

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 2 • 1

Medical Laboratory
Evaluation 

Microbiology
2021 MLE-M3

Table of Contents

Evaluation Criteria..... 2

Microbiology

MRSA Culture	3	Chlamydia (Antigen Detection).....	21
Strep A Antigen Detection.....	4	GC (Antigen Detection)	22
Miscellaneous Cultures	7	Cryptosporidium Antigen Detection	24
Throat Culture	8	Giardia lamblia Antigen Detection.....	25
Urine Culture	9	RSV Antigen Detection.....	26
Gram Stain & Morphology.....	9	Influenza A Antigen Detection	28
Antimicrobial Susceptibility Testing	11	Influenza B Antigen Detection	30
Genital Culture	12	Clostridioides difficile Antigen Detection	32
Gram Stain & Morphology.....	12	Rotavirus Antigen Detection.....	33
Colony Count/Urine Presumptive ID	13	Legionella Antigen Detection.....	34
Gram Stain & Morphology.....	13	Streptococcus pneumoniae Antigen Detection	35
Gram Stain.....	15	SARS-CoV-2 (Antigen Detection)	36
Affirm VP III		Parasitology	37
Trichomonas vaginalis.....	17	PVA Slides (Add-on).....	38
Gardnerella vaginalis	18	Dermatophyte Culture	39
Candida sp.	19	Bacterial Vaginosis Screen (OSOM).....	40
SARS-CoV-2 (Molecular Detection)	20	Trichomonas vaginalis Screen (OSOM)	40

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-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	5	100%	Acceptable

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

Specimen MSA-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	5	100%	Acceptable

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

Specimen MSA-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	5	100%	Acceptable

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

Specimen MSA-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	5	100%	Acceptable

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

Specimen MSA-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	5	100%	Acceptable

Organism(s) present: *Lactobacillus acidophilus*

STREP A ANTIGEN DETECTION

Specimen RS-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	397	387	10
Abbott ID NOW	4	4	-
Alere Acceava Strep A Test	3	3	-
Alere i Instrument - waived	6	6	-
BD Chek Strep A	1	1	-
BD Veritor - waived	7	7	-
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	51	49	2
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	46	46	-
Jant Pharmacal Accustrip	1	1	-
McKesson Strep A Cassette	2	2	-
McKesson Strep A Dipstick	15	14	1
Medline Strep A Test Strip	4	4	-
Meridian ImmunoCard STAT - waived	6	5	1
Other Waived Method	7	7	-
Quidel QuickVue Dipstick Strep	30	30	-
Quidel QuickVue In-Line	32	27	5
Quidel QuickVue+	5	5	-
Quidel Sofia / Sofia 2 - waived	2	2	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	19	18	1
Quidel Solana	4	4	-
Roche cobas Liat	4	4	-
Sekisui OSOM	84	84	-
Sekisui OSOM Ultra -waived	34	34	-
Stanbio QuStick Strep A	1	1	-

STREP A ANTIGEN DETECTION

Specimen RS-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	394	6	388
Abbott ID NOW	4	-	4
Alere Acceava Strep A Test	3	-	3
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	51	1	50
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	46	2	44
Jant Pharmacal Accustrip	1	-	1
McKesson Strep A Cassette	2	-	2
McKesson Strep A Dipstick	14	-	14
Medline Strep A Test Strip	4	-	4
Meridian ImmunoCard STAT - waived	6	-	6
Other Waived Method	7	-	7
Quidel QuickVue Dipstick Strep	29	-	29
Quidel QuickVue In-Line	32	1	31
Quidel QuickVue+	5	-	5
Quidel Sofia / Sofia 2 - waived	2	-	2
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	19	1	18
Quidel Solana	4	-	4
Roche cobas Liat	4	-	4
Sekisui OSOM	84	1	83
Sekisui OSOM Ultra -waived	34	-	34
Stanbio QuStick Strep A	1	-	1

STREP A ANTIGEN DETECTION

Specimen RS-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	43	42	1
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	6	6	-
Henry Schein One Step+ - waived	3	3	-
McKesson Strep A Cassette	1	1	-
McKesson Strep A Dipstick	2	2	-
Meridian ImmunoCard STAT - waived	1	1	-
Other Waived Method	1	1	-
Quidel QuickVue Dipstick Strep	6	5	1
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	3	3	-

Specimen RS-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	43	-	43
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	6	-	6
Henry Schein One Step+ - waived	3	-	3
McKesson Strep A Cassette	1	-	1
McKesson Strep A Dipstick	2	-	2
Meridian ImmunoCard STAT - waived	1	-	1
Other Waived Method	1	-	1
Quidel QuickVue Dipstick Strep	6	-	6
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	3	-	3

STREP A ANTIGEN DETECTION

Specimen RS-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	43	43	-
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	6	6	-
Henry Schein One Step+ - waived	3	3	-
McKesson Strep A Cassette	1	1	-
McKesson Strep A Dipstick	2	2	-
Meridian ImmunoCard STAT - waived	1	1	-
Other Waived Method	1	1	-
Quidel QuickVue Dipstick Strep	6	6	-
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	3	3	-

MISCELLANEOUS CULTURES

Specimen BA-7 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Alcaligenes faecalis	4	80.00%	Acceptable
Alcaligenes sp.	1	20.00%	Acceptable

Organism(s) present: *Alcaligenes faecalis*

Specimen BA-8 – CSF Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Listeria monocytogenes	4	80.00%	Acceptable
Listeria sp.	1	20.00%	Acceptable

Organism(s) present: *Listeria monocytogenes*

Specimen BA-9 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pseudomonas aeruginosa	5	50.00%	Acceptable
Micrococcus luteus	3	30.00%	Acceptable
Micrococcus sp.	2	20.00%	Acceptable

Organism(s) present: *Pseudomonas aeruginosa* and *Micrococcus luteus*

THROAT CULTURE

Specimen TC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	54	91.53%	Acceptable
Streptococcus alpha-hemolytic	2	3.39%	Acceptable

Organism(s) present: *Fusobacterium necrophorum* and *Streptococcus salivarius*

Specimen TC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	37	63.79%	Acceptable
Presumptive Positive for Group A Strep	17	29.31%	Acceptable
Streptococcus pyogenes	2	3.45%	Acceptable

Organism(s) present: *Streptococcus pyogenes*

Specimen TC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	19	52.78%	Acceptable
Presumptive Positive for Group A Strep	15	41.67%	Acceptable

Organism(s) present: *Streptococcus pyogenes*

Specimen TC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	19	57.58%	Acceptable
Presumptive Positive for Group A Strep	13	39.39%	Acceptable

Organism(s) present: *Streptococcus pyogenes*

Specimen TC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	32	94.12%	Acceptable

Organism(s) present: *Pseudomonas aeruginosa* and *Staphylococcus haemolyticus*

URINE CULTURE

Specimen UC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Enterococcus sp.	19	61.29%	Acceptable
Growth, referred for identification	6	19.35%	Acceptable
Enterococcus faecalis	5	16.13%	Acceptable
Gram positive cocci	1	3.23%	Acceptable

Gram Stain

Gram positive	11	100.00%	Acceptable
---------------	----	---------	------------

Gram Stain Morphology

Cocci	11	100.00%	Acceptable
-------	----	---------	------------

Organism(s) present: *Enterococcus faecalis* – Vancomycin resistant

Specimen UC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Escherichia coli	25	80.65%	Acceptable
Growth, referred for identification	3	9.68%	Acceptable
Gram negative bacilli	2	6.45%	Acceptable
Presumptive Gram negative	1	3.23%	Acceptable

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

URINE CULTURE

Specimen UC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Citrobacter koseri	8	47.06%	Acceptable
Citrobacter sp.	3	17.65%	Acceptable
Growth, referred for identification	3	17.65%	Acceptable
Presumptive Gram negative	1	5.88%	Acceptable

Organism(s) present: *Citrobacter koseri*

Specimen UC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus haemolyticus	3	37.50%	Acceptable
Staph – coagulase negative	3	37.50%	Acceptable
Growth, referred for identification	1	12.50%	Acceptable
Staphylococcus sp.	1	12.50%	Acceptable

Organism(s) present: *Staphylococcus haemolyticus*

Specimen UC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Aerococcus urinae	4	36.36%	Acceptable
Staph – coagulase negative	2	18.18%	Acceptable
Growth, referred for identification	2	18.18%	Acceptable
Staphylococcus sp.	1	9.09%	Acceptable

Organism(s) present: *Aerococcus urinae* and *Staphylococcus epidermidis*

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Specimen UC-11, CC-11 (SUS-11)

<u>Antimicrobial</u>	<u>-----Disk Diffusion-----</u>				<u>-----MIC-----</u>				<u>Acceptable (%)</u>
	<u>Interpretative category data</u>				<u>Interpretative category data</u>				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Amoxicillin/Clavulanate	1	1	-	-	-	-	-	-	100.00%
Ampicillin	20	20	-	-	4	4	-	-	100.00%
Ciprofloxacin	8	-	-	8	3	-	-	3	100.00%
Daptomycin	-	-	-	-	1	1	-	-	100.00%
Fosfomycin	1	1	-	-	-	-	-	-	100.00%
Gentamicin	1	-	-	1	-	-	-	-	100.00%
Levofloxacin	6	-	-	6	4	-	-	4	100.00%
Linezolid	5	5	-	-	4	4	-	-	100.00%
Nitrofurantoin	19	19	-	-	4	4	-	-	100.00%
Norfloxacin	1	-	-	1	-	-	-	-	100.00%
Penicillin	5	5	-	-	3	3	-	-	100.00%
Rifampin	1	1	-	-	-	-	-	-	100.00%
Tetracycline	4	-	-	4	4	-	-	4	100.00%
Vancomycin	20	-	-	20	4	-	-	4	100.00%

Organism(s) present: *Enterococcus faecalis* – Vancomycin resistant

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-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive for N. gonorrhoeae	13	76.47%	Acceptable
Neisseria gonorrhoeae	2	11.76%	Acceptable
Growth, referred for identification	1	5.88%	Acceptable
Gram negative diplococci	1	5.88%	Acceptable

Gram Stain

Gram negative	6	100.00%	Acceptable
---------------	---	---------	------------

Gram Stain Morphology

Diplococci	5	100.00%	Acceptable
------------	---	---------	------------

Organism(s) present: *Neisseria gonorrhoeae*

Specimen GC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	5	83.33%	Acceptable
Staphylococcus sp.	1	16.67%	Acceptable

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

Specimen GC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive for N. gonorrhoeae	4	80.00%	Acceptable
Negative for N. gonorrhoeae	1	20.00%	

Organism(s) present: *Neisseria gonorrhoeae*

Specimen GC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive for N. gonorrhoeae	5	100.00%	Acceptable

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

Specimen GC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	5	100.00%	Acceptable

Organism(s) present: *Streptococcus agalactiae*

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-11

<u>Method</u>	<u>Labs</u>	<u>No growth</u>	<u><10,000 organisms/mL</u>	<u>10,000-100,000 organisms/mL</u>	<u>>100,000 organisms/mL</u>
ALL METHODS	29	3	7	18	1
Calibrated Loop	15	-	1	14	-
Uri-Check	1	1	-	-	-
Uricult	13	2	6	4	1

Identification–Specimen CC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	7	87.50%	Acceptable
Gram positive cocci	1	12.50%	Acceptable

Gram Stain

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	5	100.00%	Acceptable

Gram Stain Morphology

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Cocci	5	100.00%	Acceptable

Organism(s) present: 88,000 CFU/mL of *Enterococcus faecalis* – Vancomycin resistant

Specimen CC-12

<u>Method</u>	<u>Labs</u>	<u>No growth</u>	<u><10,000 organisms/mL</u>	<u>10,000-100,000 organisms/mL</u>	<u>>100,000 organisms/mL</u>
ALL METHODS	29	-	1	11	17
Calibrated Loop	15	-	-	5	10
Uri-Check	1	-	-	1	-
Uricult	13	-	1	5	7

Identification–Specimen CC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	7	87.50%	Acceptable
Gram negative bacilli	1	12.50%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Escherichia coli* and <10,000 CFU/mL of *Lactobacillus* sp.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification—Specimen CC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	5	83.33%	Acceptable
Gram negative bacilli	1	16.67%	Acceptable

Organism(s) present: 71,000 CFU/mL of *Citrobacter koseri*

Identification—Specimen CC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	5	83.33%	Acceptable
Gram positive cocci	1	16.67%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Staphylococcus haemolyticus*

Identification—Specimen CC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	5	83.33%	Acceptable
Gram positive cocci	1	16.67%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Aerococcus urinae* and 70,000 CFU/mL of *Staphylococcus epidermidis*

GRAM STAIN

Specimen GS-11

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	9	100.00%	Acceptable

Gram Stain Morphology

Diplococci	3	50.00%	Acceptable
Cocci	3	50.00%	Acceptable

Organism(s) present: *Streptococcus pneumoniae*

Specimen GS-12

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	8	88.89%	Acceptable
Gram negative	1	11.11%	

Gram Stain Morphology

Cocci	5	83.33%	Acceptable
Diplococci	1	16.67%	

Organism(s) present: *Enterococcus faecalis*

GRAM STAIN

Specimen GS-13

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	9	100.00%	Acceptable

Gram Stain Morphology

Diplococci	2	33.33%	Acceptable
Cocci	3	50.00%	Acceptable
Coccobacilli	1	16.67%	

Organism(s) present: *Neisseria meningitidis*

Specimen GS-14

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	9	100.00%	Acceptable

Gram Stain Morphology

Rods/bacilli	6	100.00%	Acceptable
--------------	---	---------	------------

Organism(s) present: *Fusobacterium nucleatum*

Specimen GS-15

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	8	88.89%	Acceptable
Gram positive	1	11.11%	

Gram Stain Morphology

Rods/bacilli	3	50.00%	Not graded
Coccobacilli	2	33.33%	
Cocci	1	16.67%	

Organism(s) present: *Klebsiella oxytoca*. The gram stain morphology was not graded for this sample due to lack of participant consensus. *Klebsiella oxytoca* are gram negative rods/bacilli.

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	17	100.00%	Acceptable

Organism(s) present: *Gardnerella vaginalis*

Specimen VP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	17	100.00%	Acceptable

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

Specimen VP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	17	100.00%	Acceptable

Organism(s) present: *Escherichia coli*

Specimen VP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	17	100.00%	Acceptable

Organism(s) present: *Candida* sp.

Specimen VP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	17	100.00%	Acceptable

Organism(s) present: *Trichomonas vaginalis*

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	16	94.12%	Acceptable
Negative	1	5.88%	

Organism(s) present: *Gardnerella vaginalis*

Specimen VP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	16	94.12%	Acceptable
Positive	1	5.88%	

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

Specimen VP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	17	100.00%	Acceptable

Organism(s) present: *Escherichia coli*

Specimen VP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	17	100.00%	Acceptable

Organism(s) present: *Candida* sp.

Specimen VP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	17	100.00%	Acceptable

Organism(s) present: *Trichomonas vaginalis*

AFFIRM VP III–Candida sp.

Specimen VP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	17	100.00%	Acceptable

Organism(s) present: *Gardnerella vaginalis*

Specimen VP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	17	100.00%	Acceptable

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

Specimen VP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	17	100.00%	Acceptable

Organism(s) present: *Escherichia coli*

Specimen VP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	16	94.12%	Acceptable
Negative	1	5.88%	

Organism(s) present: *Candida* sp.

Specimen VP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	17	100.00%	Acceptable

Organism(s) present: *Trichomonas vaginalis*

SARS-CoV-2 (MOLECULAR DETECTION)

Specimen MCV-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	44	-	44
Abbott ID NOW	20	-	20
Applied Biosystems 7500 Fast	4	-	4
BIOFIRE	1	-	1
Cepheid GeneXpert - waived	12	-	12
Diagnovital RT-PCR	1	-	1
Perkin Elmer	1	-	1
Quidel Solana - waived	1	-	1
Roche Cobas Molecular - waived	3	-	3
Sansure Biotech	1	-	1

Specimen MCV-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	44	44	-
Abbott ID NOW	20	20	-
Applied Biosystems 7500 Fast	4	4	-
BIOFIRE	1	1	-
Cepheid GeneXpert - waived	12	12	-
Diagnovital RT-PCR	1	1	-
Perkin Elmer	1	1	-
Quidel Solana - waived	1	1	-
Roche Cobas Molecular - waived	3	3	-
Sansure Biotech	1	1	-

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	10	10	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	5	5	-
Quidel QuickVue	1	1	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Chlamydia trachomatis*

Specimen CY-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	10	10	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	5	5	-
Quidel QuickVue	1	1	-
Roche COBAS Amplicor	1	1	-

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

Specimen CY-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	1	7
BD Max	2	1	1
BD Viper	1	-	1
Cepheid GeneXpert - moderate	4	-	4
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Neisseria gonorrhoeae*

Specimen CY-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	-	9
BD Max	2	-	2
BD Viper	1	-	1
Cepheid GeneXpert - moderate	5	-	5
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Neisseria gonorrhoeae*

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	-	9
BD Max	2	-	2
BD Viper	1	-	1
Cepheid GeneXpert - moderate	5	-	5
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Neisseria gonorrhoeae*

GC (ANTIGEN DETECTION)

Specimen CY-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	-	9
BD Max	2	-	2
BD Viper	1	-	1
Cepheid GeneXpert - moderate	5	-	5
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Chlamydia trachomatis*

Specimen CY-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	9	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	5	5	-
Roche COBAS Amplicor	1	1	-

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

Specimen CY-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	8	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	4	4	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Neisseria gonorrhoeae*

GC (ANTIGEN DETECTION)

Specimen CY-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	9	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	5	5	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Neisseria gonorrhoeae*

Specimen CY-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	9	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	5	5	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Neisseria gonorrhoeae*

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Alere CRYPTOSPORIDIUM II	5	5	-

Antigen(s) present: *Cryptosporidium*

Specimen LC-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Alere CRYPTOSPORIDIUM II	5	-	5

Antigen(s) present: *Giardia lamblia*

Specimen LC-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Alere CRYPTOSPORIDIUM II	5	5	-

Antigen(s) present: *Cryptosporidium*

Specimen LC-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Alere CRYPTOSPORIDIUM II	5	5	-

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

Specimen LC-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Alere CRYPTOSPORIDIUM II	5	-	5

Antigen(s) present: *Giardia lamblia*

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Alere GIARDIA II	5	-	5

Antigen(s) present: *Cryptosporidium*

Specimen LC-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Alere GIARDIA II	5	5	-

Antigen(s) present: *Giardia lamblia*

Specimen LC-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Alere GIARDIA II	5	-	5

Antigen(s) present: *Cryptosporidium*

Specimen LC-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Alere GIARDIA II	5	5	-

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

Specimen LC-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Alere GIARDIA II	5	5	-

Antigen(s) present: *Giardia lamblia*

RSV ANTIGEN DETECTION

Specimen V-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	76	76	-
Abbott ID NOW	5	5	-
Alere Binax NOW - waived	25	25	-
BD Veritor - moderate	3	3	-
BD Veritor - waived	3	3	-
Cepheid GeneXpert - moderate	1	1	-
Cepheid GeneXpert - waived	9	9	-
Other Waived Method	1	1	-
Quidel QuickVue RSV - waived	11	11	-
Quidel QuickVue RSV 10 Test	1	1	-
Quidel Sofia / Sofia 2 - waived	14	14	-
Quidel Solana	2	2	-
Roche cobas Liat	1	1	-

Antigen(s) present: RSV

Specimen V-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	76	2	74
Abbott ID NOW	5	-	5
Alere Binax NOW - waived	25	1	24
BD Veritor - moderate	3	-	3
BD Veritor - waived	3	-	3
Cepheid GeneXpert - moderate	1	-	1
Cepheid GeneXpert - waived	9	-	9
Other Waived Method	1	-	1
Quidel QuickVue RSV - waived	11	1	10
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia / Sofia 2 - waived	14	-	14
Quidel Solana	2	-	2
Roche cobas Liat	1	-	1

Antigen(s) present: Influenza A

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	-	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	2	-	2
Quidel Solana	2	-	2

Antigen(s) present: Influenza B

RSV ANTIGEN DETECTION

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	-	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	2	-	2
Quidel Solana	2	-	2

Antigen(s) present: Negative (sterile)

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	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	2	2	-
Quidel Solana	2	2	-

Antigen(s) present: RSV

INFLUENZA A ANTIGEN DETECTION

Specimen V-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	270	9	261
Abbott ID NOW	9	-	9
Alere Binax NOW - waived	2	-	2
Alere i Instrument - waived	2	-	2
Alere Influenza A&B	2	-	2
BD Veritor - moderate	6	1	5
BD Veritor - waived	41	2	39
BioSign Flu A+B	3	-	3
Cepheid GeneXpert - waived	9	-	9
Henry Schein OneStep+ Flu A&B	1	1	-
McKesson Consult Diag. Flu A & B	31	1	30
Meridian ImmunoCard STAT - waived	1	-	1
Quidel QuickVue Influenza A+B	16	-	16
Quidel Sofia / Sofia 2 - waived	117	4	113
Quidel Solana	3	-	3
Roche cobas Liat	2	-	2
Sekisui OSOM Influenza A&B	4	-	4
Sekisui OSOM Ultra -waived	21	-	21

Antigen(s) present: RSV

Specimen V-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	270	259	11
Abbott ID NOW	9	9	-
Alere Binax NOW - waived	2	2	-
Alere i Instrument - waived	2	2	-
Alere Influenza A&B	2	2	-
BD Veritor - moderate	6	6	-
BD Veritor - waived	41	37	4
BioSign Flu A+B	3	3	-
Cepheid GeneXpert - waived	9	9	-
Henry Schein OneStep+ Flu A&B	1	-	1
McKesson Consult Diag. Flu A & B	31	29	2
Meridian ImmunoCard STAT - waived	1	1	-
Quidel QuickVue Influenza A+B	16	16	-
Quidel Sofia / Sofia 2 - waived	117	113	4
Quidel Solana	3	3	-
Roche cobas Liat	2	2	-
Sekisui OSOM Influenza A&B	4	4	-
Sekisui OSOM Ultra -waived	21	21	-

Antigen(s) present: Influenza A

INFLUENZA A ANTIGEN DETECTION

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	-	16
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	2	-	2
Quidel Solana	3	-	3

Antigen(s) present: Influenza B

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	-	16
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	2	-	2
Quidel Solana	3	-	3

Antigen(s) present: Negative (sterile)

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	-	16
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	2	-	2
Quidel Solana	3	-	3

Antigen(s) present: RSV

INFLUENZA B ANTIGEN DETECTION

Specimen V-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	268	9	259
Abbott ID NOW	8	-	8
Alere Binax NOW - waived	2	-	2
Alere i Instrument - waived	3	-	3
Alere Influenza A&B	2	-	2
BD Veritor - moderate	6	1	5
BD Veritor - waived	40	3	37
BioSign Flu A+B	3	-	3
Cepheid GeneXpert - waived	9	-	9
McKesson Consult Diag. Flu A & B	30	1	29
Meridian ImmunoCard STAT - waived	1	-	1
Quidel QuickVue Influenza A+B	17	-	17
Quidel Sofia / Sofia 2 - waived	117	3	114
Quidel Solana	3	-	3
Roche cobas Liat	2	-	2
Sekisui OSOM Influenza A&B	4	-	4
Sekisui OSOM Ultra -waived	21	1	20

Antigen(s) present: RSV

Specimen V-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	268	6	262
Abbott ID NOW	8	-	8
Alere Binax NOW - waived	2	-	2
Alere i Instrument - waived	3	-	3
Alere Influenza A&B	2	-	2
BD Veritor - moderate	6	-	6
BD Veritor - waived	40	3	37
BioSign Flu A+B	3	-	3
Cepheid GeneXpert - waived	9	-	9
McKesson Consult Diag. Flu A & B	30	-	30
Meridian ImmunoCard STAT - waived	1	-	1
Quidel QuickVue Influenza A+B	17	1	16
Quidel Sofia / Sofia 2 - waived	117	2	115
Quidel Solana	3	-	3
Roche cobas Liat	2	-	2
Sekisui OSOM Influenza A&B	4	-	4
Sekisui OSOM Ultra -waived	21	-	21

Antigen(s) present: Influenza A

INFLUENZA B ANTIGEN DETECTION

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	15	1
Abbott ID NOW	2	2	-
Alere Binax NOW - waived	1	1	-
BD Veritor - moderate	5	4	1
McKesson Consult Diag. Flu A & B	2	2	-
Quidel QuickVue Influenza A+B	1	1	-
Quidel Sofia / Sofia 2 - waived	2	2	-
Quidel Solana	3	3	-

Antigen(s) present: Influenza B

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	-	16
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	2	-	2
Quidel Solana	3	-	3

Antigen(s) present: Negative (sterile)

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	-	16
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	2	-	2
Quidel Solana	3	-	3

Antigen(s) present: RSV

CLOSTRIDIODES DIFFICILE ANTIGEN DETECTION

Specimen AG-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Alere C. diff Quik Chek	5	5	-

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

Specimen AG-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Alere C. diff Quik Chek	5	5	-

Antigen(s) present: *Clostridioides difficile*

Specimen AG-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Alere C. diff Quik Chek	5	-	5

Antigen(s) present: Rotavirus

Specimen AG-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Fisher HealthCare Sure-View	5	5	-

Antigen(s) present: *Clostridioides difficile*

Specimen AG-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Alere C. diff Quik Chek	5	-	5

Antigen(s) present: Negative (sterile)

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Fisher HealthCare Sure-Vue	5	5	-

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

Specimen AG-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Fisher HealthCare Sure-Vue	5	-	5

Antigen(s) present: *Clostridioides difficile*

Specimen AG-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	4	1
Fisher HealthCare Sure-Vue	5	4	1

Antigen(s) present: Rotavirus

Specimen AG-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Fisher HealthCare Sure-Vue	5	-	5

Antigen(s) present: *Clostridioides difficile*

Specimen AG-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Fisher HealthCare Sure-Vue	5	-	5

Antigen(s) present: Negative (sterile)

LEGIONELLA ANTIGEN DETECTION

Specimen L-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	7	7	-

Specimen L-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	7	-	7

Specimen L-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	7	-	7

Specimen L-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	7	-	7

Specimen L-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	7	7	-

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	5	-	5

Specimen SP-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	5	5	-

Specimen SP-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	5	-	5

Specimen SP-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	5	5	-

Specimen SP-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	5	5	-

SARS-CoV-2 (ANTIGEN DETECTION)

Specimen ACV-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	135	128	7
Abbott BinaxNOW - waived	12	12	-
Access Bio CareStart	9	9	-
BD Veritor - waived	13	13	-
Quidel QuickVue - waived	4	4	-
Quidel Sofia / Sofia 2 - waived	97	90	7

Specimen ACV-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	135	3	132
Abbott BinaxNOW - waived	12	-	12
Access Bio CareStart	9	-	9
BD Veritor - waived	13	-	13
Quidel QuickVue - waived	4	-	4
Quidel Sofia / Sofia 2 - waived	97	3	94

PARASITOLOGY

Specimen FP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis	1	50.00%	Acceptable
Endolimax nana	1	50.00%	Acceptable

Parasite(s) present: *Strongyloides stercoralis* and *Endolimax nana*

Specimen FP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hookworm	1	100.00%	Acceptable

Parasite(s) present: Hookworm

Specimen FP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Cystoisospora belli oocysts	1	33.33%	Acceptable
Entamoeba histolytica	1	33.33%	Acceptable
Giardia lamblia	1	33.33%	Acceptable

Parasite(s) present: *Cystoisospora belli*, *Entamoeba histolytica*, and *Giardia lamblia*

Specimen FP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides	1	50.00%	Acceptable
Entamoeba coli	1	50.00%	Acceptable

Parasite(s) present: *Ascaris lumbricoides* and *Entamoeba coli*

Specimen FP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium malariae	1	100%	Acceptable

Parasite(s) present: *Plasmodium malariae*

PVA SLIDES (Add-on)

Specimen PA-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba coli	1	100%	Acceptable
Parasite(s) present: <i>Entamoeba coli</i>			

Specimen PA-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative (sterile)	1	100%	Acceptable
Parasite(s) present: Negative (sterile)			

DERMATOPHYTE CULTURE

Specimen DM-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative (Dermatophytes absent)	4	80.00%	Acceptable
Positive (Dermatophytes present)	1	20.00%	

Organism(s) present: *Aspergillus fumigatus* and *Erysipelothrix rhusiopathiae*

Specimen DM-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive (Dermatophytes present)	5	100.00%	Acceptable

Organism(s) present: *Microsporium canis* and *Micrococcus luteus*

Specimen DM-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive (Dermatophytes present)	5	100.00%	Acceptable

Organism(s) present: *Trichophyton rubrum* and *Malassezia pachydermatis*

Specimen DM-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive (Dermatophytes present)	5	100.00%	Acceptable

Organism(s) present: *Microsporium gypseum* and *Staphylococcus epidermidis*

Specimen DM-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative (Dermatophytes absent)	3	60.00%	Not graded
Positive (Dermatophytes present)	2	40.00%	

Organism(s) present: *Candida albicans* and *Sporothrix schenckii*. This is an ungraded challenge due to lack of participant consensus.

BACTERIAL VAGINOSIS – OSOM - WAIVED

Specimen BV-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	6	-
Sekisui OSOM	6	6	-

Antigen(s) present: *Gardnerella vaginalis*

Specimen BV-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	-	6
Sekisui OSOM	6	-	6

Antigen(s) present: Negative (sterile)

TRICHOMONAS VAGINALIS – OSOM - WAIVED

Specimen TR-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Sekisui OSOM	5	-	5

Antigen(s) present: Negative (sterile)

Specimen TR-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Sekisui OSOM	5	5	-

Antigen(s) present: *Trichomonas vaginalis*

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