

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 1 • 8

Microbiology
2018 MLE-M1



Total Commitment to Education and Service
Provided by ACP, Inc.

Table of Contents

Evaluation Criteria..... 2

Microbiology

MRSA Screening	3	GC (Antigen Detection)	23
Strep A Antigen Detection.....	4	Cryptosporidium Antigen Detection	25
Miscellaneous Cultures	8	Giardia lamblia Antigen Detection.....	26
Throat Culture	9	RSV Antigen Detection.....	27
Urine Culture	10	Influenza A/B Antigen Detection.....	28
Gram Stain & Morphology.....	10	Influenza A Antigen Detection	29
Antimicrobial Susceptibility Testing	12	Influenza B Antigen Detection	32
Genital Culture	13	Clostridium difficile Antigen Detection.....	34
Gram Stain & Morphology.....	13	Rotavirus Antigen Detection.....	35
Colony Count/Urine Presumptive ID	15	Legionella Antigen Detection.....	36
Gram Stain & Morphology.....	15	Streptococcus pneumoniae Antigen Detection	37
Gram Stain.....	17	Parasitology	38
Affirm VP III		Dermatophyte Culture	39
Trichomonas vaginalis.....	19	Bacterial Vaginosis Screen (OSOM).....	40
Gardnerella vaginalis	20	Trichomonas vaginalis Screen (OSOM)	40
Candida sp.	21		
Chlamydia (Antigen Detection).....	22		

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 A/B Antigen Detection	80% Consensus
Antimicrobial Susceptibility Testing	80% Consensus	Influenza B Antigen Detection	80% Consensus
Bacterial Identification (Cultures)	80% Consensus	Legionella Antigen Detection	80% Consensus
Bacterial Vaginosis (OSOM)	80% Consensus	MRSA Screening	80% Consensus
Chlamydia (EIA, DNA)	80% Consensus	Parasite Identification	80% Consensus
Clostridium difficile Antigen Detection	80% Consensus	Rotavirus Antigen Detection	80% Consensus
Colony Count	80% Consensus	RSV Antigen Detection	80% Consensus
Cryptosporidium Antigen Detection	80% Consensus	Strep A Antigen Detection	80% Consensus
Dermatophyte Culture	80% Consensus	Streptococcus pneumoniae Antigen Detection	80% Consensus
GC (EIA, DNA)	80% Consensus	Trichomonas vaginalis (OSOM)	80% Consensus
Giardia lamblia Antigen Detection	80% Consensus	Urine Presumptive Identification	80% Consensus
Gram Stain	80% Consensus		

METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS SCREENING

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 epidermidis*.

Specimen MSA-2

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

Organism(s) present: *Streptococcus anginosus*.

Specimen MSA-3

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

Organism(s) present: *Serratia marcescens* and *Moraxella catarrhalis*.

Specimen MSA-4

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

Organism(s) present: *Staphylococcus aureus* – Methicillin resistant and *Neisseria sicca*.

Specimen MSA-5

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

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

STREP A ANTIGEN DETECTION

Specimen RS-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	516	503	13
Abbott Signify Strep A-waived	1	1	-
Alere Acceava Strep A Test	12	12	-
Alere i Instrument - waived	14	14	-
Alere Signify Strep A Dipstick	1	1	-
BD Chek Strep A	3	3	-
BD Veritor - waived	11	11	-
Beckman Coulter ICON DS	7	7	-
Beckman Coulter ICON SC	1	1	-
Binax NOW Strep A	1	1	-
Cardinal Health Strep A - waived	7	7	-
Clarity Diagnostics	2	2	-
Consult Diagnostic Strep A Dipstick - Waived	78	74	4
Fisher HealthCare Sure-Vue - waived	1	1	-
Germaine Laboratories StrepAim	1	1	-
Henry Schein One Step	2	2	-
Henry Schein One Step+ - waived	50	49	1
Immunostics Detector Strep A Direct	1	1	-
McKesson Strep A Dipstick	21	19	2
Medline Strep A Test Strip	4	4	-
Meridian Illumigene	1	1	-
Moore Medical Strep A Rapid Test	1	1	-
NDC Pro Advantage	3	3	-
Other Waived Method	12	12	-
Quidel QuickVue Dipstick Strep	60	59	1
Quidel QuickVue In-Line	47	45	2
Quidel QuickVue+	10	10	-
Quidel Sofia - waived	2	2	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	11	11	-
Quidel Solana	2	2	-
Roche cobas Liat	1	1	-
Sekisui OSOM	97	96	1
Sekisui OSOM Ultra -waived	47	45	2

STREP A ANTIGEN DETECTION

Specimen RS-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	510	6	504
Abbott Signify Strep A-waived	1	-	1
Alere Acceava Strep A Test	11	-	11
Alere i Instrument - waived	14	-	14
Alere Signify Strep A Dipstick	1	-	1
BD Chek Strep A	3	-	3
BD Veritor - waived	10	-	10
Beckman Coulter ICON DS	7	-	7
Beckman Coulter ICON SC	1	-	1
Binax NOW Strep A	1	-	1
Cardinal Health Strep A - waived	7	-	7
Clarity Diagnostics	2	-	2
Consult Diagnostic Strep A Dipstick - Waived	78	2	76
Fisher HealthCare Sure-Vue - waived	1	-	1
Germaine Laboratories StrepAim	1	-	1
Henry Schein One Step	2	-	2
Henry Schein One Step+ - waived	50	-	50
Immunostics Detector Strep A Direct	1	-	1
McKesson Strep A Dipstick	20	1	19
Medline Strep A Test Strip	4	-	4
Meridian Illumigene	1	-	1
Moore Medical Strep A Rapid Test	1	-	1
NDC Pro Advantage	3	-	3
Other Waived Method	12	-	12
Quidel QuickVue Dipstick Strep	58	1	57
Quidel QuickVue In-Line	47	-	47
Quidel QuickVue+	9	-	9
Quidel Sofia - waived	2	-	2
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	11	-	11
Quidel Solana	2	-	2
Roche cobas Liat	1	-	1
Sekisui OSOM	97	1	96
Sekisui OSOM Ultra -waived	47	1	46

STREP A ANTIGEN DETECTION

Specimen RS-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	74	1	73
Alere Aceava Strep A Test	3	-	3
Alere Signify Strep A Dipstick	1	-	1
BD Chek Strep A	1	-	1
Beckman Coulter ICON DS	2	-	2
Binax NOW Strep A	1	-	1
Clarity Diagnostics	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	12	-	12
Henry Schein One Step+ - waived	4	-	4
McKesson Strep A Dipstick	4	-	4
Meridian Illumigene	1	-	1
Quidel QuickVue Dipstick Strep	7	-	7
Quidel QuickVue In-Line	17	1	16
Quidel QuickVue+	5	-	5
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	3	-	3
Quidel Solana	2	-	2
Sekisui OSOM	1	-	1
Sekisui OSOM Ultra -waived	7	-	7

STREP A ANTIGEN DETECTION

Specimen RS-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	72	1	71
Alere Acceava Strep A Test	3	-	3
Alere Signify Strep A Dipstick	1	-	1
BD Chek Strep A	1	-	1
Beckman Coulter ICON DS	2	-	2
Binax NOW Strep A	1	-	1
Clarity Diagnostics	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	12	-	12
Henry Schein One Step+ - waived	3	-	3
McKesson Strep A Dipstick	4	-	4
Meridian Illumigene	1	-	1
Quidel QuickVue Dipstick Strep	7	-	7
Quidel QuickVue In-Line	17	-	17
Quidel QuickVue+	5	-	5
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	3	-	3
Quidel Solana	2	-	2
Sekisui OSOM	1	-	1
Sekisui OSOM Ultra -waived	6	1	5

Specimen RS-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	72	72	-
Alere Acceava Strep A Test	3	3	-
Alere Signify Strep A Dipstick	1	1	-
BD Chek Strep A	1	1	-
Beckman Coulter ICON DS	2	2	-
Binax NOW Strep A	1	1	-
Clarity Diagnostics	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	12	12	-
Henry Schein One Step+ - waived	3	3	-
McKesson Strep A Dipstick	4	4	-
Meridian Illumigene	1	1	-
Quidel QuickVue Dipstick Strep	7	7	-
Quidel QuickVue In-Line	17	17	-
Quidel QuickVue+	5	5	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	3	3	-
Quidel Solana	2	2	-
Sekisui OSOM	1	1	-
Sekisui OSOM Ultra -waived	6	6	-

MISCELLANEOUS CULTURES

Specimen BA-1 – CSF Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Cronobacter sakazakii	3	60.00%	Acceptable
Growth, referred for identification	1	20.00%	Acceptable
Enterobacter cloacae	1	20.00%	

Organism(s) present: *Cronobacter sakazakii*.

Specimen BA-2 – Sputum Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Enterococcus faecalis	2	40.00%	Acceptable
Enterococcus sp.	1	20.00%	Acceptable
Growth, referred for identification	1	20.00%	Acceptable
Pasteurella sp.	1	20.00%	

Organism(s) present: *Haemophilus parahaemolyticus* and *Enterococcus faecalis*.

Specimen BA-3 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Acinetobacter sp.	2	40.00%	Acceptable
Anaerobic culture not performed	2	40.00%	Acceptable
Growth, referred for identification	1	20.00%	Acceptable

Organism(s) present: *Acinetobacter baumannii* and *Finnegoldia magna*.

THROAT CULTURE

Specimen TC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	64	63.37%	Acceptable
Presump. Pos. Group A Strep	31	30.69%	Acceptable
Streptococcus pyogenes	2	1.98%	Acceptable

Organism(s) present: *Streptococcus pyogenes* and *Streptococcus salivarius*.

Specimen TC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	94	88.68%	Acceptable
Serratia sp.	8	7.55%	Acceptable
Serratia marcescens	1	0.94%	Acceptable

Organism(s) present: *Serratia marcescens*.

Specimen TC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	35	56.45%	Acceptable
Presump. Positive Group A Strep	27	43.55%	Acceptable

Organism(s) present: *Streptococcus pyogenes*.

Specimen TC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	53	91.38%	Acceptable

Organism(s) present: *Moraxella catarrhalis* and *Streptococcus anginosus*.

Specimen TC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	55	94.83%	Acceptable
No growth (sterile)	1	1.72%	Acceptable

Organism(s) present: No organism present.

URINE CULTURE

Specimen UC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pseudomonas aeruginosa	39	69.64%	Acceptable
Growth, referred for identification	7	12.50%	Acceptable
Presump. Gram negative	3	5.36%	Acceptable
Presump. Pseudomonas sp.	3	5.36%	Acceptable
Gram negative bacilli	3	5.36%	Acceptable
Pseudomonas sp.	1	1.79%	Acceptable

Gram Stain

Gram negative	31	100%	Acceptable
---------------	----	------	------------

Gram Stain Morphology

Rods/bacilli	31	100%	Acceptable
--------------	----	------	------------

Organism(s) present: *Pseudomonas aeruginosa*.

Specimen UC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Enterococcus sp.	30	34.48%	Acceptable
Staph – coagulase negative	18	20.69%	Acceptable
Staphylococcus sp.	13	14.94%	Acceptable
Growth, referred for identification	10	11.49%	Acceptable
Presump. Gram positive	5	5.75%	Acceptable
Enterococcus faecium	4	4.60%	Acceptable
Gram positive cocci	3	3.45%	Acceptable
Presump. Enterococcus sp.	2	2.30%	Acceptable
Presump. Staphylococcus sp.	1	1.15%	Acceptable
Staphylococcus epidermidis	1	1.15%	Acceptable

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

Specimen UC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Citrobacter freundii	20	50.00%	Acceptable
Growth, referred for identification	6	15.00%	Acceptable
Presump. Gram negative	5	12.50%	Acceptable
Citrobacter sp.	3	7.50%	Acceptable
Staph – coagulase negative	2	5.00%	Acceptable
Staphylococcus epidermidis	2	5.00%	Acceptable
Gram negative bacilli	2	5.00%	Acceptable

Organism(s) present: *Citrobacter freundii* and *Staphylococcus epidermidis*.

URINE CULTURE

Specimen UC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus aureus	10	45.45%	Acceptable
Presump. Gram positive	4	18.18%	Acceptable
Corynebacterium sp.	3	13.64%	Acceptable
Growth, referred for identification	3	13.64%	Acceptable
Gram positive cocci	1	4.55%	Acceptable
Presump. Corynebacterium sp.	1	4.55%	Acceptable

Organism(s) present: *Staphylococcus aureus* and Presump. *Corynebacterium sp.*

Specimen UC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus saprophyticus	8	50.00%	Acceptable
Staph – coagulase negative	2	12.50%	Acceptable
Growth, referred for identification	2	12.50%	Acceptable
Presump. Staphylococcus sp.	2	12.50%	Acceptable
Presump. Gram positive	1	6.25%	Acceptable
Gram positive cocci	1	6.25%	Acceptable

Organism(s) present: *Staphylococcus saprophyticus*.

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Specimen UC-1, CC-1 (SUS-1) Organism(s) present: *Pseudomonas aeruginosa*.

<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	3	3	-	-	2	-	2	-	100.00%
Amoxicillin/Clavulanate	-	-	-	-	1	-	-	1	Inappropriate drug ¹
Ampicillin	2	-	-	2	-	-	-	-	Inappropriate drug ¹
Aztreonam	3	3	-	-	2	1	-	1	80.00%
Cefazolin	1	-	-	1	2	-	-	2	Inappropriate drug ¹
Cefepime	1	1	-	-	6	5	-	1	85.71%
Cefoxitin	-	-	-	-	1	-	-	1	Inappropriate drug ¹
Ceftazidime	9	9	-	-	6	5	-	1	93.75%
Ceftriaxone	2	2	-	-	2	-	-	2	Inappropriate drug ¹
Ciprofloxacin	40	18	21	1	5	2	3	-	97.87%
Gentamicin	32	2	2	28	7	-	4	3	95.12%
Imipenem	4	4	-	-	5	5	-	-	100.00%
Levofloxacin	26	-	-	26	5	-	5	-	100.00%
Meropenem	-	-	-	-	1	1	-	-	Ungraded ²
Nitrofurantoin	4	-	-	4	-	-	-	-	Inappropriate drug ¹
Piperacillin	5	5	-	-	1	1	-	-	100.00%
Piperacillin/Tazobactam	5	5	-	-	5	3	-	2	81.82%
Tetracycline	2	-	-	2	-	-	-	-	Inappropriate drug ¹
Tobramycin	5	5	-	-	7	6	1	-	93.33%
Trimethoprim	1	-	-	1	-	-	-	-	Inappropriate drug ¹
Trimethoprim/Sulfamethoxazole	4	-	-	4	1	-	-	1	Inappropriate drug ¹

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 inappropriate drug due to discontinued marketing status.

² This is an ungraded challenge due to lack of comparison group.

GENITAL CULTURE

Specimen GC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive for <i>N. gonorrhoeae</i>	22	66.67%	Acceptable
<i>Neisseria gonorrhoeae</i>	7	21.21%	Acceptable
Gram negative diplococci	2	6.06%	Acceptable
Growth, referred for identification	2	6.06%	Acceptable

Gram Stain

Gram negative	22	100%	Acceptable
---------------	----	------	------------

Gram Stain Morphology

Diplococci	22	100%	Acceptable
------------	----	------	------------

Organism(s) present: *Neisseria gonorrhoeae*.

Specimen GC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for <i>N. gonorrhoeae</i>	11	78.57%	Acceptable
No growth (sterile)	3	21.43%	Acceptable

Organism(s) present: No organism present.

Specimen GC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for <i>N. gonorrhoeae</i>	11	68.75%	Acceptable
<i>Corynebacterium</i> sp.	2	12.50%	Acceptable
Staph – coagulase negative	2	12.50%	Acceptable
No growth (sterile)	1	6.25%	

Organism(s) present: *Staphylococcus haemolyticus* and *Corynebacterium* sp.

GENITAL CULTURE

Specimen GC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	11	91.67%	Acceptable
No growth (sterile)	1	8.33%	

Organism(s) present: *Streptococcus agalactiae*.

Specimen GC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presumptive for N. gonorrhoeae	10	83.33%	Acceptable
Growth, referred for identification	1	8.33%	Acceptable
Neisseria gonorrhoeae	1	8.33%	Acceptable

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

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-1

<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	55	-	2	13	40
Bacturcult	1	-	-	-	1
Calibrated Loop	23	-	-	6	17
HealthLink	1	-	-	-	1
Uri-Check	6	-	-	-	6
Uricult	22	-	1	7	14

Identification–Specimen CC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	6	46.15%	Acceptable
Presump. Gram negative	4	30.77%	Acceptable
Presump. Pseudomonas sp.	2	15.38%	Acceptable
Pseudomonas aeruginosa	1	7.69%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Pseudomonas aeruginosa*.

Specimen CC-2

<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	55	2	1	9	43
Bacturcult	1	-	-	1	-
Calibrated Loop	23	-	-	1	22
HealthLink	1	-	-	-	1
Uri-Check	6	-	-	1	5
Uricult	22	2	1	5	14

Identification–Specimen CC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	7	50.00%	Acceptable
Presump. Gram positive	4	28.57%	Acceptable
Presump. Enterococcus sp.	2	14.29%	Acceptable
Enterococcus faecium	1	7.14%	Acceptable

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

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	2	18.18%	Acceptable
Presump. Gram negative	1	9.09%	Acceptable
Presump. Gram positive	1	9.09%	Acceptable
Staphylococcus sp.	1	9.09%	Acceptable
Staphylococcus epidermidis	1	9.09%	Acceptable

Organism(s) present: 65,000 CFU/mL of *Citrobacter freundii* and *Staphylococcus epidermidis*. The presumptive identification was graded by 80% referee consensus.

Identification–Specimen CC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	3	30.00%	Acceptable
Growth, referred for identification	2	20.00%	Acceptable
Staphylococcus aureus	1	10.00%	Acceptable
Presump. Staphylococcus sp.	1	10.00%	Acceptable

Organism(s) present: 10,000 - 100,000 CFU/mL of *Staphylococcus aureus* and <10,000 CFU/mL *Corynebacterium sp.* The presumptive identification was graded by 80% referee consensus.

Identification–Specimen CC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	4	40.00%	Acceptable
Presump. Gram positive	3	30.00%	Acceptable
Presump. Staphylococcus	2	20.00%	Acceptable
Staphylococcus saprophyticus	1	10.00%	Acceptable

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

GRAM STAIN

Specimen GS-1

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	18	94.74%	Acceptable
Gram positive	1	5.26%	

Gram Stain Morphology

Rods/bacilli	15	100%	Acceptable
--------------	----	------	------------

Organism(s) present: *Citrobacter freundii*.

Specimen GS-2

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	18	94.74%	Acceptable
Gram negative	1	5.26%	

Gram Stain Morphology

Cocci	11	73.33%	Acceptable
Diplococci	4	26.67%	

Organism(s) present: *Staphylococcus aureus*. The Gram Stain Morphology is graded to 90% referee consensus.

GRAM STAIN

Specimen GS-3

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	18	94.74%	Acceptable
Gram negative	1	5.26%	

Gram Stain Morphology

Rods/bacilli	13	86.67%	Acceptable
Coccobacilli	2	13.33%	

Organism(s) present: *Bacillus cereus*.

Specimen GS-4

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	18	94.74%	Acceptable
Gram negative	1	5.26%	

Gram Stain Morphology

Cocci	12	80.00%	Acceptable
Diplococci	3	20.00%	

Organism(s) present: *Staphylococcus epidermidis*.

Specimen GS-5

<u>Reaction</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	18	94.74%	Acceptable
Gram positive	1	5.26%	

Gram Stain Morphology

Rods/bacilli	7	46.67%	Acceptable
Coccobacilli	6	40.00%	Acceptable
Diplococci	1	6.67%	
Cocci	1	6.67%	

Organism(s) present: *Haemophilus influenzae*.

AFFIRM VP III–*Trichomonas vaginalis*

Specimen VP-1

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

Organism(s) present: *Gardnerella vaginalis*.

Specimen VP-2

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

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

Specimen VP-3

<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* species.

Specimen VP-4

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

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

Specimen VP-5

<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* species.

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-1

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

Organism(s) present: *Gardnerella vaginalis*.

Specimen VP-2

<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-3

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

Organism(s) present: *Candida* species.

Specimen VP-4

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

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

Specimen VP-5

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

Organism(s) present: *Candida* species.

AFFIRM VP III–Candida sp.

Specimen VP-1

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

Organism(s) present: *Gardnerella vaginalis*.

Specimen VP-2

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

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

Specimen VP-3

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

Organism(s) present: *Candida* species.

Specimen VP-4

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

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

Specimen VP-5

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

Organism(s) present: *Candida* species.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	12	4
BD ProbeTec	3	3	-
BD Viper	1	1	-
Cepheid GeneXpert	5	5	-
Quidel QuickVue	4	-	4
Roche COBAS Amplicor	2	2	-

Antigen(s) present: *Neisseria gonorrhoeae* and *Chlamydia trachomatis*. This challenge was graded by 80% participant consensus.

Specimen CY-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	1	15
BD ProbeTec	3	-	3
BD Viper	1	-	1
Cepheid GeneXpert	5	-	5
Quidel QuickVue	4	-	4
Roche COBAS Amplicor	2	1	1

Antigen(s) present: No antigen present.

Specimen CY-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	14	-
BD ProbeTec	3	3	-
BD Viper	1	1	-
Cepheid GeneXpert	5	5	-
Quidel QuickVue	2	2	-
Roche COBAS Amplicor	2	2	-

Antigen(s) present: *Chlamydia trachomatis*.

Specimen CY-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	1	13
BD ProbeTec	3	-	3
BD Viper	1	-	1
Cepheid GeneXpert	5	-	5
Quidel QuickVue	2	-	2
Roche COBAS Amplicor	2	1	1

Antigen(s) present: *Neisseria gonorrhoeae*.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	14	14	-
BD ProbeTec	3	3	-
BD Viper	1	1	-
Cepheid GeneXpert	5	5	-
Quidel QuickVue	2	2	-
Roche COBAS Amplicor	2	2	-

Antigen(s) present: *Chlamydia trachomatis*.

GC (ANTIGEN DETECTION)

Specimen CY-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	12	-
BD ProbeTec	3	3	-
BD Viper	1	1	-
Cepheid GeneXpert	5	5	-
Roche COBAS Amplicor	2	2	-

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

Specimen CY-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	-	12
BD ProbeTec	3	-	3
BD Viper	1	-	1
Cepheid GeneXpert	5	-	5
Roche COBAS Amplicor	2	-	2

Antigen(s) present: No antigen present.

Specimen CY-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	-	12
BD ProbeTec	3	-	3
BD Viper	1	-	1
Cepheid GeneXpert	5	-	5
Roche COBAS Amplicor	2	-	2

Antigen(s) present: *Chlamydia trachomatis*.

GC (ANTIGEN DETECTION)

Specimen CY-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	12	-
BD ProbeTec	3	3	-
BD Viper	1	1	-
Cepheid GeneXpert	5	5	-
Roche COBAS Amplicor	2	2	-

Antigen(s) present: *Neisseria gonorrhoeae*.

Specimen CY-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	12	-	12
BD ProbeTec	3	-	3
BD Viper	1	-	1
Cepheid GeneXpert	5	-	5
Roche COBAS Amplicor	2	-	2

Antigen(s) present: *Chlamydia trachomatis*.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	2	-
Alere CRYPTOSPORIDIUM II	1	1	-
Cardinal Crypto Giardia Rapid Test	1	1	-

Antigen(s) present: *Cryptosporidium*.

Specimen LC-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	2	-
Alere CRYPTOSPORIDIUM II	1	1	-
Cardinal Crypto Giardia Rapid Test	1	1	-

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

Specimen LC-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	-	2
Alere CRYPTOSPORIDIUM II	1	-	1
Cardinal Crypto Giardia Rapid Test	1	-	1

Antigen(s) present: No antigen present.

Specimen LC-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	-	2
Alere CRYPTOSPORIDIUM II	1	-	1
Cardinal Crypto Giardia Rapid Test	1	-	1

Antigen(s) present: *Giardia lamblia*.

Specimen LC-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	2	-
Alere CRYPTOSPORIDIUM II	1	1	-
Cardinal Crypto Giardia Rapid Test	1	1	-

Antigen(s) present: *Cryptosporidium*.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	-	2
Alere GIARDIA II	1	-	1
Cardinal Crypto Giardia Rapid Test	1	-	1

Antigen(s) present: *Cryptosporidium*.

Specimen LC-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	2	-
Alere GIARDIA II	1	1	-
Cardinal Crypto Giardia Rapid Test	1	1	-

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

Specimen LC-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	-	2
Alere GIARDIA II	1	-	1
Cardinal Crypto Giardia Rapid Test	1	-	1

Antigen(s) present: No antigen present.

Specimen LC-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	2	-
Alere GIARDIA II	1	1	-
Cardinal Crypto Giardia Rapid Test	1	1	-

Antigen(s) present: *Giardia lamblia*.

Specimen LC-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	2	-	2
Alere GIARDIA II	1	-	1
Cardinal Crypto Giardia Rapid Test	1	-	1

Antigen(s) present: *Cryptosporidium*.

RSV ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	70	1	69
Alere Binax NOW - waived	38	-	38
Alere i Instrument - waived	1	-	1
BD Veritor - moderate	3	-	3
BD Veritor - waived	1	-	1
Quidel QuickVue RSV - waived	8	-	8
Quidel QuickVue RSV 10 Test	2	-	2
Quidel Sofia - waived	16	-	16

Antigen(s) present: Influenza B.

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	69	69	-
Alere Binax NOW - waived	38	38	-
Alere i Instrument - waived	1	1	-
BD Veritor - moderate	3	3	-
BD Veritor - waived	1	1	-
Quidel QuickVue RSV - waived	8	8	-
Quidel QuickVue RSV 10 Test	2	2	-
Quidel Sofia - waived	16	16	-

Antigen(s) present: RSV.

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	-	18
Alere Binax NOW - waived	2	-	2
BD Veritor - moderate	3	-	3
Quidel QuickVue RSV - waived	4	-	4
Quidel QuickVue RSV 10 Test	2	-	2
Quidel Sofia - waived	7	-	7

Antigen(s) present: Influenza A.

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	-	18
Alere Binax NOW - waived	2	-	2
BD Veritor - moderate	3	-	3
Quidel QuickVue RSV - waived	4	-	4
Quidel QuickVue RSV 10 Test	2	-	2
Quidel Sofia - waived	7	-	7

Antigen(s) present: Influenza A.

RSV ANTIGEN DETECTION

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	18	-
Alere Binax NOW - waived	2	2	-
BD Veritor - moderate	3	3	-
Quidel QuickVue RSV - waived	4	4	-
Quidel QuickVue RSV 10 Test	2	2	-
Quidel Sofia - waived	7	7	-

Antigen(s) present: RSV.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	23	22	1
Alere Influenza A&B	1	1	-
BD Veritor - waived	2	2	-
Medline Influenza A&B	3	2	1
Other Waived Method	4	4	-
Quidel QuickVue Influenza	11	11	-
Quidel QuickVue Influenza A+B	1	1	-
Sekisui OSOM Influenza A&B	1	1	-

Antigen(s) present: Influenza B.

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	23	-	23
Alere Influenza A&B	1	-	1
BD Veritor - waived	2	-	2
Medline Influenza A&B	3	-	3
Other Waived Method	4	-	4
Quidel QuickVue Influenza	11	-	11
Quidel QuickVue Influenza A+B	1	-	1
Sekisui OSOM Influenza A&B	1	-	1

Antigen(s) present: RSV.

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	9	-
Quidel QuickVue Influenza	9	9	-

Antigen(s) present: Influenza A.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	9	-
Quidel QuickVue Influenza	9	9	-

Antigen(s) present: Influenza A.

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	-	9
Quidel QuickVue Influenza	9	-	9

Antigen(s) present: RSV.

INFLUENZA A ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	261	2	259
Alere Binax NOW - waived	15	-	15
Alere i Instrument - moderate	2	-	2
Alere i Instrument - waived	8	-	8
Alere Influenza A&B	14	-	14
BD Veritor - moderate	4	-	4
BD Veritor - waived	44	-	44
Consult Diagnostics Influenza A & B	2	-	2
Henry Schein OneStep+ Flu A&B	11	-	11
Medline Influenza A&B	2	-	2
Meridian ImmunoCard STAT - waived	1	-	1
OraSure QuickFlu	3	-	3
Other Waived Method	2	-	2
Quidel QuickVue Influenza A+B	20	2	18
Quidel Sofia - waived	125	-	125
Roche cobas Liat	2	-	2
Sekisui OSOM Influenza A&B	1	-	1
Sekisui OSOM Ultra -waived	5	-	5

Antigen(s) present: Influenza B.

INFLUENZA A ANTIGEN DETECTION

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	263	8	255
Alere Binax NOW - waived	15	-	15
Alere i Instrument - moderate	2	-	2
Alere i Instrument - waived	8	-	8
Alere Influenza A&B	14	-	14
BD Veritor - moderate	4	-	4
BD Veritor - waived	45	2	43
Consult Diagnostics Influenza A & B	3	-	3
Henry Schein OneStep+ Flu A&B	11	1	10
Medline Influenza A&B	2	-	2
Meridian ImmunoCard STAT - waived	1	-	1
OraSure QuickFlu	3	-	3
Other Waived Method	2	-	2
Quidel QuickVue Influenza A+B	20	-	20
Quidel Sofia - waived	125	5	120
Roche cobas Liat	2	-	2
Sekisui OSOM Influenza A&B	1	-	1
Sekisui OSOM Ultra -waived	5	-	5

Antigen(s) present: RSV.

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	25	-
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	1	1	-
Henry Schein OneStep+ Flu A&B	1	1	-
Meridian ImmunoCard STAT - waived	1	1	-
Quidel QuickVue Influenza A+B	2	2	-
Quidel Sofia - waived	10	10	-
Sekisui OSOM Influenza A&B	1	1	-

Antigen(s) present: Influenza A.

INFLUENZA A ANTIGEN DETECTION

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	25	-
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	1	1	-
Henry Schein OneStep+ Flu A&B	1	1	-
Meridian ImmunoCard STAT - waived	1	1	-
Quidel QuickVue Influenza A+B	2	2	-
Quidel Sofia - waived	10	10	-
Sekisui OSOM Influenza A&B	1	1	-

Antigen(s) present: Influenza A.

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	-	25
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	1	-	1
Henry Schein OneStep+ Flu A&B	1	-	1
Meridian ImmunoCard STAT - waived	1	-	1
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia - waived	10	-	10
Sekisui OSOM Influenza A&B	1	-	1

Antigen(s) present: RSV.

INFLUENZA B ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	260	256	4
Alere Binax NOW - waived	17	17	-
Alere i Instrument - moderate	2	2	-
Alere i Instrument - waived	8	8	-
Alere Influenza A&B	13	13	-
BD Veritor - moderate	4	4	-
BD Veritor - waived	43	43	-
Consult Diagnostics Influenza A & B	3	3	-
Henry Schein OneStep+ Flu A&B	11	11	-
Medline Influenza A&B	2	2	-
Meridian ImmunoCard STAT - waived	1	1	-
OraSure QuickFlu	3	3	-
Other Waived Method	2	2	-
Quidel QuickVue Influenza A+B	18	17	1
Quidel Sofia - waived	125	122	3
Roche cobas Liat	2	2	-
Sekisui OSOM Influenza A&B	1	1	-
Sekisui OSOM Ultra -waived	5	5	-

Antigen(s) present: Influenza B.

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	261	4	257
Alere Binax NOW - waived	17	-	17
Alere i Instrument - moderate	2	-	2
Alere i Instrument - waived	8	-	8
Alere Influenza A&B	13	-	13
BD Veritor - moderate	4	-	4
BD Veritor - waived	44	-	44
Consult Diagnostics Influenza A & B	3	-	3
Henry Schein OneStep+ Flu A&B	11	-	11
Medline Influenza A&B	2	-	2
Meridian ImmunoCard STAT - waived	1	-	1
OraSure QuickFlu	3	-	3
Other Waived Method	2	-	2
Quidel QuickVue Influenza A+B	18	1	17
Quidel Sofia - waived	125	3	122
Roche cobas Liat	2	-	2
Sekisui OSOM Influenza A&B	1	-	1
Sekisui OSOM Ultra -waived	5	-	5

Antigen(s) present: RSV.

INFLUENZA B ANTIGEN DETECTION

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	-	25
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	1	-	1
Henry Schein OneStep+ Flu A&B	1	-	1
Meridian ImmunoCard STAT - waived	1	-	1
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia - waived	10	-	10
Sekisui OSOM Influenza A&B	1	-	1

Antigen(s) present: Influenza A.

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	24	-	24
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	1	-	1
Henry Schein OneStep+ Flu A&B	1	-	1
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia - waived	10	-	10
Sekisui OSOM Influenza A&B	1	-	1

Antigen(s) present: Influenza A.

INFLUENZA B ANTIGEN DETECTION

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	-	25
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	1	-	1
Henry Schein OneStep+ Flu A&B	1	-	1
Meridian ImmunoCard STAT - waived	1	-	1
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia - waived	10	-	10
Sekisui OSOM Influenza A&B	1	-	1

Antigen(s) present: RSV.

CLOSTRIDIUM 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: *Clostridium difficile*.

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: No antigen present.

Specimen AG-4

<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: *Clostridium difficile* and Rotavirus.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

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: *Clostridium difficile*.

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: *Clostridium difficile*.

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: No antigen present.

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: *Clostridium 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: *Clostridium difficile*.

LEGIONELLA ANTIGEN DETECTION

Specimen L-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	13	-	13

Specimen L-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	13	13	-

Specimen L-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	13	13	-

Specimen L-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	13	13	-

Specimen L-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	13	-	13

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	11	11	-

Specimen SP-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	11	11	-

Specimen SP-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	11	11	-

Specimen SP-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	11	-	11

Specimen SP-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	11	-	11

PARASITOLOGY

Specimen PA-1

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

Parasite(s) present: *Endolimax nana*.

Specimen PA-2

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

Parasite(s) present: Giardia lamblia.

Specimen PA-3

<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 PA-4

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

Parasite(s) present: *Schistosoma haematobium* eggs.

Specimen PA-5

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

Parasite(s) present: *Trypanosoma cruzi*.

DERMATOPHYTE CULTURE

Specimen DM-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte absent	10	100%	Acceptable

Organism(s) present: *Staphylococcus aureus*.

Specimen DM-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte present	10	100%	Acceptable

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

Specimen DM-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte present	9	90.00%	Acceptable
Dermatophyte absent	1	10.00%	

Organism(s) present: *Trichophyton mentagrophytes* and *Corynebacterium sp.*

Specimen DM-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte present	8	80.00%	Acceptable
Dermatophyte absent	2	20.00%	

Organism(s) present: *Microsporum canis*.

Specimen DM-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte absent	10	100%	Acceptable

Organism(s) present: No organism present.

BACTERIAL VAGINOSIS – OSOM - WAIVED

Specimen BV-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Sekisui OSOM	7	7	-

Antigen(s) present: *Gardnerella vaginalis*.

Specimen BV-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Sekisui OSOM	7	-	7

Antigen(s) present: No antigen present.

TRICHOMONAS VAGINALIS – OSOM - WAIVED

Specimen TR-1

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

Antigen(s) present: No antigen present.

Specimen TR-2

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

Antigen(s) present: *Trichomonas vaginalis*.

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