

# **MEDICAL LABORATORY EVALUATION**

**PARTICIPANT SUMMARY**

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Medical Laboratory  
Evaluation 

Microbiology  
2022 MLE-M2

# 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-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
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Negative	5	100%	Acceptable
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Organism(s) present: *Streptococcus pneumoniae* and *Staphylococcus pseudintermedius*

### Specimen MSA-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
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Positive	5	100%	Acceptable
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Organism(s) present: *Staphylococcus aureus* – Methicillin resistant and *Acinetobacter baumannii*

### Specimen MSA-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
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Positive	5	100%	Acceptable
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Organism(s) present: *Staphylococcus aureus* – Methicillin resistant and *Pediococcus acidilactici*

### Specimen MSA-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
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Positive	5	100%	Acceptable
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Organism(s) present: *Staphylococcus aureus* – Methicillin resistant and *Streptococcus dysgalactiae*

### Specimen MSA-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
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Negative	5	100%	Acceptable
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Organism(s) present: *Proteus mirabilis*

## STREP A ANTIGEN DETECTION

### Specimen RS-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	310	296	14
Abbott ID NOW	5	5	-
Alere Acceava Strep A Test	6	6	-
Alere i Instrument - waived	4	4	-
BD Chek Strep A	1	1	-
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	9	9	-
Consult Diagnostic Strep A - Moderate	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	49	48	1
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	51	47	4
Jant Pharmacal Accustrip	1	1	-
McKesson Strep A Cassette	2	2	-
McKesson Strep A Dipstick	16	15	1
McKesson Strep A Test - Twist	1	1	-
Medline Strep A Test Strip	4	3	1
Meridian (GenePOC) revogene	3	3	-
Meridian ImmunoCard STAT - waived	4	4	-
Other Waived Method	3	3	-
Quidel QuickVue Dipstick Strep	25	25	-
Quidel QuickVue In-Line	33	29	4
Quidel QuickVue+	1	1	-
Quidel Sofia / Sofia 2 - waived	6	6	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	18	18	-
Quidel Solana	3	3	-
Roche cobas Liat	4	4	-
Sekisui OSOM	11	11	-
Sekisui OSOM Ultra -waived	27	25	2

## STREP A ANTIGEN DETECTION

### Specimen RS-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	308	8	300
Abbott ID NOW	5	-	5
Alere Acceava Strep A Test	6	-	6
Alere i Instrument - waived	4	-	4
BD Chek Strep A	1	-	1
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	9	-	9
Consult Diagnostic Strep A - Moderate	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	48	-	48
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	51	2	49
Jant Pharmacal Accustrip	1	-	1
McKesson Strep A Cassette	2	-	2
McKesson Strep A Dipstick	16	-	16
McKesson Strep A Test - Twist	1	-	1
Medline Strep A Test Strip	4	-	4
Meridian (GenePOC) revogene	3	-	3
Meridian ImmunoCard STAT - waived	4	-	4
Other Waived Method	3	-	3
Quidel QuickVue Dipstick Strep	24	1	23
Quidel QuickVue In-Line	33	3	30
Quidel QuickVue+	1	-	1
Quidel Sofia / Sofia 2 - waived	6	-	6
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	18	-	18
Quidel Solana	3	-	3
Roche cobas Liat	4	-	4
Sekisui OSOM	11	-	11
Sekisui OSOM Ultra -waived	27	2	25

## STREP A ANTIGEN DETECTION

### Specimen RS-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	35	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 Cassette	1	1	-
McKesson Strep A Dipstick	2	2	-
Quidel QuickVue Dipstick Strep	4	4	-
Quidel QuickVue In-Line	8	8	-
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-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	35	-	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 Cassette	1	-	1
McKesson Strep A Dipstick	2	-	2
Quidel QuickVue Dipstick Strep	4	-	4
Quidel QuickVue In-Line	8	-	8
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-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	35	34	1
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 Cassette	1	1	-
McKesson Strep A Dipstick	2	2	-
Quidel QuickVue Dipstick Strep	4	4	-
Quidel QuickVue In-Line	8	7	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-4 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Klebsiella aerogenes	4	40.00%	Acceptable
Klebsiella sp.	1	10.00%	Acceptable
Cutibacterium acnes	4	40.00%	Acceptable
Cutibacterium sp.	1	10.00%	Acceptable

Organism(s) present: *Klebsiella aerogenes* and *Cutibacterium acnes*

### Specimen BA-5 – Sputum Culture

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

Organism(s) present: *Streptococcus pneumoniae*

### Specimen BA-6 – CSF Culture

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

Organism(s) present: *Pantoea agglomerans*

## THROAT CULTURE

### Specimen TC-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	54	77.14%	Acceptable
Pseudomonas aeruginosa	8	11.43%	Acceptable
Staphylococcus sp.	7	10.00%	Acceptable

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

### Specimen TC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	36	64.29%	Acceptable
Presumptive Positive for Group A Strep	19	33.93%	Acceptable
Streptococcus pyogenes	1	1.79%	Acceptable

Organism(s) present: *Streptococcus pyogenes*

### Specimen TC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	18	51.52%	Acceptable
Presumptive Positive for Group A Strep	17	48.57%	Acceptable

Organism(s) present: *Streptococcus pyogenes*

### Specimen TC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	17	51.52%	Acceptable
Presumptive Positive for Group A Strep	15	45.45%	Acceptable

Organism(s) present: *Streptococcus pyogenes*

### Specimen TC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	31	93.94%	Acceptable

Organism(s) present: *Haemophilus parainfluenzae* and *Staphylococcus epidermidis*



## URINE CULTURE

### Specimen UC-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus aureus	23	58.97%	Acceptable
Staphylococcus sp.	10	25.64%	Acceptable
Growth, referred for identification	5	12.82%	Acceptable
Gram positive cocci	1	2.56%	Acceptable

### Gram Stain

Gram positive	10	100%	Acceptable
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### Gram Stain Morphology

Cocci	10	100%	Acceptable
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Organism(s) present: *Staphylococcus aureus*

### Specimen UC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Escherichia coli	23	76.67%	Acceptable
Growth, referred for identification	4	13.33%	Acceptable
Presumptive Gram negative	1	3.33%	Acceptable
Gram negative bacilli	1	3.33%	Acceptable

Organism(s) present: *Escherichia coli* and *Corynebacterium xerosis*

## URINE CULTURE

### Specimen UC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Proteus mirabilis	8	47.06%	Acceptable
Proteus sp.	4	23.53%	Acceptable
Growth, referred for identification	3	17.65%	Acceptable
Presumptive Gram negative	1	5.88%	Acceptable

Organism(s) present: *Proteus mirabilis*

### Specimen UC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staph – coagulase negative	3	42.86%	Acceptable
Staphylococcus haemolyticus	2	28.57%	Acceptable
Growth, referred for identification	1	14.29%	Acceptable
Staphylococcus sp.	1	14.29%	Acceptable

Organism(s) present: *Staphylococcus haemolyticus*

### Specimen UC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Enterococcus sp.	4	40.00%	Acceptable
Growth, referred for identification	2	20.00%	Acceptable
Enterococcus faecium	2	20.00%	Acceptable

Organism(s) present: *Enterococcus faecium* and *Granulicatella adiacens*

**ANTIMICROBIAL SUSCEPTIBILITY TESTING**

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

<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>	
Ampicillin	1	-	-	1	-	-	-	-	Inappropriate drug <sup>1</sup>
Cefazolin	4	4	-	-	-	-	-	-	100.00%
Cefoxitin	9	9	-	-	-	-	-	-	100.00%
Ceftaroline	-	-	-	-	1	1	-	-	100.00%
Ceftriaxone	1	1	-	-	-	-	-	-	100.00%
Cefuroxime	1	1	-	-	-	-	-	-	100.00%
Ciprofloxacin	19	19	-	-	1	1	-	-	100.00%
Gentamicin	14	14	-	-	2	2	-	-	100.00%
Levofloxacin	2	2	-	-	2	2	-	-	100.00%
Linezolid	3	3	-	-	3	3	-	-	100.00%
Moxifloxacin	-	-	-	-	1	1	-	-	100.00%
Nitrofurantoin	15	15	-	-	3	3	-	-	100.00%
Oxacillin	10	10	-	-	3	3	-	-	100.00%
Penicillin	14	-	-	14	2	-	-	2	100.00%
Quinupristin/Dalfopristin	-	-	-	-	1	1	-	-	100.00%
Rifampin	1	1	-	-	3	3	-	-	100.00%
Tetracycline	7	7	-	-	3	3	-	-	100.00%
Trimethoprim/Sulfamethoxazole	20	20	-	-	3	3	-	-	100.00%
Vancomycin	-	-	-	-	3	3	-	-	100.00%

Organism(s) present: *Staphylococcus aureus*

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.

<sup>1</sup> This is an inappropriate drug for the organism and/or source

## GENITAL CULTURE

### Specimen GC-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	11	47.83%	Acceptable
Growth, referred for identification	1	4.33%	Acceptable
Acinetobacter baumannii	1	4.35%	Acceptable
Enterobacter sp.	8	34.78%	

### Gram Stain

Gram negative	4	80.00%	Acceptable
Gram positive	1	20.00%	

### Gram Stain Morphology

Rods/bacilli	1	20.00%	Ungraded
Cocci	2	40.00%	
Diplococci	2	40.00%	

Organism(s) present: *Acinetobacter baumannii*. The bacterial identification was graded by referee consensus. The gram stain morphology is not graded due to lack of participant consensus.

### Specimen GC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	4	50.00%	Acceptable
Enterococcus sp.	2	33.33%	Acceptable

Organism(s) present: *Enterococcus faecalis* and *Micrococcus luteus*

### Specimen GC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive for N. gonorrhoeae	5	80.00%	Acceptable

Organism(s) present: *Neisseria gonorrhoeae*

### Specimen GC-9

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

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

### Specimen GC-10

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

Organism(s) present: *Streptococcus agalactiae*

**COLONY COUNT/PRESUMPTIVE IDENTIFICATION**

**Specimen CC-6**

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

**Identification–Specimen CC-6**

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

**Gram Stain**

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

**Gram Stain Morphology**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Cocci	5	80.00%	Acceptable

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

**Specimen CC-7**

<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	28	-	1	13	14
Calibrated Loop	15	-	-	11	4
Uri-Check	2	-	-	1	1
Uricult	11	-	1	1	9

**Identification–Specimen CC-7**

<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 *Escherichia coli* and <10,000 CFU/mL of *Corynebacterium xerosis*

## COLONY COUNT/PRESUMPTIVE IDENTIFICATION

### Identification—Specimen CC-8

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

Organism(s) present: 74,000 CFU/mL of *Proteus mirabilis*

### Identification—Specimen CC-9

<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 *Staphylococcus haemolyticus*

### Identification—Specimen CC-10

<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 faecium* and <10,000 CFU/mL of *Granulicatella adiacens*

## GRAM STAIN

### Specimen GS-6

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	10	100%	Acceptable

#### Gram Stain Morphology

Cocci	4	80.00%	Acceptable
Coccobacilli	1	20.00%	

Organism(s) present: *Streptococcus pneumoniae*

### Specimen GS-7

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	9	90.00%	Acceptable
Gram negative	1	10.00%	

#### Gram Stain Morphology

Cocci	4	80.00%	Acceptable
Diplococci	1	20.00%	

Organism(s) present: *Streptococcus anginosus*

## GRAM STAIN

### Specimen GS-8

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	8	80.00%	Acceptable
Gram positive	2	20.00%	

#### Gram Stain Morphology

Diplococci	4	80.00%	Acceptable
Cocci	1	20.00%	

Organism(s) present: *Neisseria mucosa*

### Specimen GS-9

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	10	100%	Acceptable

#### Gram Stain Morphology

Rods/bacilli	5	100%	Acceptable
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Organism(s) present: *Campylobacter jejuni*

### Specimen GS-10

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	9	90.00%	Acceptable
Gram positive	1	10.00%	

#### Gram Stain Morphology

Rods/bacilli	4	80.00%	Acceptable
Coccobacilli	1	20.00%	

Organism(s) present: *Bacteroides fragilis*



### AFFIRM VP III–Trichomonas vaginalis

#### Specimen VP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
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Negative	25	100%	Acceptable
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Organism(s) present: *Gardnerella vaginalis*

#### Specimen VP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
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Positive	25	100%	Acceptable
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Organism(s) present: *Trichomonas vaginalis* and *Candida sp.*

#### Specimen VP-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
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Negative	25	100%	Acceptable
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Organism(s) present: *Escherichia coli*

#### Specimen VP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
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Negative	24	96.00%	Acceptable
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Positive	1	4.00%	
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Organism(s) present: *Candida sp.*

#### Specimen VP-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
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Positive	24	100%	Acceptable
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Organism(s) present: *Trichomonas vaginalis*

## AFFIRM VP III – Gardnerella vaginalis

### Specimen VP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	24	96.00%	Acceptable
Negative	24	4.00%	

Organism(s) present: *Gardnerella vaginalis*

### Specimen VP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	25	100%	Acceptable

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

### Specimen VP-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	25	100%	Acceptable

Organism(s) present: *Escherichia coli*

### Specimen VP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	25	100%	Acceptable

Organism(s) present: *Candida sp.*

### Specimen VP-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	25	100%	Acceptable

Organism(s) present: *Trichomonas vaginalis*

**AFFIRM VP III – Candida sp.**

**Specimen VP-6**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	25	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*

**Specimen VP-7**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	25	100%	Acceptable

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

**Specimen VP-8**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	25	100%	Acceptable

Organism(s) present: *Escherichia coli*

**Specimen VP-9**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	24	96.00%	Acceptable
Negative	1	4.00%	

Organism(s) present: *Candida sp.*

**Specimen VP-10**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	25	100%	Acceptable

Organism(s) present: *Trichomonas vaginalis*

## SARS-CoV-2 (MOLECULAR DETECTION)

### Specimen MCV-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	66	1	65
Abbott ID NOW	26	-	26
Applied Biosystems 7500 Fast	4	-	4
Atila BioSystems	1	-	1
Cepheid GeneXpert - moderate	3	-	3
Cepheid GeneXpert - waived	21	-	21
Hologic Panther Fusion - waived	1	-	1
LumiraDx	1	-	1
Mesa Biotech Accula	2	-	2
Other EUA method	1	-	1
Quidel Solana - waived	1	-	1
Roche Cobas Molecular - waived	4	1	3
Sansure Biotech	1	-	1

### Specimen MCV-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	66	64	2
Abbott ID NOW	26	26	-
Applied Biosystems 7500 Fast	4	4	-
Atila BioSystems	1	1	-
Cepheid GeneXpert - moderate	3	3	-
Cepheid GeneXpert - waived	21	21	-
Hologic Panther Fusion - waived	1	1	-
LumiraDx	1	-	1
Mesa Biotech Accula	2	2	-
Other EUA method	1	1	-
Quidel Solana - waived	1	1	-
Roche Cobas Molecular - waived	4	3	1
Sansure Biotech	1	1	-

## CHLAMYDIA (ANTIGEN DETECTION)

### Specimen CY-6

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

Antigen(s) present: *Chlamydia trachomatis*

### Specimen CY-7

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

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

### Specimen CY-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	2	11
BD Max	2	1	1
BD Viper	1	-	1
Binx Health IO Instrument	1	-	1
Cepheid GeneXpert - moderate	8	1	7
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Neisseria gonorrhoeae*

### Specimen CY-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	-	13
BD Max	2	-	2
BD Viper	1	-	1
Binx Health IO Instrument	1	-	1
Cepheid GeneXpert - moderate	8	-	8
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Neisseria gonorrhoeae*

## CHLAMYDIA (ANTIGEN DETECTION)

### Specimen CY-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	-	13
BD Max	2	-	2
BD Viper	1	-	1
Binx Health IO Instrument	1	-	1
Cepheid GeneXpert - moderate	8	-	8
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Neisseria gonorrhoeae*

## GC (ANTIGEN DETECTION)

### Specimen CY-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	-	14
BD Max	2	-	2
BD Viper	1	-	1
Binx Health IO Instrument	1	-	1
Cepheid GeneXpert - moderate	8	-	8
Hologic Panther Fusion	1	-	1
Roche COBAS Amplicor	1	-	1

Antigen(s) present: *Chlamydia trachomatis*

### Specimen CY-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	14	-
BD Max	2	2	-
BD Viper	1	1	-
Binx Health IO Instrument	1	1	-
Cepheid GeneXpert - moderate	8	8	-
Hologic Panther Fusion	1	1	-
Roche COBAS Amplicor	1	1	-

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

### Specimen CY-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	13	-
BD Max	2	2	-
BD Viper	1	1	-
Binx Health IO Instrument	1	1	-
Cepheid GeneXpert - moderate	8	8	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Neisseria gonorrhoeae*

## GC (ANTIGEN DETECTION)

### Specimen CY-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	13	-
BD Max	2	2	-
BD Viper	1	1	-
Binx Health IO Instrument	1	1	-
Cepheid GeneXpert - moderate	8	8	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Neisseria gonorrhoeae*

### Specimen CY-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	13	13	-
BD Max	2	2	-
BD Viper	1	1	-
Binx Health IO Instrument	1	1	-
Cepheid GeneXpert - moderate	8	8	-
Roche COBAS Amplicor	1	1	-

Antigen(s) present: *Neisseria gonorrhoeae*

## CRYPTOSPORIDIUM ANTIGEN DETECTION

### Specimen LC-6

<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-7

<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-8

<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-9

<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-10

<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-6

<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-7

<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-8

<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-9

<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-10

<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-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	74	5	69
Abbott ID NOW	4	-	4
Alere Binax NOW - waived	20	1	19
BD Veritor - moderate	3	-	3
BD Veritor - waived	6	-	6
Cepheid GeneXpert - moderate	2	-	2
Cepheid GeneXpert - waived	11	-	11
Other Waived Method	1	-	1
Quidel QuickVue RSV - waived	10	-	10
Quidel QuickVue RSV 10 Test	1	-	1
Quidel Sofia / Sofia 2 - waived	14	4	10
Quidel Solana	1	-	1
Roche cobas Liat	1	-	1

Antigen(s) present: Influenza A

### Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	75	70	5
Abbott ID NOW	4	4	-
Alere Binax NOW - waived	21	20	1
BD Veritor - moderate	3	3	-
BD Veritor - waived	6	6	-
Cepheid GeneXpert - moderate	2	1	1
Cepheid GeneXpert - waived	11	11	-
Other Waived Method	1	1	-
Quidel QuickVue RSV - waived	10	10	-
Quidel QuickVue RSV 10 Test	1	1	-
Quidel Sofia / Sofia 2 - waived	14	11	3
Quidel Solana	1	1	-
Roche cobas Liat	1	1	-

Antigen(s) present: RSV

### Specimen V-8

<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	1	1
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 B

## RSV ANTIGEN DETECTION

### Specimen V-9

<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: Negative (sterile)

### Specimen V-10

<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

## INFLUENZA A ANTIGEN DETECTION

### Specimen V-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	187	183	4
Abbott ID NOW	10	10	-
Alere Binax NOW - waived	2	2	-
Alere i Instrument - waived	1	-	1
Alere Influenza A&B	2	2	-
BD Veritor - moderate	4	4	-
BD Veritor - waived	39	39	-
BioSign Flu A+B	2	2	-
Cepheid GeneXpert - moderate	2	1	1
Cepheid GeneXpert - waived	11	11	-
Henry Schein OneStep+ Flu A&B	16	16	-
McKesson Consult Diag. Flu A & B	27	27	-
Meridian ImmunoCard STAT - waived	1	1	-
Quidel QuickVue Influenza A+B	17	17	-
Quidel Sofia / Sofia 2 - waived	44	42	2
Quidel Solana	2	2	-
Roche cobas Liat	2	2	-
Sekisui OSOM Influenza A&B	3	3	-
Sekisui OSOM Ultra -waived	2	2	-

Antigen(s) present: Influenza A

### Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	187	11	176
Abbott ID NOW	10	-	10
Alere Binax NOW - waived	2	-	2
Alere i Instrument - waived	1	1	-
Alere Influenza A&B	2	-	2
BD Veritor - moderate	4	-	4
BD Veritor - waived	39	5	34
BioSign Flu A+B	2	-	2
Cepheid GeneXpert - moderate	2	1	1
Cepheid GeneXpert - waived	11	-	11
Henry Schein OneStep+ Flu A&B	16	-	16
McKesson Consult Diag. Flu A & B	28	1	27
Meridian ImmunoCard STAT - waived	1	-	1
Quidel QuickVue Influenza A+B	17	-	17
Quidel Sofia / Sofia 2 - waived	43	3	40
Quidel Solana	2	-	2
Roche cobas Liat	2	-	2
Sekisui OSOM Influenza A&B	3	-	3
Sekisui OSOM Ultra -waived	2	-	2

Antigen(s) present: RSV

## INFLUENZA A ANTIGEN DETECTION

### Specimen V-8

<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-9

<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: Negative (sterile)

### Specimen V-10

<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

## INFLUENZA B ANTIGEN DETECTION

### Specimen V-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	186	6	180
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	4	-	4
BD Veritor - waived	39	2	37
BioSign Flu A+B	2	-	2
Cepheid GeneXpert - moderate	2	1	1
Cepheid GeneXpert - waived	11	-	11
Henry Schein OneStep+ Flu A&B	16	-	16
McKesson Consult Diag. Flu A & B	27	1	26
Meridian ImmunoCard STAT - waived	1	-	1
Quidel QuickVue Influenza A+B	18	-	18
Quidel Sofia / Sofia 2 - waived	42	2	40
Quidel Solana	2	-	2
Roche cobas Liat	2	-	2
Sekisui OSOM Influenza A&B	4	-	4
Sekisui OSOM Ultra -waived	1	-	1

Antigen(s) present: Influenza A

### Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	186	3	183
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	4	-	4
BD Veritor - waived	39	2	37
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	27	-	27
Meridian ImmunoCard STAT - waived	1	-	1
Quidel QuickVue Influenza A+B	18	1	17
Quidel Sofia / Sofia 2 - waived	42	-	42
Quidel Solana	2	-	2
Roche cobas Liat	2	-	2
Sekisui OSOM Influenza A&B	4	-	4
Sekisui OSOM Ultra -waived	1	-	1

Antigen(s) present: RSV

## INFLUENZA B ANTIGEN DETECTION

### Specimen V-8

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

Antigen(s) present: Influenza B

### Specimen V-9

<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: Negative (sterile)

### Specimen V-10

<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

## CLOSTRIDIoidES DIFFICILE ANTIGEN DETECTION

### Specimen AG-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	5	-

Antigen(s) present: *Clostridioides difficile*

### Specimen AG-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	5	-

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

### Specimen AG-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	-	5

Antigen(s) present: Negative (sterile)

### Specimen AG-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	-	5

Antigen(s) present: Rotavirus

### Specimen AG-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	5	-

Antigen(s) present: *Clostridioides difficile*



**ROTAVIRUS ANTIGEN DETECTION**

**Specimen AG-6**

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	-	5

Antigen(s) present: *Clostridioides difficile*

**Specimen AG-7**

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	5	-

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

**Specimen AG-8**

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	-	5

Antigen(s) present: Negative (sterile)

**Specimen AG-9**

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	5	-

Antigen(s) present: Rotavirus

**Specimen AG-10**

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	5	-	5

Antigen(s) present: *Clostridioides difficile*

## LEGIONELLA ANTIGEN DETECTION

### Specimen L-6

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

### Specimen L-7

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

### Specimen L-8

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

### Specimen L-9

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

### Specimen L-10

<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-6

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

### Specimen SP-7

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

### Specimen SP-8

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

### Specimen SP-9

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

### Specimen SP-10

<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-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	133	1	132
Abbott BinaxNOW - waived	22	-	22
Access Bio CareStart	22	-	22
BD Veritor - waived	15	-	15
Celltrion DiaTrust	10	-	10
GenBody	6	-	6
INDICAID by Phase Scientific	3	-	3
LumiraDx	2	-	2
Other EUA method	1	-	1
Quidel QuickVue - waived	7	-	7
Quidel Sofia / Sofia 2 - waived	35	1	34
Sienna-Clarity	10	-	10

### Specimen ACV-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	134	132	2
Abbott BinaxNOW - waived	22	22	-
Access Bio CareStart	22	22	-
BD Veritor - waived	15	15	-
Celltrion DiaTrust	10	10	-
GenBody	6	6	-
INDICAID by Phase Scientific	3	3	-
LumiraDx	2	2	-
Other EUA method	1	1	-
Quidel QuickVue - waived	7	7	-
Quidel Sofia / Sofia 2 - waived	36	34	2
Sienna-Clarity	10	10	-

## PARASITOLOGY

### Specimen FP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	1	50.00%	Acceptable
Trichuris trichiura eggs	1	50.00%	Acceptable

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

### Specimen FP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Giardia lamblia	1	50.00%	Acceptable
Blastocystis hominis	1	50.00%	Acceptable

Parasite(s) present: *Giardia lamblia* and *Blastocystis hominis*

### Specimen FP-8

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

Parasite(s) present: Negative (sterile)

### Specimen FP-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba coli	1	50.00%	Acceptable
Schistosoma sp.	1	50.00%	Acceptable

Parasite(s) present: *Entamoeba coli* and *Schistosoma mansoni* eggs

### Specimen FP-10

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

Parasite(s) present: *Trypanosoma brucei gambiense*

## PVA SLIDES (Add-on)

### Specimen PA-3

<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-4

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

## DERMATOPHYTE CULTURE

### Specimen DM-6

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

Organism(s) present: *Cryptococcus neoformans* and *Micrococcus luteus*

### Specimen DM-7

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

Organism(s) present: *Epidermophyton floccosum*

### Specimen DM-8

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

Organism(s) present: *Trichophyton violaceum* and *Actinomyces meyeri*

### Specimen DM-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive (Dermatophytes present)	4	100%	Acceptable

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

### Specimen DM-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative (Dermatophytes present)	1	20.00%	Ungraded
Positive (Dermatophytes present)	5	80.00%	

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

## BACTERIAL VAGINOSIS – OSOM - WAIVED

### Specimen BV-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	-	2
Sekisui OSOM	2	-	2

Antigen(s) present: Negative (sterile)

### Specimen BV-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	2	-
Sekisui OSOM	2	2	-

Antigen(s) present: *Gardnerella vaginalis*

## TRICHOMONAS VAGINALIS – OSOM - WAIVED

### Specimen TR-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	-	3
Sekisui OSOM	3	-	3

Antigen(s) present: Negative (sterile)

### Specimen TR-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	3	-
Sekisui OSOM	3	3	-

Antigen(s) present: *Trichomonas vaginalis*

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