

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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Medical Laboratory
Evaluation 

Microbiology
2022 MLE-M3

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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-11

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

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

Specimen MSA-12

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

Organism(s) present: *Haemophilus influenzae*

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 *Pseudomonas aeruginosa*

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 *Staphylococcus haemolyticus*

Specimen MSA-15

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

Organism(s) present: *Staphylococcus aureus* – Methicillin sensitive and *Erysipelothrix rhusiopathiae*

STREP A ANTIGEN DETECTION

Specimen RS-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	308	5	303
Abbott ID NOW	6	-	6
Alere Acceava Strep A Test	5	1	4
Alere i Instrument - waived	4	-	4
BD Veritor - waived	4	-	4
Beckman Coulter ICON DS	5	-	5
Beckman Coulter ICON SC	1	-	1
Cardinal Health Strep A - waived	6	-	6
Cepheid GeneXpert - moderate	1	1	-
Cepheid GeneXpert - waived	10	-	10
Consult Diagnostic Strep A Dipstick - Waived	47	1	46
Fisher HealthCare Sure-Vue	1	-	1
Fisher HealthCare Sure-Vue - waived	1	-	1
Germaine Labs StrepAim	1	-	1
Henry Schein One Step	1	-	1
Henry Schein One Step+ - waived	50	-	50
McKesson Strep A Cassette	3	-	3
McKesson Strep A Dipstick	18	-	18
Medline Strep A Test Strip	5	1	4
Meridian (GenePOC) revogene	3	-	3
Meridian ImmunoCard STAT - waived	4	-	4
Other Waived Method	4	-	4
Quidel QuickVue Dipstick Strep	26	-	26
Quidel QuickVue In-Line	29	-	29
Quidel QuickVue+	2	-	2
Quidel Sofia / Sofia 2 - waived	5	-	5
Quidel Sofia Strep A - moderate	1	-	1
Quidel Sofia Strep A+ - waived	17	-	17
Quidel Solana	3	-	3
Roche cobas Liat	5	-	5
Sekisui OSOM	12	-	12
Sekisui OSOM Ultra -waived	27	1	26
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	305	292	13
Abbott ID NOW	6	6	-
Alere Acceava Strep A Test	5	4	1
Alere i Instrument - waived	4	4	-
BD Veritor - waived	3	3	-
Beckman Coulter ICON DS	5	5	-
Beckman Coulter ICON SC	1	1	-
Cardinal Health Strep A - waived	6	6	-
Cepheid GeneXpert - moderate	1	1	-
Cepheid GeneXpert - waived	10	10	-
Consult Diagnostic Strep A Dipstick - Waived	46	44	2
Fisher HealthCare Sure-Vue	1	1	-
Fisher HealthCare Sure-Vue - waived	1	1	-
Germaine Labs StrepAim	1	1	-
Henry Schein One Step	1	1	-
Henry Schein One Step+ - waived	50	47	3
McKesson Strep A Cassette	3	3	-
McKesson Strep A Dipstick	18	15	3
Medline Strep A Test Strip	5	4	1
Meridian (GenePOC) revogene	3	3	-
Meridian ImmunoCard STAT - waived	4	4	-
Other Waived Method	4	4	-
Quidel QuickVue Dipstick Strep	25	25	-
Quidel QuickVue In-Line	29	29	-
Quidel QuickVue+	2	2	-
Quidel Sofia / Sofia 2 - waived	5	5	-
Quidel Sofia Strep A - moderate	1	1	-
Quidel Sofia Strep A+ - waived	17	17	-
Quidel Solana	3	3	-
Roche cobas Liat	5	5	-
Sekisui OSOM	12	11	1
Sekisui OSOM Ultra -waived	27	25	2
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	30	-	30
Abbott ID NOW	1	-	1
Alere i Instrument - waived	1	-	1
Cepheid GeneXpert - moderate	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	4	-	4
Henry Schein One Step+ - waived	3	-	3
McKesson Strep A Cassette	1	-	1
McKesson Strep A Dipstick	2	-	2
Quidel QuickVue Dipstick Strep	4	-	4
Quidel QuickVue In-Line	6	-	6
Quidel Sofia Strep A - moderate	1	-	1
Quidel Solana	3	-	3
Roche cobas Liat	1	-	1
Sekisui OSOM Ultra -waived	2	-	2

Specimen RS-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	30	-	30
Abbott ID NOW	1	-	1
Alere i Instrument - waived	1	-	1
Cepheid GeneXpert - moderate	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	4	-	4
Henry Schein One Step+ - waived	3	-	3
McKesson Strep A Cassette	1	-	1
McKesson Strep A Dipstick	2	-	2
Quidel QuickVue Dipstick Strep	4	-	4
Quidel QuickVue In-Line	6	-	6
Quidel Sofia Strep A - moderate	1	-	1
Quidel Solana	3	-	3
Roche cobas Liat	1	-	1
Sekisui OSOM Ultra -waived	2	-	2

STREP A ANTIGEN DETECTION

Specimen RS-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	30	30	-
Abbott ID NOW	1	1	-
Alere i Instrument - waived	1	1	-
Cepheid GeneXpert - moderate	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	4	4	-
Henry Schein One Step+ - waived	3	3	-
McKesson Strep A Cassette	1	1	-
McKesson Strep A Dipstick	2	2	-
Quidel QuickVue Dipstick Strep	4	4	-
Quidel QuickVue In-Line	6	6	-
Quidel Sofia Strep A - moderate	1	1	-
Quidel Solana	3	3	-
Roche cobas Liat	1	1	-
Sekisui OSOM Ultra -waived	2	2	-

MISCELLANEOUS CULTURES

Specimen BA-7 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
<i>Plesiomonas shigelloides</i>	4	80.00%	Acceptable
<i>Plesiomonas</i> sp.	1	20.00%	Acceptable

Organism(s) present: *Plesiomonas shigelloides*

Specimen BA-8 – Sputum Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
<i>Pasteurella multocida</i>	3	33.33%	Acceptable
<i>Pasteurella</i> sp.	1	11.11%	Acceptable
<i>Streptococcus mutans</i>	4	44.45%	Acceptable
<i>Streptococcus viridans</i> group	1	11.11%	Acceptable

Organism(s) present: *Pasteurella multocida* and *Streptococcus mutans*

Specimen BA-9 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
<i>Streptococcus agalactiae</i>	3	60.00%	Acceptable
<i>Staphylococcus epidermidis</i>	1	20.00%	Acceptable
Staph – coagulase negative	1	20.00%	Acceptable

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

THROAT CULTURE

Specimen TC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	36	60.00%	Acceptable
Presump. Positive Group A Strep	18	30.00%	Acceptable
Streptococcus pyogenes	4	6.67%	Acceptable

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

Specimen TC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	58	100%	Acceptable

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

Specimen TC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep.	19	51.35%	Acceptable
Presump. Positive Group A Strep.	17	45.95%	Acceptable

Organism(s) present: *Streptococcus pyogenes*.

Specimen TC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	25	71.43%	Acceptable

Organism(s) present: *Serratia marcescens* and *Micrococcus luteus*. The specimen identification was graded by 89% referee consensus.

Specimen TC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	34	97.14%	Acceptable

Organism(s) present: *Klebsiella pneumoniae*.

URINE CULTURE

Specimen UC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	10	35.71%	Acceptable
Providencia sp.	8	28.57%	Acceptable
Growth, referred for identification	5	13.89%	Acceptable
Gram positive cocci	1	2.78%	

Gram Stain

Gram negative	11	100%	Acceptable
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Gram Stain Morphology

Rods/bacilli	10	90.91%	Acceptable
Coccobacilli	1	9.09%	

Organism(s) present: *Providencia stuartii*.

Specimen UC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Enterococcus sp.	19	52.78%	Acceptable
Staph – coagulase negative	9	25.00%	Acceptable
Growth, referred for identification	5	13.89%	Acceptable
Gram positive cocci	1	2.78%	Acceptable

Organism(s) present: *Enterococcus gallinarum* and *Staphylococcus epidermidis*.

URINE CULTURE

Specimen UC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Escherichia coli	10	47.62%	Acceptable
Growth, referred for identification	7	33.33%	Acceptable
Lactobacillus sp.	2	9.52%	Acceptable
Gram negative bacilli	1	4.76%	Acceptable
Presump. Gram negative	1	4.76%	Acceptable

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

Specimen UC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Streptococcus agalactiae	5	60.50%	Acceptable
Streptococcus alpha-hemolytic	2	25.00%	Acceptable
Growth, referred for identification	1	12.50%	Acceptable

Organism(s) present: *Streptococcus agalactiae* and *Streptococcus mitis*.

Specimen UC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	6	54.55%	Acceptable
Klebsiella aerogenes	3	27.27%	Acceptable
Enterobacter sp.	2	18.18%	

Organism(s) present: *Klebsiella aerogenes*.

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>	
Amikacin	-	-	-	-	1	-	1	-	100.00%
Amoxicillin/Clavulanate	3	-	-	3	1	-	-	1	100.00%
Ampicillin	17	-	-	17	3	-	-	3	100.00%
Ampicillin/Sulbactam	-	-	-	-	3	-	-	3	100.00%
Cefazolin	14	-	-	14	3	-	-	3	100.00%
Cefepime	-	-	-	-	3	1	-	2	Ungraded ¹
Cefoxitin	-	-	-	-	2	-	-	2	100.00%
Ceftazidime	-	-	-	-	2	-	-	2	100.00%
Ceftriaxone	3	2	-	1	3	-	1	2	Ungraded ¹
Cefuroxime	3	-	-	3	1	-	-	1	100.00%
Ciprofloxacin	20	-	-	20	3	-	-	3	100.00%
Ertapenem	-	-	-	-	1	-	-	1	100.00%
Gentamicin	17	-	-	17	3	-	-	3	100.00%
Imipenem	-	-	-	-	2	-	1	1	100.00%
Levofloxacin	4	-	-	4	3	-	-	3	100.00%
Meropenem	-	-	-	-	1	1	-	-	100.00%
Nitrofurantoin	14	-	-	14	3	-	-	3	100.00%
Piperacillin/Tazobactam	1	1	-	-	4	3	-	1	80.00%
Tetracycline	9	-	-	9	1	-	-	1	100.00%
Tobramycin	-	-	-	-	3	-	-	3	100.00%
Trimethoprim/Sulfamethoxazole	20	-	-	20	3	-	-	3	100.00%

Organism(s) present: *Providencia stuartii*

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 This is an ungraded challenge due to lack of participant consensus.

GENITAL CULTURE

Specimen GC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive for N. gonorrhoeae	12	75.00%	Acceptable
Neisseria gonorrhoeae	2	12.50%	Acceptable
Gram negative diplococci	1	6.25%	Acceptable
Growth, referred for identification	1	6.25%	Acceptable

Gram Stain

Gram negative	6	100%	Acceptable
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Gram Stain Morphology

Diplococci	6	100%	Acceptable
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Organism(s) present: *Neisseria gonorrhoeae*.

Specimen GC-12

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

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

Specimen GC-13

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

Organism(s) present: *Streptococcus anginosus* and *Lactobacillus casei*.

Specimen GC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	4	100%	Acceptable

Organism(s) present: *Streptococcus agalactiae*.

Specimen GC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive for N. gonorrhoeae	4	100%	Acceptable

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

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	28	-	-	5	23
Calibrated Loop	15	-	-	5	10
Uri-Check	2	-	-	-	2
Uricult	11	-	-	-	11

Identification–Specimen CC-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	5	100%	Acceptable

Gram Stain

Gram negative	5	100%	Acceptable
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Gram Stain Morphology

Rods/bacilli	5	100%	Acceptable
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Organism(s) present: >100,000 CFU/mL of *Providencia stuartii*.

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	28	1	4	18	5
Calibrated Loop	15	-	1	13	1
Uri-Check	2	-	1	1	-
Uricult	11	1	2	4	4

Identification–Specimen CC-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	5	100%	Acceptable

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

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification—Specimen CC-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	3	100%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Escherichia coli* and 73,000 CFU/mL *Lactobacillus casei*.

Identification—Specimen CC-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	3	100%	Acceptable

Organism(s) present: 67,000 CFU/mL of *Streptococcus agalactiae* and < 10,000 CFU/mL *Streptococcus mitis*.

Identification—Specimen CC-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	3	100%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Klebsiella aerogenes*,

GRAM STAIN

Specimen GS-11

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	6	85.71	Acceptable

Gram Stain Morphology

Rods/bacilli	5	100%	Acceptable
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Organism(s) present: *Proteus vulgaris*.

Specimen GS-12

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	6	85.71%	Acceptable
Gram negative	1	14.29%	

Gram Stain Morphology

Rods/bacilli	4	80.00%	Acceptable
Cocci	1	20.00%	

Organism(s) present: *Corynebacterium striatum*.

GRAM STAIN

Specimen GS-13

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	7	100%	Acceptable

Gram Stain Morphology

Rods/bacilli	4	80.00%	Acceptable
Cocci	1	20.00%	

Organism(s) present: *Actinomyces odontolyticus*.

Specimen GS-14

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	7	100%	Acceptable

Gram Stain Morphology

Cocci	4	80.00%	Acceptable
Diplococci	1	20.00%	

Organism(s) present: *Enterococcus faecium*.

Specimen GS-15

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	7	100%	Acceptable

Gram Stain Morphology

Coccobacilli	2	40.00%	Acceptable
Rods/bacilli	2	40.00%	Acceptable
Diplococcus	1	20.00%	

Organism(s) present: *Haemophilus influenzae*.

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	26	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*.

Specimen VP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	26	96.30%	Acceptable
Negative	1	3.70%	

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

Specimen VP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	26	96.30%	Acceptable
Positive	1	3.70%	

Organism(s) present: *Candida* sp.

Specimen VP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	27	100%	Acceptable

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

Specimen VP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	26	96.30%	Acceptable
Positive	1	3.70%	

Organism(s) present: *Candida* sp.

AFFIRM VP III – Gardnerella vaginalis

Specimen VP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	24	92.31%	Acceptable
Negative	2	7.69%	

Organism(s) present: *Gardnerella vaginalis*

Specimen VP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	26	100%	Acceptable

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

Specimen VP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	26	100%	Acceptable

Organism(s) present: *Candida* sp.

Specimen VP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	26	100%	Acceptable

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

Specimen VP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	26	100%	Acceptable

Organism(s) present: *Candida* sp.

AFFIRM VP III – Candida sp.

Specimen VP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	26	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*

Specimen VP-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	25	96.15%	Acceptable
Positive	1	3.85%	

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

Specimen VP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	26	100%	Acceptable

Organism(s) present: *Candida* sp.

Specimen VP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	26	100%	Acceptable

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

Specimen VP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	26	100%	Acceptable

Organism(s) present: *Candida* sp.

SARS-CoV-2 (MOLECULAR DETECTION)

Specimen MCV-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	68	-	68
Abbott ID NOW	26	-	26
Applied Biosystems 7500 Fast	4	-	4
Atila BioSystems	1	-	1
BioGX XFree RT-PCR	1	-	1
Cepheid GeneXpert - moderate	3	-	3
Cepheid GeneXpert - waived	22	-	22
Hologic Panther Fusion - waived	1	-	1
QIAGEN QIAstat-Dx	1	-	1
Quidel Solana - waived	3	-	3
Roche Cobas Molecular - waived	5	-	5
Sansure Biotech	1	-	1

Specimen MCV-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	68	68	-
Abbott ID NOW	26	26	-
Applied Biosystems 7500 Fast	4	4	-
Atila BioSystems	1	1	-
BioGX XFree RT-PCR	1	1	-
Cepheid GeneXpert - moderate	3	3	-
Cepheid GeneXpert - waived	22	22	-
Hologic Panther Fusion - waived	1	1	-
QIAGEN QIAstat-Dx	1	1	-
Quidel Solana - waived	3	3	-
Roche Cobas Molecular - waived	5	5	-
Sansure Biotech	1	1	-

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	16	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	9	9	-
Hologic Panther Fusion	1	1	-
Quidel QuickVue	2	2	-
Roche COBAS Amplicor	1	1	-

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

Specimen CY-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	1	15
BD Max	2	-	2
BD Viper	1	-	1
Cepheid GeneXpert - moderate	9	1	8
Hologic Panther Fusion	1	-	1
Quidel QuickVue	2	-	2
Roche COBAS Amplicor	1	-	1

Antigen(s) present: Specimen is negative for antigens.

Specimen CY-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	14	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	9	9	-
Quidel QuickVue	1	1	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Chlamydia trachomatis*.

Specimen CY-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	-	14
BD Max	2	-	2
BD Viper	1	-	1
Cepheid GeneXpert - moderate	9	-	9
Quidel QuickVue	1	-	1
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	14	14	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	9	9	-
Quidel QuickVue	1	1	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Chlamydia trachomatis*.

GC (ANTIGEN DETECTION)

Specimen CY-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	14	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	9	9	-
Hologic Panther Fusion	1	1	-
Roche COBAS Amplicor	1	1	-

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

Specimen CY-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	-	14
BD Max	2	-	2
BD Viper	1	-	1
Cepheid GeneXpert - moderate	9	-	9
Hologic Panther Fusion	1	-	1
Roche COBAS Amplicor	1	-	1

Antigen(s) present: Negative (sterile).

Specimen CY-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	-	13
BD Max	2	-	2
BD Viper	1	-	1
Cepheid GeneXpert - moderate	9	-	9
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Chlamydia trachomatis*.

GC (ANTIGEN DETECTION)

Specimen CY-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	13	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	9	9	-
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	13	-	13
BD Max	2	-	2
BD Viper	1	-	1
Cepheid GeneXpert - moderate	9	-	9
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Chlamydia trachomatis*.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Meridian ImmunoCard STAT	5	-	5

Antigen(s) present: *Giardia lamblia*.

Specimen LC-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Meridian ImmunoCard STAT	5	-	5

Antigen(s) present: Negative (sterile).

Specimen LC-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Meridian ImmunoCard STAT	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	-
Meridian ImmunoCard STAT	5	5	-

Antigen(s) present: *Cryptosporidium*.

Specimen LC-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Meridian ImmunoCard STAT	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	4	1
Meridian ImmunoCard STAT	5	4	1

Antigen(s) present: *Giardia lamblia*.

Specimen LC-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Meridian ImmunoCard STAT	5	-	5

Antigen(s) present: Negative (sterile).

Specimen LC-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
Meridian ImmunoCard STAT	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
Meridian ImmunoCard STAT	5	-	5

Antigen(s) present: *Cryptosporidium*

Specimen LC-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	5	-
Meridian ImmunoCard STAT	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	77	2	75
Abbott ID NOW	5	-	5
Alere Binax NOW - waived	19	-	19
BD Veritor - moderate	3	-	3
BD Veritor - waived	4	-	4
Cepheid GeneXpert - moderate	2	-	2
Cepheid GeneXpert - waived	12	-	12
Quidel QuickVue RSV - waived	12	-	12
Quidel Sofia / Sofia 2 - waived	17	2	15
Quidel Solana	1	-	1
Roche cobas Liat	2	-	2

Antigen(s) present: Influenza B

Specimen V-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	77	74	3
Abbott ID NOW	5	5	-
Alere Binax NOW - waived	19	19	-
BD Veritor - moderate	3	3	-
BD Veritor - waived	4	4	-
Cepheid GeneXpert - moderate	2	2	-
Cepheid GeneXpert - waived	12	12	-
Quidel QuickVue RSV - waived	12	12	-
Quidel Sofia / Sofia 2 - waived	17	14	3
Quidel Solana	1	1	-
Roche cobas Liat	2	2	-

Antigen(s) present: RSV

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	-	12
BD Veritor - moderate	3	-	3
BD Veritor - waived	1	-	1
Cepheid GeneXpert - moderate	1	-	1
Cepheid GeneXpert - waived	1	-	1
Quidel QuickVue RSV - waived	3	-	3
Quidel Sofia / Sofia 2 - waived	1	-	1
Quidel Solana	1	-	1
Roche cobas Liat	1	-	1

Antigen(s) present: Influenza A

RSV ANTIGEN DETECTION

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	-	12
BD Veritor - moderate	3	-	3
BD Veritor - waived	1	-	1
Cepheid GeneXpert - moderate	1	-	1
Cepheid GeneXpert - waived	1	-	1
Quidel QuickVue RSV - waived	3	-	3
Quidel Sofia / Sofia 2 - waived	1	-	1
Quidel Solana	1	-	1
Roche cobas Liat	1	-	1

Antigen(s) present: Influenza B

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	12	-
BD Veritor - moderate	3	3	-
BD Veritor - waived	1	1	-
Cepheid GeneXpert - moderate	1	1	-
Cepheid GeneXpert - waived	1	1	-
Quidel QuickVue RSV - waived	3	3	-
Quidel Sofia / Sofia 2 - waived	1	1	-
Quidel Solana	1	1	-
Roche cobas Liat	1	1	-

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	188	11	177
Abbott ID NOW	12	2	10
Alere Binax NOW - waived	2	-	2
Alere i Instrument - waived	1	-	1
Alere Influenza A&B	1	-	1
BD Veritor - moderate	4	-	4
BD Veritor - waived	38	4	34
BioSign Flu A+B	1	-	1
Cepheid GeneXpert - moderate	2	-	2
Cepheid GeneXpert - waived	11	-	11
Henry Schein OneStep+ Flu A&B	19	1	18
McKesson Consult Diag. Flu A & B	26	-	26
Meridian ImmunoCard STAT - waived	3	-	3
Quidel QuickVue Influenza A+B	14	-	14
Quidel Sofia / Sofia 2 - waived	45	4	41
Quidel Solana	2	-	2
Roche cobas Liat	3	-	3
Sekisui OSOM Influenza A&B	3	-	3
Sekisui OSOM Ultra -waived	1	-	1

Antigen(s) present: Influenza B

Specimen V-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	188	5	183
Abbott ID NOW	12	-	12
Alere Binax NOW - waived	2	-	2
Alere i Instrument - waived	1	-	1
Alere Influenza A&B	1	-	1
BD Veritor - moderate	4	-	4
BD Veritor - waived	38	3	35
BioSign Flu A+B	1	-	1
Cepheid GeneXpert - moderate	2	-	2
Cepheid GeneXpert - waived	11	-	11
Henry Schein OneStep+ Flu A&B	19	-	19
McKesson Consult Diag. Flu A & B	26	-	26
Meridian ImmunoCard STAT - waived	3	-	3
Quidel QuickVue Influenza A+B	14	-	14
Quidel Sofia / Sofia 2 - waived	45	2	43
Quidel Solana	2	-	2
Roche cobas Liat	3	-	3
Sekisui OSOM Influenza A&B	3	-	3
Sekisui OSOM Ultra -waived	1	-	1

Antigen(s) present: RSV

INFLUENZA A ANTIGEN DETECTION

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	17	-
Abbott ID NOW	2	2	-
Alere Binax NOW - waived	1	1	-
BD Veritor - moderate	4	4	-
Cepheid GeneXpert - moderate	1	1	-
Cepheid GeneXpert - waived	1	1	-
McKesson Consult Diag. Flu A & B	2	2	-
Quidel QuickVue Influenza A+B	2	2	-
Quidel Sofia / Sofia 2 - waived	1	1	-
Quidel Solana	2	2	-
Roche cobas Liat	1	1	-

Antigen(s) present: Influenza A

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	-	17
Abbott ID NOW	2	-	2
Alere Binax NOW - waived	1	-	1
BD Veritor - moderate	4	-	4
Cepheid GeneXpert - moderate	1	-	1
Cepheid GeneXpert - waived	1	-	1
McKesson Consult Diag. Flu A & B	2	-	2
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia / Sofia 2 - waived	1	-	1
Quidel Solana	2	-	2
Roche cobas Liat	1	-	1

Antigen(s) present: Influenza B

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	-	17
Abbott ID NOW	2	-	2
Alere Binax NOW - waived	1	-	1
BD Veritor - moderate	4	-	4
Cepheid GeneXpert - moderate	1	-	1
Cepheid GeneXpert - waived	1	-	1
McKesson Consult Diag. Flu A & B	2	-	2
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia / Sofia 2 - waived	1	-	1
Quidel Solana	2	-	2
Roche cobas Liat	1	-	1

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	188	179	9
Abbott ID NOW	12	11	1
Alere Binax NOW - waived	2	2	-
Alere i Instrument - waived	1	1	-
Alere Influenza A&B	1	1	-
BD Veritor - moderate	4	4	-
BD Veritor - waived	38	37	1
BioSign Flu A+B	1	1	-
Cepheid GeneXpert - moderate	2	2	-
Cepheid GeneXpert - waived	11	11	-
Henry Schein OneStep+ Flu A&B	19	17	2
McKesson Consult Diag. Flu A & B	26	25	1
Meridian ImmunoCard STAT - waived	3	3	-
Quidel QuickVue Influenza A+B	15	14	1
Quidel Sofia / Sofia 2 - waived	45	42	3
Quidel Solana	2	2	-
Roche cobas Liat	3	3	-
Sekisui OSOM Influenza A&B	3	3	-

Antigen(s) present: Influenza B

Specimen V-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	188	7	181
Abbott ID NOW	12	1	11
Alere Binax NOW - waived	2	-	2
Alere i Instrument - waived	1	-	1
Alere Influenza A&B	1	-	1
BD Veritor - moderate	4	-	4
BD Veritor - waived	38	3	35
BioSign Flu A+B	1	-	1
Cepheid GeneXpert - moderate	2	-	2
Cepheid GeneXpert - waived	11	-	11
Henry Schein OneStep+ Flu A&B	19	1	18
McKesson Consult Diag. Flu A & B	26	1	25
Meridian ImmunoCard STAT - waived	3	-	3
Quidel QuickVue Influenza A+B	15	-	15
Quidel Sofia / Sofia 2 - waived	45	1	44
Quidel Solana	2	-	2
Roche cobas Liat	3	-	3
Sekisui OSOM Influenza A&B	3	-	3

Antigen(s) present: RSV

INFLUENZA B ANTIGEN DETECTION

Specimen V-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	-	17
Abbott ID NOW	2	-	2
Alere Binax NOW - waived	1	-	1
BD Veritor - moderate	4	-	4
Cepheid GeneXpert - moderate	1	-	1
Cepheid GeneXpert - waived	1	-	1
McKesson Consult Diag. Flu A & B	2	-	2
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia / Sofia 2 - waived	1	-	1
Quidel Solana	2	-	2
Roche cobas Liat	1	-	1

Antigen(s) present: Influenza A

Specimen V-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	17	-
Abbott ID NOW	2	2	-
Alere Binax NOW - waived	1	1	-
BD Veritor - moderate	4	4	-
Cepheid GeneXpert - moderate	1	1	-
Cepheid GeneXpert - waived	1	1	-
McKesson Consult Diag. Flu A & B	2	2	-
Quidel QuickVue Influenza A+B	2	2	-
Quidel Sofia / Sofia 2 - waived	1	1	-
Quidel Solana	2	2	-
Roche cobas Liat	1	1	-

Antigen(s) present: Influenza B

Specimen V-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	1	16
Abbott ID NOW	2	1	1
Alere Binax NOW - waived	1	-	1
BD Veritor - moderate	4	-	4
Cepheid GeneXpert - moderate	1	-	1
Cepheid GeneXpert - waived	1	-	1
McKesson Consult Diag. Flu A & B	2	-	2
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia / Sofia 2 - waived	1	-	1
Quidel Solana	2	-	2
Roche cobas Liat	1	-	1

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
Alere C. diff Quik Chek	5	-	5

Antigen(s) present: Negative (sterile)

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: *Clostridioides difficile* and Rotavirus

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	5	-
Fisher HealthCare Sure-Vue	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-Vue	5	-	5

Antigen(s) present: Negative (sterile)

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: *Clostridioides difficile* and Rotavirus

LEGIONELLA ANTIGEN DETECTION

Specimen L-11

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	-	6
Binax NOW	6	-	6

Specimen L-12

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	6	-
Binax NOW	6	6	-

Specimen L-13

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	6	-
Binax NOW	6	6	-

Specimen L-14

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	6	-
Binax NOW	6	6	-

Specimen L-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	-	6
Binax NOW	6	-	6

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-11

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

Specimen SP-12

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

Specimen SP-13

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

Specimen SP-14

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

Specimen SP-15

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5
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	141	135	6
Abbott BinaxNOW - waived	24	24	-
Access Bio CareStart	20	20	-
BD Veritor - waived	13	12	1
Celltrion DiaTrust	13	13	-
GenBody	7	3	4
INDICAID by Phase Scientific	3	3	-
LumiraDx	3	3	-
Other EUA method	1	1	-
Quidel QuickVue - waived	8	8	-
Quidel Sofia / Sofia 2 - waived	35	35	-
Sienna-Clarity	13	13	-
Status by LifeSign	1	-	1

Specimen ACV-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	140	-	140
Abbott BinaxNOW - waived	24	-	24
Access Bio CareStart	20	-	20
BD Veritor - waived	13	-	13
Celltrion DiaTrust	13	-	13
GenBody	7	-	7
INDICAID by Phase Scientific	3	-	3
LumiraDx	3	-	3
Other EUA method	1	-	1
Quidel QuickVue - waived	8	-	8
Quidel Sofia / Sofia 2 - waived	35	-	35
Sienna-Clarity	13	-	13

PARASITOLOGY

Specimen FP-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Strongyloides stercoralis	1	33.33%	Acceptable
Balantidium coli	1	33.33%	Acceptable
Enterobius vermicularis	1	33.33%	Acceptable

Parasite(s) present: *Strongyloides stercoralis*, *Balantidium coli*, and *Enterobius vermicularis*

Specimen FP-12

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

Parasite(s) present: Negative (sterile)

Specimen FP-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Clonorchis sinensis	1	100%	Acceptable

Parasite(s) present: *Clonorchis sinensis*

Specimen FP-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. eggs	1	100%	Acceptable

Parasite(s) present: *Taenia sp.* eggs

Specimen FP-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Babesia sp.	1	100%	Acceptable

Parasite(s) present: *Babesia sp.*

PVA SLIDES (Add-on)

Specimen PA-5

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

Specimen PA-6

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

DERMATOPHYTE CULTURE

Specimen DM-11

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative (Dermatophytes absent)	2	66.67%	Acceptable
Positive (Dermatophytes present)	1	33.33%	

Organism(s) present: *Fusobacterium necrophorum* and *Candida rugosa*

Specimen DM-12

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive (Dermatophytes present)	5	100%	Acceptable

Organism(s) present: *Microsporum gypseum* and *Corynebacterium sp.*

Specimen DM-13

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive (Dermatophytes present)	5	100%	Acceptable

Organism(s) present: *Trichophyton mentagrophytes*

Specimen DM-14

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive (Dermatophytes present)	2	66.67%	Ungraded
Negative (Dermatophytes absent)	1	33.33%	

Organism(s) present: *Aspergillus flavus*. This is an ungraded challenge due to lack of participant consensus.

Specimen DM-15

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive (Dermatophytes present)	3	100%	Acceptable

Organism(s) present: *Trichophyton rubrum* and *Acremonium sp.*

BACTERIAL VAGINOSIS – OSOM - WAIVED

Specimen BV-5

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

Antigen(s) present: *Gardnerella vaginalis*

Specimen BV-6

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

Antigen(s) present: *Escherichia coli*

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: *Trichomonas vaginalis*

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: Negative (sterile)

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