MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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Microbiology
2021 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	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-6

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

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

Specimen MSA-7

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

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

Specimen MSA-8

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

Organism(s) present: *Staphylococcus haemolyticus*

Specimen MSA-9

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

Organism(s) present: *Staphylococcus aureus* – Methicillin sensitive and *Haemophilus influenzae*

Specimen MSA-10

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

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

STREP A ANTIGEN DETECTION

Specimen RS-6

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	404	399	5
Abbott ID NOW	2	2	-
Alere Acceava Strep A Test	5	5	-
Alere i Instrument - waived	6	6	-
BD Chek Strep A	1	1	-
BD Veritor - waived	6	6	-
Beckman Coulter ICON DS	5	5	-
Beckman Coulter ICON SC	1	1	-
Binax NOW Strep A	1	1	-
Cardinal Health Strep A - waived	5	5	-
Cepheid GeneXpert - waived	9	9	-
Consult Diagnostic Strep A Dipstick - Waived	52	52	-
Fisher HealthCare Sure-Vue	1	1	-
Fisher HealthCare Sure-Vue - waived	1	1	-
GenePOC revogene	4	4	-
Germaine Laboratories StrepAim	2	2	-
Henry Schein One Step+ - waived	48	47	1
Jant Pharmacal Accustrip	1	1	-
McKesson Strep A Cassette	1	1	-
McKesson Strep A Dipstick	18	18	-
Medline Strep A Test Strip	5	5	-
Meridian ImmunoCard STAT - waived	5	5	-
Other Moderately Complex Method	1	1	-
Other Waived Method	7	6	1
Quidel QuickVue Dipstick Strep	30	30	-
Quidel QuickVue In-Line	28	26	2
Quidel QuickVue+	6	6	-
Quidel Sofia / Sofia 2 - waived	2	2	-
Quidel Sofia Strep A - moderate	3	3	-
Quidel Sofia Strep A+ - waived	17	17	-
Quidel Solana	4	4	-
Roche cobas Liat	2	2	-
Sekisui OSOM	89	89	-
Sekisui OSOM Ultra -waived	36	35	1

STREP A ANTIGEN DETECTION

Specimen RS-7

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	401	390	11
Abbott ID NOW	2	2	-
Alere Acceava Strep A Test	5	5	-
Alere i Instrument - waived	6	6	-
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	1	1	-
Cardinal Health Strep A - waived	5	5	-
Cepheid GeneXpert - waived	9	9	-
Consult Diagnostic Strep A Dipstick - Waived	52	50	2
Fisher HealthCare Sure-Vue	1	1	-
Fisher HealthCare Sure-Vue - waived	1	1	-
GenePOC revogene	4	4	-
Germaine Laboratories StrepAim	2	2	-
Henry Schein One Step+ - waived	48	48	-
Jant Pharmacal Accustrip	1	1	-
McKesson Strep A Cassette	1	1	-
McKesson Strep A Dipstick	17	16	1
Medline Strep A Test Strip	5	5	-
Meridian ImmunoCard STAT - waived	5	5	-
Other Moderately Complex Method	1	1	-
Other Waived Method	7	7	-
Quidel QuickVue Dipstick Strep	29	27	2
Quidel QuickVue In-Line	28	24	4
Quidel QuickVue+	6	6	-
Quidel Sofia / Sofia 2 - waived	2	2	-
Quidel Sofia Strep A - moderate	3	3	-
Quidel Sofia Strep A+ - waived	17	17	-
Quidel Solana	4	4	-
Roche cobas Liat	2	2	-
Sekisui OSOM	89	87	2
Sekisui OSOM Ultra -waived	36	36	-

STREP A ANTIGEN DETECTION

Specimen RS-8

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	47	-	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	9	-	9
GenePOC revogene	1	-	1
Henry Schein One Step+ - waived	3	-	3
McKesson Strep A Dipstick	2	-	2
Other Waived Method	1	-	1
Quidel QuickVue Dipstick Strep	7	-	7
Quidel QuickVue In-Line	6	-	6
Quidel QuickVue+	2	-	2
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-9

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	47	-	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	9	-	9
GenePOC revogene	1	-	1
Henry Schein One Step+ - waived	3	-	3
McKesson Strep A Dipstick	2	-	2
Other Waived Method	1	-	1
Quidel QuickVue Dipstick Strep	7	-	7
Quidel QuickVue In-Line	6	-	6
Quidel QuickVue+	2	-	2
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	2	-	2
Quidel Solana	4	-	4
Sekisui OSOM Ultra -waived	4	-	4

STREP A ANTIGEN DETECTION

Specimen RS-10

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	47	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	9	9	-
GenePOC revogene	1	1	-
Henry Schein One Step+ - waived	3	3	-
McKesson Strep A Dipstick	2	2	-
Other Waived Method	1	1	-
Quidel QuickVue Dipstick Strep	7	7	-
Quidel QuickVue In-Line	6	6	-
Quidel QuickVue+	2	2	-
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-4 – Sputum Culture

Identification	*Labs*	*Percent*	*Performance*
Burkholderia cepacia	2	33.33%	Acceptable
Burkholderia sp.	1	16.67%	Acceptable
Streptococcus mitis	2	33.33%	Acceptable
Streptococcus alpha-hemolytic	1	16.67%	Acceptable

Organism(s) present: *Burkholderia cepacia* and *Streptococcus mitis*

Specimen BA-5 – Stool Culture

Identification	*Labs*	*Percent*	*Performance*
Aeromonas hydrophila	2	33.33%	Acceptable
Aeromonas sp.	1	16.67%	Acceptable
Escherichia coli	3	50.00%	Acceptable

Organism(s) present: *Aeromonas hydrophila* and *Escherichia coli*

Specimen BA-6 – Ear Culture

Identification	*Labs*	*Percent*	*Performance*
Proteus mirabilis	3	100%	Acceptable

Organism(s) present: *Proteus mirabilis*

THROAT CULTURE

Specimen TC-6

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	37	58.73%	Acceptable
Presumptive Positive for Group A Strep	20	31.75%	Acceptable
Streptococcus pyogenes	5	7.94%	Acceptable

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

Specimen TC-7

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	61	96.83%	Acceptable
Neisseria gonorrhoeae	1	1.59%	Acceptable

Organism(s) present: *Neisseria gonorrhoeae*

Specimen TC-8

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	42	100%	Acceptable

Organism(s) present: *Moraxella catarrhalis* and *Staphylococcus saprophyticus*

Specimen TC-9

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	40	100%	Acceptable

Organism(s) present: *Haemophilus parainfluenzae* and *Streptococcus mitis*

Specimen TC-10

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	24	60.00%	Acceptable
Presumptive Positive for Group A Strep	16	40.00%	Acceptable

Organism(s) present: *Streptococcus pyogenes*

URINE CULTURE

Specimen UC-6

Identification	***Labs***	***Percent***	***Performance***
Escherichia coli	24	80.00%	Acceptable
Growth referred for identification	3	10.00%	Acceptable
Gram negative bacilli	2	6.67%	Acceptable
Presumptive gram negative	1	3.33%	Acceptable
Gram Stain			
Gram negative	11	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	11	100%	Acceptable

Organism(s) present: *Escherichia coli*

Specimen UC-7

Identification	***Labs***	***Percent***	***Performance***
Corynebacterium sp.	3	9.09%	Acceptable
Streptococcus salivarius	4	12.12%	Acceptable
Growth referred for identification	11	33.33%	Acceptable
Streptococcus alpha-hemolytic	10	30.30%	Acceptable
Gram positive cocci	1	3.03%	Acceptable

Organism(s) present: *Corynebacterium urealyticum* and *Streptococcus salivarius*

This sample contains a mix of *Corynebacterium urealyticum (80,000 CFU/mL) & Streptococcus salivarius (1,000 CFU/mL).*

Corynebacterium urealyticum is a slow growing gram-positive club shaped bacillus. They are opportunistic nosocomial pathogens, once considered contaminants. *Corynebacterium urealyticum* is responsible for urinary tract infections (UTI) such as acute cystitis, pyelonephritis, and encrusted pyelitis in the immunocompromised population. Non-UTI infections such as sepsis, endocarditis, pneumonia, and peritonitis have also been reported. Recently the rise of clinically significant infections is prompting the need for laboratories to identify these organisms correctly.

Corynebacterium urealyticum on blood agar are pinpoint non-hemolytic whitish- opaque colonies that are smooth, convex, and circular in shape. Cultures require 48 hours of incubation at 35°C–37°C for adequate growth. Shorter incubation times can result in missed identification.

Corynebacterium urealyticum is often underreported (assumed a contaminant) or missed due to slow growth. It is therefore important to identify this organism as a pathogen, when in pure culture, in blood or sterile body fluids, and when present as the predominant organism in a mixed culture.

URINE CULTURE

Specimen UC-8

Identification	***Labs***	***Percent***	***Performance***
No growth (sterile)	15	93.75%	Acceptable

Organism(s) present: No growth (sterile)

Specimen UC-9

Identification	***Labs***	***Percent***	***Performance***
Morganella morganii	6	46.15%	Acceptable
Enterococcus sp.	5	38.46%	Acceptable
Growth referred for identification	1	7.69%	Acceptable
Gram negative bacilli	1	7.69%	Acceptable

Organism(s) present: *Morganella morganii* and *Enterococcus faecium*

Specimen UC-10

Identification	***Labs***	***Percent***	***Performance***
Enterobacter cloacae	5	62.50%	Acceptable
Enterobacter sp.	2	25.00%	Acceptable
Growth referred for identification	1	12.50%	Acceptable

Organism(s) present: *Enterobacter cloacae* and *Lactobacillus* sp.

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen UC-6, CC-6 (SUS-6)

	------Disk Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Amikacin	-	-	-	-	2	2	-	-	100.00%
Amoxicillin/Clavulanate	6	4	2	-	1	1	-	-	100.00%
Ampicillin	21	-	-	21	4	-	-	4	100.00%
Ampicillin/Sulbactam	-	-	-	-	3	-	2	1	100.00%
Aztreonam	-	-	-	-	1	1	-	-	100.00%
Cefazolin	18	18	-	-	3	3	-	-	100.00%
Cefepime	-	-	-	-	3	3	-	-	100.00%
Cefixime	4	4	-	-	-	-	-	-	100.00%
Cefotaxime	1	1	-	-	1	1	-	-	100.00%
Cefotetan	-	-	-	-	1	1	-	-	100.00%
Cefoxitin	1	1	-	-	1	1	-	-	100.00%
Cefpodoxime	1	1	-	-	-	-	-	-	100.00%
Ceftazidime	1	1	-	-	2	2	-	-	100.00%
Ceftriaxone	6	6	-	-	4	4	-	-	100.00%
Cefuroxime	3	3	-	-	-	-	-	-	100.00%
Ciprofloxacin	23	23	-	-	4	4	-	-	100.00%
Ertapenem	-	-	-	-	2	2	-	-	100.00%
Fosfomycin	3	3	-	-	-	-	-	-	100.00%
Gentamicin	21	21	-	-	3	3	-	-	100.00%
Imipenem	1	1	-	-	1	1	-	-	100.00%
Levofloxacin	5	5	-	-	4	4	-	-	100.00%
Meropenem	-	-	-	-	2	2	-	-	100.00%
Nitrofurantoin	21	21	-	-	2	2	-	-	100.00%
Piperacillin/Tazobactam	1	1	-	-	3	3	-	-	100.00%
Sulfonamides	1	1	-	-	-	-	-	-	100.00%
Tetracycline	5	5	-	-	1	1	-	-	100.00%
Tobramycin	1	1	-	-	3	3	-	-	100.00%
Trimethoprim/Sulfamethoxazole	23	23	-	-	4	4	-	-	100.00%

Organism(s) present: *Escherichia coli*

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.

GENITAL CULTURE

Specimen GC-6

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	14	40.00%	Acceptable
Streptococcus agalactiae	10	28.57%	Acceptable
Staphylococcus sp.	7	20.00%	Acceptable
Staph – coagulase negative	2	5.71%	Acceptable
Gram positive cocci	1	2.86%	Acceptable

Gram Stain

Gram positive	5	83.33%	Acceptable
Gram negative	1	16.67%	

Gram Stain Morphology

Cocci	5	83.33%	Acceptable

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

Specimen GC-7

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhoeae	5	100%	Acceptable

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

Specimen GC-8

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	5	83.33%	Acceptable
Escherichia coli	1	16.67%	Acceptable

Organism(s) present: *Escherichia coli* and *Lactobacillus* sp.

Specimen GC-9

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

Organism(s) present: *Enterococcus faecalis* and *Streptococcus mitis*

Specimen GC-10

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

Organism(s) present: *Neisseria gonorrhoeae*

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	30	-	-	11	19
Calibrated Loop	16	-	-	6	10
Uri-Check	2	-	-	1	1
Uricult	12	-	-	4	8

Identification–Specimen CC-6

Identification	***Labs***	***Percent***	***Performance***
Growth referred for identification	7	100%	Acceptable
Gram Stain			
Gram negative	1	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	1	100%	Acceptable

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

Specimen CC-7

Method	***Labs***	***No growth***	***<10,000 organisms/mL***	***10,000-100,000 organisms/mL***	***>100,000 organisms/mL***
ALL METHODS	30	17	12	1	-
Calibrated Loop	16	6	9	1	-
Uri-Check	2	1	1	-	-
Uricult	12	10	2	-	-

Identification–Specimen CC-7

Identification	***Labs***	***Percent***	***Performance***
Growth referred for identification	4	57.14%	Acceptable
Gram positive cocci	2	28.57%	Acceptable

Organism(s) present: 80,000 CFU/mL of *Corynebacterium urealyticum* and <1,000 CFU/mL of *Streptococcus salivarius*. **The Colony Count is not graded for this specimen due to lack of participant consensus.**

Corynebacterium urealyticum is a slow growing gram-positive club shaped bacillus. They are opportunistic nosocomial pathogens, once considered contaminants. *Corynebacterium urealyticum* is responsible for urinary tract infections (UTI) such as acute cystitis, pyelonephritis, and encrusted pyelitis in the immunocompromised population. Non-UTI infections such as sepsis, endocarditis, pneumonia, and peritonitis have also been reported. Recently the rise of clinically significant infections is prompting the need for laboratories to identify these organisms correctly.

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Corynebacterium urealyticum is often underreported (assumed a contaminant) or missed due to slow growth. It is therefore important to identify this organism as a pathogen, when in pure culture, in blood or sterile body fluids, and when present as the predominant organism in a mixed culture.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-8

Identification	***Labs***	***Percent***	***Performance***
No growth (sterile)	5	100%	Acceptable

Organism(s) present: No Growth (sterile)

Identification–Specimen CC-9

Identification	***Labs***	***Percent***	***Performance***
Growth referred for identification	5	100%	Acceptable

Organism(s) present: 42,000 CFU/mL of *Morganella morganii* and 4,000 CFU/mL of *Enterococcus faecium*

Identification–Specimen CC-10

Identification	***Labs***	***Percent***	***Performance***
Growth referred for identification	5	100%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Enterobacter cloacae* and 7,000 CFU/mL of *Lactobacillus* sp.

GRAM STAIN

Specimen GS-6

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	13	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	8	88.89%	Acceptable

Organism(s) present: *Escherichia coli*

Specimen GS-7

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	13	100%	Acceptable
Gram Stain Morphology			
Diplococci	6	66.67%	Acceptable
Cocci	3	33.33%	Acceptable

Organism(s) present: *Moraxella catarrhalis*

GRAM STAIN

Specimen GS-8

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	13	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	9	100%	Acceptable

Organism(s) present: *Lactobacillus rhamnosus*

Specimen GS-9

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	13	100%	Acceptable
Gram Stain Morphology			
Cocci	8	88.89%	Acceptable

Organism(s) present: *Staphylococcus aureus*

Specimen GS-10

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	12	92.31%	Acceptable
Gram Stain Morphology			
Rods/bacilli	9	100%	Acceptable

Organism(s) present: *Actinomyces odontolyticus*

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-6

Identification	***Labs***	***Percent***	***Performance***
Positive	17	100%	Acceptable

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

Specimen VP-7

Identification	***Labs***	***Percent***	***Performance***
Positive	17	100%	Acceptable

Organism(s) present: *Trichomonas vaginalis*

Specimen VP-8

Identification	***Labs***	***Percent***	***Performance***
Negative	17	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*

Specimen VP-9

Identification	***Labs***	***Percent***	***Performance***
Negative	17	100%	Acceptable

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

Specimen VP-10

Identification	***Labs***	***Percent***	***Performance***
Negative	17	100%	Acceptable

Organism(s) present: *Escherichia coli*

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-6

Identification	***Labs***	***Percent***	***Performance***
Positive	17	100%	Acceptable

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

Specimen VP-7

Identification	***Labs***	***Percent***	***Performance***
Negative	17	100%	Acceptable

Organism(s) present: *Trichomonas vaginalis*

Specimen VP-8

Identification	***Labs***	***Percent***	***Performance***
Positive	17	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*

Specimen VP-9

Identification	***Labs***	***Percent***	***Performance***
Positive	17	100%	Acceptable

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

Specimen VP-10

Identification	***Labs***	***Percent***	***Performance***
Negative	17	100%	Acceptable

Organism(s) present: *Escherichia coli*

AFFIRM VP III–Candida sp.

Specimen VP-6

Identification	***Labs***	***Percent***	***Performance***
Negative	17	100%	Acceptable

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

Specimen VP-7

Identification	***Labs***	***Percent***	***Performance***
Negative	17	100%	Acceptable

Organism(s) present: *Trichomonas vaginalis*

Specimen VP-8

Identification	***Labs***	***Percent***	***Performance***
Negative	17	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*

Specimen VP-9

Identification	***Labs***	***Percent***	***Performance***
Positive	17	100%	Acceptable

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

Specimen VP-10

Identification	***Labs***	***Percent***	***Performance***
Negative	17	100%	Acceptable

Organism(s) present: *Escherichia coli*

SARS-CoV-2 (MOLECULAR DETECTION)

Specimen MCV-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	35	34	1
Abbott ID NOW	17	17	-
Applied Biosystems	3	3	-
BIOFIRE	1	1	-
Cepheid GeneXpert - waived	5	4	1
Diagnovital RT-PCR	1	1	-
Other EUA method	2	2	-
Roche Cobas Molecular - waived	5	5	-
Sansure Biotech	1	1	-

Specimen MCV-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	35	1	34
Abbott ID NOW	17	-	17
Applied Biosystems	3	-	3
Cepheid GeneXpert - waived	1	-	1
Other EUA method	5	1	4
Perkin Elmer	1	-	1
Roche Cobas Molecular - waived	2	-	2
Sansure Biotech	5	-	5

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-6

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	10	1	9
BD Max	2	-	2
BD ProbeTec	1	-	1
BD Viper	1	-	1
Cepheid GeneXpert - moderate	3	-	3
Quidel QuickVue	2	-	2
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Neisseria gonorrhoeae*

Specimen CY-7

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	10	10	-
BD Max	2	2	-
BD ProbeTec	1	1	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	3	3	-
Quidel QuickVue	2	2	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Chlamydia trachomatis*

Specimen CY-8

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	9	-	9
BD Max	2	-	2
BD ProbeTec	1	-	1
BD Viper	1	-	1
Cepheid GeneXpert - moderate	3	-	3
Quidel QuickVue	1	-	1
Roche COBAS Amplicor	1	-	1

Antigen(s) present: Negative (sterile)

Specimen CY-9

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	9	9	-
BD Max	2	2	-
BD ProbeTec	1	1	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	3	3	-
Quidel QuickVue	1	1	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Chlamydia trachomatis*

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-10

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	9	9	-
BD Max	2	2	-
BD ProbeTec	1	1	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	3	3	-
Quidel QuickVue	1	1	-
Roche COBAS Amplicor	1	1	-

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

GC (ANTIGEN DETECTION)

Specimen CY-6

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	8	8	-
BD Max	2	2	-
BD ProbeTec	1	1	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	3	3	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Neisseria gonorrhoeae*

Specimen CY-7

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	8	-	8
BD Max	2	-	2
BD ProbeTec	1	-	1
BD Viper	1	-	1
Cepheid GeneXpert - moderate	3	-	3
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Chlamydia trachomatis*

Specimen CY-8

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	8	-	8
BD Max	2	-	2
BD ProbeTec	1	-	1
BD Viper	1	-	1
Cepheid GeneXpert - moderate	3	-	3
Roche COBAS Amplicor	1	-	1

Antigen(s) present: Negative (sterile)

GC (ANTIGEN DETECTION)

Specimen CY-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	8	-	8
BD Max	2	-	2
BD ProbeTec	1	-	1
BD Viper	1	-	1
Cepheid GeneXpert - moderate	3	-	3
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Chlamydia trachomatis*

Specimen CY-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	8	8	-
BD Max	2	2	-
BD ProbeTec	1	1	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	3	3	-
Roche COBAS Amplicor	1	1	-

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

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-6

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	5	-
Alere CRYPTOSPORIDIUM II	5	5	-

Antigen(s) present: *Cryptosporidium parvum*

Specimen LC-7

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	-	5
Alere CRYPTOSPORIDIUM II	5	-	5

Antigen(s) present: *Giardia lamblia*

Specimen LC-8

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	5	-
Alere CRYPTOSPORIDIUM II	5	5	-

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

Specimen LC-9

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	5	-
Alere CRYPTOSPORIDIUM II	5	5	-

Antigen(s) present: *Cryptosporidium parvum*

Specimen LC-10

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	-	5
Alere CRYPTOSPORIDIUM II	5	-	5

Antigen(s) present: Negative (sterile)

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-6

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Alere GIARDIA II	5	-	5

Antigen(s) present: *Cryptosporidium parvum*

Specimen LC-7

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Alere GIARDIA II	5	5	-

Antigen(s) present: *Giardia lamblia*

Specimen LC-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Alere GIARDIA II	5	5	-

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

Specimen LC-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Alere GIARDIA II	5	-	5

Antigen(s) present: *Cryptosporidium parvum*

Specimen LC-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	**5**
Alere GIARDIA II	5	-	**5**

Antigen(s) present: Negative (sterile)

RSV ANTIGEN DETECTION

Specimen V-6

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	68	68	-
Abbott ID NOW	3	3	-
Alere Binax NOW - waived	28	28	-
BD Veritor - moderate	3	3	-
BD Veritor - waived	4	4	-
Cepheid GeneXpert - waived	1	1	-
Other Waived Method	1	1	-
Quidel QuickVue RSV - waived	10	10	-
Quidel QuickVue RSV 10 Test	1	1	-
Quidel Sofia / Sofia 2 - waived	16	16	-
Quidel Solana	1	1	-

Antigen(s) present: RSV

Specimen V-7

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	68	1	67
Abbott ID NOW	3	-	3
Alere Binax NOW - waived	28	1	27
BD Veritor - moderate	3	-	3
BD Veritor - waived	4	-	4
Cepheid GeneXpert - waived	1	-	1
Other Waived Method	1	-	1
Quidel QuickVue RSV - waived	10	-	10
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia / Sofia 2 - waived	16	-	16
Quidel Solana	1	-	1

Antigen(s) present: Influenza A

Specimen V-8

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	14	14	-
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	1	1	-

Antigen(s) present: RSV

RSV ANTIGEN DETECTION

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	14	1	13
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	1	3
Quidel Solana	1	-	1

Antigen(s) present: Influenza B

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	14	-	14
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	1	-	1

Antigen(s) present: Influenza A

INFLUENZA A ANTIGEN DETECTION

Specimen V-6

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	279	9	270
Abbott ID NOW	6	-	6
Alere Binax NOW - waived	2	1	1
Alere i Instrument - waived	3	-	3
Alere Influenza A&B	2	1	1
BD Veritor - moderate	5	-	5
BD Veritor - waived	43	3	40
BioSign Flu A+B	4	-	4
Cepheid GeneXpert - waived	7	-	7
Henry Schein OneStep+ Flu A&B	1	-	1
McKesson Consult Diag. Flu A & B	36	2	34
Meridian ImmunoCard STAT - waived	1	-	1
OraSure QuickFlu	1	-	1
Quidel QuickVue Influenza A+B	14	1	13
Quidel Sofia / Sofia 2 - waived	122	1	121
Quidel Solana	3	-	3
Roche cobas Liat	4	-	4
Sekisui OSOM Influenza A&B	3	-	3
Sekisui OSOM Ultra -waived	22	-	22

Antigen(s) present: RSV

Specimen V-7

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	280	273	7
Abbott ID NOW	6	6	-
Alere Binax NOW - waived	2	2	-
Alere i Instrument - waived	3	3	-
Alere Influenza A&B	2	2	-
BD Veritor - moderate	5	5	-
BD Veritor - waived	43	40	3
BioSign Flu A+B	4	4	-
Cepheid GeneXpert - waived	8	8	-
Henry Schein OneStep+ Flu A&B	1	1	-
McKesson Consult Diag. Flu A & B	36	35	1
Meridian ImmunoCard STAT - waived	1	1	-
OraSure QuickFlu	1	1	-
Quidel QuickVue Influenza A+B	14	14	-
Quidel Sofia / Sofia 2 - waived	122	120	2
Quidel Solana	3	3	-
Roche cobas Liat	4	4	-
Sekisui OSOM Influenza A&B	3	2	1
Sekisui OSOM Ultra -waived	22	22	-

Antigen(s) present: Influenza A

INFLUENZA A ANTIGEN DETECTION

Specimen V-8

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	18	-	18
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	1	-	1
Quidel Sofia / Sofia 2 - waived	4	-	4
Quidel Solana	3	-	3

Antigen(s) present: RSV

Specimen V-9

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	18	-	18
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	1	-	1
Quidel Sofia / Sofia 2 - waived	4	-	4
Quidel Solana	3	-	3

Antigen(s) present: Influenza B

Specimen V-10

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	18	18	-
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	1	1	-
Quidel Sofia / Sofia 2 - waived	4	4	-
Quidel Solana	3	3	-

Antigen(s) present: Influenza A

INFLUENZA B ANTIGEN DETECTION

Specimen V-6

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	278	5	273
Abbott ID NOW	6	-	6
Alere Binax NOW - waived	2	-	2
Alere i Instrument - waived	3	-	3
Alere Influenza A&B	2	-	2
BD Veritor - moderate	5	-	5
BD Veritor - waived	43	2	41
BioSign Flu A+B	4	-	4
Cepheid GeneXpert - waived	7	-	7
Henry Schein OneStep+ Flu A&B	1	-	1
McKesson Consult Diag. Flu A & B	34	-	34
Meridian ImmunoCard STAT - waived	1	-	1
OraSure QuickFlu	1	-	1
Quidel QuickVue Influenza A+B	14	1	13
Quidel Sofia / Sofia 2 - waived	123	1	122
Quidel Solana	3	-	3
Roche cobas Liat	4	-	4
Sekisui OSOM Influenza A&B	4	1	3
Sekisui OSOM Ultra -waived	21	-	21

Antigen(s) present: RSV

Specimen V-7

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	279	6	273
Abbott ID NOW	6	-	6
Alere Binax NOW - waived	2	-	2
Alere i Instrument - waived	3	-	3
Alere Influenza A&B	2	-	2
BD Veritor - moderate	5	-	5
BD Veritor - waived	43	2	41
BioSign Flu A+B	4	-	4
Cepheid GeneXpert - waived	8	-	8
Henry Schein OneStep+ Flu A&B	1	-	1
McKesson Consult Diag. Flu A & B	34	1	33
Meridian ImmunoCard STAT - waived	1	-	1
OraSure QuickFlu	1	-	1
Quidel QuickVue Influenza A+B	14	1	13
Quidel Sofia / Sofia 2 - waived	123	2	121
Quidel Solana	3	-	3
Roche cobas Liat	4	-	4
Sekisui OSOM Influenza A&B	4	-	4
Sekisui OSOM Ultra -waived	21	-	21

Antigen(s) present: Influenza A

INFLUENZA B ANTIGEN DETECTION

Specimen V-8

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	18	-	18
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	1	-	1
Quidel Sofia / Sofia 2 - waived	4	-	4
Quidel Solana	3	-	3

Antigen(s) present: RSV

Specimen V-9

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	18	18	-
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	1	1	-
Quidel Sofia / Sofia 2 - waived	4	4	-
Quidel Solana	3	3	-

Antigen(s) present: Influenza B

Specimen V-10

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	18	-	18
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	1	-	1
Quidel Sofia / Sofia 2 - waived	4	-	4
Quidel Solana	3	-	3

Antigen(s) present: Influenza A

CLOSTRIDIOIDES DIFFICILE ANTIGEN DETECTION

Specimen AG-6

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

Antigen(s) present: Rotavirus

Specimen AG-7

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

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

Specimen AG-8

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

Antigen(s) present: Negative (sterile)

Specimen AG-9

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

Antigen(s) present: Rotavirus

Specimen AG-10

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

Antigen(s) present: *Clostridioides difficile*

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-6

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

Antigen(s) present: Rotavirus

Specimen AG-7

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

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

Specimen AG-8

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

Antigen(s) present: Negative (sterile)

Specimen AG-9

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

Antigen(s) present: Rotavirus

Specimen AG-10

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

Antigen(s) present: *Clostridioides difficile*

LEGIONELLA ANTIGEN DETETION

Specimen L-6

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

Specimen L-7

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

Specimen L-8

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

Specimen L-9

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

Specimen L-10

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

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-6

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

Specimen SP-7

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

Specimen SP-8

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

Specimen SP-9

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

Specimen SP-10

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

SARS-CoV-2 (ANTIGEN DETECTION)

Specimen ACV-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	136	1	135
Abbott BinaxNOW - waived	50	1	49
Access Bio CareStart	8	-	8
BD Veritor - waived	11	-	11
Other EUA method	1	-	1
Quidel QuickVue - waived	1	-	1
Quidel Sofia / Sofia 2 - waived	65	-	65

Specimen ACV-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	136	133	3
Abbott BinaxNOW - waived	50	48	2
Access Bio CareStart	8	8	-
BD Veritor - waived	11	11	-
Other EUA method	1	1	-
Quidel QuickVue - waived	1	1	-
Quidel Sofia / Sofia 2 - waived	65	64	1

PARASITOLOGY

Specimen FP-6

Identification	***Labs***	***Percent***	***Performance***
Negative	1	100%	Acceptable

Parasite(s) present: Negative (with Nematode-like artifacts)

Specimen FP-7

Identification	***Labs***	***Percent***	***Performance***
Ascaris lumbricoides eggs	1	50.00%	Acceptable
Trichuris trichiura eggs	1	50.00%	Acceptable

Parasite(s) present: *Ascaris lumbricoides* eggs and *Trichuris trichiura* eggs

Specimen FP-8

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

Parasite(s) present: *Diphyllobothrium latum*

Specimen FP-9

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

Parasite(s) present: *Hymenolepis nana*

Specimen FP-10

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

Parasite(s) present: Negative (sterile)

PVA SLIDES (Add-on)

Specimen PA-3

Identification	***Labs***	***Percent***	***Performance***
Iodamoeba buetschlii	1	100%	Acceptable

Parasite(s) present: *Iodamoeba buetschlii*

Specimen PA-4

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

Parasite(s) present: *Giardia lamblia*

DERMATOPHYTE CULTURE

Specimen DM-6

Identification	***Labs***	***Percent***	***Performance***
Positive (Dermatophytes present)	9	100%	Acceptable

Organism(s) present: *Trichophyton tonsurans* and *Staphylococcus epidermidis*

Specimen DM-7

Identification	***Labs***	***Percent***	***Performance***
Negative (Dermatophytes absent)	9	100%	Acceptable

Organism(s) present: Negative (sterile)

Specimen DM-8

Identification	***Labs***	***Percent***	***Performance***
Negative (Dermatophytes absent)	9	100%	Acceptable

Organism(s) present: *Fusobacterium nucleatum* and *Mucor circinelloides*

Specimen DM-9

Identification	***Labs***	***Percent***	***Performance***
Positive (Dermatophytes present)	9	100%	Acceptable

Organism(s) present: *Microsporum canis* and *Alternaria* sp.

Specimen DM-10

Identification	***Labs***	***Percent***	***Performance***
Positive (Dermatophytes present)	9	100%	Acceptable

Organism(s) present: *Trichophyton mentagrophytes* and *Aspergillus niger*

BACTERIAL VAGINOSIS – OSOM - WAIVED

Specimen BV-3

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	-	6
Sekisui OSOM	6	-	6

Antigen(s) present: Negative (sterile)

Specimen BV-4

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	6	6	-
Sekisui OSOM	6	6	-

Antigen(s) present: *Gardnerella vaginalis*

TRICHOMONAS VAGINALIS – OSOM - WAIVED

Specimen TR-3

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

Antigen(s) present: *Trichomonas vaginalis*

Specimen TR-4

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

Antigen(s) present: Negative (sterile)

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