MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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Microbiology
2017 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 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***
Positive for Group A Strep	71	60.17%	Acceptable
Presump. Pos. Group A Strep	42	33.59%	Acceptable
Streptococcus pyogenes	5	4.24%	Acceptable

Organism(s) present: *Streptococcus pyogenes* and *Streptococcus salivarius.*

Specimen TC-7

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	109	97.32%	Acceptable
No growth (sterile)	3	2.68%	Acceptable

Organism(s) present: No growth (sterile).

Specimen TC-8

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	36	51.43%	Acceptable
Presump. Pos. Group A Strep	34	48.57%	Acceptable

Organism(s) present: *Streptococcus pyogenes.*

Specimen TC-9

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	62	95.38%	Acceptable

Organism(s) present: *Pseudomonas aeruginosa* and *Corynebacterium sp*.

Specimen TC-10

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	62	95.38%	Acceptable

Organism(s) present: *Neisseria sicca.*

STREP A ANTIGEN DETECTION

Specimen RS-6

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	531	7	524
Abbott Signify Strep A-waived	1	-	1
Alere Acceava Strep A Test	11	-	11
Alere i Instrument - waived	13	1	12
Alere Signify Strep A Dipstick	1	-	1
BD Chek Strep A	4	1	3
BD Veritor - waived	1	-	1
Beckman Coulter ICON DS	7	-	7
Beckman Coulter ICON SC	1	-	1
Binax NOW Strep A	1	-	1
Cardinal Health Strep A - moderate	1	-	1
Cardinal Health Strep A - waived	8	-	8
Consult Diagnostic Strep A - Moderate	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	93	2	91
Fisher HealthCare Sure-Vue - waived	1	-	1
Germaine Laboratories StrepAim	2	-	2
Henry Schein One Step	2	-	2
Henry Schein One Step+ - waived	45	-	45
McKesson Strep A Cassette	1	-	1
McKesson Strep A Dipstick	15	-	15
Medline Strep A Test Strip	3	-	3
Moore Medical Strep A Rapid Test	2	-	2
Other Waived Method	16	1	15
Polymedco Poly Stat Strep A - waived	1	-	1
Quidel QuickVue Dipstick Strep	65	1	64
Quidel QuickVue In-Line	50	-	50
Quidel QuickVue+	14	-	14
Quidel Sofia - waived	1	-	1
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	13	-	13
Sekisui OSOM	98	1	97
Sekisui OSOM Ultra Strep A	54	-	54

STREP A ANTIGEN DETECTION

Specimen RS-7

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	527	492	35
Abbott Signify Strep A-waived	1	1	-
Alere Acceava Strep A Test	10	10	-
Alere i Instrument - waived	13	13	-
Alere Signify Strep A Dipstick	1	1	-
BD Chek Strep A	4	3	1
BD Veritor - waived	1	1	-
Beckman Coulter ICON DS	7	7	-
Beckman Coulter ICON SC	1	1	-
Binax NOW Strep A	1	1	-
Cardinal Health Strep A - moderate	1	1	-
Cardinal Health Strep A - waived	8	8	-
Consult Diagnostic Strep A - Moderate	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	93	83	10
Fisher HealthCare Sure-Vue - waived	1	1	-
Germaine Laboratories StrepAim	2	1	1
Henry Schein One Step	2	2	-
Henry Schein One Step+ - waived	45	38	7
McKesson Strep A Cassette	1	-	1
McKesson Strep A Dipstick	14	12	2
Medline Strep A Test Strip	3	2	1
Moore Medical Strep A Rapid Test	2	2	-
Other Waived Method	16	13	3
Polymedco Poly Stat Strep A - waived	1	1	-
Quidel QuickVue Dipstick Strep	64	62	2
Quidel QuickVue In-Line	50	47	3
Quidel QuickVue+	13	13	-
Quidel Sofia - waived	1	1	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	13	13	-
Sekisui OSOM	98	97	1
Sekisui OSOM Ultra Strep A	54	53	1

STREP A ANTIGEN DETECTION

Specimen RS-8

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	75	-	75
Alere Acceava Strep A Test	3	-	3
BD Chek Strep A	2	-	2
Beckman Coulter ICON DS	1	-	1
Binax NOW Strep A	1	-	1
Cardinal Health Strep A - moderate	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	13	-	13
Henry Schein One Step	1	-	1
Henry Schein One Step+ - waived	3	-	3
McKesson Strep A Dipstick	4	-	4
Other Waived Method	1	-	1
Quidel QuickVue Dipstick Strep	7	-	7
Quidel QuickVue In-Line	17	-	17
Quidel QuickVue+	7	-	7
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	3	-	3
Sekisui OSOM	1	-	1
Sekisui OSOM Ultra Strep A	8	-	8

STREP A ANTIGEN DETECTION

Specimen RS-9

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	71	-	71
Alere Acceava Strep A Test	3	-	3
BD Chek Strep A	2	-	2
Beckman Coulter ICON DS	1	-	1
Binax NOW Strep A	1	-	1
Cardinal Health Strep A - moderate	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	13	-	13
Henry Schein One Step+ - waived	3	-	3
McKesson Strep A Dipstick	3	-	3
Other Waived Method	1	-	1
Quidel QuickVue Dipstick Strep	7	-	7
Quidel QuickVue In-Line	17	-	17
Quidel QuickVue+	7	-	7
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	3	-	3
Sekisui OSOM	1	-	1
Sekisui OSOM Ultra Strep A	6	-	6

Specimen RS-10

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	71	70	1
Alere Acceava Strep A Test	3	3	-
BD Chek Strep A	2	2	-
Beckman Coulter ICON DS	1	1	-
Binax NOW Strep A	1	1	-
Cardinal Health Strep A - moderate	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	13	13	-
Henry Schein One Step+ - waived	3	3	-
McKesson Strep A Dipstick	3	3	-
Other Waived Method	1	1	-
Quidel QuickVue Dipstick Strep	7	7	-
Quidel QuickVue In-Line	17	16	1
Quidel QuickVue+	7	7	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	3	3	-
Sekisui OSOM	1	1	-
Sekisui OSOM Ultra Strep A	6	6	-

GENERAL BACTERIOLOGY

Specimen BA-4 – Spinal Fluid (CSF) Culture

Identification	***Labs***	***Percent***	***Performance***
Neisseria meningitidis	5	83.33%	Acceptable

Organism(s) present: *Neisseria meningitidis.* .

Specimen BA-5 – Sputum Culture

Identification	***Labs***	***Percent***	***Performance***
Haemophilus parainfluenzae	3	30.00%	Acceptable
Haemophilus sp.	3	30.00%	Acceptable
Corynebacterium sp.	2	20.00%	Acceptable
Growth, referred for identification	1	10.00%	Acceptable
Gram positive bacilli	1	10.00%	Acceptable

Organism(s) present: *Haemophilus parainfluenzae* and *Corynebacterium sp.*

Specimen BA-6 – Wound Culture

Identification	***Labs***	***Percent***	***Performance***
Staphylococcus aureus	6	75.00%	Acceptable
Anaerobic cultures not perform	2	25.00%	Acceptable

Organism(s) present: *Staphylococcus aureus* and *Peptostreptococcus anaerobius.*

METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS SCREEN

Specimen MSA-6

Identification	***Labs***	***Percent***	***Performance***
Positive	3	60%	Ungraded
Negative	2	40%	

Organism(s) present: *Staphylococcus aureus* – Methicillin resistant and *Corynebacterium sp.* This is an ungraded challenge due to less than 80% consensus.

Specimen MSA-7

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

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

Specimen MSA-8

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

Organism(s) present: *Klebsiella pneumoniae* and *Neisseria sicca.*

Specimen MSA-9

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

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

Specimen MSA-10

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

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

URINE CULTURE

Specimen UC-6

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	21	34.43%	Acceptable
Providencia stuartii	16	26.23%	Acceptable
Providencia sp.	10	16.39%	Acceptable
Gram negative bacilli	9	14.75%	Acceptable
Presump. Gram negative	4	6.56%	Acceptable

Gram Stain

Gram negative	34	100%	Acceptable

Gram Stain Morphology

Rods/bacilli	34	100%	Acceptable

Organism(s) present: *Providencia stuartii.*

Specimen UC-7

Identification	***Labs***	***Percent***	***Performance***
Staphylococcus aureus	35	38.46%	Acceptable
Streptococcus agalactiae	32	35.16%	Acceptable
Growth, referred for identification	11	12.09%	Acceptable
Gram positive cocci	4	4.40%	Acceptable
Presump. Gram positive	3	3.30%	Acceptable
Presump. Staphylococcus sp.	2	2.20%	Acceptable
Presump. Streptococcus sp.	2	2.20%	Acceptable
Strep – beta hemo, not Grp. A	1	1.10%	Acceptable

Organism(s) present: *Staphylococcus aureus* and *Streptococcus agalactiae*.

Specimen UC-8

Identification	***Labs***	***Percent***	***Performance***
Escherichia coli	25	49.02%	Acceptable
Staph – coagulase negative	11	21.57%	Acceptable
Growth, referred for identification	5	9.80%	Acceptable
Gram negative bacilli	4	7.84%	Acceptable
Presump. Gram negative	2	3.92%	Acceptable
Presump. Escherichia coli	2	3.92%	Acceptable
Staphylococcus epidermidis	1	1.96%	Acceptable

Organism(s) present: *Escherichia coli* and *Staphylococcus epidermidis*.

URINE CULTURE

Specimen UC-9

Identification	***Labs***	***Percent***	***Performance***
Staphylococcus saprophyticus	7	33.33%	Acceptable
Staph – coagulase negative	4	19.05%	Acceptable
Growth, referred for identification	3	14.29%	Acceptable
Staphylococcus epidermidis	3	14.29%	Acceptable
Presump. Staphylococcus sp.	2	9.52%	Acceptable
Gram positive cocci	1	4.76%	Acceptable

Organism(s) present: *Staphylococcus saprophyticus* and *Staphylococcus epidermidis.*

Specimen UC-10

Identification	***Labs***	***Percent***	***Performance***
Corynebacterium sp.	7	43.75%	Acceptable
Presump. Gram positive	3	18.75%	Acceptable
Gram positive bacilli	2	12.50%	Acceptable
Growth, referred for identification	2	12.50%	Acceptable
Presump. Corynebacterium sp.	1	6.25%	Acceptable

Organism(s) present: *Corynebacterium sp.*

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen UC-6, CC-6 (SUS-6) Organism(s) present: *Providencia stuartii.*

	------Disk Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Amikacin	-	-	-	-	2	2	-	-	Ungraded[1]
Amoxicillin/Clavulanate	15	1	-	14	2	-	-	2	95.00%
Ampicillin	36	6	1	29	7	-	-	7	82.98%
Ampicillin/Sulbactam	-	-	-	-	5	5	-	-	100.00%
Carbenicillin	1	1	-	-	-	-	-	-	Inappropriate drug[2]
Cefaclor	1	-	-	1	-	-	-	-	Ungraded[1]
Cefazolin	17	2	-	15	6	-	-	6	92.00%
Cefepime	-	-	-	-	5	5	-	-	100.00%
Cefixime	5	5	-	-	-	-	-	-	100.00%
Cefoxitin	-	-	-	-	1	1	-	-	Ungraded[1]
Cefpodoxime	5	5	-	-	-	-	-	-	100.00%
Ceftazidime	1	1	-	-	4	4	-	-	100.00%
Ceftriaxone	9	9	-	-	5	5	-	-	100.00%
Cefuroxime	15	5	-	10	-	-	-	-	Referee[3]
Cephalothin	12	-	1	11	1	-	-	1	Inappropriate drug[2]
Ciprofloxacin	41	41	-	-	7	7	-	-	100.00%
Ertapenem	-	-	-	-	5	5	-	-	100.00%
Gentamicin	32	32	-	-	6	1	-	5	97.37%
Imipenem	-	-	-	-	5	5	-	-	100.00%
Levofloxacin	11	11	-	-	6	6	-	-	100.00%
Meropenem	-	-	-	-	1	1	-	-	Ungraded[1]
Nitrofurantoin	36	-	-	36	7	-	-	7	100.00%
Piperacillin/Tazobactam	3	3	-	-	5	5	-	-	100.00%
Sulfisoxazole	1	1	-	-	-	-	-	-	Ungraded[1]
Tetracycline	29	-	-	29	1	-	-	1	100.00%
Tobramycin	2	2	-	-	5	1	-	4	Ungraded[4]
Trimethoprim	5	5	-	-	-	-	-	-	100.00%
Trimethoprim/Sulfamethoxazole	37	37	-	-	7	7	-	-	100.00%

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

[1] This is an ungraded challenge due to lack of comparison group.
[2] This is an inappropriate drug due to discontinued marketing status.
[3] Drug graded by 82% referee consensus
[4] This is an ungraded challenge due to less than 80% participant consensus.

GENITAL CULTURE

Specimen GC-6

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhoeae	20	62.50%	Acceptable
Neisseria gonorrhoeae	10	31.25%	Acceptable
Gram negative diplococci	1	3.13%	Acceptable
Growth, referred for identification	1	3.13%	Acceptable
Gram Stain			
Gram negative	22	100%	Acceptable
Gram Stain Morphology			
Diplococci	22	95.65%	Acceptable
Rods/bacilli	1	4.35%	

Organism(s) present: *Neisseria gonorrhoeae*.

Specimen GC-7

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	9	81.82%	Acceptable
No growth (sterile)	2	18.18%	Acceptable

Organism(s) present: No growth (sterile).

Specimen GC-8

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	9	69.23%	Acceptable
Staph – coagulase negative	2	15.38%	Acceptable
Staphylococcus aureus	2	15.38%	Acceptable

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

Specimen GC-9

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	8	88.89%	Acceptable

Organism(s) present: *Lactobacillus sp.*

Specimen GC-10

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

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

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	63	1	8	38	16
Calibrated Loop	24	-	2	16	6
Uri-Check	8	-	-	6	2
Uricult	30	1	6	15	8

Identification–Specimen CC-6

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	6	46.15%	Acceptable
Presump. Gram negative	4	30.77%	Acceptable
Providencia stuartii	1	7.69%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Providencia stuartii.*

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	63	12	39	12	-
Calibrated Loop	24	2	13	9	-
Uri-Check	8	1	7	-	-
Uricult	30	9	18	3	-

Identification–Specimen CC-7

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	6	46.15%	Acceptable
Presump. Staphylococcus sp.	2	15.38%	Acceptable
Presump. Gram positive	1	7.69%	Acceptable
Staphylococcus aureus	1	7.69%	Acceptable

Organism(s) present: 10,000 -100,000 CFU/mL of *Staphylococcus aureus* and <10,000 CFU/mL of *Streptococcus agalactiae.*
Specimen CC-7 was graded by 90% referee consensus.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-8

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	4	40.00%	Acceptable
Presump. Gram negative	3	30.00%	Acceptable
Presump. Escherichia coli	2	20.00%	Acceptable
Escherichia coli	1	10.00%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Escherichia coli* and 10,000 – 100,000 CFU/mL *of Staphylococcus epidermidis*.

Identification–Specimen CC-9

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	3	30.00%	Acceptable
Presump. Gram positive	2	20.00%	Acceptable
Presump. Staphylococcus sp.	2	20.00%	Acceptable
Staphylococcus saprophyticus	1	10.00%	Acceptable

Organism(s) present: 10,000 -100,000 CFU/mL of *Staphylococcus saprophyticus* and <10,000 CFU/mL *Staphylococcus epidermidis*.

Identification–Specimen CC-10

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

Organism(s) present: >100,000 CFU/mL of *Enterococcus (Strep) faecium.*

DERMATOPHYTE SCREEN

Specimen DM-3

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte absent	11	100%	Acceptable

Organism(s) present: *Escherichia coli.*

Specimen DM-4

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte present	10	90.91%	Acceptable

Organism(s) present: *Trichophyton tonsurans.*

GRAM STAIN

Specimen GS-6

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	16	88.89%	Acceptable
Gram positive	1	5.56%	
No organism(s) present	1	5.56%	

Gram Stain Morphology

Rods/bacilli	13	81.25%	Acceptable
No organism(s) present	1	6.25%	
Cocci	1	6.25%	
Coccobacilli	1	6.25%	

Organism(s) present: *Proteus vulgaris.*

Specimen GS-7

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	15	83.33%	Acceptable
Gram negative	3	16.67%	

Gram Stain Morphology

Cocci	13	81.25%	Acceptable
Coccobacilli	2	12.50%	
Diplococci	1	6.25%	

Organism(s) present: *Streptococcus aeruginosa.*

GRAM STAIN

Specimen GS-8

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	18	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	15	93.75%	Acceptable
Cocci	1	6.25%	

Organism(s) present: *Listeria monocytogenes.*

Specimen GS-9

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	16	88.89%	Acceptable
Gram negative	2	11.11%	
Gram Stain Morphology			
Cocci	13	81.25%	Acceptable
Diplococci	3	18.75%	

Organism(s) present: *Enterococcus (Strep) faecalis*.

Specimen GS-10

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	17	94.44%	Acceptable
Gram positive	1	5.56%	
Gram Stain Morphology			
Rods/bacilli	9	56.25%	Acceptable
Coccobacilli	4	25.00%	Acceptable
Cocci	3	18.75%	

Organism(s) present: *Haemophilus influenzae.*

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-6

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*.

Specimen VP-7

Identification	***Labs***	***Percent***	***Performance***
Positive	27	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis* and *Trichomonas vaginalis*

Specimen VP-8

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

Organism(s) present: *Candida* species.

Specimen VP-9

Identification	***Labs***	***Percent***	***Performance***
Positive	27	100%	Acceptable

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

Specimen VP-10

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

Organism(s) present: *Candida* species.

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-6

Identification	***Labs***	***Percent***	***Performance***
Positive	27	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*.

Specimen VP-7

Identification	***Labs***	***Percent***	***Performance***
Positive	27	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis* and *Trichomonas vaginalis*

Specimen VP-8

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

Organism(s) present: *Candida* species.

Specimen VP-9

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

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

Specimen VP-10

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

Organism(s) present: *Candida* species.

AFFIRM VP III–Candida sp.

Specimen VP-6

Identification	***Labs***	***Percent***	***Performance***
Negative	26	96.30%	Acceptable
Positive	1	3.70%	

Organism(s) present: *Gardnerella vaginalis*.

Specimen VP-7

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis* and *Trichomonas vaginalis*

Specimen VP-8

Identification	***Labs***	***Percent***	***Performance***
Positive	27	100%	Acceptable

Organism(s) present: *Candida* species.

Specimen VP-9

Identification	***Labs***	***Percent***	***Performance***
Positive	27	100%	Acceptable

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

Specimen VP-10

Identification	***Labs***	***Percent***	***Performance***
Positive	27	100%	Acceptable

Organism(s) present: *Candida* species.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-6

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

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

Specimen CY-7

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

Antigen(s) present: No antigen present.

Specimen CY-8

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

Antigen(s) present: *Chlamydia trachomatis.*

Specimen CY-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	13	6	7
BD ProbeTec	3	1	2
BD Viper	1	1	-
Cepheid GeneXpert	3	1	2
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	2	-	2
Roche COBAS Amplicor	2	2	-

Antigen(s) present: *Neisseria gonorrhoeae.* This is an ungraded challenge due to lack of referee consensus.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-10

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	13	12	1
BD ProbeTec	3	2	1
BD Viper	1	1	-
Cepheid GeneXpert	3	3	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	2	2	-
Roche COBAS Amplicor	2	2	-

Antigen(s) present: *Neisseria gonorrhoeae*.

GC (ANTIGEN DETECTION)

Specimen CY-6

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

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

Specimen CY-7

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	11	2	9
BD ProbeTec	3	1	2
BD Viper	1	1	-
Cepheid GeneXpert	3	-	3
Gen-Probe APTIMA	1	-	1
Roche COBAS Amplicor	2	-	2

Antigen(s) present: No antigen present.

Specimen CY-8

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

Antigen(s) present: *Chlamydia trachomatis.*

GC (ANTIGEN DETECTION)

Specimen CY-9

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

Antigen(s) present: *Neisseria gonorrhoeae*.

Specimen CY-10

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

Antigen(s) present: *Chlamydia trachomatis*.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-6

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

Antigen(s) present: *Cryptosporidium.*

Specimen LC-7

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

Antigen(s) present: *Giardia lamblia.*

Specimen LC-8

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

Antigen(s) present: No antigen present.

Specimen LC-9

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

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

Specimen LC-10

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

Antigen(s) present: *Giardia lamblia*.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-6

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

Antigen(s) present: *Cryptosporidium.*

Specimen LC-7

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

Antigen(s) present: *Giardia lamblia*.

Specimen LC-8

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

Antigen(s) present: No antigen present.

Specimen LC-9

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

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

Specimen LC-10

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

Antigen(s) present: *Giardia lamblia*.

RSV ANTIGEN DETECTION

Specimen V-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	64	1	63
Alere Binax NOW - waived	38	-	38
Quidel QuickVue RSV - waived	11	-	11
Quidel QuickVue RSV 10 Test	2	-	2
Quidel Sofia - waived	12	-	12

Antigen(s) present: Influenza B.

Specimen V-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	63	63	-
Alere Binax NOW - waived	38	38	-
Quidel QuickVue RSV - waived	11	11	-
Quidel QuickVue RSV 10 Test	2	2	-
Quidel Sofia - waived	12	12	-

Antigen(s) present: RSV.

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	16	-	16
Alere Binax NOW - waived	3	-	3
Quidel QuickVue RSV - waived	6	-	6
Quidel QuickVue RSV 10 Test	2	-	2
Quidel Sofia - waived	5	-	5

Antigen(s) present: Influenza A.

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	16	-	16
Alere Binax NOW - waived	3	-	3
Quidel QuickVue RSV - waived	6	-	6
Quidel QuickVue RSV 10 Test	2	-	2
Quidel Sofia - waived	5	-	5

Antigen(s) present: Influenza A.

RSV ANTIGEN DETECTION

Specimen V-10

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	16	16	-
Alere Binax NOW - waived	3	3	-
Quidel QuickVue RSV - waived	6	6	-
Quidel QuickVue RSV 10 Test	2	2	-
Quidel Sofia - waived	5	5	-

Antigen(s) present: RSV.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-6

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	46	42	4
Alere Binax NOW - waived	5	5	-
BD Veritor - waived	1	1	-
Medline Influenza A&B	1	1	-
Other Waived Method	3	3	-
Quidel QuickVue Influenza	26	24	2
Quidel QuickVue Influenza A+B	3	3	-
Quidel QuickVue RSV - waived	2	2	-
Sekisui OSOM Influenza A&B	2	1	1

Antigen(s) present: Influenza B.

Specimen V-7

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	47	3	44
Alere Binax NOW - waived	5	-	5
BD Veritor - waived	1	-	1
Medline Influenza A&B	1	-	1
Other Waived Method	3	-	3
Quidel QuickVue Influenza	26	1	25
Quidel QuickVue Influenza A+B	3	-	3
Quidel QuickVue RSV - waived	2	-	2
Sekisui OSOM Influenza A&B	2	-	2

Antigen(s) present: RSV.

Specimen V-8

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

Antigen(s) present: Influenza A.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-9

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

Antigen(s) present: Influenza A.

Specimen V-10

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

Antigen(s) present: RSV.

INFLUENZA A ANTIGEN DETECTION

Specimen V-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	275	-	275
Alere Binax NOW - waived	58	-	58
Alere i Instrument - moderate	7	-	7
Alere i Instrument - waived	3	-	3
Alere Influenza A&B	12	-	12
BD Veritor - waived	34	-	34
Henry Schein OneStep+ Flu A&B	6	-	6
Medline Influenza A&B	1	-	1
Quidel QuickVue Influenza	1	-	1
Quidel QuickVue Influenza A+B	30	-	30
Quidel Sofia - waived	114	-	114
Remel Xpect	2	-	2
Sekisui OSOM Influenza A&B	6	-	6

Antigen(s) present: Influenza B.

INFLUENZA A ANTIGEN DETECTION

Specimen V-7

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	276	2	274
Alere Binax NOW - waived	58	-	58
Alere i Instrument - moderate	7	-	7
Alere i Instrument - waived	3	-	3
Alere Influenza A&B	12	-	12
BD Veritor - waived	34	1	33
Henry Schein OneStep+ Flu A&B	6	-	6
Medline Influenza A&B	1	-	1
Other Waived Method	1	-	1
Quidel QuickVue Influenza	1	-	1
Quidel QuickVue Influenza A+B	30	-	30
Quidel Sofia - waived	114	1	113
Remel Xpect	2	-	2
Sekisui OSOM Influenza A&B	6	-	6

Antigen(s) present: RSV.

Specimen V-8

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	92	92	-
Alere Binax NOW - waived	5	5	-
Alere Influenza A&B	3	3	-
BD Veritor - waived	1	1	-
Henry Schein OneStep+ Flu A&B	1	1	-
Quidel QuickVue Influenza A+B	3	3	-
Quidel Sofia - waived	74	74	-
Remel Xpect	2	2	-
Sekisui OSOM Influenza A&B	3	3	-

Antigen(s) present: Influenza A.

Specimen V-9

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	92	92	-
Alere Binax NOW - waived	5	5	-
Alere Influenza A&B	3	3	-
BD Veritor - waived	1	1	-
Henry Schein OneStep+ Flu A&B	1	1	-
Quidel QuickVue Influenza A+B	3	3	-
Quidel Sofia - waived	74	74	-
Remel Xpect	2	2	-
Sekisui OSOM Influenza A&B	3	3	-

Antigen(s) present: Influenza A.

INFLUENZA A ANTIGEN DETECTION

Specimen V-10

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	92	-	92
Alere Binax NOW - waived	5	-	5
Alere Influenza A&B	3	-	3
BD Veritor - waived	1	-	1
Henry Schein OneStep+ Flu A&B	1	-	1
Quidel QuickVue Influenza A+B	3	-	3
Quidel Sofia - waived	74	-	74
Remel Xpect	2	-	2
Sekisui OSOM Influenza A&B	3	-	3

Antigen(s) present: RSV.

INFLUENZA B ANTIGEN DETECTION

Specimen V-6

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	276	272	4
Alere Binax NOW - waived	58	58	-
Alere i Instrument - moderate	7	5	2
Alere i Instrument - waived	3	3	-
Alere Influenza A&B	12	12	-
BD Veritor - waived	34	33	1
Henry Schein OneStep+ Flu A&B	6	6	-
Medline Influenza A&B	1	1	-
Other Waived Method	1	1	-
Quidel QuickVue Influenza	1	1	-
Quidel QuickVue Influenza A+B	30	30	-
Quidel Sofia - waived	114	113	1
Remel Xpect	2	2	-
Sekisui OSOM Influenza A&B	6	6	-

Antigen(s) present: Influenza B.

INFLUENZA B ANTIGEN DETECTION

Specimen V-7

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

Antigen(s) present: RSV.

Specimen V-8

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	92	-	92
Alere Binax NOW - waived	5	-	5
Alere Influenza A&B	3	-	3
BD Veritor - waived	1	-	1
Henry Schein OneStep+ Flu A&B	1	-	1
Quidel QuickVue Influenza A+B	3	-	3
Quidel Sofia - waived	74	-	74
Remel Xpect	2	-	2
Sekisui OSOM Influenza A&B	3	-	3

Antigen(s) present: Influenza A.

Specimen V-9

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	92	1	91
Alere Binax NOW - waived	5	-	5
Alere Influenza A&B	3	-	3
BD Veritor - waived	1	-	1
Henry Schein OneStep+ Flu A&B	1	-	1
Quidel QuickVue Influenza A+B	3	-	3
Quidel Sofia - waived	74	1	73
Remel Xpect	2	-	2
Sekisui OSOM Influenza A&B	3	-	3

Antigen(s) present: Influenza A.

INFLUENZA B ANTIGEN DETECTION

Specimen V-10

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	92	1	91
Alere Binax NOW - waived	5	-	5
Alere Influenza A&B	3	-	3
BD Veritor - waived	1	-	1
Henry Schein OneStep+ Flu A&B	1	-	1
Quidel QuickVue Influenza A+B	3	-	3
Quidel Sofia - waived	74	-	74
Remel Xpect	2	1	1
Sekisui OSOM Influenza A&B	3	-	3

Antigen(s) present: RSV.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-6

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

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

Specimen AG-7

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

Antigen(s) present: Rotavirus.

Specimen AG-8

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

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

Specimen AG-9

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

Antigen(s) present: No antigen present.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-10

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

Antigen(s) present: *Clostridium difficile.*

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-6

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

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

Specimen AG-7

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

Antigen(s) present: Rotavirus.

Specimen AG-8

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

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

Specimen AG-9

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

Antigen(s) present: No antigen present.

Specimen AG-10

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

Antigen(s) present: *Clostridium difficile.*

LEGIONELLA ANTIGEN DETETION

Specimen L-6

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

Specimen L-7

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

Specimen L-8

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

Specimen L-9

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

Specimen L-10

Method	***Labs***	***Positive***	***Negative***
Binax NOW	16	1	15

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-6

Method	***Labs***	***Positive***	***Negative***
Binax NOW	14	14	-

Specimen SP-7

Method	***Labs***	***Positive***	***Negative***
Binax NOW	14	13	1

Specimen SP-8

Method	***Labs***	***Positive***	***Negative***
Binax NOW	14	13	1

Specimen SP-9

Method	***Labs***	***Positive***	***Negative***
Binax NOW	14	1	13

Specimen SP-10

Method	***Labs***	***Positive***	***Negative***
Binax NOW	14	1	13

PARASITOLOGY

Specimen PA-6

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

Parasite(s) present: No parasites seen.

Specimen PA-7

Identification	***Labs***	***Percent***	***Performance***
Endolimax nana	1	100%	Acceptable

Parasite(s) present: *Endolimax nana*.

Specimen PA-8

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

Parasite(s) present: *Giardia lamblia* and *Entamoeba histolytica*.

Specimen PA-9

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

Parasite(s) present: *Ascaris lumbricoides.*

Specimen PA-10

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

Parasite(s) present: *Diphyllobothrium latum.*

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