus sp.	2	11.11%	Acceptable
Staph – coagulase negative	1	5.56%	Acceptable
Staphylococcus saprophyticus	1	5.56%	Acceptable

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

DERMATOPHYTE SCREEN

Specimen DM-3

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte present	19	100%	Acceptable

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

Specimen DM-4

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte absent	10	52.63%	Acceptable
Dermatophyte present	9	47.37%	

Organism present in specimen DM-4: *Candida albicans*. This specimen was graded by 80% referee consensus. Dermatophytes are absent from this specimen. Dermatophytes are a specific group of fungi that commonly cause infections of the hair, skin and nails. These infections are most often caused by the genera Trichophyton, Microsporum, and Epidermophyton. Presumptive identification of dermatophytes using special media such as Dermatophyte Test Medium (DTM) is based on both gross morphology and color change. Dermatophytes produce typical morphology and a red color change in the medium around the colony within 10-14 days of incubation. Yeasts and other non-dermatophyte fungi may grow on DTM. Candida species appear as small, dull (matte), white or cream color bacteria-like colonies on DTM agars. Some strains of yeast may produce a pink-red color change on DTM with prolonged incubation. Consult your manufacturer's package insert instructions for length of incubation, interpretation of results, and limitations of the test, to determine if the test was performed properly. Call the manufacturer for technical assistance if needed.

Reference:
Hardy Diagnostics Bacti-Lab Skin Culture Systems
https://catalog.hardydiagnostics.com/cp_prod/content/hugo/BactiLabSkinCultureSystems.pdf

GRAM STAIN

Specimen GS-6

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	17	94.44%	Acceptable
Gram negative	1	5.56%	

Gram Stain Morphology

Cocci	12	70.59%	Acceptable
Diplococci	4	23.53%	Acceptable
Coccobacilli	1	5.88%	

Organism present in specimen GS-6: *Streptococcus agalactiae*.

Specimen GS-7

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

Gram Stain Morphology

Rods/bacilli	17	100%	Acceptable

Organism present in specimen GS-7: *Pseudomonas aeruginosa.*

GRAM STAIN

Specimen GS-8

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	18	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	12	70.59%	Acceptable
Coccobacilli	4	23.53%	Acceptable
Diplococci	1	5.88%	

Organism present in specimen GS-8: *Klebsiella pneumoniae.*

Specimen GS-9

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	16	88.89%	Acceptable
Gram positive	2	11.11%	
Gram Stain Morphology			
Diplococci	9	52.94%	Acceptable
Cocci	6	32.59%	Acceptable
Coccibacilli	2	11.76%	

Organism present in specimen GS-9: *Neisseria mucosa.*

Specimen GS-10

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	17	94.44%	Acceptable
Gram negative	1	5.56%	
Gram Stain Morphology			
Cocci	9	52.94%	Acceptable
Diplococci	7	41.18%	Acceptable
Coccobacilli	1	5.88%	

Organism present in specimen GS-10: *Enterococcus faecalis.*

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-6

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

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

Specimen VP-7

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

Organisms present in specimen VP-7: *Candida albicans* and *Gardnerella vaginalis.*

Specimen VP-8

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

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

Specimen VP-9

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

Organism present in specimen VP-9: *Gardnerella vaginalis* and *Trichomonas vaginalis*.

Specimen VP-10

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

Organism present in specimen VP-10: *Candida albicans.*

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-6

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

Specimen VP-7

Identification	***Labs***	***Percent***	***Performance***
Positive	28	96.55%	Acceptable
Negative	1	3.45%	

Specimen VP-8

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

Specimen VP-9

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

Specimen VP-10

Identification	***Labs***	***Percent***	***Performance***
Negative	28	96.55%	Acceptable
Positive	1	3.45%	

AFFIRM VP III–Candida sp.

Specimen VP-6

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

Specimen VP-7

Identification	***Labs***	***Percent***	***Performance***
Positive	28	96.55%	Acceptable
Negative	1	3.45%	

AFFIRM VP III–Candida sp.

Specimen VP-8

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

Specimen VP-9

Identification	***Labs***	***Percent***	***Performance***
Negative	22	75.86%	Acceptable
Positive	7	24.14%	

This specimen was graded by 92% referee consensus.

Specimen VP-10

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

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	17	1	16
BD ProbeTec	2	-	2
Cepheid GeneXpert	1	-	1
Gen-Probe APTIMA	2	-	2
Quidel QuickVue	6	-	6
Roche COBAS Amplicor	3	-	3

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

Specimen CY-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	17	17	-
BD ProbeTec	2	2	-
Cepheid GeneXpert	1	1	-
Gen-Probe APTIMA	2	2	-
Quidel QuickVue	6	6	-
Roche COBAS Amplicor	3	3	-

Organisms present in specimen CY-7: *Chlamydia trachomatis* and *Neisseria gonorrhea*.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	15	-
BD ProbeTec	2	2	-
Cepheid GeneXpert	1	1	-
Gen-Probe APTIMA	2	2	-
Quidel QuickVue	4	4	-
Roche COBAS Amplicor	3	3	-

Organism present in specimen CY-8: *Chlamydia trachomatis.*

Specimen CY-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	1	14
BD ProbeTec	2	-	2
Cepheid GeneXpert	1	-	1
Gen-Probe APTIMA	2	1	1
Quidel QuickVue	4	-	4
Roche COBAS Amplicor	3	-	3

Organism present in specimen CY-9: No organism present.

Specimen CY-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	2	13
BD ProbeTec	2	-	2
Cepheid GeneXpert	1	-	1
Gen-Probe APTIMA	2	1	1
Quidel QuickVue	4	-	4
Roche COBAS Amplicor	3	-	3

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

GC (ANTIGEN DETECTION)

Specimen CY-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	11	11	-
BD ProbeTec	2	2	-
Cepheid GeneXpert	1	1	-
Gen-Probe APTIMA	2	2	-
Roche COBAS Amplicor	3	3	-

Specimen CY-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	11	11	-
BD ProbeTec	2	2	-
Cepheid GeneXpert	1	1	-
Gen-Probe APTIMA	2	2	-
Roche COBAS Amplicor	3	3	-

Specimen CY-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	11	-	11
BD ProbeTec	2	-	2
Cepheid GeneXpert	1	-	1
Gen-Probe APTIMA	2	-	2
Roche COBAS Amplicor	3	-	3

Specimen CY-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	11	1	10
BD ProbeTec	2	-	2
Cepheid GeneXpert	1	-	1
Gen-Probe APTIMA	2	-	2
Roche COBAS Amplicor	3	-	3

Specimen CY-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	11	11	-
BD ProbeTec	2	2	-
Cepheid GeneXpert	1	1	-
Gen-Probe APTIMA	2	2	-
Roche COBAS Amplicor	3	3	-

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	1	-

Antigen present in specimen LC-6: *Cryptosporidium*.

Specimen LC-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	-	1

Antigen present in specimen LC-7: *Giardia lamblia*.

Specimen LC-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	1	-

Antigens present in specimen LC-8: *Cryptosporidium* and *Giardia lamblia.*

Specimen LC-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	-	1

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

Specimen LC-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	-	1

Antigen present in specimen LC-10: No antigens present.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	-	1

Specimen LC-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	1	-

Specimen LC-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	1	-

Specimen LC-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	1	-

Specimen LC-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	1	-	1

RSV ANTIGEN DETECTION

Specimen V-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	67	-	67
Alere Binax NOW - waived	45	-	45
Alere Clearview RSV - waived	4	-	4
Quidel QuickVue RSV - waived	8	-	8
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia - waived	8	-	8
Remel Xpect - waived	1	-	1

Antigen present in specimen V-6: Influenza A.

Specimen V-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	67	67	-
Alere Binax NOW - waived	45	45	-
Alere Clearview RSV - waived	4	4	-
Quidel QuickVue RSV - waived	8	8	-
Quidel QuickVue RSV 10 Test	1	1	-
Quidel Sofia - waived	8	8	-
Remel Xpect - waived	1	1	-

Antigen present in specimen V-7: RSV.

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	18	-	18
Alere Binax NOW - waived	4	-	4
Alere Clearview RSV - waived	3	-	3
Quidel QuickVue RSV - waived	4	-	4
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia - waived	6	-	6

Antigen present in specimen V-8: Influenza B.

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	18	-	18
Alere Binax NOW - waived	4	-	4
Alere Clearview RSV - waived	3	-	3
Quidel QuickVue RSV - waived	4	-	4
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia - waived	6	-	6

Antigen present in specimen V-9: Influenza A.

RSV ANTIGEN DETECTION

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	18	18	-
Alere Binax NOW - waived	4	4	-
Alere Clearview RSV - waived	3	3	-
Quidel QuickVue RSV - waived	4	4	-
Quidel QuickVue RSV 10 Test	1	1	-
Quidel Sofia - waived	6	6	-

Antigen present in specimen V-10: RSV.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	31	31	-
Quidel QuickVue Influenza	24	24	-

Antigen present in specimen V-6: Influenza A.

Specimen V-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	32	1	31
Quidel QuickVue Influenza	25	1	24

Antigen present in specimen V-7: RSV.

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	10	10	-
Quidel QuickVue Influenza	10	10	-

Antigen present in specimen V-8: Influenza B.

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	10	10	-
Quidel QuickVue Influenza	10	10	-

Antigen present in specimen V-9: Influenza A.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	10	-	10
Quidel QuickVue Influenza	10	-	10

Antigen present in specimen V-10: RSV.

INFLUENZA A ANTIGEN DETECTION

Specimen V-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	321	318	3
Alere Binax NOW - waived	107	106	1
Alere i Instrument Influenza	1	1	-
Alere Influenza A&B	11	11	-
BD Veritor - waived	27	27	-
Cepheid GeneXpert	1	1	-
Henry Schein OneStep+ Flu A&B	2	2	-
Labsco Advantage Flu A&B	1	1	-
Medline Influenza A&B	2	2	-
Quidel QuickVue Influenza A+B	37	35	2
Quidel Sofia - waived	58	58	-
Remel Xpect	3	3	-
Sekisui OSOM Influenza A&B	51	51	-

Antigen present in specimen V-6: Influenza A.

Specimen V-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	318	5	313
Alere Binax NOW - waived	106	2	104
Alere i Instrument Influenza	1	-	1
Alere Influenza A&B	11	-	11
BD Veritor - waived	27	-	27
Cepheid GeneXpert	1	-	1
Henry Schein OneStep+ Flu A&B	2	-	2
Labsco Advantage Flu A&B	1	-	1
Medline Influenza A&B	2	-	2
Quidel QuickVue Influenza A+B	36	2	34
Quidel Sofia - waived	58	1	57
Remel Xpect	3	-	3
Sekisui OSOM Influenza A&B	51	-	51

Antigen present in specimen V-7: RSV.

INFLUENZA A ANTIGEN DETECTION

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	111	-	111
Alere Binax NOW - waived	19	-	19
Alere Influenza A&B	3	-	3
BD Veritor - waived	3	-	3
Cepheid GeneXpert	1	-	1
Labsco Advantage Flu A&B	1	-	1
Quidel QuickVue Influenza A+B	5	-	5
Quidel Sofia - waived	29	-	29
Remel Xpect	2	-	2
Sekisui OSOM Influenza A&B	45	-	45

Antigen present in specimen V-8: Influenza B.

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	111	111	-
Alere Binax NOW - waived	19	19	-
Alere Influenza A&B	3	3	-
BD Veritor - waived	3	3	-
Cepheid GeneXpert	1	1	-
Labsco Advantage Flu A&B	1	1	-
Quidel QuickVue Influenza A+B	5	5	-
Quidel Sofia - waived	29	29	-
Remel Xpect	2	2	-
Sekisui OSOM Influenza A&B	45	45	-

Antigen present in specimen V-9: Influenza A.

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	111	-	111
Alere Binax NOW - waived	19	-	19
Alere Influenza A&B	3	-	3
BD Veritor - waived	3	-	3
Cepheid GeneXpert	1	-	1
Labsco Advantage Flu A&B	1	-	1
Quidel QuickVue Influenza A+B	5	-	5
Quidel Sofia - waived	29	-	29
Remel Xpect	2	-	2
Sekisui OSOM Influenza A&B	45	-	45

Antigen present in specimen V-10: RSV.

INFLUENZA B ANTIGEN DETECTION

Specimen V-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	318	3	315
Alere Binax NOW - waived	105	-	105
Alere i Instrument Influenza	1	-	1
Alere Influenza A&B	10	-	10
BD Veritor - waived	26	-	26
Cepheid GeneXpert	1	-	1
Henry Schein OneStep+ Flu A&B	2	-	2
Labsco Advantage Flu A&B	1	-	1
Medline Influenza A&B	2	-	2
Quidel QuickVue Influenza A+B	36	-	36
Quidel Sofia - waived	55	-	55
Remel Xpect	4	-	4
Sekisui OSOM Influenza A&B	54	3	51

Antigen present in specimen V-6: Influenza A.

Specimen V-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	318	8	310
Alere Binax NOW - waived	105	1	104
Alere i Instrument Influenza	1	-	1
Alere Influenza A&B	10	-	10
BD Veritor - waived	26	-	26
Cepheid GeneXpert	1	-	1
Henry Schein OneStep+ Flu A&B	2	-	2
Labsco Advantage Flu A&B	1	-	1
Medline Influenza A&B	2	-	2
Quidel QuickVue Influenza A+B	36	-	36
Quidel Sofia - waived	55	-	55
Remel Xpect	4	-	4
Sekisui OSOM Influenza A&B	54	7	47

Antigen present in specimen V-7: RSV.

INFLUENZA B ANTIGEN DETECTION

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	111	108	3
Alere Binax NOW - waived	19	19	-
Alere Influenza A&B	3	3	-
BD Veritor - waived	3	3	-
Cepheid GeneXpert	1	1	-
Labsco Advantage Flu A&B	1	1	-
Quidel QuickVue Influenza A+B	5	5	-
Quidel Sofia - waived	27	27	-
Remel Xpect	3	3	-
Sekisui OSOM Influenza A&B	47	44	3

Antigen present in specimen V-8: Influenza B.

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	111	2	109
Alere Binax NOW - waived	19	-	19
Alere Influenza A&B	3	-	3
BD Veritor - waived	3	-	3
Cepheid GeneXpert	1	-	1
Labsco Advantage Flu A&B	1	-	1
Quidel QuickVue Influenza A+B	5	-	5
Quidel Sofia - waived	27	-	27
Remel Xpect	3	-	3
Sekisui OSOM Influenza A&B	47	2	45

Antigen present in specimen V-9: Influenza A.

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	111	5	106
Alere Binax NOW - waived	19	-	19
Alere Influenza A&B	3	-	3
BD Veritor - waived	3	-	3
Cepheid GeneXpert	1	-	1
Labsco Advantage Flu A&B	1	-	1
Quidel QuickVue Influenza A+B	5	-	5
Quidel Sofia - waived	27	-	27
Remel Xpect	3	-	3
Sekisui OSOM Influenza A&B	47	5	42

Antigen present in specimen V-10: RSV.

LEGIONELLA ANTIGEN DETETION

Specimen L-6

Method	***Labs***	***Positive***	***Negative***
Binax NOW	22	22	-

Specimen L-6: Positive for Legionella antigen.

Specimen L-7

Method	***Labs***	***Positive***	***Negative***
Binax NOW	22	-	22

Specimen L-7: Negative for Legionella antigen.

Specimen L-8

Method	***Labs***	***Positive***	***Negative***
Binax NOW	22	-	22

Specimen L-8: Negative for Legionella antigen.

Specimen L-9

Method	***Labs***	***Positive***	***Negative***
Binax NOW	22	22	-

Specimen L-9: Positive for Legionella antigen.

Specimen L-10

Method	***Labs***	***Positive***	***Negative***
Binax NOW	22	22	-

Specimen L-10: Positive for Legionella antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	7	-	7
Alere C. diff Quik Chek	5	-	5
Meridian Illumigene	1	-	1
Meridian Premier	1	-	1

Antigen present in specimen AG-6: Rotavirus.

Specimen AG-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	7	7	-
Alere C. diff Quik Chek	5	5	-
Meridian Illumigene	1	1	-
Meridian Premier	1	1	-

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

Specimen AG-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	7	7	-
Alere C. diff Quik Chek	5	5	-
Meridian Illumigene	1	1	-
Meridian Premier	1	1	-

Antigen present in specimen AG-8: *Clostridium difficile*.

Specimen AG-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	7	7	-
Alere C. diff Quik Chek	5	5	-
Meridian Illumigene	1	1	-
Meridian Premier	1	1	-

Antigens present in specimen AG-9: *Clostridium difficile* and Rotavirus.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	7	-	7
Alere C. diff Quik Chek	5	-	5
Meridian Illumigene	1	-	1
Meridian Premier	1	-	1

Antigen present in specimen AG-10: Rotavirus.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	6	-
Fisher HealthCare Sure-Vue	6	6	-

Specimen AG-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	-	6
Fisher HealthCare Sure-Vue	6	-	6

Specimen AG-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	-	6
Fisher HealthCare Sure-Vue	6	-	6

Specimen AG-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	6	-
Fisher HealthCare Sure-Vue	6	6	-

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	6	-
Fisher HealthCare Sure-Vue	6	6	-

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-6

Method	***Labs***	***Positive***	***Negative***
Binax NOW	20	19	1

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

Specimen SP-7

Method	***Labs***	***Positive***	***Negative***
Binax NOW	20	-	20

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

Specimen SP-8

Method	***Labs***	***Positive***	***Negative***
Binax NOW	20	20	-

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

Specimen SP-9

Method	***Labs***	***Positive***	***Negative***
Binax NOW	20	-	20

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

Specimen SP-10

Method	***Labs***	***Positive***	***Negative***
Binax NOW	20	20	-

Specimen SP-10: Positive for *Streptococcus pneumoniae* antigen.

PARASITOLOGY

Specimen PA-6

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

Parasite present in specimen PA-6: *Giardia lamblia.*

Specimen PA-7

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

Parasite present in specimen PA-7: No parasite present.

Specimen PA-8

Identification	***Labs***	***Percent***	***Performance***
Fasciola hepatica eggs	1	100%	Acceptable

Parasite present in specimen PA-8: *Fasciola hepatica eggs*.

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***
Hookworm	1	100%	Acceptable

Parasite present in specimen PA-10: Hookworm.

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