MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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Microbiology
2019 MLE-M1

ACP | Medical Laboratory Evaluation

Total Commitment to Education and Service
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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 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 Culture	80% Consensus
Chlamydia (EIA, DNA)	80% Consensus	Parasite Identification	80% Consensus
Clostridioides 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 CULTURE

Specimen MSA-1

Identification	***Labs***	***Percent***	***Performance***
Positive	5	100%	Acceptable

Organism(s) present: *Staphylococcus aureus* - Methicillin resistant and *Micrococcus luteus.*

Specimen MSA-2

Identification	***Labs***	***Percent***	***Performance***
Positive	5	100%	Acceptable

Organism(s) present: *Staphylococcus aureus* - Methicillin resistant and *Enterococcus faecalis.*

Specimen MSA-3

Identification	***Labs***	***Percent***	***Performance***
Negative	5	100%	Acceptable

Organism(s) present: *Streptococcus sanguinis.*

Specimen MSA-4

Identification	***Labs***	***Percent***	***Performance***
Negative	5	100%	Acceptable

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

Specimen MSA-5

Identification	***Labs***	***Percent***	***Performance***
Positive	5	100%	Acceptable

Organism(s) present: *Staphylococcus aureus* - Methicillin resistant.

STREP A ANTIGEN DETECTION

Specimen RS-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	479	467	12
Abbott Signify Strep A-waived	1	1	-
Alere Acceava Strep A Test	8	8	-
Alere i Instrument - waived	15	15	-
BD Chek Strep A	1	-	1
BD Veritor - waived	9	9	-
Beckman Coulter ICON DS	6	6	-
Beckman Coulter ICON SC	1	1	-
Cardinal Health Strep A - waived	5	5	-
Cepheid GeneXpert - moderate	1	1	-
Cepheid GeneXpert - waived	7	7	-
Clarity Diagnostics	1	1	-
Consult Diagnostic Strep A - Moderate	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	71	70	1
Fisher HealthCare Sure-Vue - waived	2	2	-
Germaine Laboratories StrepAim	1	1	-
Henry Schein One Step+ - waived	45	41	4
Immunostics Detector Strep A Direct	1	1	-
McKesson Strep A Dipstick	13	13	-
Medline Strep A Test Strip	2	2	-
Meridian Illumigene	1	1	-
Meridian ImmunoCard STAT - waived	10	10	-
Other Waived Method	10	10	-
Quidel QuickVue Dipstick Strep	43	43	-
Quidel QuickVue In-Line	42	36	6
Quidel QuickVue+	8	8	-
Quidel Sofia / Sofia 2 - waived	1	1	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	17	17	-
Quidel Solana	3	3	-
Roche cobas Liat	3	3	-
Sekisui OSOM	99	99	-
Sekisui OSOM Ultra -waived	43	43	-

STREP A ANTIGEN DETECTION

Specimen RS-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	475	462	13
Abbott Signify Strep A-waived	1	1	-
Alere Acceava Strep A Test	8	8	-
Alere i Instrument - waived	15	15	-
BD Chek Strep A	1	-	1
BD Veritor - waived	8	7	1
Beckman Coulter ICON DS	6	6	-
Beckman Coulter ICON SC	1	1	-
Cardinal Health Strep A - waived	5	5	-
Cepheid GeneXpert - moderate	1	1	-
Cepheid GeneXpert - waived	7	7	-
Clarity Diagnostics	1	1	-
Consult Diagnostic Strep A - Moderate	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	71	68	3
Fisher HealthCare Sure-Vue - waived	2	2	-
Germaine Laboratories StrepAim	1	1	-
Henry Schein One Step+ - waived	44	42	2
Immunostics Detector Strep A Direct	1	1	-
McKesson Strep A Dipstick	12	12	-
Medline Strep A Test Strip	2	2	-
Meridian Illumigene	1	1	-
Meridian ImmunoCard STAT - waived	10	10	-
Other Waived Method	10	10	-
Quidel QuickVue Dipstick Strep	42	42	-
Quidel QuickVue In-Line	42	37	5
Quidel QuickVue+	8	8	-
Quidel Sofia / Sofia 2 - waived	1	1	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	17	17	-
Quidel Solana	3	3	-
Roche cobas Liat	3	3	-
Sekisui OSOM	99	99	-
Sekisui OSOM Ultra -waived	43	43	-

STREP A ANTIGEN DETECTION

Specimen RS-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	66	-	66
Alere Acceava Strep A Test	2	-	2
Alere i Instrument - waived	2	-	2
BD Veritor - waived	2	-	2
Beckman Coulter ICON DS	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	11	-	11
Henry Schein One Step+ - waived	4	-	4
McKesson Strep A Dipstick	2	-	2
Meridian Illumigene	1	-	1
Quidel QuickVue Dipstick Strep	9	-	9
Quidel QuickVue In-Line	16	-	16
Quidel QuickVue+	3	-	3
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	3	-	3
Quidel Solana	3	-	3
Sekisui OSOM	1	-	1
Sekisui OSOM Ultra -waived	4	-	4

STREP A ANTIGEN DETECTION

Specimen RS-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	66	1	65
Alere Acceava Strep A Test	2	-	2
Alere i Instrument - waived	2	-	2
BD Veritor - waived	2	-	2
Beckman Coulter ICON DS	1	-	1
Consult Diagnostic Strep A Dipstick - Waived	11	-	11
Henry Schein One Step+ - waived	4	1	3
McKesson Strep A Dipstick	2	-	2
Meridian Illumigene	1	-	1
Quidel QuickVue Dipstick Strep	9	-	9
Quidel QuickVue In-Line	16	-	16
Quidel QuickVue+	3	-	3
Quidel Sofia Strep A - moderate	2	-	2
Quidel Sofia Strep A+ - waived	3	-	3
Quidel Solana	3	-	3
Sekisui OSOM	1	-	1
Sekisui OSOM Ultra -waived	4	-	4

Specimen RS-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	66	65	1
Alere Acceava Strep A Test	2	2	-
Alere i Instrument - waived	2	2	-
BD Veritor - waived	2	2	-
Beckman Coulter ICON DS	1	1	-
Consult Diagnostic Strep A Dipstick - Waived	11	11	-
Henry Schein One Step+ - waived	4	3	1
McKesson Strep A Dipstick	2	2	-
Meridian Illumigene	1	1	-
Quidel QuickVue Dipstick Strep	9	9	-
Quidel QuickVue In-Line	16	16	-
Quidel QuickVue+	3	3	-
Quidel Sofia Strep A - moderate	2	2	-
Quidel Sofia Strep A+ - waived	3	3	-
Quidel Solana	3	3	-
Sekisui OSOM	1	1	-
Sekisui OSOM Ultra -waived	4	4	-

MISCELLANEOUS CULTURES

Specimen BA-1 – Blood Culture

Identification	***Labs***	***Percent***	***Performance***
Bacillus cereus	2	40.00%	Acceptable
Bacillus sp.	3	60.00%	Acceptable

Organism(s) present: *Bacillus cereus.*

Specimen BA-2 – Stool Culture

Identification	***Labs***	***Percent***	***Performance***
Salmonella Group D	5	100%	Acceptable

Organism(s) present: *Salmonella enteritidis.*

Specimen BA-3 – Wound Culture

Identification	***Labs***	***Percent***	***Performance***
Staphylococcus sp.	5	55.56%	Acceptable
Vibrio sp.	4	44.44%	Acceptable

Organism(s) present: *Vibrio vulnificus* and *Staphylococcus pseudintermedius.*

THROAT CULTURE

Specimen TC-1

Identification	***Labs***	***Percent***	***Performance***
Positive for Group A Strep	46	49.46%	Acceptable
Presump. Pos. Group A Strep	33	35.48%	Acceptable
Streptococcus pyogenes	7	7.53%	Acceptable
Staphylococcus sp.	4	4.30%	Acceptable
Staph – coagulase neg.	2	2.15%	Acceptable

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

Specimen TC-2

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	84	87.50%	Acceptable
Growth, referred for identification	8	8.33%	Acceptable

Organism(s) present: *Elizabethkingia meningoseptica.*

Specimen TC-3

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	51	100%	Acceptable

Organism(s) present: *Streptococcus sanguinis* and *Haemophilus influenzae*.

Specimen TC-4

Identification	***Labs***	***Percent***	***Performance***
Negative for Group A Strep	48	97.96%	Acceptable

Organism(s) present: Neisseria sicca and Staphylococcus lugdunensis.

Specimen TC-5

Identification	***Labs***	***Percent***	***Performance***
Presump. Pos. Group A Strep	26	53.06%	Acceptable
Positive for Group A Strep	22	44.90%	Acceptable

Organism(s) present: *Streptococcus pyogenes.*

URINE CULTURE

Specimen UC-1

Identification	***Labs***	***Percent***	***Performance***
Citrobacter koseri	24	47.06%	Acceptable
Citrobacter sp.	14	27.45%	Acceptable
Growth, referred for identification	6	11.76%	Acceptable
Presump. Gram negative	5	9.80%	Acceptable
Gram negative bacilli	2	3.92%	Acceptable

Gram Stain

Gram negative	23	100%	Acceptable

Gram Stain Morphology

Rods/bacilli	23	100%	Acceptable

Organism(s) present: *Citrobacter koseri.*

Specimen UC-2

Identification	***Labs***	***Percent***	***Performance***
Staphylococcus saprophyticus	31	37.33%	Acceptable
Growth, referred for identification	22	26.51%	Acceptable
Presump. Gram positive	3	3.61%	Acceptable
Presump. Staphylococcus sp.	2	2.41%	Acceptable
Micrococcus sp.	2	2.41%	Acceptable
Gram positive cocci	2	2.41%	Acceptable
Staph – coagulase neg.	2	2.41%	Acceptable
Staphylococcus sp.	1	1.20%	Acceptable

Organism(s) present: *Micrococcus luteus* and *Staphylococcus saprophyticus.* This challenge was graded by 93% referee consensus.

Micrococcus luteus is an opportunistic pathogen commonly seen in nosocomial infections. It is found in dust, soil, water and normal human skin flora. Patients with meningitis, septic arthritis, endocarditis, catheter infections and HIV are most susceptible to *M. luteus* infections. Clinically, skin infections similar to *Staphylococcus aureus* are seen. *M. luteus* can also cause body odor when breaking down components of sweat.

Micrococcus luteus is an obligate aerobe, forming gram-positive cocci in tetrads or irregular clusters. It can grow on several types of media including nutrient and sheep blood agar. The small bright yellow circular colonies are often mistaken for *Staphylococcus aureus*. *M. luteus* grows slowly, requiring incubation of plates for up to 48 hours.

Staphylococcus saprophyticus is a facultative anaerobe, forming gram-positive cocci in clusters. It appears as white non-hemolytic colonies on sheep blood agar. It is found as normal flora in the female genital tract. It can cause uncomplicated UTI in the female and symptomatic UTI in the male.

URINE CULTURE

Specimen UC-3

Identification	***Labs***	***Percent***	***Performance***
No growth (sterile)	30	93.75%	Acceptable

Organism(s) present: No organism present.

Specimen UC-4

Identification	***Labs***	***Percent***	***Performance***
Escherichia coli	7	33.33%	Acceptable
Growth, referred for identification	5	23.81%	Acceptable
Streptococcus alpha-hemolytic	2	9.52%	Acceptable
Presump. Gram negative	2	9.52%	Acceptable
Presump. Gram positive	2	9.52%	Acceptable
Presump. Streptococcus sp.	1	4.76%	Acceptable
Streptococcus salivarius	1	4.76%	Acceptable

Organism(s) present: *Escherichia coli* and *Streptococcus salivarius*.

Specimen UC-5

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	7	38.89%	Acceptable
Morganella morganii	4	22.22%	Acceptable
Corynebacterium sp.	3	16.67%	Acceptable
Presump. Gram negative	2	11.11%	Acceptable
Presump. Gram positive	2	11.11%	Acceptable

Organism(s) present: *Morganella morganii* and *Corynebacterium* sp.

ANTIMICROBIAL SUSCEPTIBILIY TESTING

Specimen UC-1, CC-1 (SUS-1) Organism(s) present: *Citrobacter koseri.*

	------Disk Diffusion------ Interpretative category data				------MIC------ Interpretative category data				
Antimicrobial	***Labs***	***S***	***I***	***R***	***Labs***	***S***	***I***	***R***	***Acceptable (%)***
Amikacin	-	-	-	-	5	5	-	-	100.00%
Amoxicillin/Clavulanate	13	13	-	-	2	2	-	-	100.00%
Ampicillin	34	-	-	34	3	-	-	3	100.00%
Ampicillin/Sulbactam	-	-	-	-	1	1	-	-	Ungraded[1]
Aztreonam	-	-	-	-	1	1	-	-	Ungraded[1]
Cefaclor	1	1	-	-	-	-	-	-	Ungraded[1]
Cefamandole	1	1	-	-	-	-	-	-	Ungraded[1]
Cefazolin	28	28	-	-	5	5	-	-	100.00%
Cefdinir	1	1	-	-	-	-	-	-	Inappropriate drug[2]
Cefepime	-	-	-	-	5	5	-	-	100.00%
Cefixime	5	5	-	-	-	-	-	-	100.00%
Cefotaxime	-	-	-	-	1	1	-	-	Ungraded[1]
Cefoxitin	-	-	-	-	5	5	-	-	100.00%
Cefpodoxime	5	5	-	-	-	-	-	-	100.00%
Ceftazidime	2	2	-	-	3	3	-	-	100.00%
Ceftizoxime	1	1	-	-	-	-	-	-	Ungraded[1]
Ceftriaxone	8	8	-	-	3	3	-	-	100.00%
Cefuroxime	7	7	-	-	2	1	1	-	90.00%
Ciprofloxacin	37	37	-	-	4	4	-	-	100.00%
Ertapenem	-	-	-	-	5	5	-	-	100.00%
Gentamicin	30	30	-	-	4	4	-	-	100.00%
Imipenem	-	-	-	-	5	5	-	-	100.00%
Levofloxacin	7	7	-	-	4	4	-	-	100.00%
Meropenem	-	-	-	-	1	1	-	-	Ungraded[1]
Nalidixic Acid	1	1	-	-	-	-	-	-	Ungraded[1]
Nitrofurantoin	31	31	-	-	5	5	-	-	100.00%
Piperacillin/Tazobactam	1	1	-	-	4	4	-	-	100.00%
Sulfonamides	1	1	-	-	-	-	-	-	Ungraded[1]
Tetracycline	10	10	-	-	1	1	-	-	100.00%
Tobramycin	2	2	-	-	3	3	-	-	100.00%
Trimethoprim	3	3	-	-	2	2	-	-	100.00%
Trimethoprim/Sulfamethoxazole	34	34	-	-	4	4	-	-	100.00%

NOTE: Please be aware that CLSI issues annual editions of M100, the standards used by all proficiency testing programs for grading of susceptibilities. Drugs considered appropriate may change significantly with subsequent editions. The current edition of the CLSI M100 document is accessible online at CLSI.org under Standards>Free Resources.

[1] This is an ungraded challenge due to lack of comparison group.

[2] Inappropriate method reported for this drug.

GENITAL CULTURE

Specimen GC-1

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhoeae	18	69.23%	Acceptable
Neisseria gonorrhoeae	5	19.23%	Acceptable
Growth, referred for identification	2	7.69%	Acceptable
Gram negative diplococci	1	3.85%	Acceptable
Gram Stain			
Gram negative	17	94.44%	Acceptable
Gram positive	1	5.56%	
Gram Stain Morphology			
Diplococci	17	94.44%	Acceptable
Rods/bacilli	1	5.56%	

Organism(s) present: *Neisseria gonorrhoeae*.

Specimen GC-2

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhoeae	6	50.00%	Acceptable
Staphylococcus aureus	3	25.00%	Acceptable
Neisseria gonorrhoeae	3	25.00%	Acceptable

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

Specimen GC-3

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	8	57.14%	Acceptable
Enterococcus sp.	3	21.43%	Acceptable
Escherichia coli	2	14.29%	Acceptable

Organism(s) present: *Enterococcus faecalis and Escherichia coli.*

GENITAL CULTURE

Specimen GC-4

Identification	***Labs***	***Percent***	***Performance***
Negative for N. gonorrhoeae	6	100%	Acceptable

Organism(s) present: *Serratia marcescens and Staphylococcus saprophyticus.*

Specimen GC-5

Identification	***Labs***	***Percent***	***Performance***
Presumptive for N. gonorrhoeae	5	83.33%	Acceptable
Neisseria gonorrhoeae	1	16.67%	Acceptable

Organism(s) present: *Neisseria gonorrhoeae.*

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-1

Method	Labs	No growth	<10,000 organisms/mL	10,000-100,000 organisms/mL	>100,000 organisms/mL
ALL METHODS	46	1	1	7	37
Calibrated Loop	20	-	1	3	16
Uri-Check	5	1	-	1	3
Uricult	20	-	-	3	17

Identification–Specimen CC-1

Identification	Labs	Percent	Performance
Growth, referred for identification	6	50.00%	Acceptable
Presump. Gram negative	5	41.67%	Acceptable
Citrobacter koseri	1	8.33%	Acceptable

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

Specimen CC-2

Method	Labs	No growth	<10,000 organisms/mL	10,000-100,000 organisms/mL	>100,000 organisms/mL
ALL METHODS	45	21	21	2	1
Calibrated Loop	20	8	11	-	1
Uri-Check	5	3	2	-	-
Uricult	19	10	7	2	-

Identification–Specimen CC-2

Identification	Labs	Percent	Performance
Growth, referred for identification	3	27.27%	Acceptable
Presump. Gram positive	1	9.09%	Acceptable
Presump. Staphylococcus sp.	1	9.09%	Acceptable

Organism(s) present: 9,000 CFU/mL of *Micrococcus luteus* and 5,000 CFU/mL of *Staphylococcus saprophyticus.* The presumptive identification was graded by 93% referee consensus and the colony count was graded by 82% referee consensus.

Micrococcus luteus is an opportunistic pathogen commonly seen in nosocomial infections. It is found in dust, soil, water and normal human skin flora. Patients with meningitis, septic arthritis, endocarditis, catheter infections and HIV are most susceptible to *M. luteus* infections. Clinically, skin infections similar to *Staphylococcus aureus* are seen. *M. luteus* can also cause body odor when breaking down components of sweat.

Micrococcus luteus is an obligate aerobe, forming gram-positive cocci in tetrads or irregular clusters. It can grow on several types of media including nutrient and sheep blood agar. The small bright yellow circular colonies are often mistaken for *Staphylococcus aureus*. *M. luteus* grows slowly, requiring incubation of plates for up to 48 hours.

Staphylococcus saprophyticus is a facultative anaerobe, forming gram-positive cocci in clusters. It appears as white non-hemolytic colonies on sheep blood agar. It is found as normal flora in the female genital tract. It can cause uncomplicated UTI in the female and symptomatic UTI in the male.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-3

Identification	***Labs***	***Percent***	***Performance***
No growth (sterile)	10	90.91%	Acceptable

Organism(s) present: No Organism present.

Identification–Specimen CC-4

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	5	45.45%	Acceptable
Presump. Gram negative	3	27.27%	Acceptable
Presump. Escherichia coli	2	18.18%	Acceptable
Escherichia coli	1	9.09%	Acceptable

Organism(s) present: 12,000 CFU/mL of *Escherichia coli* and 5,000 CFU/mL of *Streptococcus salivarius*.

Identification–Specimen CC-5

Identification	***Labs***	***Percent***	***Performance***
Growth, referred for identification	5	45.45%	Acceptable
Presump. Gram negative	5	45.45%	Acceptable
Morganella morganii	1	9.09%	Acceptable

Organism(s) present: >100,000 CFU/mL of *Morganella morganii* and <*10,000* CFU/mL of *Corynebacterium* sp.

GRAM STAIN

Specimen GS-1

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	15	100%	Acceptable
Gram Stain Morphology			
Rods/bacilli	11	100%	Acceptable

Organism(s) present: *Campylobacter jejuni.*

Specimen GS-2

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	13	86.67%	Acceptable
Gram positive	2	13.33%	
Gram Stain Morphology			
Diplococci	8	72.73%	Acceptable
Cocci	3	27.27%	

Organism(s) present: *Moraxella catarrhalis.*

GRAM STAIN

Specimen GS-3

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	14	93.33%	Acceptable
Gram negative	1	6.67%	

Gram Stain Morphology

Cocci	8	72.73%	Acceptable
Diplococci	3	27.27%	

Organism(s) present: *Micrococcus luteus.* The gram stain morphology was graded by 80% referee consensus.

Specimen GS-4

Reaction	***Labs***	***Percent***	***Performance***
Gram positive	14	93.33%	Acceptable
Gram negative	1	6.67%	

Gram Stain Morphology

Rods/bacilli	7	63.64%	Acceptable
Cocci	2	18.18%	
Coccobacilli	2	18.18%	

Organism(s) present: *Actinomyces odontolyticus.* The gram stain morphology was graded by 80% referee consensus.

Specimen GS-5

Reaction	***Labs***	***Percent***	***Performance***
Gram negative	14	100%	Acceptable

Gram Stain Morphology

Rods/bacilli	7	70.00%	Acceptable
Coccobacilli	2	20.00%	
Diplococci	1	10.00%	

Organism(s) present: *Bacteroides fragilis.* The gram stain morphology was graded by 80% referee consensus.

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-1

Identification	***Labs***	***Percent***	***Performance***
Positive	27	100%	Acceptable

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

Specimen VP-2

Identification	***Labs***	***Percent***	***Performance***
Positive	27	100%	Acceptable

Organism(s) present: *Trichomonas vaginalis.*

Specimen VP-3

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*.

Specimen VP-4

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

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

Specimen VP-5

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

Organism(s) present: No organism present.

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-1

Identification	***Labs***	***Percent***	***Performance***
Positive	27	100%	Acceptable

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

Specimen VP-2

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

Organism(s) present: *Trichomonas vaginalis.*

Specimen VP-3

Identification	***Labs***	***Percent***	***Performance***
Positive	27	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*.

Specimen VP-4

Identification	***Labs***	***Percent***	***Performance***
Positive	27	100%	Acceptable

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

Specimen VP-5

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

Organism(s) present: No organism present.

AFFIRM VP III–Candida sp.

Specimen VP-1

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

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

Specimen VP-2

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

Organism(s) present: *Trichomonas vaginalis*

Specimen VP-3

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

Organism(s) present: *Gardnerella vaginalis*.

Specimen VP-4

Identification	***Labs***	***Percent***	***Performance***
Positive	26	96.30%	Acceptable
Negative	1	3.70%	

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

Specimen VP-5

Identification	***Labs***	***Percent***	***Performance***
Negative	27	100%	Acceptable

Organism(s) present: No organism present.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-1

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	18	-	18
BD Max	1	-	1
BD ProbeTec	4	-	4
Cepheid GeneXpert - moderate	8	-	8
Quidel QuickVue	3	-	3
Roche COBAS Amplicor	2	-	2

Antigen(s) present: *Neisseria gonorrhoeae*.

Specimen CY-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	18	18	-
BD Max	1	1	-
BD ProbeTec	4	4	-
Cepheid GeneXpert - moderate	8	8	-
Quidel QuickVue	3	3	-
Roche COBAS Amplicor	2	2	-

Antigen(s) present: *Chlamydia trachomatis.*

Specimen CY-3

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	16	-	16
BD Max	1	-	1
BD ProbeTec	4	-	4
Cepheid GeneXpert - moderate	8	-	8
Quidel QuickVue	1	-	1
Roche COBAS Amplicor	2	-	2

Antigen(s) present: No antigen present.

Specimen CY-4

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	16	16	-
BD Max	1	1	-
BD ProbeTec	4	4	-
Cepheid GeneXpert - moderate	8	8	-
Quidel QuickVue	1	1	-
Roche COBAS Amplicor	2	2	-

Antigen(s) present: *Chlamydia trachomatis.*

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-5

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	16	16	-
BD Max	1	1	-
BD ProbeTec	4	4	-
Cepheid GeneXpert - moderate	8	8	-
Quidel QuickVue	1	1	-
Roche COBAS Amplicor	2	2	-

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

GC (ANTIGEN DETECTION)

Specimen CY-1

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	15	-
BD Max	1	1	-
BD ProbeTec	4	4	-
Cepheid GeneXpert - moderate	8	8	-
Roche COBAS Amplicor	2	2	-

Antigen(s) present: *Neisseria gonorrhoeae*.

Specimen CY-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	-	15
BD Max	1	-	1
BD ProbeTec	4	-	4
Cepheid GeneXpert - moderate	8	-	8
Roche COBAS Amplicor	2	-	2

Antigen(s) present: *Chlamydia trachomatis.*

Specimen CY-3

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	-	15
BD Max	1	-	1
BD ProbeTec	4	-	4
Cepheid GeneXpert - moderate	8	-	8
Roche COBAS Amplicor	2	-	2

Antigen(s) present: No antigen present.

GC (ANTIGEN DETECTION)

Specimen CY-4

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	-	15
BD Max	1	-	1
BD ProbeTec	4	-	4
Cepheid GeneXpert - moderate	8	-	8
Roche COBAS Amplicor	2	-	2

Antigen(s) present: *Chlamydia trachomatis*.

Specimen CY-5

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	15	15	-
BD Max	1	1	-
BD ProbeTec	4	4	-
Cepheid GeneXpert - moderate	8	8	-
Roche COBAS Amplicor	2	2	-

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

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	2	2	-
Alere CRYPTOSPORIDIUM II	1	1	-
Cardinal Crypto Giardia Rapid Test	1	1	-

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

Specimen LC-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	2	-	2
Alere CRYPTOSPORIDIUM II	1	-	1
Cardinal Crypto Giardia Rapid Test	1	-	1

Antigen(s) present: No antigen present.

Specimen LC-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	2	1	1
Alere CRYPTOSPORIDIUM II	1	1	-
Cardinal Crypto Giardia Rapid Test	1	-	1

Antigen(s) present: *Cryptosporidium.* This is an ungraded challenge due to lack of participant consensus.

Specimen LC-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	2	2	-
Alere CRYPTOSPORIDIUM II	1	1	-
Cardinal Crypto Giardia Rapid Test	1	1	-

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

Specimen LC-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	2	-	2
Alere CRYPTOSPORIDIUM II	1	-	1
Cardinal Crypto Giardia Rapid Test	1	-	1

Antigen(s) present: *Giardia lamblia*.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	2	2	-
Alere GIARDIA II	1	1	-
Cardinal Crypto Giardia Rapid Test	1	1	-

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

Specimen LC-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	2	-	2
Alere GIARDIA II	1	-	1
Cardinal Crypto Giardia Rapid Test	1	-	1

Antigen(s) present: No antigen present.

Specimen LC-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	2	-	2
Alere GIARDIA II	1	-	1
Cardinal Crypto Giardia Rapid Test	1	-	1

Antigen(s) present: *Cryptosporidium.*

Specimen LC-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	2	2	-
Alere GIARDIA II	1	1	-
Cardinal Crypto Giardia Rapid Test	1	1	-

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

Specimen LC-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	2	2	-
Alere GIARDIA II	1	1	-
Cardinal Crypto Giardia Rapid Test	1	1	-

Antigen(s) present: *Giardia lamblia*.

RSV ANTIGEN DETECTION

Specimen V-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	68	68	-
Alere Binax NOW - waived	30	30	-
Alere i Instrument - waived	1	1	-
BD Veritor - moderate	3	3	-
BD Veritor - waived	2	2	-
Quidel QuickVue RSV - waived	10	10	-
Quidel QuickVue RSV 10 Test	2	2	-
Quidel Sofia / Sofia 2 - waived	13	13	-
Roche cobas Liat	6	6	-

Antigen(s) present: RSV.

Specimen V-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	68	-	68
Alere Binax NOW - waived	30	-	30
Alere i Instrument - waived	1	-	1
BD Veritor - moderate	3	-	3
BD Veritor - waived	2	-	2
Quidel QuickVue RSV - waived	10	-	10
Quidel QuickVue RSV 10 Test	2	-	2
Quidel Sofia / Sofia 2 - waived	13	-	13
Roche cobas Liat	6	-	6

Antigen(s) present: Influenza A.

Specimen V-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	18	-	18
Alere Binax NOW - waived	3	-	3
BD Veritor - moderate	3	-	3
BD Veritor - waived	1	-	1
Quidel QuickVue RSV - waived	4	-	4
Quidel QuickVue RSV 10 Test	2	-	2
Quidel Sofia / Sofia 2 - waived	5	-	5

Antigen(s) present: Influenza A.

RSV ANTIGEN DETECTION

Specimen V-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	18	1	17
Alere Binax NOW - waived	3	-	3
BD Veritor - moderate	3	-	3
BD Veritor - waived	1	-	1
Quidel QuickVue RSV - waived	4	-	4
Quidel QuickVue RSV 10 Test	2	-	2
Quidel Sofia / Sofia 2 - waived	5	1	4

Antigen(s) present: Influenza B.

Specimen V-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	18	-	18
Alere Binax NOW - waived	3	-	3
BD Veritor - moderate	3	-	3
BD Veritor - waived	1	-	1
Quidel QuickVue RSV - waived	4	-	4
Quidel QuickVue RSV 10 Test	2	-	2
Quidel Sofia / Sofia 2 - waived	5	-	5

Antigen(s) present: No antigen present.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	23	-	23
BD Veritor - waived	2	-	2
BioSign Flu A+B	2	-	2
Cepheid GeneXpert - moderate	1	-	1
Consult Diagnostics Influenza A & B	2	-	2
Meridian ImmunoCard STAT - waived	1	-	1
Other Waived Method	1	-	1
Quidel QuickVue Influenza	6	-	6
Quidel QuickVue Influenza A+B	1	-	1
Quidel Sofia / Sofia 2 - waived	5	-	5
Sekisui OSOM Ultra -waived	1	-	1

Antigen(s) present: RSV.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	23	23	-
BD Veritor - waived	2	2	-
BioSign Flu A+B	2	2	-
Cepheid GeneXpert - moderate	1	1	-
Consult Diagnostics Influenza A & B	2	2	-
Meridian ImmunoCard STAT - waived	1	1	-
Other Waived Method	1	1	-
Quidel QuickVue Influenza	6	6	-
Quidel QuickVue Influenza A+B	1	1	-
Quidel Sofia / Sofia 2 - waived	5	5	-
Sekisui OSOM Ultra -waived	1	1	-

Antigen(s) present: Influenza A.

Specimen V-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	6	6	-
Quidel QuickVue Influenza	6	6	-

Antigen(s) present: Influenza A.

Specimen V-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	6	6	-
Quidel QuickVue Influenza	6	6	-

Antigen(s) present: Influenza B.

Specimen V-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	6	-	6
Quidel QuickVue Influenza	6	-	6

Antigen(s) present: No antigen present.

INFLUENZA A ANTIGEN DETECTION

Specimen V-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	302	5	297
Alere Binax NOW - waived	3	-	3
Alere i Instrument - moderate	1	-	1
Alere i Instrument - waived	10	-	10
Alere Influenza A&B	5	-	5
BD Veritor - moderate	4	-	4
BD Veritor - waived	54	2	52
BioSign Flu A+B	2	-	2
Cepheid GeneXpert - waived	7	-	7
Consult Diagnostics Influenza A & B	19	-	19
Henry Schein OneStep+ Flu A&B	2	1	1
Meridian ImmunoCard STAT - waived	7	-	7
OraSure QuickFlu	2	-	2
Quidel QuickVue Influenza A+B	15	-	15
Quidel Sofia / Sofia 2 - waived	127	1	126
Quidel Solana	1	-	1
Roche cobas Liat	10	-	10
Sekisui OSOM Influenza A&B	7	-	7
Sekisui OSOM Ultra -waived	24	-	24
Sekisui OSOM Ultra -waived	302	5	297

Antigen(s) present: RSV.

Specimen V-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	304	300	4
Alere Binax NOW - waived	3	3	-
Alere i Instrument - moderate	1	1	-
Alere i Instrument - waived	10	10	-
Alere Influenza A&B	5	5	-
BD Veritor - moderate	4	4	-
BD Veritor - waived	54	53	1
BioSign Flu A+B	2	2	-
Cepheid GeneXpert - waived	7	7	-
Consult Diagnostics Influenza A & B	20	20	-
Henry Schein OneStep+ Flu A&B	2	1	1
Meridian ImmunoCard STAT - waived	7	7	-
OraSure QuickFlu	2	2	-
Quidel QuickVue Influenza A+B	15	15	-
Quidel Sofia / Sofia 2 - waived	127	125	2
Quidel Solana	1	1	-
Roche cobas Liat	10	10	-
Sekisui OSOM Influenza A&B	7	7	-
Sekisui OSOM Ultra -waived	24	24	-

Antigen(s) present: Influenza A.

INFLUENZA A ANTIGEN DETECTION

Specimen V-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	28	28	-
Alere Binax NOW - waived	1	1	-
Alere i Instrument - waived	1	1	-
BD Veritor - moderate	4	4	-
BD Veritor - waived	1	1	-
Consult Diagnostics Influenza A & B	2	2	-
Meridian ImmunoCard STAT - waived	6	6	-
Quidel QuickVue Influenza A+B	2	2	-
Quidel Sofia / Sofia 2 - waived	9	9	-
Quidel Solana	1	1	-
Sekisui OSOM Influenza A&B	1	1	-

Antigen(s) present: Influenza A.

Specimen V-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	28	-	28
Alere Binax NOW - waived	1	-	1
Alere i Instrument - waived	1	-	1
BD Veritor - moderate	4	-	4
BD Veritor - waived	1	-	1
Consult Diagnostics Influenza A & B	2	-	2
Meridian ImmunoCard STAT - waived	6	-	6
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia / Sofia 2 - waived	9	-	9
Quidel Solana	1	-	1
Sekisui OSOM Influenza A&B	1	-	1

Antigen(s) present: Influenza B.

Specimen V-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	28	-	28
Alere Binax NOW - waived	1	-	1
Alere i Instrument - waived	1	-	1
BD Veritor - moderate	4	-	4
BD Veritor - waived	1	-	1
Consult Diagnostics Influenza A & B	2	-	2
Meridian ImmunoCard STAT - waived	6	-	6
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia / Sofia 2 - waived	9	-	9
Quidel Solana	1	-	1
Sekisui OSOM Influenza A&B	1	-	1

Antigen(s) present: No antigen present.

INFLUENZA B ANTIGEN DETECTION

Specimen V-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	274	4	270
Alere Binax NOW - waived	7	-	7
Alere i Instrument - moderate	1	-	1
Alere i Instrument - waived	9	-	9
Alere Influenza A&B	11	1	10
BD Veritor - moderate	4	-	4
BD Veritor - waived	42	-	42
BioSign Flu A+B	1	-	1
Cepheid GeneXpert - waived	14	1	13
Consult Diagnostics Influenza A & B	9	-	9
Henry Schein OneStep+ Flu A&B	5	-	5
Meridian ImmunoCard STAT - waived	2	-	2
OraSure QuickFlu	2	1	1
Quidel QuickVue Influenza A+B	1	-	1
Quidel Sofia / Sofia 2 - waived	16	-	16
Quidel Solana	123	1	122
Roche cobas Liat	1	-	1
Sekisui OSOM Influenza A&B	3	-	3
Sekisui OSOM Ultra -waived	2	-	2

Antigen(s) present: RSV.

Specimen V-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	301	1	300
Alere Binax NOW - waived	4	-	4
Alere i Instrument - moderate	1	-	1
Alere i Instrument - waived	10	-	10
Alere Influenza A&B	5	-	5
BD Veritor - moderate	4	-	4
BD Veritor - waived	53	-	53
BioSign Flu A+B	2	-	2
Cepheid GeneXpert - waived	7	-	7
Consult Diagnostics Influenza A & B	19	-	19
Henry Schein OneStep+ Flu A&B	2	-	2
Meridian ImmunoCard STAT - waived	7	-	7
OraSure QuickFlu	2	-	2
Quidel QuickVue Influenza A+B	15	1	14
Quidel Sofia / Sofia 2 - waived	126	-	126
Quidel Solana	1	-	1
Roche cobas Liat	10	-	10
Sekisui OSOM Influenza A&B	7	-	7
Sekisui OSOM Ultra -waived	24	-	24

Antigen(s) present: Influenza A.

INFLUENZA B ANTIGEN DETECTION

Specimen V-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	28	-	28
Alere Binax NOW - waived	1	-	1
Alere i Instrument - waived	1	-	1
BD Veritor - moderate	4	-	4
BD Veritor - waived	1	-	1
Consult Diagnostics Influenza A & B	2	-	2
Meridian ImmunoCard STAT - waived	6	-	6
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia / Sofia 2 - waived	9	-	9
Quidel Solana	1	-	1
Sekisui OSOM Influenza A&B	1	-	1

Antigen(s) present: Influenza A.

Specimen V-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	28	28	-
Alere Binax NOW - waived	1	1	-
Alere i Instrument - waived	1	1	-
BD Veritor - moderate	4	4	-
BD Veritor - waived	1	1	-
Consult Diagnostics Influenza A & B	2	2	-
Meridian ImmunoCard STAT - waived	6	6	-
Quidel QuickVue Influenza A+B	2	2	-
Quidel Sofia / Sofia 2 - waived	9	9	-
Quidel Solana	1	1	-
Sekisui OSOM Influenza A&B	1	1	-

Antigen(s) present: Influenza B.

INFLUENZA B ANTIGEN DETECTION

Specimen V-5

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	28	-	28
Alere Binax NOW - waived	1	-	1
Alere i Instrument - waived	1	-	1
BD Veritor - moderate	4	-	4
BD Veritor - waived	1	-	1
Consult Diagnostics Influenza A & B	2	-	2
Meridian ImmunoCard STAT - waived	6	-	6
Quidel QuickVue Influenza A+B	2	-	2
Quidel Sofia / Sofia 2 - waived	9	-	9
Quidel Solana	1	-	1
Sekisui OSOM Influenza A&B	1	-	1

Antigen(s) present: No antigen present.

CLOSTRIDIOIDES DIFFICILE ANTIGEN DETECTION

Specimen AG-1

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	5	-
Alere C. diff Quik Chek	5	5	-

Antigen(s) present: *Clostridioides difficile*.

Specimen AG-2

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	-	5
Alere C. diff Quik Chek	5	-	5

Antigen(s) present: No antigen present.

Specimen AG-3

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	5	-
Alere C. diff Quik Chek	5	5	-

Antigen(s) present: *Clostridioides difficile*.

Specimen AG-4

Method	*Labs*	*Positive*	*Negative*
ALL METHODS	5	5	-
Alere C. diff Quik Chek	5	5	-

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

CLOSTRIDIOIDES DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-5

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Alere C. diff Quik Chek	5	-	5

Antigen(s) present: Rotavirus.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-1

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Fisher HealthCare Sure-Vue	5	-	5

Antigen(s) present: *Clostridioides difficile*.

Specimen AG-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Fisher HealthCare Sure-Vue	5	-	5

Antigen(s) present: No antigen present.

Specimen AG-3

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Fisher HealthCare Sure-Vue	5	-	5

Antigen(s) present: *Clostridioides difficile.*

Specimen AG-4

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Fisher HealthCare Sure-Vue	5	5	-

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

Specimen AG-5

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Fisher HealthCare Sure-Vue	5	5	-

Antigen(s) present: Rotavirus.

LEGIONELLA ANTIGEN DETETION

Specimen L-1

Method	***Labs***	***Positive***	***Negative***
Binax NOW	12	12	-

Specimen L-2

Method	***Labs***	***Positive***	***Negative***
Binax NOW	12	-	12

Specimen L-3

Method	***Labs***	***Positive***	***Negative***
Binax NOW	12	-	12

Specimen L-4

Method	***Labs***	***Positive***	***Negative***
Binax NOW	12	12	-

Specimen L-5

Method	***Labs***	***Positive***	***Negative***
Binax NOW	12	-	12

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-1

Method	***Labs***	***Positive***	***Negative***
Binax NOW	11	11	-

Specimen SP-2

Method	***Labs***	***Positive***	***Negative***
Binax NOW	11	-	11

Specimen SP-3

Method	***Labs***	***Positive***	***Negative***
Binax NOW	11	11	-

Specimen SP-4

Method	***Labs***	***Positive***	***Negative***
Binax NOW	11	-	11

Specimen SP-5

Method	***Labs***	***Positive***	***Negative***
Binax NOW	11	-	11

PARASITOLOGY

Specimen PA-1

Identification	***Labs***	***Percent***	***Performance***
Giardia lamblia	1	100%	Acceptable

Parasite(s) present: *Giardia lamblia.*

Specimen PA-2

Identification	***Labs***	***Percent***	***Performance***
Dientamoeba fragilis	1	100%	Acceptable

Parasite(s) present: *Dientamoeba fragilis*.

Specimen PA-3

Identification	***Labs***	***Percent***	***Performance***
No parasite seen	1	100%	Acceptable

Parasite(s) present: No parasite seen but Pollen artifact seen.

Specimen PA-4

Identification	***Labs***	***Percent***	***Performance***
Taenia sp. Eggs	1	100%	Acceptable

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

Specimen PA-5

Identification	***Labs***	***Percent***	***Performance***
Plasmodium sp.	1	100%	Acceptable

Parasite(s) present: *Plasmodium falciparum.*

DERMATOPHYTE CULTURE

Specimen DM-1

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte present	8	100%	Acceptable

Organism(s) present: *Microsporum canis* and *Streptococcus mitis.*

Specimen DM-2

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte present	5	62.50%	Ungraded
Dermatophyte absent	3	37.50%	

Organism(s) present: *Sporothrix schenckii*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen DM-3

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte present	7	87.50%	Acceptable
Dermatophyte absent	1	12.50%	

Organism(s) present: *Trichophyton tonsurans and Pantoea agglomerans.*

Specimen DM-4

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte absent	7	87.50%	Acceptable
Dermatophytes present	1	12.50%	

Organism(s) present: *Staphylococcus epidermidis.*

Specimen DM-5

Identification	***Labs***	***Percent***	***Performance***
Dermatophyte present	6	75.00%	Ungraded
Dermatophyte absent	2	25.00%	

Organism(s) present: *Trichophyton rubrum and Pseudomonas aeruginosa.* This is an ungraded challenge due to less than 80% participant consensus

BACTERIAL VAGINOSIS – OSOM - WAIVED

Specimen BV-1

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	8	-	8
Sekisui OSOM	8	-	8

Antigen(s) present: No antigen present.

Specimen BV-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	8	8	-
Sekisui OSOM	8	8	-

Antigen(s) present: *Gardnerella vaginalis.*

TRICHOMONAS VAGINALIS – OSOM - WAIVED

Specimen TR-1

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	5	-
Sekisui OSOM	5	5	-

Antigen(s) present: *Trichomonas vaginalis.*

Specimen TR-2

Method	***Labs***	***Positive***	***Negative***
ALL METHODS	5	-	5
Sekisui OSOM	5	-	5

Antigen(s) present: No antigen present.

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