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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Table of Contents

Evaluation Criteria **2**

Microbiology

Throat Culture **3**
Strep A Antigen Detection **4**
General Bacteriology **8**
MRSA Screening **9**
Urine Culture **10**
Gram Stain 10
Antimicrobial Susceptibility Testing **12**
Genital Culture **13**
Gram Stain 13
Colony Count/Presumptive ID **15**
Gram Stain 15
Dermatophyte Screen **18**
Gram Stain **18**
Affirm VP III
Trichomonas vaginalis **20**
Gardnerella vaginalis **21**
Candida sp. **21**
Chlamydia (Antigen Detection) **22**
GC (Antigen Detection) **24**
Cryptosporidium Antigen Detection **25**
Giardia lamblia Antigen Detection **26**
RSV Antigen Detection **27**
Influenza A/B Antigen Detection **28**
Influenza A Antigen Detection **29**
Influenza B Antigen Detection **31**
Legionella Antigen Detection **33**
Clostridium Difficile Toxin Antigen Detection **34**
Rotavirus Antigen Detection **35**
Streptococcus pneumoniae Antigen Detection **36**
Parasitology **37**

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***
Negative for Group A Strep	133	86.36%	Acceptable
Staphylococcus aureus	15	9.74%	Acceptable
Normal flora	1	0.65%	Acceptable

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

Specimen TC-7

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	81	57.86%	Acceptable
Presump. Pos. Group A Strep	55	39.29%	Acceptable
Streptococcus pyogenes	1	0.71%	Acceptable

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

Specimen TC-8

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	87	96.67%	Acceptable

Organisms present in specimen TC-8: *Moraxella catarrhalis* and *Neisseria mucosa.*

Specimen TC-9

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	75	98.68%	Acceptable
No growth (sterile)	1	1.32%	Acceptable

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

Specimen TC-10

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	40	52.63%	Acceptable
Presump. Pos. Group A Strep	34	44.74%	Acceptable

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

STREP A ANTIGEN DETECTION

Specimen RS-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	538	526	12
Abbott Signify Strep A-waived	3	3	-
BD Chek Strep A	3	3	-
Beckman Coulter ICON DS	3	3	-
Beckman Coulter ICON SC	3	3	-
Binax NOW Strep A	3	3	-
Cardinal Health Strep A - waived	17	17	-
Consult Diagnostic Strep A - Moderate	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	67	65	2
Fisher HealthCare Sure-Vue	1	1	-
Fisher HealthCare Sure-Vue - waived	2	2	-
Henry Schein One Step+ - waived	41	41	-
Immunostics Detector Strep A Direct	6	6	-
Inverness Acceava Strep A Test	13	12	1
Inverness Signify Strep A Dipstick	1	1	-
McKesson Strep A Dipstick	36	35	1
Meridian Illumigene	1	-	1
Other Moderately Complex Method	2	2	-
Other Waived Method	13	12	1
Polymedco Poly Stat Strep A - moderate	1	1	-
Polymedco Poly Stat Strep A - waived	8	8	-
PSS Select Diag. Strep A Dipstick - waived	6	6	-
Quidel QuickVue Dipstick Strep	85	84	1
Quidel QuickVue In-Line	59	57	2
Quidel QuickVue+	23	23	-
Quidel Sofia - waived	1	1	-
Sekisui OSOM	85	83	2
Sekisui OSOM Ultra Strep A	51	50	1

STREP A ANTIGEN DETECTION

Specimen RS-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	531	9	522
Abbott Signify Strep A-waived	3	-	3
BD Chek Strep A	3	-	3
Beckman Coulter ICON DS	3	-	3
Beckman Coulter ICON SC	3	-	3
Binax NOW Strep A	3	-	3
Cardinal Health Strep A - waived	17	-	17
Consult Diagnostic Strep A - Moderate	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	66	2	64
Fisher HealthCare Sure-Vue	1	-	1
Fisher HealthCare Sure-Vue - waived	2	-	2
Henry Schein One Step+ - waived	41	-	41
Immunostics Detector Strep A Direct	6	-	6
Inverness Acceava Strep A Test	13	-	13
Inverness Signify Strep A Dipstick	1	-	1
McKesson Strep A Dipstick	35	1	34
Meridian Illumigene	1	-	1
Other Moderately Complex Method	2	-	2
Other Waived Method	12	1	11
Polymedco Poly Stat Strep A - moderate	1	-	1
Polymedco Poly Stat Strep A - waived	8	-	8
PSS Select Diag. Strep A Dipstick - waived	6	1	5
Quidel QuickVue Dipstick Strep	84	1	83
Quidel QuickVue In-Line	58	-	58
Quidel QuickVue+	21	-	21
Quidel Sofia - waived	1	-	1
Sekisui OSOM	85	2	83
Sekisui OSOM Ultra Strep A	51	1	50

STREP A ANTIGEN DETECTION

Specimen RS-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	106	104	2
BD Chek Strep A	2	2	-
Beckman Coulter ICON DS	2	2	-
Binax NOW Strep A	1	1	-
Cardinal Health Strep A - waived	3	3	-
Consult Diagnostic Strep A Dipstick - Waived	8	8	-
Henry Schein One Step+ - waived	4	4	-
Inverness Acceava Strep A Test	2	2	-
McKesson Strep A Dipstick	11	10	1
Meridian Illumigene	1	-	1
Other Moderately Complex Method	2	2	-
Other Waived Method	3	3	-
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	11	11	-
Quidel QuickVue In-Line	20	20	-
Quidel QuickVue+	15	15	-
Quidel Sofia - waived	1	1	-
Sekisui OSOM	5	5	-
Sekisui OSOM Ultra Strep A	11	11	-

STREP A ANTIGEN DETECTION

Specimen RS-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	89	1	88
BD Chek Strep A	1	-	1
Beckman Coulter ICON DS	2	-	2
Binax NOW Strep A	1	-	1
Cardinal Health Strep A - waived	3	-	3
Consult Diagnostic Strep A Dipstick - Waived	7	-	7
Henry Schein One Step+ - waived	3	-	3
Inverness Acceava Strep A Test	2	-	2
McKesson Strep A Dipstick	10	-	10
Other Moderately Complex Method	2	-	2
Other Waived Method	3	-	3
PSS Select Diag. Strep A Dipstick - waived	1	-	1
Quidel QuickVue Dipstick Strep	10	-	10
Quidel QuickVue In-Line	19	1	18
Quidel QuickVue+	12	-	12
Quidel Sofia - waived	1	-	1
Sekisui OSOM	3	-	3
Sekisui OSOM Ultra Strep A	8	-	8

Specimen RS-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	89	87	2
BD Chek Strep A	1	1	-
Beckman Coulter ICON DS	2	2	-
Binax NOW Strep A	1	1	-
Cardinal Health Strep A - waived	3	3	-
Consult Diagnostic Strep A Dipstick - Waived	7	7	-
Henry Schein One Step+ - waived	3	3	-
Inverness Acceava Strep A Test	2	2	-
McKesson Strep A Dipstick	10	9	1
Other Moderately Complex Method	2	2	-
Other Waived Method	3	3	-
PSS Select Diag. Strep A Dipstick - waived	1	1	-
Quidel QuickVue Dipstick Strep	10	10	-
Quidel QuickVue In-Line	19	18	1
Quidel QuickVue+	12	12	-
Quidel Sofia - waived	1	1	-
Sekisui OSOM	3	3	-
Sekisui OSOM Ultra Strep A	8	8	-

GENERAL BACTERIOLOGY

Specimen BA-4 – CSF Culture

Identification	***Labs***	***Percent***	***Performance***
Haemophilus influenzae	12	92.31%	Acceptable
Growth, referred for identification	1	7.69%	Acceptable

Organism present in specimen BA-4: *Haemophilus influenzae.*

Specimen BA-5 – Respiratory Culture

Identification	***Labs***	***Percent***	***Performance***
Streptococcus pneumoniae	13	100%	Acceptable

Organisms present in specimen BA-5: *Streptococcus pneumoniae* and *Streptococcus viridans.*

Specimen BA-6 – Wound Culture

Identification	***Labs***	***Percent***	***Performance***
Pasturella multocida	13	54.17%	Acceptable
Corynebacterium sp.	10	41.67%	Acceptable
Growth, referred for identification	1	4.17%	Acceptable

Organisms present in specimen BA-6: *Pasturella multocida* and *Corynebacterium* species.

METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS SCREEN

Specimen MSA-6

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

Organisms present in specimen MSA-6: *Staphylococcus aureus* – Methicillin sensitive and *Staphylococcus epidermidis.*

Specimen MSA-7

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

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

Specimen MSA-8

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

Organisms present in specimen MSA-8: *Staphylococcus aureus* and *Corynebacterium* species*.*

Specimen MSA-9

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

Organism present in specimen MSA-9: *Streptococcus pneumonia.*

Specimen MSA-10

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

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

URINE CULTURE

Specimen UC-6

Identification	***Labs***	***Percent***	***Performance***
Klebsiella pneumoniae	38	51.35%	Acceptable
Growth, referred for identification	14	18.92%	Acceptable
Klebsiella sp.	8	10.81%	Acceptable
Gram negative bacilli	7	9.46%	Acceptable
Presump. Klebsiella sp.	4	5.41%	Acceptable
Presump. Gram negative	3	4.05%	Acceptable

Gram Stain

Gram negative	44	100%	Acceptable

Gram Stain Morphology

Rods/bacilli	43	97.73%	Acceptable
Coccobacilli	1	2.27%	

Organism present in specimen UC-6: *Klebsiella pneumoniae.*

Specimen UC-7

Identification	***Labs***	***Percent***	***Performance***
Staphylococcus saprophyticus	24	38.71%	Acceptable
Growth, referred for identification	19	30.65%	Acceptable
Gram positive cocci	8	12.90%	Acceptable
Presump. Staphylococcus	5	8.06%	Acceptable
Staphylococcus sp.	2	3.23%	Acceptable
Staph – coagulase negative	2	3.23%	Acceptable
Presump. Gram positive	1	1.61%	Acceptable

Organisms present in specimen UC-7: *Staphylococcus saprophyticus* and *Lactobacillus* species.

Specimen UC-8

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	13	30.23%	Acceptable
Enterobacter cloacae	12	27.91%	Acceptable
Enterobacter sp.	7	16.28%	Acceptable
Gram negative bacilli	4	9.30%	Acceptable
Presump. Gram negative	3	6.98%	Acceptable
Staphylococcus epidermidis	2	4.65%	Acceptable
Presump. Enterobacter sp.	1	2.33%	Acceptable
Staphylococcus sp.	1	2.33%	Acceptable

Organisms present in specimen UC-8: *Enterobacter cloacae* and *Staphylococcus epidermidis.*

URINE CULTURE

Specimen UC-9

Identification	***Labs***	***Percent***	***Performance***
Escherichia coli	11	57.89%	Acceptable
Growth, referred for identification	4	21.05%	Acceptable
Gram negative bacilli	1	5.26%	Acceptable
Presump. Gram negative	1	5.26%	Acceptable
Presump. Escherichia coli	1	5.26%	Acceptable

Organisms present in specimen UC-9: *Escherichia coli* and *Corynebacterium* species.

Specimen UC-10

Identification	***Labs***	***Percent***	***Performance***
Streptococcus agalactiae	8	44.44%	Acceptable
Growth, referred for identification	3	16.67%	Acceptable
Presumptive Streptococcus sp.	2	11.11%	Acceptable
Presump. Gram positive	1	5.56%	Acceptable
Presump. Gram positive	1	5.56%	Acceptable
Gram positive cocci	1	5.56%	Acceptable
Strep – beta hemo, not Grp A	1	5.56%	Acceptable

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

ANTIMICROBIAL SUSCEPTIBILIY TESTING

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

	------Disk Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Amikacin	-	-	-	-	2	2	-	-	Not graded[1]
Amoxicillin/Clavulanate	8	8	-	-	5	5	-	-	100.00%
Ampicillin	25	-	-	25	11	-	-	11	100.00%
Ampicillin/Sulbactam	-	-	-	-	4	4	-	-	100.00%
Aztreonam	-	-	-	-	1	1	-	-	Not graded[1]
Cefamandole	1	1	-	-	-	-	-	-	Not graded[1]
Cefazolin	1	1	-	-	11	11	-	-	100.00%
Cefepime	-	-	-	-	4	4	-	-	100.00%
Cefixime	5	5	-	-	-	-	-	-	100.00%
Cefotaxime	-	-	-	-	2	2	-	-	Not graded[1]
Cefoxitin	-	-	-	-	3	3	-	-	100.00%
Cefpodoxime	1	1	-	-	-	-	-	-	Not graded[1]
Ceftazidime	2	2	-	-	4	4	-	-	100.00%
Ceftriaxone	5	5	-	-	8	8	-	-	100.00%
Cefuroxime	4	4	-	-	5	5	-	-	100.00%
Cephalothin	26	25	1	-	2	2	-	-	97.62%
Ciprofloxacin	28	28	-	-	11	11	-	-	100.00%
Doxycycline	2	2	-	-	-	-	-	-	Not graded[1]
Ertapenem	-	-	-	-	3	3	-	-	Not graded[1]
Gentamicin	18	18	-	-	7	7	-	-	100.00%
Imipenem	-	-	-	-	5	5	-	-	100.00%
Levofloxacin	9	9	-	-	10	10	-	-	100.00%
Meropenem	-	-	-	-	1	1	-	-	100.00%
Nalidixic Acid	2	2	-	-	-	-	-	-	100.00%
Nitrofurantoin	29	25	2	2	11	9	2	-	84.48%
Norfloxacin	4	4	-	-	-	-	-	-	100.00%
Ofloxacin	-	-	-	-	1	1	-	-	Not graded[1]
Piperacillin/Tazobactam	1	1	-	-	4	4	-	-	100.00%
Sulfisoxazole	6	6	-	-	-	-	-	-	100.00%
Tetracycline	9	9	-	-	1	1	-	-	100.00%
Tobramycin	2	2	-	-	9	9	-	-	100.00%
Trimethoprim	4	3	1	-	4	4	-	-	88.89%
Trimethoprim/Sulfamethoxazole	30	30	-	-	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.

GENITAL CULTURE

Specimen GC-6

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	21	43.75%	Acceptable
Streptococcus agalactiae	17	35.42%	Acceptable
No growth (sterile)	4	8.33%	Acceptable
Staph – coagulase negative	3	6.25%	Acceptable
Staphylococcus epidermidis	2	4.17%	Acceptable
Gram positive cocci	1	2.08%	Acceptable

Gram Stain

Gram positive	23	100%	Acceptable

Gram Stain Morphology

Cocci	23	100%	Acceptable

Organisms present in specimen GC-6: *Streptococcus agalactiae* and *Staphylococcus epidermidis*.

Specimen GC-7

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhoeae	12	85.71%	Acceptable
Neisseria gonorrhoeae	2	14.29%	Acceptable

Organisms present in specimen GC-7: *Neisseria gonorrhoeae* and *Corynebacterium* species.

Specimen GC-8

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhoeae	10	71.43%	Acceptable
Neisseria gonorrhoeae	3	21.43%	Acceptable

Organism present in specimen GC-8: *Neisseria gonorrhoeae.*

GENITAL CULTURE

Specimen GC-9

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	12	85.71%	Acceptable
Gram positive cocci	1	7.14%	Acceptable
Growth, referred for identification	1	7.14%	Acceptable

Organisms present in specimen GC-9: *Staphylococcus aureus and Lactobacillus* species.

Specimen GC-10

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	12	85.71%	Acceptable
No growth (sterile)	2	14.29%	Acceptable

Organism present in specimen GC-10: No organism present.

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	81	2	1	3	75
Bulls Eye	3	-	-	-	3
Calibrated Loop	23	-	-	-	23
Dip-N-Count	1	-	-	-	1
HealthLink	2	-	-	-	2
Troy Bacti-Urine, Plate	1	-	-	-	1
Uri-Check	8	-	-	1	7
Uricult	39	2	1	2	34

Identification–Specimen CC-6

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram negative	10	50%	Acceptable
Growth, referred for identification	5	25%	Acceptable
Presump. Klebsiella sp.	2	10%	Acceptable
Klebsiella pneumoniae	2	10%	Acceptable
Gram Stain			
Gram negative	5	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	5	100%	Acceptable

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

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	80	75	3	1	1
Bulls Eye	3	3	-	-	-
Calibrated Loop	23	22	1	-	-
Dip-N-Count	1	1	-	-	-
HealthLink	2	2	-	-	-
Troy Bacti-Urine, Plate	1	1	-	-	-
Uri-Check	8	8	-	-	-
Uricult	38	34	2	1	1

Identification–Specimen CC-7

Identification	*Labs*	*Percent*	*Performance*
No growth (sterile)	18	94.74%	Acceptable

Organism present in specimen CC-7: No organism present.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-8

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram negative	9	47.37%	Acceptable
Growth, referred for identification	5	26.32%	Acceptable
Presump. Enterobacter sp.	1	5.26%	Acceptable
Enterobacter cloacae	1	5.26%	Acceptable
Staph – coagulase negative	1	5.26%	Acceptable
Staphylococcus epidermidis	1	5.26%	Acceptable

Organisms present in specimen CC-8: 50,000 – 75,000 CFU/mL of *Enterobacter cloacae* and <10,000 CFU/mL of *Staphylococcus epidermidis*.

Identification–Specimen CC-9

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram negative	6	35.29%	Ungraded
Growth, referred for identification	3	17.65%	
Presump. Escherichia coli	2	11.76%	

Organisms present in specimen CC-9: 50,000 – 75,000 CFU/mL of *Escherichia coli* and <10,000 CFU/mL of *Corynebacterium* species. This is an ungraded challenge due to less than 80% referee consensus.

Identification–Specimen CC-10

Identification	***Labs***	***Percent***	***Performance***
Presump. Gram positive	6	35.29%	Acceptable
Growth, referred for identification	4	23.53%	Acceptable
Strep – beta hemo; not Grp A	1	5.88%	Acceptable
Streptococcus agalactiae	1	5.88%	Acceptable

Organism present in specimen CC-10: >100,000 CFU/mL of *Streptococcus agalactiae.* This challenge was graded by 80% referee consensus.

DERMATOPHYTE SCREEN

Specimen DM-3

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

Organism present in specimen DM-3: *Staphylococcus aureus*.

Specimen DM-4

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

Organism present in specimen DM-4: *Microsporum gypseum.*

GRAM STAIN

Specimen GS-6

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	11	52.38%	Acceptable
Gram negative	10	47.62%	

Gram Stain Morphology

Rods/bacilli	19	95%	Acceptable
Coccobacilli	1	5%	

This Gram Stain was graded by 80% referee consensus.

Organism present in specimen GS-6: *Lactobacillus rhamnosus.*

Specimen GS-7

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	20	95.24%	Acceptable
Gram positive	1	4.76%	

Gram Stain Morphology

Rods/bacilli	17	85%	Acceptable
Cocci	1	5%	
Coccobacilli	1	5%	
Diplococci	1	5%	

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

GRAM STAIN

Specimen GS-8

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	21	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	14	70%	Acceptable
Coccobacilli	4	20%	
Cocci	2	10%	

Organism present in specimen GS-8: *Enterobacter cloacae.*

The Gram Stain Morphology was graded by 90% referee consensus.

Specimen GS-9

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	20	95.24%	Acceptable
Gram negative	1	4.76%	
Gram Stain Morphology			
Cocci	17	85%	Acceptable
Diplococci	2	10%	
Rods/bacilli	1	5%	

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

Specimen GS-10

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	21	100%	Acceptable
Gram Stain Morphology			
Cocci	17	85%	Acceptable
Diplococci	2	10%	Acceptable
Coccobacilli	1	5%	

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

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-6

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

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

Specimen VP-7

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

Organism present in specimen VP-7: *Candida albicans.*

Specimen VP-8

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

Organisms present in specimen VP-8: *Gardnerella vaginalis* and *Trichomonas vaginalis*.

Specimen VP-9

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

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

Specimen VP-10

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

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

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-6

Identification	***Labs***	***Percent***	***Performance***
Positive	30	90.91%	Acceptable
Negative	3	9.09%	

Specimen VP-7

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

Specimen VP-8

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

Specimen VP-9

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

Specimen VP-10

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

AFFIRM VP III–Candida sp.

Specimen VP-6

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

Specimen VP-7

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

AFFIRM VP III–Candida sp.

Specimen VP-8

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

Specimen VP-9

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

Specimen VP-10

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

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	17	-	17
BD ProbeTec	6	-	6
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	5	-	5
Roche COBAS Amplicor	1	-	1
Wampole Clearview	3	-	3

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

Specimen CY-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	17	17	-
BD ProbeTec	6	6	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	5	5	-
Roche COBAS Amplicor	1	1	-
Wampole Clearview	3	3	-

Organism present in specimen CY-7: *Chlamydia trachomatis*.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	16	-	16
BD ProbeTec	6	-	6
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	5	-	5
Roche COBAS Amplicor	1	-	1
Wampole Clearview	3	-	3

Organism present in specimen CY-8: *Neisseria gonorrhoeae.*

Specimen CY-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	16	-	16
BD ProbeTec	6	-	6
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	5	-	5
Roche COBAS Amplicor	1	-	1
Wampole Clearview	3	-	3

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

Specimen CY-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	16	16	-
BD ProbeTec	6	6	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	5	5	-
Roche COBAS Amplicor	1	1	-
Wampole Clearview	3	3	-

Organism present in specimen CY-10: *Chlamydia trachomatis*.

GC (ANTIGEN DETECTION)

Specimen CY-6

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

Specimen CY-7

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

Specimen CY-8

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

Specimen CY-9

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

Specimen CY-10

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-6

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

Antigens present in specimen LC-6: *Cryptosporidium* and *Giardia lamblia*.

Specimen LC-7

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

Antigen present in specimen LC-7: No antigens present.

Specimen LC-8

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

Antigen present in specimen LC-8: *Giardia lamblia.*

Specimen LC-9

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

Antigen present in specimen LC-9: *Cryptosporidium*.

Specimen LC-10

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

Antigen present in specimen LC-10: *Giardia lamblia.*

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	70	1	69
Alere Clearview RSV - waived	7	-	7
Binax NOW - waived	47	-	47
Quidel QuickVue RSV - waived	6	-	6
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia - waived	5	-	5
Remel Xpect - waived	3	-	3

Antigen present in specimen V-6: Influenza B.

Specimen V-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	70	69	1
Alere Clearview RSV - waived	7	7	-
Binax NOW - waived	47	47	-
Quidel QuickVue RSV - waived	6	6	-
Quidel QuickVue RSV 10 Test	1	1	-
Quidel Sofia - waived	5	5	-
Remel Xpect - waived	3	3	-

Antigen present in specimen V-7: RSV.

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	19	1	18
Binax NOW - waived	9	-	9
Quidel QuickVue RSV - waived	3	-	3
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia - waived	3	-	3
Remel Xpect - waived	2	-	2

Antigen present in specimen V-8: Influenza A.

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	19	1	18
Binax NOW - waived	9	-	9
Quidel QuickVue RSV - waived	3	-	3
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia - waived	3	-	3
Remel Xpect - waived	2	-	2

Antigen present in specimen V-9: Influenza A.

RSV ANTIGEN DETECTION

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	19	18	1
Binax NOW - waived	9	9	-
Quidel QuickVue RSV - waived	3	3	-
Quidel QuickVue RSV 10 Test	1	1	-
Quidel Sofia - waived	3	3	-
Remel Xpect - waived	2	2	-

Antigen present in specimen V-10: RSV.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	42	40	2
Quidel QuickVue Influenza	37	36	1

Antigen present in specimen V-6: Influenza B.

Specimen V-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	42	-	42
Quidel QuickVue Influenza	37	-	37

Antigen present in specimen V-7: RSV.

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	13	13	-
Quidel QuickVue Influenza	13	13	-

Antigen present in specimen V-8: Influenza A.

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	13	13	-
Quidel QuickVue Influenza	13	13	-

Antigen present in specimen V-9: Influenza A.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	13	-	13
Quidel QuickVue Influenza	13	-	13

Antigen present in specimen V-10: RSV.

INFLUENZA A ANTIGEN DETECTION

Specimen V-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	324	3	321
BD Directigen	1	-	1
BD Veritor - waived	32	-	32
Binax NOW - waived	120	1	119
OraSure QuickFlu	1	-	1
Other Waived Method	1	-	1
Quidel QuickVue Influenza A+B	36	-	36
Quidel Sofia - waived	28	-	28
Remel Xpect	4	-	4
Sekisui OSOM Influenza A&B	77	2	75

Antigen present in specimen V-6: Influenza B.

Specimen V-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	325	3	322
BD Directigen	1	-	1
BD Veritor - waived	32	-	32
Binax NOW - waived	121	1	120
OraSure QuickFlu	1	-	1
Other Waived Method	1	-	1
Quidel QuickVue Influenza A+B	36	2	34
Quidel Sofia - waived	28	-	28
Remel Xpect	4	-	4
Sekisui OSOM Influenza A&B	77	-	77

Antigen present in specimen V-7: RSV.

INFLUENZA A ANTIGEN DETECTION

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	104	102	2
BD Directigen	1	1	-
BD Veritor - waived	3	3	-
Binax NOW - waived	13	13	-
Quidel QuickVue Influenza A+B	3	3	-
Quidel Sofia - waived	6	6	-
Remel Xpect	3	3	-
Sekisui OSOM Influenza A&B	70	68	2

Antigen present in specimen V-8: Influenza A.

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	104	103	1
BD Directigen	1	1	-
BD Veritor - waived	3	3	-
Binax NOW - waived	13	13	-
Quidel QuickVue Influenza A+B	3	3	-
Quidel Sofia - waived	6	6	-
Remel Xpect	3	3	-
Sekisui OSOM Influenza A&B	70	69	1

Antigen present in specimen V-9: Influenza A.

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	104	-	104
BD Directigen	1	-	1
BD Veritor - waived	3	-	3
Binax NOW - waived	13	-	13
Quidel QuickVue Influenza A+B	3	-	3
Quidel Sofia - waived	6	-	6
Remel Xpect	3	-	3
Sekisui OSOM Influenza A&B	70	-	70

Antigen present in specimen V-10: RSV.

INFLUENZA B ANTIGEN DETECTION

Specimen V-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	326	319	7
BD Directigen	1	1	-
BD Veritor - waived	28	27	1
Binax NOW - waived	120	118	2
OraSure QuickFlu	1	1	-
Other Waived Method	2	2	-
Quidel QuickVue Influenza A+B	38	36	2
Quidel Sofia - waived	28	28	-
Remel Xpect	4	4	-
Sekisui OSOM Influenza A&B	75	73	2

Antigen present in specimen V-6: Influenza B.

Specimen V-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	324	3	321
BD Directigen	1	-	1
BD Veritor - waived	28	1	27
Binax NOW - waived	119	1	118
OraSure QuickFlu	1	-	1
Other Waived Method	2	-	2
Quidel QuickVue Influenza A+B	38	-	38
Quidel Sofia - waived	28	1	27
Remel Xpect	4	-	4
Sekisui OSOM Influenza A&B	75	-	75

Antigen present in specimen V-7: RSV.

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	104	1	103
BD Directigen	1	-	1
BD Veritor - waived	3	-	3
Binax NOW - waived	13	-	13
Quidel QuickVue Influenza A+B	5	-	5
Quidel Sofia - waived	6	-	6
Remel Xpect	3	-	3
Sekisui OSOM Influenza A&B	68	1	67

Antigen present in specimen V-8: Influenza A.

INFLUENZA B ANTIGEN DETECTION

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	104	1	103
BD Directigen	1	-	1
BD Veritor - waived	3	-	3
Binax NOW - waived	13	-	13
Quidel QuickVue Influenza A+B	5	-	5
Quidel Sofia - waived	6	-	6
Remel Xpect	3	-	3
Sekisui OSOM Influenza A&B	68	1	67

Antigen present in specimen V-9: Influenza A.

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	104	-	104
BD Directigen	1	-	1
BD Veritor - waived	3	-	3
Binax NOW - waived	13	-	13
Quidel QuickVue Influenza A+B	5	-	5
Quidel Sofia - waived	6	-	6
Remel Xpect	3	-	3
Sekisui OSOM Influenza A&B	68	-	68

Antigen present in specimen V-10: RSV.

LEGIONELLA ANTIGEN DETETION

Specimen L-6

Method	***Labs***	***Positive***	***Negative***
Binax NOW	26	-	26

Specimen L-6: Negative for Legionella antigen.

Specimen L-7

Method	***Labs***	***Positive***	***Negative***
Binax NOW	26	26	-

Specimen L-7: Positive for Legionella antigen.

Specimen L-8

Method	***Labs***	***Positive***	***Negative***
Binax NOW	26	26	-

Specimen L-8: Positive for Legionella antigen.

Specimen L-9

Method	***Labs***	***Positive***	***Negative***
Binax NOW	26	26	-

Specimen L-9: Positive for Legionella antigen.

Specimen L-10

Method	***Labs***	***Positive***	***Negative***
Binax NOW	26	-	26

Specimen L-10: Negative for Legionella antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	11	1	10
Alere C. diff Quik Chek	7	-	7
Meridian Illumigene	1	1	-
Meridian Premier	1	-	1
Remel Xpect	1	-	1

Antigen present in specimen AG-6: Rotavirus.

Specimen AG-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	11	11	-
Alere C. diff Quik Chek	7	7	-
Meridian Illumigene	1	1	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-

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

Specimen AG-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	11	11	-
Alere C. diff Quik Chek	7	7	-
Meridian Illumigene	1	1	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-

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

Specimen AG-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	11	1	10
Alere C. diff Quik Chek	7	-	7
Meridian Illumigene	1	-	1
Meridian Premier	1	-	1
Remel Xpect	1	1	-

Antigen present in specimen AG-9: Rotavirus.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	11	10	1
Alere C. diff Quik Chek	7	7	-
Meridian Illumigene	1	1	-
Meridian Premier	1	1	-
Remel Xpect	1	-	1

Antigen present in specimen AG-10: *Clostridium difficile.*

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Fisher HealthCare Sure-Vue	1	1	-
Meridian ImmunoCard	4	4	-

Specimen AG-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Fisher HealthCare Sure-Vue	1	1	-
Meridian ImmunoCard	4	4	-

Specimen AG-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Fisher HealthCare Sure-Vue	1	-	1
Meridian ImmunoCard	4	-	4

Specimen AG-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Fisher HealthCare Sure-Vue	1	1	-
Meridian ImmunoCard	4	4	-

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Fisher HealthCare Sure-Vue	1	-	1
Meridian ImmunoCard	4	-	4

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-6

Method	***Labs***	***Positive***	***Negative***
Binax NOW	24	24	-

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

Specimen SP-7

Method	***Labs***	***Positive***	***Negative***
Binax NOW	24	-	24

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

Specimen SP-8

Method	***Labs***	***Positive***	***Negative***
Binax NOW	24	24	-

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

Specimen SP-9

Method	***Labs***	***Positive***	***Negative***
Binax NOW	24	24	-

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

Specimen SP-10

Method	***Labs***	***Positive***	***Negative***
Binax NOW	24	-	24

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

PARASITOLOGY

Specimen PA-6

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

Parasite present in specimen PA-6: *Dientamoeba fragilis.*

Specimen PA-7

Identification	***Labs***	***Percent***	***Performance***
Entamoeba coli	1	100%	Acceptable

Parasite present in specimen PA-7: *Entamoeba coli.*

Specimen PA-8

Identification	***Labs***	***Percent***	***Performance***
Hymenolepis nana eggs	1	100%	Acceptable

Parasite present in specimen PA-8: *Hymenolepis nana eggs*.

Specimen PA-9

Identification	***Labs***	***Percent***	***Performance***
Ascaris lumbricoides eggs	1	100%	Acceptable

Parasites present in specimen PA-9: *Ascaris lumbricoides* eggs and *Trichuris trichiura* eggs.

Specimen PA-10

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

Parasite present in specimen PA-10: No parasite present.

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