

# **MEDICAL LABORATORY EVALUATION**

**PARTICIPANT SUMMARY**

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Medical Laboratory  
Evaluation 

Microbiology  
2022 MLE-M1

# Table of Contents

**Evaluation Criteria..... 2**

## Microbiology

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

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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-1

<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 saprophyticus*

### Specimen MSA-2

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

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

### Specimen MSA-3

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

Organism(s) present: *Burkholderia cepacia*

### Specimen MSA-4

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

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

### Specimen MSA-5

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

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

## STREP A ANTIGEN DETECTION

### Specimen RS-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	315	304	11
Abbott ID NOW	5	5	-
Alere Acceava Strep A Test	6	6	-
Alere i Instrument - waived	5	5	-
BD Chek Strep A	1	1	-
BD Veritor - waived	7	7	-
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	9	9	-
Consult Diagnostic Strep A Dipstick - Waived	47	42	5
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	49	45	4
Jant Pharmacal Accustrip	1	1	-
McKesson Strep A Cassette	1	1	-
McKesson Strep A Dipstick	20	20	-
McKesson Strep A Test - Twist	1	1	-
Medline Strep A Test Strip	5	5	-
Meridian (GenePOC) revogene	4	4	-
Meridian ImmunoCard STAT - waived	3	3	-
Other Waived Method	5	5	-
Quidel QuickVue Dipstick Strep	28	28	-
Quidel QuickVue In-Line	27	26	1
Quidel QuickVue+	3	3	-
Quidel Sofia / Sofia 2 - waived	4	4	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	18	18	-
Quidel Solana	3	3	-
Roche cobas Liat	2	2	-
Sekisui OSOM	12	12	-
Sekisui OSOM Ultra -waived	29	29	-
Stanbio QuStick Strep A	1	1	-

## STREP A ANTIGEN DETECTION

### Specimen RS-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	311	299	12
Abbott ID NOW	5	5	-
Alere Acceava Strep A Test	6	6	-
Alere i Instrument - waived	5	5	-
BD Chek Strep A	1	1	-
BD Veritor - waived	6	5	1
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	9	9	-
Consult Diagnostic Strep A Dipstick - Waived	46	43	3
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	49	47	2
Jant Pharmacal Accustrip	1	1	-
McKesson Strep A Cassette	1	1	-
McKesson Strep A Dipstick	19	19	-
McKesson Strep A Test - Twist	1	1	-
Medline Strep A Test Strip	5	5	-
Meridian (GenePOC) revogene	4	4	-
Meridian ImmunoCard STAT - waived	3	3	-
Other Waived Method	5	5	-
Quidel QuickVue Dipstick Strep	27	27	-
Quidel QuickVue In-Line	27	23	4
Quidel QuickVue+	3	3	-
Quidel Sofia / Sofia 2 - waived	4	4	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	18	17	1
Quidel Solana	3	3	-
Roche cobas Liat	2	2	-
Sekisui OSOM	12	12	-
Sekisui OSOM Ultra -waived	29	29	-
Stanbio QuStick Strep A	1	1	-

## STREP A ANTIGEN DETECTION

### Specimen RS-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	36	1	35
Abbott ID NOW	2	-	2
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 Dipstick	2	-	2
Meridian (GenePOC) revogene	1	-	1
Quidel QuickVue Dipstick Strep	5	-	5
Quidel QuickVue In-Line	7	1	6
Quidel QuickVue+	1	-	1
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	2	-	2
Quidel Solana	3	-	3
Sekisui OSOM Ultra -waived	2	-	2

### Specimen RS-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	36	-	36
Abbott ID NOW	2	-	2
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 Dipstick	2	-	2
Meridian (GenePOC) revogene	1	-	1
Quidel QuickVue Dipstick Strep	5	-	5
Quidel QuickVue In-Line	7	-	7
Quidel QuickVue+	1	-	1
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	2	-	2
Quidel Solana	3	-	3
Sekisui OSOM Ultra -waived	2	-	2

## STREP A ANTIGEN DETECTION

### Specimen RS-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	36	36	-
Abbott ID NOW	2	2	-
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 Dipstick	2	2	-
Meridian (GenePOC) revogene	1	1	-
Quidel QuickVue Dipstick Strep	5	5	-
Quidel QuickVue In-Line	7	7	-
Quidel QuickVue+	1	1	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	2	2	-
Quidel Solana	3	3	-
Sekisui OSOM Ultra -waived	2	2	-

## MISCELLANEOUS CULTURES

### Specimen BA-1 – Eye Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Serratia marcescens	4	50.00%	Acceptable
Staphylococcus epidermidis	4	50.00%	Acceptable

Organism(s) present: *Serratia marcescens* and *Staphylococcus epidermidis*

### Specimen BA-2 – Stool Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Shigella boydii	2	25.00%	Acceptable
Shigella sp.	2	25.00%	Acceptable
Escherichia coli	4	50.00%	Acceptable

Organism(s) present: *Shigella boydii* and *Escherichia coli*

### Specimen BA-3 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Eikenella corrodens	4	100%	Acceptable

Organism(s) present: *Eikenella corrodens*

## THROAT CULTURE

### Specimen TC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	34	52.31%	Acceptable
Presumptive Positive for Group A Strep	19	29.23%	Acceptable
Streptococcus pyogenes	4	6.15%	Acceptable
Staphylococcus aureus	7	10.77%	Acceptable

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

### Specimen TC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	52	85.25%	Acceptable
Haemophilus influenzae	3	4.92%	Acceptable
Haemophilus sp.	2	3.28%	Acceptable
No growth (sterile)	3	4.92%	

Organism(s) present: *Haemophilus influenzae*

### Specimen TC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	35	100%	Acceptable

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

### Specimen TC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	33	100%	Acceptable

Organism(s) present: *Granulicatella adiacens* and *Neisseria mucosa*

### Specimen TC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	18	54.55%	Acceptable
Presumptive Positive for Group A Strep	15	45.45%	Acceptable

Organism(s) present: *Streptococcus pyogenes*



## URINE CULTURE

### Specimen UC-1

<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

### Gram Stain

Gram negative	12	100%	Acceptable
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### Gram Stain Morphology

Rods/bacilli	12	100%	Acceptable
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Organism(s) present: *Escherichia coli*

### Specimen UC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus saprophyticus	12	35.29%	Acceptable
Staphylococcus sp.	11	32.35%	Acceptable
Presumptive Staphylococcus sp.	1	2.94%	Acceptable
Streptococcus Group D	3	8.82%	Acceptable
Gram positive cocci	1	2.94%	Acceptable
Growth, referred for identification	6	17.65%	Acceptable

Organism(s) present: *Staphylococcus saprophyticus* and *Streptococcus bovis*

## URINE CULTURE

### Specimen UC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No growth (sterile)	16	94.12%	Acceptable
Growth, referred for identification	1	5.88%	

Organism(s) present: No growth (sterile)

### Specimen UC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Citrobacter freundii	3	23.08%	Acceptable
Citrobacter sp.	3	23.08%	Acceptable
Micrococcus luteus	1	7.69%	Acceptable
Micrococcus sp.	2	15.38%	Acceptable
Growth, referred for identification	2	15.38%	Acceptable

Organism(s) present: *Citrobacter freundii* and *Micrococcus luteus*

### Specimen UC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Stenotrophomonas maltophilia	4	30.77%	Acceptable
Growth, referred for identification	3	23.08%	Acceptable
Staphylococcus epidermidis	1	7.69%	Acceptable
Staphylococcus – coagulase negative	2	15.38%	Acceptable
Staphylococcus sp.	1	7.69%	Acceptable

Organism(s) present: *Stenotrophomonas maltophilia* and *Staphylococcus epidermidis*

**ANTIMICROBIAL SUSCEPTIBILITY TESTING**

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

<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	-	-	-	-	2	2	-	-	100.00%
Amoxicillin/Clavulanate	6	5	1	-	2	2	-	-	87.50%
Ampicillin	21	-	-	21	4	-	-	4	100.00%
Ampicillin/Sulbactam	-	-	-	-	4	-	3	1	100.00%
Aztreonam	-	-	-	-	1	1	-	-	100.00%
Cefazolin	17	17	-	-	4	4	-	-	100.00%
Cefepime	-	-	-	-	4	4	-	-	100.00%
Cefixime	4	4	-	-	-	-	-	-	100.00%
Cefotaxime	-	-	-	-	1	1	-	-	100.00%
Cefotetan	-	-	-	-	1	1	-	-	100.00%
Cefoxitin	2	2	-	-	2	2	-	-	100.00%
Cefpodoxime	1	1	-	-	-	-	-	-	100.00%
Ceftazidime	1	1	-	-	3	3	-	-	100.00%
Ceftriaxone	8	8	-	-	4	4	-	-	100.00%
Cefuroxime	4	4	-	-	1	1	-	-	100.00%
Ciprofloxacin	23	23	-	-	4	4	-	-	100.00%
Ertapenem	-	-	-	-	2	2	-	-	100.00%
Fosfomycin	4	4	-	-	-	-	-	-	100.00%
Gentamicin	22	22	-	-	4	4	-	-	100.00%
Imipenem	1	1	-	-	2	2	-	-	100.00%
Levofloxacin	4	4	-	-	4	4	-	-	100.00%
Meropenem	-	-	-	-	2	2	-	-	100.00%
Minocycline	-	-	-	-	1	1	-	-	100.00%
Nitrofurantoin	19	19	-	-	4	4	-	-	100.00%
Piperacillin/Tazobactam	2	2	-	-	3	3	-	-	100.00%
Tetracycline	8	8	-	-	2	2	-	-	100.00%
Tobramycin	-	-	-	-	4	4	-	-	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-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	12	48.00%	Acceptable
Staphylococcus sp.	8	32.00%	Acceptable
Gram positive cocci	2	8.00%	Acceptable
Growth, referred for identification	1	4.00%	Acceptable
Staphylococcus haemolyticus	1	4.00%	Acceptable
Staph – coagulase negative	1	4.00%	Acceptable

### Gram Stain

Gram positive	5	100%	Acceptable
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### Gram Stain Morphology

Cocci	5	100%	Acceptable
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Organism(s) present: *Staphylococcus haemolyticus* and *Micrococcus luteus*

### Specimen GC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive for N. gonorrhoeae	5	83.33%	Acceptable
Streptococcus alpha-hemolytic	1	16.67%	Acceptable

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

### Specimen GC-3

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

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

### Specimen GC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	5	100%	Acceptable

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

### Specimen GC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive for N. gonorrhoeae	5	100%	Acceptable

Organism(s) present: *Neisseria gonorrhoeae*

**COLONY COUNT/PRESUMPTIVE IDENTIFICATION**

**Specimen CC-1**

<u>Method</u>	<u>Labs</u>	<u>No growth</u>	<u>&lt;10,000 organisms/mL</u>	<u>10,000-100,000 organisms/mL</u>	<u>&gt;100,000 organisms/mL</u>
ALL METHODS	30	-	1	16	13
Calibrated Loop	16	-	-	10	6
Uri-Check	2	-	-	1	1
Uricult	12	-	1	5	6

**Identification–Specimen CC-1**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	6	100%	Acceptable

**Gram Stain**

Gram negative	1	100%	Acceptable
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**Gram Stain Morphology**

Rods/bacilli	1	100%	Acceptable
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Organism(s) present: >100,000 CFU/mL of *Escherichia coli*

**Specimen CC-2**

<u>Method</u>	<u>Labs</u>	<u>No growth</u>	<u>&lt;10,000 organisms/mL</u>	<u>10,000-100,000 organisms/mL</u>	<u>&gt;100,000 organisms/mL</u>
ALL METHODS	30	3	14	13	-
Calibrated Loop	16	1	5	10	-
Uri-Check	2	-	2	-	-
Uricult	12	2	7	3	-

**Identification–Specimen CC-2**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	6	100%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Staphylococcus saprophyticus* and <10,000 CFU/mL of *Streptococcus bovis*

## COLONY COUNT/PRESUMPTIVE IDENTIFICATION

### Identification—Specimen CC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No growth (sterile)	6	100%	Acceptable

Organism(s) present: No growth (sterile)

### Identification—Specimen CC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	6	100%	Acceptable

Organism(s) present: >50,000 CFU/mL of *Citrobacter freundii* and <10,000 CFU/mL of *Micrococcus luteus*

### Identification—Specimen CC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	6	100%	Acceptable

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

## GRAM STAIN

### Specimen GS-1

<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	5	83.33%	Acceptable
Coccobacilli	1	16.67%	

Organism(s) present: *Citrobacter freundii*

### Specimen GS-2

<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

Diplococci	3	50,00%	Acceptable
Cocci	2	33.33%	Acceptable
Coccobacilli	1	16.67%	

Organism(s) present: *Moraxella catarrhalis*

## GRAM STAIN

### Specimen GS-3

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	9	100%	Acceptable

#### Gram Stain Morphology

Rods/bacilli	5	83.33%	Acceptable
Coccobacilli	1	16.67%	

Organism(s) present: *Listeria monocytogenes*

### Specimen GS-4

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	9	100%	Acceptable

#### Gram Stain Morphology

Cocci	5	83.33%	Acceptable
Diplococci	1	16.67%	

Organism(s) present: *Staphylococcus aureus*

### Specimen GS-5

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	9	100%	Acceptable

#### Gram Stain Morphology

Rods/bacilli	4	66.67%	Acceptable
Coccobacilli	2	33.33%	Acceptable

Organism(s) present: *Eikenella corrodens*



**AFFIRM VP III–Trichomonas vaginalis**

**Specimen VP-1**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	24	100%	Acceptable

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

**Specimen VP-2**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	24	100%	Acceptable

Organism(s) present: *Trichomonas vaginalis*

**Specimen VP-3**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	24	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*

**Specimen VP-4**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	24	100%	Acceptable

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

**Specimen VP-5**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	24	100%	Acceptable

Organism(s) present: *Escherichia coli*

**AFFIRM VP III–Gardnerella vaginalis**

**Specimen VP-1**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	24	100%	Acceptable

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

**Specimen VP-2**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	24	100%	Acceptable

Organism(s) present: *Trichomonas vaginalis*

**Specimen VP-3**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	24	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*

**Specimen VP-4**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	24	100%	Acceptable

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

**Specimen VP-5**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	24	100%	Acceptable

Organism(s) present: *Escherichia coli*

**AFFIRM VP III–Candida sp.**

**Specimen VP-1**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	24	100%	Acceptable

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

**Specimen VP-2**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	24	100%	Acceptable

Organism(s) present: *Trichomonas vaginalis*

**Specimen VP-3**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	24	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*

**Specimen VP-4**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	24	100%	Acceptable

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

**Specimen VP-5**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	24	100%	Acceptable

Organism(s) present: *Escherichia coli*

## SARS-CoV-2 (MOLECULAR DETECTION)

### Specimen MCV-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	59	57	2
Abbott ID NOW	23	23	-
Applied Biosystems 7500 Fast	3	3	-
Cepheid GeneXpert - moderate	2	2	-
Cepheid GeneXpert - waived	21	20	1
Diagnovital RT-PCR	1	1	-
Hologic Panther Fusion	1	1	-
Other EUA method	2	1	1
Perkin Elmer	1	1	-
Roche Cobas Molecular - waived	4	4	-
Sansure Biotech	1	1	-

### Specimen MCV-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	59	2	57
Abbott ID NOW	23	1	22
Applied Biosystems 7500 Fast	3	-	3
Cepheid GeneXpert - moderate	2	-	2
Cepheid GeneXpert - waived	21	1	20
Diagnovital RT-PCR	1	-	1
Hologic Panther Fusion	1	-	1
Other EUA method	2	-	2
Perkin Elmer	1	-	1
Roche Cobas Molecular - waived	4	-	4
Sansure Biotech	1	-	1

## CHLAMYDIA (ANTIGEN DETECTION)

### Specimen CY-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	-	12
BD Max	2	-	2
BD Viper	1	-	1
Cepheid GeneXpert - moderate	7	-	7
Quidel QuickVue	1	-	1
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Neisseria gonorrhoeae*

### Specimen CY-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	12	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	7	7	-
Quidel QuickVue	1	1	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Chlamydia trachomatis*

### Specimen CY-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	-	11
BD Max	2	-	2
BD Viper	1	-	1
Cepheid GeneXpert - moderate	7	-	7
Roche COBAS Amplicor	1	-	1

Antigen(s) present: Negative (sterile)

### Specimen CY-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	11	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	7	7	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Chlamydia trachomatis*

## CHLAMYDIA (ANTIGEN DETECTION)

### Specimen CY-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	11	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	7	7	-
Roche COBAS Amplicor	1	1	-

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

## GC (ANTIGEN DETECTION)

### Specimen CY-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	11	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	7	7	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Neisseria gonorrhoeae*

### Specimen CY-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	-	11
BD Max	2	-	2
BD Viper	1	-	1
Cepheid GeneXpert - moderate	7	-	7
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Chlamydia trachomatis*

### Specimen CY-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	-	11
BD Max	2	-	2
BD Viper	1	-	1
Cepheid GeneXpert - moderate	7	-	7
Roche COBAS Amplicor	1	-	1

Antigen(s) present: Negative (sterile)

## GC (ANTIGEN DETECTION)

### Specimen CY-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	-	11
BD Max	2	-	2
BD Viper	1	-	1
Cepheid GeneXpert - moderate	7	-	7
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Chlamydia trachomatis*

### Specimen CY-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	11	-
BD Max	2	2	-
BD Viper	1	1	-
Cepheid GeneXpert - moderate	7	7	-
Roche COBAS Amplicor	1	1	-

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

## CRYPTOSPORIDIUM ANTIGEN DETECTION

### Specimen LC-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	4	1
Alere CRYPTOSPORIDIUM II	5	4	1

Antigen(s) present: *Cryptosporidium*

### Specimen LC-2

<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-3

<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-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	4	1
Alere CRYPTOSPORIDIUM II	5	4	1

Antigen(s) present: *Cryptosporidium*

### Specimen LC-5

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

Antigen(s) present: Negative (sterile)



## GIARDIA LAMBLIA ANTIGEN DETECTION

### Specimen LC-1

<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-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	4	1
Alere GIARDIA II	5	4	1

Antigen(s) present: *Giardia lamblia*

### Specimen LC-3

<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-4

<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-5

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

Antigen(s) present: Negative (sterile)

## RSV ANTIGEN DETECTION

### Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	75	71	4
Abbott ID NOW	4	4	-
Alere Binax NOW - waived	22	22	-
BD Veritor - moderate	3	3	-
BD Veritor - waived	3	3	-
Cepheid GeneXpert - moderate	3	3	-
Cepheid GeneXpert - waived	11	10	1
Other Waived Method	1	1	-
Quidel QuickVue RSV - waived	10	9	1
Quidel QuickVue RSV 10 Test	1	1	-
Quidel Sofia / Sofia 2 - waived	15	13	2
Quidel Solana	1	1	-
Roche cobas Liat	1	1	-

Antigen(s) present: RSV

### Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	75	5	70
Abbott ID NOW	4	-	4
Alere Binax NOW - waived	22	1	21
BD Veritor - moderate	3	-	3
BD Veritor - waived	3	-	3
Cepheid GeneXpert - moderate	3	-	3
Cepheid GeneXpert - waived	11	1	10
Other Waived Method	1	-	1
Quidel QuickVue RSV - waived	10	-	10
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia / Sofia 2 - waived	15	3	12
Quidel Solana	1	-	1
Roche cobas Liat	1	-	1

Antigen(s) present: Influenza A

### Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	14	-
BD Veritor - moderate	3	3	-
BD Veritor - waived	1	1	-
Cepheid GeneXpert - moderate	2	2	-
Cepheid GeneXpert - 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	1	1	-

Antigen(s) present: RSV

## RSV ANTIGEN DETECTION

### Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	1	13
BD Veritor - moderate	3	-	3
BD Veritor - waived	1	-	1
Cepheid GeneXpert - moderate	2	-	2
Cepheid GeneXpert - waived	1	-	1
Quidel QuickVue RSV - waived	3	-	3
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia / Sofia 2 - waived	2	1	1
Quidel Solana	1	-	1

Antigen(s) present: Influenza B

### Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	-	14
BD Veritor - moderate	3	-	3
BD Veritor - waived	1	-	1
Cepheid GeneXpert - moderate	2	-	2
Cepheid GeneXpert - 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	1	-	1

Antigen(s) present: Influenza A

## INFLUENZA A ANTIGEN DETECTION

### Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	190	6	184
Abbott ID NOW	10	-	10
Alere Binax NOW - waived	2	-	2
Alere i Instrument - waived	2	-	2
Alere Influenza A&B	2	-	2
BD Veritor - moderate	4	-	4
BD Veritor - waived	40	4	36
BioSign Flu A+B	2	-	2
Cepheid GeneXpert - moderate	2	-	2
Cepheid GeneXpert - waived	11	1	10
Henry Schein OneStep+ Flu A&B	16	-	16
McKesson Consult Diag. Flu A & B	31	-	31
Meridian ImmunoCard STAT - waived	1	-	1
Quidel QuickVue Influenza A+B	17	-	17
Quidel Sofia / Sofia 2 - waived	39	1	38
Quidel Solana	2	-	2
Roche cobas Liat	2	-	2
Sekisui OSOM Influenza A&B	3	-	3
Sekisui OSOM Ultra -waived	4	-	4

Antigen(s) present: RSV

### Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	190	181	9
Abbott ID NOW	10	10	-
Alere Binax NOW - waived	2	2	-
Alere i Instrument - waived	2	2	-
Alere Influenza A&B	2	2	-
BD Veritor - moderate	4	4	-
BD Veritor - waived	40	38	2
BioSign Flu A+B	2	1	1
Cepheid GeneXpert - moderate	2	2	-
Cepheid GeneXpert - waived	11	10	1
Henry Schein OneStep+ Flu A&B	16	16	-
McKesson Consult Diag. Flu A & B	31	29	2
Meridian ImmunoCard STAT - waived	1	1	-
Quidel QuickVue Influenza A+B	17	16	1
Quidel Sofia / Sofia 2 - waived	39	38	1
Quidel Solana	2	2	-
Roche cobas Liat	2	2	-
Sekisui OSOM Influenza A&B	3	2	1
Sekisui OSOM Ultra -waived	4	4	-

Antigen(s) present: Influenza A

## INFLUENZA A ANTIGEN DETECTION

### Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	-	18
Abbott ID NOW	2	-	2
Alere Binax NOW - waived	1	-	1
BD Veritor - moderate	4	-	4
Cepheid GeneXpert - moderate	2	-	2
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	2	-	2
Quidel Solana	2	-	2

Antigen(s) present: RSV

### Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	-	18
Abbott ID NOW	2	-	2
Alere Binax NOW - waived	1	-	1
BD Veritor - moderate	4	-	4
Cepheid GeneXpert - moderate	2	-	2
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	2	-	2
Quidel Solana	2	-	2

Antigen(s) present: Influenza B

### Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	17	1
Abbott ID NOW	2	1	1
Alere Binax NOW - waived	1	1	-
BD Veritor - moderate	4	4	-
Cepheid GeneXpert - moderate	2	2	-
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	2	2	-
Quidel Solana	2	2	-

Antigen(s) present: Influenza A

## INFLUENZA B ANTIGEN DETECTION

### Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	189	6	183
Abbott ID NOW	9	-	9
Alere Binax NOW - waived	2	-	2
Alere i Instrument - waived	3	-	3
Alere Influenza A&B	2	-	2
BD Veritor - moderate	4	-	4
BD Veritor - waived	39	1	38
BioSign Flu A+B	2	1	1
Cepheid GeneXpert - moderate	2	-	2
Cepheid GeneXpert - waived	11	-	11
Henry Schein OneStep+ Flu A&B	16	-	16
McKesson Consult Diag. Flu A & B	31	1	30
Meridian ImmunoCard STAT - waived	1	-	1
Quidel QuickVue Influenza A+B	17	1	16
Quidel Sofia / Sofia 2 - waived	39	1	38
Quidel Solana	2	-	2
Roche cobas Liat	2	-	2
Sekisui OSOM Influenza A&B	4	1	3
Sekisui OSOM Ultra -waived	3	-	3

Antigen(s) present: RSV

### Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	189	6	183
Abbott ID NOW	9	-	9
Alere Binax NOW - waived	2	-	2
Alere i Instrument - waived	3	-	3
Alere Influenza A&B	2	-	2
BD Veritor - moderate	4	-	4
BD Veritor - waived	39	1	38
BioSign Flu A+B	2	-	2
Cepheid GeneXpert - moderate	2	-	2
Cepheid GeneXpert - waived	11	-	11
Henry Schein OneStep+ Flu A&B	16	-	16
McKesson Consult Diag. Flu A & B	31	2	29
Meridian ImmunoCard STAT - waived	1	-	1
Quidel QuickVue Influenza A+B	17	1	16
Quidel Sofia / Sofia 2 - waived	39	2	37
Quidel Solana	2	-	2
Roche cobas Liat	2	-	2
Sekisui OSOM Influenza A&B	4	-	4
Sekisui OSOM Ultra -waived	3	-	3

Antigen(s) present: Influenza A

## INFLUENZA B ANTIGEN DETECTION

### Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	-	18
Abbott ID NOW	2	-	2
Alere Binax NOW - waived	1	-	1
BD Veritor - moderate	4	-	4
Cepheid GeneXpert - moderate	2	-	2
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	2	-	2
Quidel Solana	2	-	2

Antigen(s) present: RSV

### Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	18	-
Abbott ID NOW	2	2	-
Alere Binax NOW - waived	1	1	-
BD Veritor - moderate	4	4	-
Cepheid GeneXpert - moderate	2	2	-
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	2	2	-
Quidel Solana	2	2	-

Antigen(s) present: Influenza B

### Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	1	17
Abbott ID NOW	2	1	1
Alere Binax NOW - waived	1	-	1
BD Veritor - moderate	4	-	4
Cepheid GeneXpert - moderate	2	-	2
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	2	-	2
Quidel Solana	2	-	2

Antigen(s) present: Influenza A

## CLOSTRIDIOIDES DIFFICILE ANTIGEN DETECTION

### Specimen AG-1

<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-2

<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-3

<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-4

<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-5

<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



## ROTAVIRUS ANTIGEN DETECTION

### Specimen AG-1

<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-2

<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-3

<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-4

<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-5

<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

## LEGIONELLA ANTIGEN DETECTION

### Specimen L-1

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

### Specimen L-2

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

### Specimen L-3

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

### Specimen L-4

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

### Specimen L-5

<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-1

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

### Specimen SP-2

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

### Specimen SP-3

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

### Specimen SP-4

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

### Specimen SP-5

<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-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	125	-	125
Abbott BinaxNOW - waived	15	-	15
Access Bio CareStart	22	-	22
BD Veritor - waived	16	-	16
Celltrion DiaTrust	9	-	9
GenBody	4	-	4
INDICAID by Phase Scientific	3	-	3
LumiraDx	1	-	1
Other EUA method	3	-	3
Quidel QuickVue - waived	6	-	6
Quidel Sofia / Sofia 2 - waived	36	-	36
Sienna-Clarity	10	-	10

### Specimen ACV-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	125	125	-
Abbott BinaxNOW - waived	15	15	-
Access Bio CareStart	22	22	-
BD Veritor - waived	16	16	-
Celltrion DiaTrust	9	9	-
GenBody	4	4	-
INDICAID by Phase Scientific	3	3	-
LumiraDx	1	1	-
Other EUA method	3	3	-
Quidel QuickVue - waived	6	6	-
Quidel Sofia / Sofia 2 - waived	36	36	-
Sienna-Clarity	10	10	-

## PARASITOLOGY

### Specimen FP-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Schistosoma mansoni eggs	1	100%	Acceptable

Parasite(s) present: *Schistosoma mansoni* eggs

### Specimen FP-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasites seen	1	100%	Acceptable

Parasite(s) present: Negative

### Specimen FP-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Hymenolepis nana eggs	1	50.00%	Acceptable
Trichuris trichiura eggs	1	50.00%	Acceptable

Parasite(s) present: *Hymenolepis nana* eggs and *Trichuris trichiura* eggs

### Specimen FP-4

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

Parasite(s) present: *Diphyllobothrium latum*

### Specimen FP-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasites seen	1	100%	Acceptable

Parasite(s) present: Negative (sterile)

**PVA SLIDES (Add-on)**

**Specimen PA-1**

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

**Specimen PA-2**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasites seen	1	100%	Acceptable
Parasite(s) present: Negative (sterile)			

## DERMATOPHYTE CULTURE

### Specimen DM-1

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

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

### Specimen DM-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative (Dermatophytes absent)	5	100%	Acceptable

Organism(s) present: Negative (sterile)

### Specimen DM-3

<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: *Achromobacter xylosoxidans* and *Lactobacillus* sp.

### Specimen DM-4

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

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

### Specimen DM-5

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

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

## BACTERIAL VAGINOSIS – OSOM - WAIVED

### Specimen BV-1

<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 BV-2

<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*

## TRICHOMONAS VAGINALIS – OSOM - WAIVED

### Specimen TR-1

<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-2

<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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