MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 2 • 1

Microbiology
2021 MLE-M1

ACP | Medical Laboratory Evaluation

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

Table of Contents

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	Gram Stain Morphology	80% Consensus
Affirm VP III Gardnerella Ag Detection	80% Consensus	Influenza A 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 (Cultures)	80% Consensus	MRSA Culture	80% Consensus
Bacterial Vaginosis (OSOM)	80% Consensus	Parasite Identification	80% Consensus
Chlamydia (EIA, DNA)	80% Consensus	Rotavirus Antigen Detection	80% Consensus
Clostridioides difficile Antigen Detection	80% Consensus	RSV Antigen Detection	80% Consensus
Colony Count	80% Consensus	SARS-CoV-2 Antigen Detection	80% Consensus
Cryptosporidium Antigen Detection	80% Consensus	SARS-CoV-2 Molecular Detection	80% Consensus
Dermatophyte Culture	80% Consensus	Strep A Antigen Detection	80% Consensus
GC (EIA, DNA)	80% Consensus	Streptococcus pneumoniae Antigen Detection	80% Consensus
Giardia lamblia Antigen Detection	80% Consensus	Trichomonas vaginalis (OSOM)	80% Consensus
Gram Stain	80% Consensus		

METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS CULTURE

Specimen MSA-1

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

Organism(s) present: *Staphylococcus aureus* – Methicillin resistant and *Micrococcus luteus*

Specimen MSA-2

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

Organism(s) present: *Listeria monocytogenes*

Specimen MSA-3

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

Organism(s) present: *Staphylococcus aureus* – Methicillin resistant and *Streptococcus salivarius*

Specimen MSA-4

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

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

Specimen MSA-5

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

Organism(s) present: *Streptococcus dysgalactiae* and *Staphylococcus aureus* – Methicillin sensitive

STREP A ANTIGEN DETECTION

Specimen RS-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	404	2	402
Abbott ID NOW	1	-	1
Alere Acceava Strep A Test	6	-	6
Alere i Instrument - waived	5	-	5
BD Chek Strep A	1	-	1
BD Veritor - waived	5	-	5
Beckman Coulter ICON DS	5	-	5
Beckman Coulter ICON SC	1	-	1
Binax NOW Strep A	2	-	2
Cardinal Health Strep A - waived	5	-	5
Cepheid GeneXpert - waived	8	-	8
Consult Diagnostic Strep A Dipstick - Waived	54	-	54
Fisher HealthCare Sure-Vue	1	-	1
Fisher HealthCare Sure-Vue - waived	1	-	1
GenePOC revogene	3	-	3
Germaine Laboratories StrepAim	1	-	1
Henry Schein One Step+ - waived	52	-	52
LifeSign Status Strep A	1	-	1
McKesson Strep A Cassette	2	-	2
McKesson Strep A Dipstick	12	-	12
Medline Strep A Test Strip	4	-	4
Meridian ImmunoCard STAT - waived	7	-	7
Other Moderately Complex Method	1	-	1
Other Waived Method	4	-	4
Quidel QuickVue Dipstick Strep	34	-	34
Quidel QuickVue In-Line	29	-	29
Quidel QuickVue+	7	-	7
Quidel Sofia / Sofia 2 - waived	3	-	3
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	18	-	18
Quidel Solana	4	-	4
Roche cobas Liat	2	-	2
Sekisui OSOM	88	2	86
Sekisui OSOM Ultra -waived	34	-	34
Stanbio QuStick Strep A	1	-	1

STREP A ANTIGEN DETECTION

Specimen RS-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	401	390	11
Abbott ID NOW	1	1	-
Alere Acceava Strep A Test	6	6	-
Alere i Instrument - waived	5	5	-
BD Chek Strep A	1	1	-
BD Veritor - waived	4	4	-
Beckman Coulter ICON DS	5	5	-
Beckman Coulter ICON SC	1	1	-
Binax NOW Strep A	2	2	-
Cardinal Health Strep A - waived	5	5	-
Cepheid GeneXpert - waived	8	8	-
Consult Diagnostic Strep A Dipstick - Waived	54	53	1
Fisher HealthCare Sure-Vue	1	1	-
Fisher HealthCare Sure-Vue - waived	1	1	-
GenePOC revogene	3	3	-
Germaine Laboratories StrepAim	1	1	-
Henry Schein One Step+ - waived	52	51	1
LifeSign Status Strep A	1	1	-
McKesson Strep A Cassette	2	2	-
McKesson Strep A Dipstick	11	11	-
Medline Strep A Test Strip	4	4	-
Meridian ImmunoCard STAT - waived	7	6	1
Other Moderately Complex Method	1	1	-
Other Waived Method	4	2	2
Quidel QuickVue Dipstick Strep	33	33	-
Quidel QuickVue In-Line	29	26	3
Quidel QuickVue+	7	6	1
Quidel Sofia / Sofia 2 - waived	3	3	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	18	18	-
Quidel Solana	4	4	-
Roche cobas Liat	2	2	-
Sekisui OSOM	88	86	2
Sekisui OSOM Ultra -waived	34	34	-
Stanbio QuStick Strep A	1	1	-

STREP A ANTIGEN DETECTION

Specimen RS-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	48	-	48
Abbott ID NOW	1	-	1
Alere i Instrument - waived	1	-	1
BD Veritor - waived	1	-	1
Binax NOW Strep A	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	11	-	11
Henry Schein One Step+ - waived	3	-	3
McKesson Strep A Dipstick	2	-	2
Quidel QuickVue Dipstick Strep	8	-	8
Quidel QuickVue In-Line	5	-	5
Quidel QuickVue+	2	-	2
Quidel Sofia / Sofia 2 - waived	1	-	1
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	2	-	2
Quidel Solana	4	-	4
Sekisui OSOM Ultra -waived	4	-	4

Specimen RS-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	48	1	47
Abbott ID NOW	1	-	1
Alere i Instrument - waived	1	-	1
BD Veritor - waived	1	-	1
Binax NOW Strep A	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	11	-	11
Henry Schein One Step+ - waived	3	-	3
McKesson Strep A Dipstick	2	-	2
Quidel QuickVue Dipstick Strep	8	-	8
Quidel QuickVue In-Line	5	-	5
Quidel QuickVue+	2	-	2
Quidel Sofia / Sofia 2 - waived	1	-	1
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	2	-	2
Quidel Solana	4	-	4
Sekisui OSOM Ultra -waived	4	1	3

STREP A ANTIGEN DETECTION

Specimen RS-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	48	48	-
Abbott ID NOW	1	1	-
Alere i Instrument - waived	1	1	-
BD Veritor - waived	1	1	-
Binax NOW Strep A	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	11	11	-
Henry Schein One Step+ - waived	3	3	-
McKesson Strep A Dipstick	2	2	-
Quidel QuickVue Dipstick Strep	8	8	-
Quidel QuickVue In-Line	5	5	-
Quidel QuickVue+	2	2	-
Quidel Sofia / Sofia 2 - waived	1	1	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	2	2	-
Quidel Solana	4	4	-
Sekisui OSOM Ultra -waived	4	4	-

MISCELLANEOUS CULTURES

Specimen BA-1 – Blood Culture

Identification	*Labs*	*Percent*	*Performance*
Pseudomonas luteola	3	75.00%	Acceptable
Pseudomonas sp.	1	25.00%	Acceptable

Organism(s) present: *Pseudomonas luteola*

Specimen BA-2 – Stool Culture

Identification	*Labs*	*Percent*	*Performance*
Bacillus cereus	2	40.00%	Acceptable
Enterococcus faecium	2	40.00%	Acceptable
Enterococcus sp.	1	20.00%	Acceptable

Organism(s) present: *Bacillus cereus* and *Enterococcus faecium*

Specimen BA-3 – Wound Culture (Aerobic and Anaerobic)

Identification	*Labs*	*Percent*	*Performance*
Corynebacterium striatum	3	30.00%	Acceptable
Corynebacterium sp.	2	20.00%	Acceptable
Prevotella bivia	2	20.00%	Acceptable
Prevotella sp.	2	20.00%	Acceptable
Anaerobic cultures not performed – would refer	1	10.00%	Acceptable

Organism(s) present: *Corynebacterium striatum* and *Prevotella bivia*

THROAT CULTURE

Specimen TC-1

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	42	56.76%	Acceptable
Presumptive Positive for Group A Strep	23	31.08%	Acceptable
Streptococcus pyogenes	5	6.76%	Acceptable
Staphylococcus sp.	3	4.05%	Acceptable
Staph – coagulase negative	1	1.35%	Acceptable

Organism(s) present: *Streptococcus pyogenes* and *Staphylococcus epidermidis*

Specimen TC-2

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	63	91.30%	Acceptable
No growth (sterile)	4	5.80%	Acceptable

Organism(s) present: No growth (sterile)

Specimen TC-3

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	25	54.35%	Acceptable
Presumptive Positive for Group A Strep	21	45.65%	Acceptable

Organism(s) present: *Streptococcus pyogenes*

Specimen TC-4

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	42	95.45%	Acceptable

Organism(s) present: *Neisseria subflava* and *Staphylococcus aureus*

Specimen TC-5

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	42	95.45%	Acceptable

Organism(s) present: *Elizabethkingia meningoseptica*

URINE CULTURE

Specimen UC-1

Identification	***Labs***	***Percent***	***Performance***
Salmonella sp.	26	81.25%	Acceptable
Growth, referred for identification	4	12.50%	Acceptable
Presumptive Gram negative	1	3.13%	Acceptable
Gram negative bacilli	1	3.13%	Acceptable
Gram Stain			
Gram negative	14	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	14	100%	Acceptable

Organism(s) present: *Salmonella enteritidis*

Specimen UC-2

Identification	***Labs***	***Percent***	***Performance***
Staphylococcus aureus	25	75.76%	Acceptable
Growth, referred for identification	5	15.15%	Acceptable
Staph – coagulase negative	2	6.06%	Acceptable
Gram positive cocci	1	3.03%	Acceptable

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

URINE CULTURE

Specimen UC-3

Identification	***Labs***	***Percent***	***Performance***
Escherichia coli	13	72.22%	Acceptable
Growth, referred for identification	3	16.67%	Acceptable
Presumptive Gram negative	1	5.56%	Acceptable
Gram negative bacilli	1	5.56%	Acceptable

Organism(s) present: *Escherichia coli* and *Granulicatella adiacens*

Specimen UC-4

Identification	***Labs***	***Percent***	***Performance***
Streptococcus agalactiae	6	54.55%	Acceptable
Growth, referred for identification	2	18.18%	Acceptable
Aerococcus viridans	2	18.18%	Acceptable

Organism(s) present: *Streptococcus agalactiae* and *Aerococcus viridans*

Specimen UC-5

Identification	***Labs***	***Percent***	***Performance***
Proteus vulgaris	3	42.86%	Acceptable
Growth, referred for identification	2	28.57%	Acceptable
Proteus sp.	2	28.57%	Acceptable

Organism(s) present: Proteus vulgaris

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen UC-1, CC-1 (SUS-1)

	------Disk Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Amoxicillin/Clavulanate	4	4	-	-	-	-	-	-	100.00%
Ampicillin	20	20	-	-	4	4	-	-	100.00%
Cefazolin	17	17	-	-	-	-	-	-	Inappropriate drug[1]
Cefepime	-	-	-	-	1	1	-	-	100.00%
Cefixime	3	3	-	-	-	-	-	-	100.00%
Cefotaxime	-	-	-	-	1	1	-	-	100.00%
Cefoxitin	1	1	-	-	-	-	-	-	Inappropriate drug[1]
Cefpodoxime	1	1	-	-	-	-	-	-	100.00%
Ceftazidime	3	3	-	-	2	2	-	-	100.00%
Ceftriaxone	6	6	-	-	4	4	-	-	100.00%
Cefuroxime	5	5	-	-	-	-	-	-	Inappropriate drug[1]
Ciprofloxacin	22	22	-	-	4	4	-	-	100.00%
Gentamicin	21	21	-	-	-	-	-	-	Inappropriate drug[1]
Levofloxacin	10	10	-	-	3	3	-	-	100.00%
Meropenem	-	-	-	-	1	1	-	-	100.00%
Nitrofurantoin	20	20	-	-	1	1	-	-	100.00%
Piperacillin/Tazobactam	1	1	-	-	1	1	-	-	100.00%
Tetracycline	4	4	-	-	-	-	-	-	100.00%
Tobramycin	1	1	-	-	-	-	-	-	Inappropriate drug[1]
Trimethoprim/Sulfamethoxazole	22	22	-	-	4	4	-	-	100.00%

Organism(s) present: *Salmonella enteritidis*

Susceptibility patterns for *Salmonella enteritidis* follow that of the Enterobacteriales (formerly named Enterobacteriaceae) family with a few important exceptions. Most of these exceptions are within the cephalosporin group of antibiotics. Cephalosporins are divided into five different generations (1st, 2nd , 3rd , 4th, and 5th) based on their effectiveness against gram positive and gram negative organisms. The 1st through 3rd generation cephalosporins are ranked on a scale from gram positive to gram negative, with the 1st generation being most effective against gram positive infections. The 4th generation cephalosporin specifically covers *Pseudomonas* infections and the 5th generation is used for MRSA (methicillin resistant *staphylococcus aureus*).

Although 1st and 2nd generation cephalosporins like cefazolin and cefuroxime will appear susceptible to *Salmonella enteritidis* on an antimicrobial susceptibility test, the CLSI specifically states that they should not be reported as they are not clinically valid. Similarly, aminoglycosides like gentamicin and tobramycin should not be reported even though they appear susceptible to *Salmonella ssp*. and *Shigella ssp*. However, 3rd generation cephalosporin susceptibility testing is recommended by the CLSI when *Salmonella enteritidis* is found in an extra intestinal source such as urine.

NOTE: Please be aware that CLSI issues annual editions of M100, the standards used by all proficiency testing programs for grading of susceptibilities. Drugs considered appropriate may change significantly with subsequent editions. The current edition of the CLSI M100 document is accessible online at CLSI.org under Standards>Free Resources.

[1] Inappropriate drug for organism and/or source

GENITAL CULTURE

Specimen GC-1

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhoeae	13	76.47%	Acceptable
Neisseria gonorrhoeae	3	17.65%	Acceptable
Gram negative diplococci	1	5.88%	Acceptable

Gram Stain

Gram negative	5	100%	Acceptable

Gram Stain Morphology

Diplococci	5	100%	Acceptable

Organism(s) present: *Neisseria gonorrhoeae*

Specimen GC-2

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	4	80.00%	Acceptable
No growth (sterile)	1	20.00%	Acceptable

Organism(s) present: No growth (sterile)

Specimen GC-3

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	5	83.33%	Acceptable

Organism(s) present: *Enterococcus faecium* and *Staphylococcus haemolyticus*

Specimen GC-4

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	4	100%	Acceptable

Organism(s) present: *Streptococcus agalactiae*

Specimen GC-5

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhoeae	4	100%	Acceptable

Organism(s) present: *Neisseria gonorrhoeae* and *Staphylococcus aureus*

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-1

Method	Labs	No growth	<10,000 organisms/mL	10,000-100,000 organisms/mL	>100,000 organisms/mL
ALL METHODS	32	-	1	13	18
Calibrated Loop	17	-	1	6	10
Uri-Check	2	-	-	1	1
Uricult	13	-	-	6	7

Identification–Specimen CC-1

Identification	Labs	Percent	Performance
Growth, referred for identification	7	87.50%	Acceptable
Presump. Salmonella sp.	1	12.50%	Acceptable
Gram Stain			
Gram negative	1	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	1	100%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Salmonella enteritidis*

Specimen CC-2

Method	Labs	No growth	<10,000 organisms/mL	10,000-100,000 organisms/mL	>100,000 organisms/mL
ALL METHODS	32	5	13	14	-
Calibrated Loop	17	-	6	11	-
Uri-Check	2	1	1	-	-
Uricult	13	4	6	3	-

Identification–Specimen CC-2

Identification	Labs	Percent	Performance
Growth, referred for identification	7	87.50%	Acceptable
Presump. Staphylococcus sp.	1	12.50%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Staphylococcus aureus* and <10,000 CFU/mL of *Staphylococcus epidermidis*

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-3

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	5	83.33%	Acceptable
Presump. Escherichia coli	1	16.67%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Escherichia coli* and 53,000 CFU/mL of *Granulicatella adiacens*

Identification–Specimen CC-4

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	4	66.67%	Acceptable
Presump. Streptococcus sp.	1	16.67%	Acceptable

Organism(s) present: 66,000 CFU/mL of *Streptococcus agalactiae* and 2,,000 CFU/mL of *Aerococcus viridans*

Identification–Specimen CC-5

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	5	83.33%	Acceptable
Presump. Proteus sp.	1	16.67%	Acceptable

Organism(s) present: >100,000 CFU/ mL of *Proteus vulgaris*

GRAM STAIN

Specimen GS-1

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	14	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	9	90.00%	Acceptable
Coccobacilli	1	10.00%	

Organism(s) present: *Pseudomonas aeruginosa*

Specimen GS-2

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	14	100%	Acceptable
Gram Stain Morphology			
Cocci	6	60.00%	Not graded
Coccobacilli	2	20.00%	
Diplococci	2	20.00%	

Organism(s) present: Streptococcus bovis. The gram stain morphology is ungraded due to lack of consensus. The correct response is cocci.

GRAM STAIN

Specimen GS-3

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	7	50.00%	Not graded
Gram negative	7	50.00%	
Gram Stain Morphology			
Rods/bacilli	7	87.50%	Acceptable
Cocci	1	12.50%	

Organism(s) present: *Nocardia brasiliensis*. The gram stain is ungraded due to less than 80% referee consensus. *Nocardia* spp. is Gram Positive.

Specimen GS-4

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	13	92.86%	Acceptable
Gram negative	1	7.14%	
Gram Stain Morphology			
Cocci	4	40.00%	Not graded
Diplococci	6	60.00%	

Organism(s) present: *Micrococcus luteus.* The gram stain morphology is ungraded due to lack of consensus. The correct response is cocci.

Specimen GS-5

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	14	100%	Acceptable
Gram Stain Morphology			
Coccobacilli	4	40.00%	Acceptable
Rods/bacilli	4	40.00%	Acceptable
Cocci	2	20.00%	

Organism(s) present: *Haemophilus influenzae*

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-1

Identification	***Labs***	***Percent***	***Performance***
Negative	20	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*

Specimen VP-2

Identification	***Labs***	***Percent***	***Performance***
Positive	20	100%	Acceptable

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

Specimen VP-3

Identification	***Labs***	***Percent***	***Performance***
Negative	20	100%	Acceptable

Organism(s) present: *Candida sp.*

Specimen VP-4

Identification	***Labs***	***Percent***	***Performance***
Positive	20	100%	Acceptable

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

Specimen VP-5

Identification	***Labs***	***Percent***	***Performance***
Negative	20	100%	Acceptable

Organism(s) present: *Candida sp.*

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-1

Identification	***Labs***	***Percent***	***Performance***
Positive	20	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*

Specimen VP-2

Identification	***Labs***	***Percent***	***Performance***
Positive	20	100%	Acceptable

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

Specimen VP-3

Identification	***Labs***	***Percent***	***Performance***
Negative	20	100%	Acceptable

Organism(s) present: *Candida sp.*

Specimen VP-4

Identification	***Labs***	***Percent***	***Performance***
Negative	20	100%	Acceptable

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

Specimen VP-5

Identification	***Labs***	***Percent***	***Performance***
Negative	19	95.00%	Acceptable
Positive	1	5.00%	

Organism(s) present: *Candida sp.*

AFFIRM VP III–Candida sp.

Specimen VP-1

Identification	***Labs***	***Percent***	***Performance***
Negative	20	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*

Specimen VP-2

Identification	***Labs***	***Percent***	***Performance***
Negative	20	100%	Acceptable

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

Specimen VP-3

Identification	***Labs***	***Percent***	***Performance***
Positive	20	100%	Acceptable

Organism(s) present: *Candida sp.*

Specimen VP-4

Identification	***Labs***	***Percent***	***Performance***
Positive	20	100%	Acceptable

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

Specimen VP-5

Identification	***Labs***	***Percent***	***Performance***
Positive	20	100%	Acceptable

Organism(s) present: *Candida sp.*

SARS-CoV-2 (MOLECULAR DETECTION)

Specimen MCV-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	25	25	-
Abbott ID NOW	12	12	-
Applied Biosystems	1	1	-
Cepheid GeneXpert - waived	3	3	-
Other EUA method	2	2	-
Perkin Elmer	1	1	-
Roche Cobas Molecular - waived	5	5	-
Sansure Biotech	1	1	-

Specimen MCV-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	25	-	25
Abbott ID NOW	12	-	12
Applied Biosystems	1	-	1
Cepheid GeneXpert - waived	3	-	3
Other EUA method	2	-	2
Perkin Elmer	1	-	1
Roche Cobas Molecular - waived	5	-	5
Sansure Biotech	1	-	1

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	12	12	-
BD Max	2	2	-
BD ProbeTec	1	1	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	4	4	-
Quidel QuickVue	3	3	-
Roche COBAS Amplicor	1	1	-

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

Specimen CY-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	12	-	12
BD Max	2	-	2
BD ProbeTec	1	-	1
BD Viper	1	-	1
Cepheid GeneXpert - moderate	4	-	4
Quidel QuickVue	3	-	3
Roche COBAS Amplicor	1	-	1

Antigen(s) present: Negative (sterile)

Specimen CY-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	10	10	-
BD Max	2	2	-
BD ProbeTec	1	1	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	4	4	-
Quidel QuickVue	1	1	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Chlamydia trachomatis*

Specimen CY-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	10	-	10
BD Max	2	-	2
BD ProbeTec	1	-	1
BD Viper	1	-	1
Cepheid GeneXpert - moderate	4	-	4
Quidel QuickVue	1	-	1
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Neisseria gonorrhoeae*

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	10	10	-
BD Max	2	2	-
BD ProbeTec	1	1	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	4	4	-
Quidel QuickVue	1	1	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Chlamydia trachomatis*

GC (ANTIGEN DETECTION)

Specimen CY-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	9	9	-
BD Max	2	2	-
BD ProbeTec	1	1	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	4	4	-
Roche COBAS Amplicor	1	1	-

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

Specimen CY-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	9	-	9
BD Max	2	-	2
BD ProbeTec	1	-	1
BD Viper	1	-	1
Cepheid GeneXpert - moderate	4	-	4
Roche COBAS Amplicor	1	-	1

Antigen(s) present: Negative (sterile)

Specimen CY-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	9	-	9
BD Max	2	-	2
BD ProbeTec	1	-	1
BD Viper	1	-	1
Cepheid GeneXpert - moderate	4	-	4
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Chlamydia trachomatis*

GC (ANTIGEN DETECTION)

Specimen CY-4

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	9	9	-
BD Max	2	2	-
BD ProbeTec	1	1	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	4	4	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Neisseria gonorrhoeae*

Specimen CY-5

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	9	-	9
BD Max	2	-	2
BD ProbeTec	1	-	1
BD Viper	1	-	1
Cepheid GeneXpert - moderate	4	-	4
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Chlamydia trachomatis*

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	-	5
Alere CRYPTOSPORIDIUM II	3	-	3
Alere Giardia/Crypto Quik Chek	2	-	2

Antigen(s) present: *Giardia lamblia*

Specimen LC-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	-	5
Alere CRYPTOSPORIDIUM II	3	-	3
Alere Giardia/Crypto Quik Chek	2	-	2

Antigen(s) present: Negative (sterile)

Specimen LC-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	5	
Alere CRYPTOSPORIDIUM II	3	3	
Alere Giardia/Crypto Quik Chek	2	2	

Antigen(s) present: *Cryptosporidium parvum*

Specimen LC-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	5	-
Alere CRYPTOSPORIDIUM II	3	3	-
Alere Giardia/Crypto Quik Chek	2	2	-

Antigen(s) present: *Cryptosporidium parvum*

Specimen LC-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	-	5
Alere CRYPTOSPORIDIUM II	3	-	3
Alere Giardia/Crypto Quik Chek	2	-	2

Antigen(s) present: *Giardia lamblia*

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-1

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Alere GIARDIA II	3	3	-
Alere Giardia/Crypto Quik Chek	2	2	-

Antigen(s) present: *Giardia lamblia*

Specimen LC-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Alere GIARDIA II	3	-	3
Alere Giardia/Crypto Quik Chek	2	-	2

Antigen(s) present: Negative (sterile)

Specimen LC-3

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Alere GIARDIA II	3	-	3
Alere Giardia/Crypto Quik Chek	2	-	2

Antigen(s) present: *Cryptosporidium parvum*

Specimen LC-4

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Alere GIARDIA II	3	-	3
Alere Giardia/Crypto Quik Chek	2	-	2

Antigen(s) present: *Cryptosporidium parvum*

Specimen LC-5

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Alere GIARDIA II	3	3	-
Alere Giardia/Crypto Quik Chek	2	2	-

Antigen(s) present: *Giardia lamblia*

RSV ANTIGEN DETECTION

Specimen V-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	72	2	70
Abbott ID NOW	2	-	2
Alere Binax NOW - waived	29	-	29
BD Veritor - moderate	3	-	3
BD Veritor - waived	6	1	5
Cepheid GeneXpert - waived	2	-	2
Quidel QuickVue RSV - waived	9	1	8
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia / Sofia 2 - waived	18	-	18
Quidel Solana	2	-	2

Antigen(s) present: Influenza B

Specimen V-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	72	71	1
Abbott ID NOW	2	2	-
Alere Binax NOW - waived	29	29	-
BD Veritor - moderate	3	3	-
BD Veritor - waived	6	5	1
Cepheid GeneXpert - waived	2	2	-
Quidel QuickVue RSV - waived	9	9	-
Quidel QuickVue RSV 10 Test	1	1	-
Quidel Sofia / Sofia 2 - waived	18	18	-
Quidel Solana	2	2	-

Antigen(s) present: RSV

Specimen V-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	15	-	15
Alere Binax NOW - waived	1	-	1
BD Veritor - moderate	3	-	3
BD Veritor - waived	1	-	1
Quidel QuickVue RSV - waived	3	-	3
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia / Sofia 2 - waived	4	-	4
Quidel Solana	2	-	2

Antigen(s) present: Influenza A

RSV ANTIGEN DETECTION

Specimen V-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	15	-	15
Alere Binax NOW - waived	1	-	1
BD Veritor - moderate	3	-	3
BD Veritor - waived	1	-	1
Quidel QuickVue RSV - waived	3	-	3
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia / Sofia 2 - waived	4	-	4
Quidel Solana	2	-	2

Antigen(s) present: Influenza B

Specimen V-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	15	14	1
Alere Binax NOW - waived	1	1	-
BD Veritor - moderate	3	3	-
BD Veritor - waived	1	1	-
Quidel QuickVue RSV - waived	3	3	-
Quidel QuickVue RSV 10 Test	1	1	-
Quidel Sofia / Sofia 2 - waived	4	4	-
Quidel Solana	2	1	1

Antigen(s) present: RSV

INFLUENZA A ANTIGEN DETECTION

Specimen V-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	283	9	274
Abbott ID NOW	7	-	7
Alere Binax NOW - waived	2	-	2
Alere i Instrument - waived	2	-	2
Alere Influenza A&B	2	-	2
BD Veritor - moderate	5	-	5
BD Veritor - waived	41	2	39
BioSign Flu A+B	4	-	4
Cepheid GeneXpert - waived	9	-	9
Henry Schein OneStep+ Flu A&B	2	-	2
McKesson Consult Diag. Flu A & B	36	4	32
Meridian ImmunoCard STAT - waived	1	-	1
OraSure QuickFlu	1	-	1
Quidel QuickVue Influenza A+B	19	1	18
Quidel Sofia / Sofia 2 - waived	122	2	120
Quidel Solana	3	-	3
Roche cobas Liat	4	-	4
Sekisui OSOM Influenza A&B	4	-	4
Sekisui OSOM Ultra -waived	19	-	19

Antigen(s) present: Influenza B

Specimen V-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	283	6	277
Abbott ID NOW	7	-	7
Alere Binax NOW - waived	2	-	2
Alere i Instrument - waived	2	-	2
Alere Influenza A&B	2	-	2
BD Veritor - moderate	5	-	5
BD Veritor - waived	41	4	37
BioSign Flu A+B	4	-	4
Cepheid GeneXpert - waived	9	-	9
Henry Schein OneStep+ Flu A&B	2	-	2
McKesson Consult Diag. Flu A & B	36	1	35
Meridian ImmunoCard STAT - waived	1	-	1
OraSure QuickFlu	1	-	1
Quidel QuickVue Influenza A+B	19	-	19
Quidel Sofia / Sofia 2 - waived	122	1	121
Quidel Solana	3	-	3
Roche cobas Liat	4	-	4
Sekisui OSOM Influenza A&B	4	-	4
Sekisui OSOM Ultra -waived	19	-	19

Antigen(s) present: RSV

INFLUENZA A ANTIGEN DETECTION

Specimen V-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	19	19	-
Abbott ID NOW	2	2	-
Alere Binax NOW - waived	1	1	-
BD Veritor - moderate	5	5	-
McKesson Consult Diag. Flu A & B	2	2	-
Quidel QuickVue Influenza A+B	2	2	-
Quidel Sofia / Sofia 2 - waived	4	4	-
Quidel Solana	3	3	-

Antigen(s) present: Influenza A

Specimen V-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	19	-	19
Abbott ID NOW	2	-	2
Alere Binax NOW - waived	1	-	1
BD Veritor - moderate	5	-	5
McKesson Consult Diag. Flu A & B	2	-	2
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia / Sofia 2 - waived	4	-	4
Quidel Solana	3	-	3

Antigen(s) present: Influenza B

Specimen V-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	19	-	19
Abbott ID NOW	2	-	2
Alere Binax NOW - waived	1	-	1
BD Veritor - moderate	5	-	5
McKesson Consult Diag. Flu A & B	2	-	2
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia / Sofia 2 - waived	4	-	4
Quidel Solana	3	-	3

Antigen(s) present: RSV

INFLUENZA B ANTIGEN DETECTION

Specimen V-1

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	283	272	11
Abbott ID NOW	7	6	1
Alere Binax NOW - waived	2	2	-
Alere i Instrument - waived	2	2	-
Alere Influenza A&B	2	2	-
BD Veritor - moderate	5	5	-
BD Veritor - waived	41	40	1
BioSign Flu A+B	4	4	-
Cepheid GeneXpert - waived	9	8	1
Henry Schein OneStep+ Flu A&B	2	2	-
McKesson Consult Diag. Flu A & B	34	31	3
Meridian ImmunoCard STAT - waived	1	1	-
OraSure QuickFlu	1	-	1
Quidel QuickVue Influenza A+B	20	17	3
Quidel Sofia / Sofia 2 - waived	123	122	1
Quidel Solana	3	3	-
Roche cobas Liat	4	4	-
Sekisui OSOM Influenza A&B	5	5	-
Sekisui OSOM Ultra -waived	18	18	-

Antigen(s) present: Influenza B

Specimen V-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	283	16	267
Abbott ID NOW	7	1	6
Alere Binax NOW - waived	2	-	2
Alere i Instrument - waived	2	1	1
Alere Influenza A&B	2	-	2
BD Veritor - moderate	5	-	5
BD Veritor - waived	41	2	39
BioSign Flu A+B	4	-	4
Cepheid GeneXpert - waived	9	1	8
Henry Schein OneStep+ Flu A&B	2	-	2
McKesson Consult Diag. Flu A & B	34	3	31
Meridian ImmunoCard STAT - waived	1	-	1
OraSure QuickFlu	1	1	-
Quidel QuickVue Influenza A+B	20	2	18
Quidel Sofia / Sofia 2 - waived	123	5	118
Quidel Solana	3	-	3
Roche cobas Liat	4	-	4
Sekisui OSOM Influenza A&B	5	-	5
Sekisui OSOM Ultra -waived	18	-	18

Antigen(s) present: RSV

INFLUENZA B ANTIGEN DETECTION

Specimen V-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	19	-	19
Abbott ID NOW	2	-	2
Alere Binax NOW - waived	1	-	1
BD Veritor - moderate	5	-	5
McKesson Consult Diag. Flu A & B	2	-	2
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia / Sofia 2 - waived	4	-	4
Quidel Solana	3	-	3

Antigen(s) present: Influenza A

Specimen V-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	19	19	-
Abbott ID NOW	2	2	-
Alere Binax NOW - waived	1	1	-
BD Veritor - moderate	5	5	-
McKesson Consult Diag. Flu A & B	2	2	-
Quidel QuickVue Influenza A+B	2	2	-
Quidel Sofia / Sofia 2 - waived	4	4	-
Quidel Solana	3	3	-

Antigen(s) present: Influenza B

Specimen V-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	19	-	19
Abbott ID NOW	2	-	2
Alere Binax NOW - waived	1	-	1
BD Veritor - moderate	5	-	5
McKesson Consult Diag. Flu A & B	2	-	2
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia / Sofia 2 - waived	4	-	4
Quidel Solana	3	-	3

Antigen(s) present: RSV

CLOSTRIDIOIDES DIFFICILE ANTIGEN DETECTION

Specimen AG-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	5	-
Alere C. diff Quik Chek	5	5	-

Antigen(s) present: *Clostridioides difficile*

Specimen AG-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	-	5
Alere C. diff Quik Chek	5	-	5

Antigen(s) present: Rotavirus

Specimen AG-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	5	-
Alere C. diff Quik Chek	5	5	-

Antigen(s) present: *Clostridioides difficile* and Rotavirus

Specimen AG-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	-	5
Fisher HealthCare Sure-Vue	5	-	5

Antigen(s) present: Negative (sterile)

Specimen AG-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	5	-
Alere C. diff Quik Chek	5	5	-

Antigen(s) present: *Clostridioides difficile* and Rotavirus

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-1

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Fisher HealthCare Sure-Vue	5	-	5

Antigen(s) present: *Clostridioides difficile*

Specimen AG-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Fisher HealthCare Sure-Vue	5	5	-

Antigen(s) present: Rotavirus

Specimen AG-3

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Fisher HealthCare Sure-Vue	5	5	-

Antigen(s) present: *Clostridioides difficile* and Rotavirus

Specimen AG-4

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Fisher HealthCare Sure-Vue	5	-	5

Antigen(s) present: Negative (sterile)

Specimen AG-5

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Fisher HealthCare Sure-Vue	5	5	-

Antigen(s) present: *Clostridioides difficile* and Rotavirus

LEGIONELLA ANTIGEN DETETION

Specimen L-1

Method	***Labs***	***Positive***	***Negative***
Binax NOW	7	-	7

Specimen L-2

Method	***Labs***	***Positive***	***Negative***
Binax NOW	7	7	-

Specimen L-3

Method	***Labs***	***Positive***	***Negative***
Binax NOW	7	7	-

Specimen L-4

Method	***Labs***	***Positive***	***Negative***
Binax NOW	7	7	-

Specimen L-5

Method	***Labs***	***Positive***	***Negative***
Binax NOW	7	-	7

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-1

Method	***Labs***	***Positive***	***Negative***
Binax NOW	5	5	-

Specimen SP-2

Method	***Labs***	***Positive***	***Negative***
Binax NOW	5	5	-

Specimen SP-3

Method	***Labs***	***Positive***	***Negative***
Binax NOW	5	5	-

Specimen SP-4

Method	***Labs***	***Positive***	***Negative***
Binax NOW	5	-	5

Specimen SP-5

Method	***Labs***	***Positive***	***Negative***
Binax NOW	5	-	5

SARS-CoV-2 (ANTIGEN DETECTION)

Specimen ACV-1

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	116	114	2
Abbott BinaxNOW - waived	31	30	1
Access Bio CareStart	5	5	-
BD Veritor - waived	7	7	-
Quidel Sofia / Sofia 2 - waived	73	72	1

Specimen ACV-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	116	2	114
Abbott BinaxNOW - waived	31	-	31
Access Bio CareStart	5	-	5
BD Veritor - waived	7	-	7
Quidel Sofia / Sofia 2 - waived	73	2	71

PARASITOLOGY

Specimen FP-1

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

Parasite(s) present: *Fasciola hepatica* eggs

Specimen FP-2

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

Parasite(s) present: *Giardia lamblia*

Specimen FP-3

Identification	***Labs***	***Percent***	***Performance***
Negative (Sterile)	1	100%	Acceptable

Parasite(s) present: Negative (sterile)

Specimen FP-4

Identification	***Labs***	***Percent***	***Performance***
Taenia sp.	1	100%	Acceptable

Parasite(s) present: *Taenia* sp.

Specimen FP-5

Identification	***Labs***	***Percent***	***Performance***
Plasmodium ovale	1	100%	Acceptable

Parasite(s) present: *Plasmodium ovale*

PVA SLIDES (Add-on)

Specimen PA-1

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

Parasite(s) present: *Entamoeba hartmanni*

Specimen PA-2

Identification	***Labs***	***Percent***	***Performance***
Negative (sterile)	1	100%	Acceptable

Parasite(s) present: Negative (sterile)

DERMATOPHYTE CULTURE

Specimen DM-1

Identification	***Labs***	***Percent***	***Performance***
Negative (Dermatophytes absent)	5	100%	Acceptable

Organism(s) present: *Aspergillus niger* and *Penicillium chrysogenum*

Specimen DM-2

Identification	***Labs***	***Percent***	***Performance***
Positive (Dermatophytes present)	4	80.00%	Acceptable
Negative (Dermatophytes absent)	1	20.00%	

Organism(s) present: *Trichophyton rubrum*

Specimen DM-3

Identification	***Labs***	***Percent***	***Performance***
Positive (Dermatophytes present)	4	80.00%	Acceptable
Negative (Dermatophytes absent)	1	20.00%	

Organism(s) present: *Trichophyton mentagrophytes*

Specimen DM-4

Identification	***Labs***	***Percent***	***Performance***
Negative (Dermatophytes absent)	5	100%	Acceptable

Organism(s) present: *Saccharomyces cerevisiae*

Specimen DM-5

Identification	***Labs***	***Percent***	***Performance***
Positive (Dermatophytes present)	5	100%	Acceptable

Organism(s) present: *Microsporum gypseum* and *Cryptococcus neoformans*

BACTERIAL VAGINOSIS – OSOM - WAIVED

Specimen BV-1

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Sekisui OSOM	5	-	5

Antigen(s) present: Negative (sterile)

Specimen BV-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Sekisui OSOM	5	5	-

Antigen(s) present: *Gardnerella vaginalis*

TRICHOMONAS VAGINALIS – OSOM - WAIVED

Specimen TR-1

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	4	4	-
Sekisui OSOM	4	4	-

Antigen(s) present: *Trichomonas vaginalis*

Specimen TR-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	4	-	4
Sekisui OSOM	4	-	4

Antigen(s) present: Negative (sterile)

Medical Laboratory Evaluation
25 Massachusetts Ave NW Ste 700
Washington, DC 20001-7401
800-338-2746 • 202-261-4500 • Fax: 202-835-0440