

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

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

Microbiology
MLE – M1

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2006 Evaluation Criteria 2

Microbiology

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2006 Evaluation Criteria

The evaluation criteria used in the 2006 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.

Bacterial Identification	80% Consensus	Rotavirus Antigen Detection	80% Consensus
Urine Presumptive Identification	80% Consensus	RSV Antigen Detection	80% Consensus
Colony Count	80% Consensus	GC (EIA, DNA)	80% Consensus
Parasite Identification	80% Consensus	Antimicrobial Susceptibility Testing	80% Consensus
Strep A Antigen Detection	80% Consensus	Gram Stain	80% Consensus
Affirm VP III Gardnerella Ag Detection	80% Consensus	Gram Stain Morphology	Not Graded
Affirm VP III Candida Antigen Detection	80% Consensus	Beta-lactamase Testing	Not Graded
Affirm VP III Trichomonas Ag Detection	80% Consensus	C. Difficile Toxin/Antigen Detection	80% Consensus
Chlamydia (EIA, DNA)	80% Consensus	Dermatophyte Screen	80% Consensus
Cryptosporidium Antigen Detection	80% Consensus	Legionella Antigen Detection	80% Consensus
Giardia lamblia Antigen Detection	80% Consensus	Streptococcus pneumoniae Antigen Detection	80% Consensus
Influenza A/B Antigen Detection	80% Consensus		
Influenza A Antigen Detection	80% Consensus		
Influenza B Antigen Detection	80% Consensus		

THROAT CULTURE

Specimen TC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	114	52.7%	Acceptable
Presump. Pos. Group A Strep	82	37.96%	Acceptable
Streptococcus pyogenes	13	6.02%	Acceptable
Gram positive cocci	1	0.46%	Acceptable
Negative for Group A Strep	5	2.31%	

Organisms present in specimen TC-1: *Streptococcus pyogenes* and *Staphylococcus epidermidis*.

Specimen TC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	192	90.14%	Acceptable
Streptococcus pneumoniae	9	4.23%	Acceptable
Streptococcus alpha-hemolytic	3	1.41%	Acceptable
Gram positive cocci	1	0.47%	Acceptable
Growth, referred for identification	1	0.47%	Acceptable

Organism present in specimen TC-2: *Streptococcus pneumoniae*.

Specimen TC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	47	51.09%	Acceptable
Presump. Pos. Group A Strep	41	44.57%	Acceptable
Streptococcus pyogenes	1	1.09%	Acceptable
Gram positive cocci	1	1.09%	Acceptable

Organism present in specimen TC-3: *Streptococcus pyogenes*.

Specimen TC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	45	56.25%	Acceptable
Presump. Pos. Group A Strep	31	38.75%	Acceptable
Streptococcus pyogenes	1	1.25%	Acceptable

Organisms present in specimen TC-4: *Streptococcus pyogenes* and *Staphylococcus epidermidis*.

Specimen TC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	69	85.19%	Acceptable
No growth (sterile)	11	13.58%	Acceptable

Organism present in specimen TC-5: *Haemophilus influenzae*.

STREP A ANTIGEN DETECTION

Specimen RS-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	699	5	694
Abbott Signify Strep A-waived	43	-	43
Abbott TESTPACK	1	-	1
Applied Biotech Signify	9	-	9
Applied Biotech SureStep II - waived	2	-	2
BD LINK 2	1	-	1
BD QTest	26	2	24
Beckman Coulter ICON DS	19	-	19
Beckman Coulter ICON Fx Strep A	2	-	2
Beckman Coulter ICON SC	10	-	10
Binax NOW Strep A	3	-	3
BioStar Acceava Strep A Test	52	-	52
BioStar Strep A MAX OIA	31	1	30
Cardinal Health Strep A - waived	21	-	21
DE Healthcare TruView	4	-	4
Fisher HealthCare Sure-Vue	5	-	5
Fisher HealthCare Sure-Vue - waived	2	-	2
Genzyme OSOM	2	-	2
Genzyme OSOM Ultra Strep A	71	-	71
Henry Schein One Step	8	1	7
Instant Technologies i Strep	6	-	6
Inverness Signify Strep A Dipstick	17	-	17
LifeSign Status Strep A	1	-	1
Mainline Confirms	3	-	3
Mainline Confirms Strep A Dots	1	-	1
McKesson Strep A Cassette	10	-	10
McKesson Strep A Dipstick	6	-	6
Polymedco Poly Stat Strep A - moderate	19	-	19
Polymedco Poly Stat Strep A - waived	20	-	20
Polymedco Strep A Liquid Test	2	-	2
Quidel QuickVue Dipstick Strep	83	1	82
Quidel QuickVue In-Line	89	-	89
Quidel QuickVue+	93	-	93
Stanbio QuStick Strep A	1	-	1
Wampole Clearview	3	-	3
Wyntek OSOM Strep A - waived	2	-	2

STREP A ANTIGEN DETECTION

Specimen RS-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>	<u>Strength of Reaction</u>		
				<u>Strong</u>	<u>Moderate</u>	<u>Weak</u>
ALL METHODS	669	654	15	471	123	11
Abbott Signify Strep A-waived	40	40	-	28	10	2
Abbott TESTPACK	1	1	-	1	-	-
Applied Biotech Signify	8	8	-	3	2	-
Applied Biotech SureStep II - waived	2	2	-	-	1	-
BD LINK 2	1	1	-	-	1	-
BD QTest	23	23	-	18	5	-
Beckman Coulter ICON DS	19	19	-	9	10	-
Beckman Coulter ICON Fx Strep A	2	2	-	-	2	-
Beckman Coulter ICON SC	10	10	-	7	3	-
Binax NOW Strep A	3	3	-	2	1	-
BioStar Aceava Strep A Test	51	51	-	35	12	-
BioStar Strep A MAX OIA	30	30	-	25	1	1
Cardinal Health Strep A - waived	21	21	-	6	-	-
DE Healthcare TruView	3	3	-	2	1	-
Fisher HealthCare Sure-Vue	2	2	-	2	-	-
Fisher HealthCare Sure-Vue - waived	2	2	-	1	-	-
Genzyme OSOM	2	2	-	3	-	-
Genzyme OSOM Ultra Strep A	69	69	-	41	19	-
Henry Schein One Step	8	8	-	5	3	-
Instant Technologies i Strep	6	6	-	4	2	-
Inverness Signify Strep A Dipstick	16	16	-	14	2	-
LifeSign Status Strep A	1	1	-	1	-	-
Mainline Confirms	1	1	-	1	-	-
Mainline Confirms Strep A Dots	1	1	-	-	1	-
McKesson Strep A Cassette	9	9	-	6	2	-
McKesson Strep A Dipstick	6	6	-	5	1	-
Polymedco Poly Stat Strep A - moderate	19	19	-	13	6	-
Polymedco Poly Stat Strep A - waived	20	20	-	11	7	-
Polymedco Strep A Liquid Test	2	2	-	1	1	-
Quidel QuickVue Dipstick Strep	82	80	2	68	9	-
Quidel QuickVue In-Line	88	76	12	56	6	7
Quidel QuickVue+	87	86	1	76	4	1
Stanbio QuStick Strep A	1	1	-	-	1	-
Wampole Clearview	3	3	-	3	-	-
Wyntek OSOM Strep A - waived	2	2	-	-	-	-

STREP A ANTIGEN DETECTION

Specimen RS-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	369	4	365
Abbott Signify Strep A-waived	23	-	23
Abbott TESTPACK	1	-	1
Applied Biotech Signify	6	-	6
Applied Biotech SureStep II - waived	2	-	2
BD QTest	21	2	19
Beckman Coulter ICON DS	7	-	7
Beckman Coulter ICON Fx Strep A	2	-	2
Beckman Coulter ICON SC	7	-	7
Binax NOW Strep A	3	-	3
BioStar Acceava Strep A Test	22	-	22
BioStar Strep A MAX OIA	30	-	30
Cardinal Health Strep A - waived	17	-	17
DE Healthcare TruView	2	1	1
Fisher HealthCare Sure-Vue	1	-	1
Fisher HealthCare Sure-Vue - waived	2	-	2
Genzyme OSOM	2	-	2
Genzyme OSOM Ultra Strep A	32	-	32
Henry Schein One Step	3	-	3
Instant Technologies i Strep	3	-	3
Inverness Signify Strep A Dipstick	3	-	3
Mainline Confirms	1	-	1
Mainline Confirms Strep A Dots	1	-	1
McKesson Strep A Cassette	5	-	5
McKesson Strep A Dipstick	2	-	2
Polymedco Poly Stat Strep A - moderate	19	-	19
Polymedco Poly Stat Strep A - waived	7	-	7
Quidel QuickVue Dipstick Strep	19	-	19
Quidel QuickVue In-Line	27	-	27
Quidel QuickVue+	82	1	81
Wampole Clearview	2	-	2
Wyntek OSOM Strep A - waived	1	-	1

STREP A ANTIGEN DETECTION

Specimen RS-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	312	4	308
Abbott Signify Strep A-waived	20	-	20
Applied Biotech Signify	6	-	6
Applied Biotech SureStep II - waived	2	-	2
BD QTest	18	2	16
Beckman Coulter ICON DS	7	-	7
Beckman Coulter ICON Fx Strep A	2	-	2
Beckman Coulter ICON SC	4	-	4
Binax NOW Strep A	3	-	3
BioStar Aceava Strep A Test	19	-	19
BioStar Strep A MAX OIA	30	-	30
Cardinal Health Strep A - waived	15	-	15
DE Healthcare TruView	2	-	2
Fisher HealthCare Sure-Vue	1	-	1
Fisher HealthCare Sure-Vue - waived	2	-	2
Genzyme OSOM	2	-	2
Genzyme OSOM Ultra Strep A	24	-	24
Henry Schein One Step	2	-	2
Instant Technologies i Strep	2	-	2
Inverness Signify Strep A Dipstick	3	-	3
Mainline Confirms	1	-	1
Mainline Confirms Strep A Dots	1	-	1
McKesson Strep A Cassette	4	-	4
McKesson Strep A Dipstick	1	-	1
Polymedco Poly Stat Strep A - moderate	18	-	18
Polymedco Poly Stat Strep A - waived	5	-	5
Quidel QuickVue Dipstick Strep	11	-	11
Quidel QuickVue In-Line	25	1	24
Quidel QuickVue+	68	1	67
Wampole Clearview	2	-	2

STREP A ANTIGEN DETECTION

Specimen RS-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>	<u>Strength of Reaction</u>		
				<u>Strong</u>	<u>Moderate</u>	<u>Weak</u>
ALL METHODS	312	308	4	222	52	8
Abbott Signify Strep A-waived	20	20	-	10	8	1
Applied Biotech Signify	6	6	-	3	-	-
Applied Biotech SureStep II - waived	2	2	-	-	1	-
BD QTest	18	18	-	11	7	-
Beckman Coulter ICON DS	7	7	-	4	2	1
Beckman Coulter ICON Fx Strep A	2	2	-	2	-	-
Beckman Coulter ICON SC	4	4	-	4	-	-
Binax NOW Strep A	3	3	-	2	1	-
BioStar Aceava Strep A Test	19	19	-	12	3	1
BioStar Strep A MAX OIA	30	30	-	27	-	-
Cardinal Health Strep A - waived	15	15	-	4	-	-
DE Healthcare TruView	2	2	-	1	1	-
Fisher HealthCare Sure-Vue	1	1	-	-	1	-
Fisher HealthCare Sure-Vue - waived	2	1	1	-	-	1
Genzyme OSOM	2	2	-	2	-	-
Genzyme OSOM Ultra Strep A	24	24	-	13	8	1
Henry Schein One Step	2	2	-	2	-	-
Instant Technologies i Strep	2	2	-	2	-	-
Inverness Signify Strep A Dipstick	3	3	-	3	-	-
Mainline Confirms	1	1	-	-	1	-
Mainline Confirms Strep A Dots	1	1	-	1	-	-
McKesson Strep A Cassette	4	4	-	2	1	-
McKesson Strep A Dipstick	1	1	-	-	1	-
Polymedco Poly Stat Strep A - moderate	18	18	-	13	5	-
Polymedco Poly Stat Strep A - waived	5	5	-	3	1	-
Quidel QuickVue Dipstick Strep	11	11	-	9	2	-
Quidel QuickVue In-Line	25	22	3	15	4	-
Quidel QuickVue+	68	68	-	60	3	1
Wampole Clearview	2	2	-	2	-	-

GENERAL BACTERIOLOGY

Specimen UC-1 – Urine Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Escherichia coli	14	100%	Acceptable
<u>Gram Stain</u>			
Gram negative	9	100%	Acceptable
<u>Gram Stain Morphology</u>			
Rods/bacilli	9	100%	

Organism present in specimen UC-1: *Escherichia coli*.

GENERAL BACTERIOLOGY

Specimen TC-1 – Throat Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Streptococcus pyogenes	10	83.33%	Acceptable
Positive for Group A Strep	1	8.33%	Acceptable

Organisms present in specimen TC-1: *Streptococcus pyogenes* and *Staphylococcus epidermidis*.

Specimen BA-1 – Respiratory Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Haemophilus influenzae	8	66.67%	Acceptable
Staph – coagulase negative	2	16.67%	Acceptable
Staphylococcus epidermidis	1	8.33%	Acceptable
Growth, referred for identification	1	8.33%	Acceptable

Organisms present in specimen BA-1: *Haemophilus influenzae* and *Staphylococcus epidermidis*.

Specimen BA-2 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pseudomonas aeruginosa	9	100%	Acceptable

Organism present in specimen BA-2: *Pseudomonas aeruginosa*.

Specimen BA-3 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus aureus	10	100%	Acceptable

Organisms present in specimen BA-3: *Staphylococcus aureus* and *Staphylococcus epidermidis*.

URINE CULTURE

Specimen UC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Escherichia coli	69	47.9%	Acceptable
Growth, referred for identification	28	19.44%	Acceptable
Gram negative bacilli	20	13.89%	Acceptable
Presump. Gram negative	18	12.50%	Acceptable
Presump. Escherichia coli	9	6.25%	Acceptable

Gram Stain

Gram negative	66	100%	Acceptable
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Gram Stain Morphology

Rods/bacilli	63	100%	
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Organism present in specimen UC-1: *Escherichia coli*.

Specimen UC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	52	29.5%	Acceptable
Enterococcus sp.	30	16.76%	Acceptable
Gram positive cocci	19	10.61%	Acceptable
Presump. Gram positive	14	7.82%	Acceptable
Corynebacterium sp.	11	6.15%	Acceptable
Enterococcus (Strep) faecium	10	5.59%	Acceptable
Presump. Enterococcus sp.	4	2.23%	Acceptable
Streptococcus Group D	3	1.68%	Acceptable
Strep. Grp. D – enterococcus	3	1.68%	Acceptable
Streptococcus alpha-hemolytic	2	1.12%	Acceptable
Gram positive bacilli	1	0.56%	Acceptable
Contaminated specimen	11	6.15%	
Staphylococcus sp.	5	2.79%	
Presump. Staphylococcus sp.	5	2.79%	

Organisms present in specimen UC-2: *Enterococcus faecium* and *Corynebacterium species*.

URINE CULTURE

Specimen UC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	21	23.33%	Acceptable
Gram negative bacilli	19	21.11%	Acceptable
Proteus mirabilis	18	20.00%	Acceptable
Presump. Gram negative	14	15.56%	Acceptable
Proteus sp.	8	8.89%	Acceptable
Presump. Proteus sp.	7	7.78%	Acceptable
Presump. Gram positive	1	1.11%	Acceptable

Organisms present in specimen UC-3: *Proteus mirabilis* and *Lactobacillus casei*.

Specimen UC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No growth (sterile)	53	96.36%	Acceptable

Organism present in specimen UC-4: Negative – Sterile Culture.

Specimen UC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	17	30.91%	Acceptable
Presump. Gram positive	11	20.00%	Acceptable
Staphylococcus aureus	10	18.18%	Acceptable
Gram positive cocci	10	18.18%	Acceptable
Staphylococcus sp.	4	7.27%	Acceptable
Presump. Staphylococcus sp.	2	3.64%	Acceptable

Organisms present in specimen UC-5: *Staphylococcus aureus* and *Lactobacillus casei*.

ANTIMICROBIAL SUSCEPTIBILITY TESTING
Specimen UC-1, CC-1 (SUS-1)

<u>Antimicrobial</u>	-----Agar Diffusion-----				-----MIC-----				<u>Acceptable (%)</u>
	<i>Interpretative category data</i>				<i>Interpretative category data</i>				
	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	<u>Labs</u>	<u>S</u>	<u>I</u>	<u>R</u>	
Amikacin	1	1	-	-	7	7	-	-	100%
Amoxicillin/Clavulanate	14	13	1	-	16	16	-	-	97.3%
Ampicillin	73	71	1	1	24	24	-	-	98.4%
Ampicillin/Sulbactam	-	-	-	-	8	8	-	-	100%
Aztreonam	-	-	-	-	3	3	-	-	100%
Carbenicillin	26	26	-	-	2	2	-	-	100%
Cefaclor	2	2	-	-	-	-	-	-	100%
Cefazolin	11	11	-	-	10	10	-	-	100%
Cefepime	-	-	-	-	2	2	-	-	100%
Cefixime	8	8	-	-	-	-	-	-	100%
Cefotaxime	1	1	-	-	3	3	-	-	100%
Cefotetan	-	-	-	-	1	1	-	-	100%
Cefoxitin	2	2	-	-	-	-	-	-	100%
Ceftazidime	3	3	-	-	9	9	-	-	100%
Ceftizoxime	1	1	-	-	-	-	-	-	100%
Ceftriaxone	6	6	-	-	13	13	-	-	100%
Cefuroxime	5	5	-	-	10	10	-	-	100%
Cephalothin	73	54	13	6	21	16	5	-	Not graded ¹
Cinoxacin	3	3	-	-	1	1	-	-	100%
Ciprofloxacin	74	74	-	-	23	23	-	-	100%
Doxycycline	5	5	-	-	2	2	-	-	100%
Fosfomycin	1	1	-	-	-	-	-	-	100%
Gatifloxacin	1	1	-	-	5	5	-	-	100%
Gentamicin	38	38	-	-	17	17	-	-	100%
Imipenem	1	1	-	-	4	4	-	-	100%
Kanamycin	1	1	-	-	-	-	-	-	100%
Levofloxacin	15	15	-	-	16	16	-	-	100%
Lomefloxacin	2	2	-	-	2	2	-	-	100%
Loracarbef	1	1	-	-	-	-	-	-	100%
Mezlocillin	1	1	-	-	-	-	-	-	100%
Nalidixic Acid	3	3	-	-	1	1	-	-	100%
Nitrofurantoin	84	84	-	-	25	24	-	1	99.3%
Norfloxacin	23	23	-	-	8	8	-	-	100%
Ofloxacin	25	25	-	-	5	5	-	-	100%
Piperacillin	1	1	-	-	6	6	-	-	100%
Piperacillin/Tazobactam	-	-	-	-	4	4	-	-	100%
Sulfamethoxazole	7	7	-	-	3	3	-	-	100%
Sulfisoxazole	6	5	-	1	2	1	-	1	83.3%
Tetracycline	49	48	1	-	16	15	-	1	97.5%
Ticarcillin	-	-	-	-	2	2	-	-	100%
Ticarcillin/Clavulanate	1	1	-	-	5	5	-	-	100%
Tobramycin	4	4	-	-	11	11	-	-	100%
Trimethoprim	8	8	-	-	10	10	-	-	100%
Trimethoprim/Sulfamethoxazole	80	80	-	-	22	22	-	-	100%

Organism present in specimen UC-1, CC-1 (SUS-1): Escherichia coli

¹ This is an ungraded challenge due to less than 80% participant consensus.

GC CULTURE

Specimen GC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	25	52.08%	Acceptable
Neisseria gonorrhoeae	21	43.75%	Acceptable
Growth select media, referred	1	2.08%	Acceptable

Beta-lactamase Testing

Negative	7	100%
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Gram Stain

Gram negative	39	100%
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Gram Stain Morphology

Diplococci	38	88.37%
Cocci in pairs	3	6.98%
Cocci	2	4.65%

Organism present in specimen GC-1: *Neisseria gonorrhoeae*.

Specimen GC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	14	58.33%	Acceptable
No growth (sterile)	10	41.67%	Acceptable

Organisms present in specimen GC-2: *Streptococcus agalactiae* and *Lactobacillus casei*.

Specimen GC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	14	63.64%	Acceptable
Neisseria gonorrhoeae	7	31.82%	Acceptable
Growth select media, referred	1	4.55%	Acceptable

Beta-lactamase Testing

Negative	3	75.00%
Positive	1	25.00%

Organism present in specimen GC-3: *Neisseria gonorrhoeae*.

GC CULTURE

Specimen GC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	15	68.18%	Acceptable
Neisseria gonorrhoeae	6	27.27%	Acceptable
Growth select media, referred	1	4.55%	Acceptable

Beta-lactamase Testing

Negative	4	100%
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Organisms present in specimen GC-4: *Neisseria gonorrhoeae* and *Staphylococcus epidermidis*.

Specimen GC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	13	59.09%	Acceptable
No growth (sterile)	9	40.91%	Acceptable

Organisms present in specimen GC-5: *Gardnerella vaginalis*.

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	115	1	-	5	109
Bacti-Star	1	-	-	-	1
Bacturcult	3	-	-	-	3
Bulls Eye	7	-	-	-	7
Calibrated Loop	32	-	-	1	31
HealthLink	1	-	-	-	1
Henry Schein One Step	1	-	-	-	1
Uri-Check	17	-	-	1	16
Uricult	45	1	-	3	41
Uri-Kit	1	-	-	-	1
Uri-Three	1	-	-	-	1

Identification—Specimen CC-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Escherichia coli	22	48.89%	Acceptable
Presump. Gram negative	14	31.11%	Acceptable
Growth, referred for identification	6	13.33%	Acceptable
Escherichia coli	2	4.44%	Acceptable

Gram Stain

Gram negative	6	100%	Acceptable
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Gram Stain Morphology

Rods/bacilli	7	100%
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Organism present in specimen CC-1: >100,000 CFU/mL of *Escherichia coli*.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

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	114	4	11	55	44
Bacti-Star	1	-	-	1	-
Bacturcult	3	2	-	-	1
Bulls Eye	7	-	-	4	3
Calibrated Loop	31	-	-	14	17
HealthLink	1	-	-	1	-
Henry Schein One Step	1	-	1	-	-
Uri-Check	17	1	2	11	3
Uricult	45	1	6	22	16
Uri-Kit	1	-	-	1	-
Uri-Three	1	-	1	-	-

Identification–Specimen CC-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	22	44.90%	Acceptable
Presump. Enterococcus sp.	14	28.57%	Acceptable
Growth, referred for identification	7	14.29%	Acceptable
Enterococcus sp.	1	2.04%	Acceptable
Enterococcus (Strep) faecium	1	2.04%	Acceptable

Organisms present in specimen CC-2: >100,000 CFU/mL *Enterococcus faecium* and approximately 1,700 CFU/mL of *Corynebacterium* species.

Identification–Specimen CC-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram negative	12	37.50%	Acceptable
Presump. Proteus sp.	12	37.50%	Acceptable
Proteus mirabilis	3	9.38%	Acceptable
Growth, referred for identification	3	9.38%	Acceptable
Presump. Gram positive	1	3.13%	Acceptable

Organisms present in specimen CC-3: >100,000 CFU/mL of *Proteus mirabilis* and approximately 8,500 CFU/mL of *Lactobacillus casei*.

Identification–Specimen CC-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No growth (sterile)	31	100%	Acceptable

Organism present in specimen CC-4: Negative – Sterile culture.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Staphylococcus sp.	11	34.38%	Acceptable
Presump. Gram positive	10	31.25%	Acceptable
Staphylococcus aureus	3	9.38%	Acceptable
Growth, referred for identification	1	3.13%	Acceptable
Staphylococcus sp.	1	3.13%	Acceptable

Organisms present in specimen CC-5: 22,000 CFU/mL of *Staphylococcus aureus* and approximately 8,500 of *Lactobacillus casei*.

DERMATOPHYTE SCREEN

Specimen DM-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte present	21	100%	Acceptable

Organism present in specimen DM-1: *Tricophyton rubrum*.

Specimen DM-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte absent	21	100%	Acceptable

Organisms present in specimen DM-2: *Escherichia coli* and *Lactobacillus casei*.

GRAM STAIN

Specimen GS-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	54	98.18%	Acceptable
Gram positive	1	1.82%	

Gram Stain Morphology

Rods/bacilli	46	95.83%
Cocco-bacilli	2	4.17%

Organism present in specimen GS-1: *Escherichia coli*.

Specimen GS-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	54	98.18%	Acceptable
Gram negative	1	1.82%	

Gram Stain Morphology

Cocci	34	70.83%
Cocci in pairs	9	18.75%
Cocci in chains	4	8.33%
Diplococci	1	2.08%

Organism present in specimen GS-2: *Staphylococcus aureus*.

GRAM STAIN

Specimen GS-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	52	96.30%	Acceptable
Gram positive	2	3.70%	

Gram Stain Morphology

Rods/bacilli	45	95.74%
Cocco-bacilli	2	4.26%

Organism present in specimen GS-3: *Pseudomonas aeruginosa*.

Specimen GS-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	53	96.36%	Acceptable
Gram negative	2	3.64%	

Gram Stain Morphology

Cocci in chains	29	60.42%
Cocci	15	31.25%
Diplococci	4	8.33%

Organism present in specimen GS-4: Streptococcus species Group B.

Specimen GS-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	53	96.36%	Acceptable
Gram negative	2	3.64%	

Gram Stain Morphology

Cocci	20	41.67%
Cocci in pairs	14	29.17%
Diplococci	12	25.00%
Cocco-bacilli	2	4.17%

Organism present in specimen GS-5: *Streptococcus pneumoniae*.

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	24	96%	Acceptable
Negative	1	4%	

Organism present in specimen VP-1: *Trichomonas vaginalis*.

AFFIRM VP III–Trichomonas vaginalis

Specimen VP-2

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

Organism present in specimen VP-2: *Trichomonas vaginalis*.

Specimen VP-3

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

Organism present in specimen VP-3: *Candida albicans*.

Specimen VP-4

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

Organisms present in specimen VP-4: *Gardnerella vaginalis* and *Candida albicans*.

Specimen VP-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	22	88%	Acceptable
Negative	3	12%	

Organisms present in specimen VP-5: *Gardnerella vaginalis* and *Trichomonas vaginalis*.

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-1

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

Specimen VP-2

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

Specimen VP-3

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

AFFIRM VP III–Gardnerella vaginalis**Specimen VP-4**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	18	72%	Not graded
Negative	7	28%	

This specimen is ungraded due to lack of 80% referee consensus.

Specimen VP-5

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

AFFIRM VP III–Candida sp.**Specimen VP-1**

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

Specimen VP-2

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

Specimen VP-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	24	96%	Acceptable
Negative	1	4%	

Specimen VP-4

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

Specimen VP-5

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

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	23	23	-
BD ProbeTec	3	3	-
bioMerieux Vitek, Mini Vidas	1	1	-
BioStar OIA	3	3	-
Gen-Probe	3	3	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	11	11	-

Organism present in specimen CY-1: *Chlamydia trachomatis*.

Specimen CY-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	23	-	23
BD ProbeTec	3	-	3
bioMerieux Vitek, Mini Vidas	1	-	1
BioStar OIA	3	-	3
Gen-Probe	3	-	3
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	11	-	11

Organism present in specimen CY-2: *Neisseria gonorrhoeae*.

Specimen CY-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	16	1
BD ProbeTec	3	2	1
bioMerieux Vitek, Mini Vidas	1	1	-
BioStar OIA	3	3	-
Gen-Probe	3	3	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	5	5	-

Organism present in specimen CY-3: *Chlamydia trachomatis*.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	-	17
BD ProbeTec	3	-	3
bioMerieux Vitek, Mini Vidas	1	-	1
BioStar OIA	3	-	3
Gen-Probe	3	-	3
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	5	-	5

Organism present in specimen CY-4: *Neisseria gonorrhoeae*.

Specimen CY-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	17	-
BD ProbeTec	3	3	-
bioMerieux Vitek, Mini Vidas	1	1	-
BioStar OIA	3	3	-
Gen-Probe	3	3	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	5	5	-

Organisms present in specimen CY-5: *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

GC (ANTIGEN DETECTION)

Specimen CY-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	10	1	9
BD ProbeTec	3	1	2
BioStar OIA	3	-	3
Gen-Probe	3	-	3
Gen-Probe APTIMA	1	-	1

Specimen CY-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	10	10	-
BD ProbeTec	3	3	-
BioStar OIA	3	3	-
Gen-Probe	3	3	-
Gen-Probe APTIMA	1	1	-

GC (ANTIGEN DETECTION)

Specimen CY-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	10	-	10
BD ProbeTec	3	-	3
BioStar OIA	3	-	3
Gen-Probe	3	-	3
Gen-Probe APTIMA	1	-	1

Specimen CY-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	10	10	-
BD ProbeTec	3	3	-
BioStar OIA	3	3	-
Gen-Probe	3	3	-
Gen-Probe APTIMA	1	1	-

Specimen CY-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	10	10	-
BD ProbeTec	3	3	-
BioStar OIA	3	3	-
Gen-Probe	3	3	-
Gen-Probe APTIMA	1	1	-

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-1

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

Antigen present in specimen LC-1: *Giardia lamblia*.

Specimen LC-2

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

Antigen present in specimen LC-2: *Cryptosporidium*.

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-3

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

Antigen present in specimen LC-3: *Cryptosporidium*.

Specimen LC-4

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

Antigen present in specimen LC-4: *Giardia lamblia*.

Specimen LC-5

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

Antigens present in specimen LC-5: *Cryptosporidium* and *Giardia lamblia*.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	7	-
Alexon (Hycor)	1	1	-
Meridian ImmunoCard STAT	1	1	-
Remel Xpect	5	5	-

Specimen LC-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	7
Alexon (Hycor)	1	-	1
Meridian ImmunoCard STAT	1	-	1
Remel Xpect	5	-	5

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	7
Alexon (Hycor)	1	-	1
Meridian ImmunoCard STAT	1	-	1
Remel Xpect	5	-	5

Specimen LC-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	7	-
Alexon (Hycor)	1	1	-
Meridian ImmunoCard STAT	1	1	-
Remel Xpect	5	5	-

Specimen LC-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	7	-
Alexon (Hycor)	1	1	-
Meridian ImmunoCard STAT	1	1	-
Remel Xpect	5	5	-

RSV ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	35	20	15
BD Directigen	3	3	-
BD Directigen EZ	1	1	-
Binax NOW – waived	13	11	2
BioStar OIA	6	1	5
Fisher HealthCare Sure-Vue – waived	2	2	-
Remel Xpect – waived	1	-	1
Wampole Clearview RSV – waived	6	2	4

Specimen V-1: Positive for RSV antigen.

RSV ANTIGEN DETECTION

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	35	3	32
BD Directigen	3	-	3
BD Directigen EZ	1	-	1
Binax NOW – waived	13	-	13
BioStar OIA	6	-	6
Fisher HealthCare Sure-Vue – waived	2	-	2
Remel Xpect – waived	1	-	1
Wampole Clearview RSV – waived	6	-	6

Specimen V-2: Negative for RSV antigen.

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	26	-	26
BD Directigen	3	-	3
BD Directigen EZ	1	-	1
Binax NOW – waived	10	-	10
BioStar OIA	6	-	6
Fisher HealthCare Sure-Vue – waived	2	-	2
Remel Xpect – waived	1	-	1
Wampole Clearview RSV – waived	10	-	10

Specimen V-3: Negative for RSV antigen.

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	26	17	9
BD Directigen	3	2	1
BD Directigen EZ	1	1	-
Binax NOW – waived	10	9	1
BioStar OIA	6	-	6
Fisher HealthCare Sure-Vue – waived	2	2	-
Remel Xpect – waived	1	1	-
Wampole Clearview RSV – waived	2	2	-

Specimen V-4: Positive for RSV antigen.

RSV ANTIGEN DETECTION

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	26	1	25
BD Directigen	3	-	3
BD Directigen EZ	1	-	1
Binax NOW – waived	10	-	10
BioStar OIA	6	1	5
Fisher HealthCare Sure-Vue – waived	2	-	2
Remel Xpect – waived	1	-	1
Wampole Clearview RSV – waived	2	-	2

Specimen V-5: Negative for RSV antigen.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	103	2	101
Biostar OIA	9	1	8
Quidel QuickVue Influenza	88	1	87

Specimen V-1: Negative for Influenza A/B antigen.

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	102	98	4
BioStar OIA	9	7	2
Quidel QuickVue Influenza	87	86	1

Specimen V-2: Positive for Influenza A/B antigen.

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	31	18	13
BioStar OIA	7	1	6
Quidel QuickVue Influenza	22	15	7

Specimen V-3: Positive for Influenza A/B antigen.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	31	1	30
BioStar OIA	7	1	6
Quidel QuickVue Influenza	22	-	22

Specimen V-4: Negative for Influenza A/B antigen.

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	31	30	1
BioStar OIA	7	6	1
Quidel QuickVue Influenza	22	22	-

Specimen V-5: Positive for Influenza A/B antigen.

INFLUENZA A ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	84	3	81
BD Directigen	4	-	4
Binax NOW – waived	12	-	12
BioStar Flu OIA A/B	8	-	8
Quidel QuickVue Influenza A+B	46	1	45
Remel Xpect	6	1	5
Wampole Clearview	2	-	2

Specimen V-1: Negative for Influenza A antigen.

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	85	83	2
BD Directigen	4	4	-
Binax NOW – waived	12	12	-
BioStar Flu OIA A/B	8	7	1
Quidel QuickVue Influenza A+B	46	45	1
Remel Xpect	6	6	-
Wampole Clearview	2	2	-

Specimen V-2: Positive for Influenza A antigen.

INFLUENZA A ANTIGEN DETECTION

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	44	-	44
BD Directigen	3	-	3
Binax Now – waived	5	-	5
BioStar Flu OIA A/B	8	-	8
Quidel QuickVue Influenza A+B	16	-	16
Remel Xpect	6	-	6
Wampole Clearview	2	-	2

Specimen V-3: Negative for Influenza A antigen.

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	44	-	44
BD Directigen	3	-	3
Binax NOW – waived	5	-	5
BioStar Flu OIA A/B	8	-	8
Quidel QuickVue Influenza A+B	16	-	16
Remel Xpect	6	-	6
Wampole Clearview	2	-	2

Specimen V-4: Negative for Influenza A antigen.

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	44	42	2
BD Directigen	3	2	1
Binax NOW – waived	5	5	-
BioStar Flu OIA A/B	8	7	1
Quidel QuickVue Influenza A+B	16	16	-
Remel Xpect	6	6	-
Wampole Clearview	2	2	-

Specimen V-5: Positive for Influenza A antigen.

INFLUENZA B ANTIGEN DETECTION

Specimen V-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	82	-	82
BD Directigen	4	-	4
Binax NOW – waived	11	-	11
BioStar Flu OIA A/B	8	-	8
Quidel QuickVue Influenza A+B	45	-	45
Remel Xpect	6	-	6
Wampole Clearview	2	-	2

Specimen V-1: Negative for Influenza B antigen.

Specimen V-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	82	1	81
BD Directigen	4	-	4
Binax NOW – waived	11	-	11
BioStar Flu OIA A/B	8	-	8
Quidel QuickVue Influenza A+B	45	1	44
Remel Xpect	6	-	6
Wampole Clearview	2	-	2

Specimen V-2: Negative for Influenza B antigen.

Specimen V-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	43	29	14
BD Directigen	3	2	1
Binax NOW – waived	4	4	-
BioStar Flu OIA A/B	8	-	8
Quidel QuickVue Influenza A+B	16	14	2
Remel Xpect	6	5	1
Wampole Clearview	2	-	2

Specimen V-3: Positive for Influenza B antigen.

INFLUENZA B ANTIGEN DETECTION

Specimen V-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	43	-	43
BD Directigen	3	-	3
Binax NOW – waived	4	-	4
BioStar Flu OIA A/B	8	-	8
Quidel QuickVue Influenza A+B	16	-	16
Remel Xpect	6	-	6
Wampole Clearview	2	-	2

Specimen V-4: Negative for Influenza B antigen.

Specimen V-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	43	-	43
BD Directigen	3	-	3
Binax NOW – waived	4	-	4
BioStar Flu OIA A/B	8	-	8
Quidel QuickVue Influenza A+B	16	-	16
Remel Xpect	6	-	6
Wampole Clearview	2	-	2

Specimen V-5: Negative for Influenza B antigen.

LEGIONELLA ANTIGEN DETECTION

Specimen L-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	83	-	83

Specimen L-1: Negative for Legionella antigen.

Specimen L-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	83	-	83

Specimen L-2: Negative for Legionella antigen.

Specimen L-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	83	83	-

Specimen L-3: Positive for Legionella antigen.

LEGIONELLA ANTIGEN DETECTION

Specimen L-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	83	83	-

Specimen L-4: Positive for Legionella antigen.

Specimen L-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	83	-	83

Specimen L-5: Negative for Legionella antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	-	18
Alexon (Hycor)	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	5	-	5
BioStar OIA	6	-	6
Meridian ImmunoCard	1	-	1
Meridian Premier	1	-	1

Antigen present in specimen AG-1: Rotavirus.

Specimen AG-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	18	-
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	5	5	-
BioStar OIA	6	6	-
Meridian ImmunoCard	1	1	-
Meridian Premier	1	1	-

Antigens present in specimen AG-2: *Clostridium difficile* and Rotavirus.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	17	17	-
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	5	5	-
BioStar OIA	5	5	-
Meridian ImmunoCard	1	1	-
Meridian Premier	1	1	-

Antigen present in specimen AG-3: *Clostridium difficile*.

Specimen AG-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	-	18
Alexon (Hycor)	1	-	1
bioMerieux Vitek, Mini Vidas	2	-	2
Biosite Triage	5	-	5
BioStar OIA	6	-	6
Meridian ImmunoCard	1	-	1
Meridian Premier	1	-	1

Antigen present in specimen AG-4: Rotavirus.

Specimen AG-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	18	18	-
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	2	2	-
Biosite Triage	5	5	-
BioStar OIA	6	6	-
Meridian ImmunoCard	1	1	-
Meridian Premier	1	1	-

Antigen present in specimen AG-5: *Clostridium difficile*.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	8	-
bioMerieux Vitek, Mini Vidas	1	1	-
Fisher HealthCare Sure-Vue	3	3	-
Meridian ImmunoCard	3	3	-

Specimen AG-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	8	-
bioMerieux Vitek, Mini Vidas	1	1	-
Fisher HealthCare Sure-Vue	3	3	-
Meridian ImmunoCard	3	3	-

Specimen AG-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	7
bioMerieux Vitek, Mini Vidas	1	-	1
Fisher HealthCare Sure-Vue	3	-	3
Meridian ImmunoCard	2	-	2

Specimen AG-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	8	8	-
bioMerieux Vitek, Mini Vidas	1	1	-
Fisher HealthCare Sure-Vue	3	3	-
Meridian ImmunoCard	3	3	-

Specimen AG-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	7	-	7
bioMerieux Vitek, Mini Vidas	1	-	1
Fisher HealthCare Sure-Vue	3	-	3
Meridian ImmunoCard	2	-	2

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-1

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	71	71	-

Specimen SP-1: Positive for *Streptococcus pneumoniae* antigen.

Specimen SP-2

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	70	-	70

Specimen SP-2: Negative for *Streptococcus pneumoniae* antigen.

Specimen SP-3

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	71	71	-

Specimen SP-3: Positive for *Streptococcus pneumoniae* antigen.

Specimen SP-4

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	71	71	-

Specimen SP-4: Positive for *Streptococcus pneumoniae* antigen.

Specimen SP-5

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
All Methods	71	-	71

Specimen SP-5: Negative for *Streptococcus pneumoniae* antigen.

PARASITOLOGY – DOMESTIC

Specimen PA-1

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba coli	3	75%	Not graded
Blastocystis hominis	1	25%	

Parasite present in specimen PA-1: *Entamoeba coli*. This is an ungraded challenge due to less than 80% participant consensus.

PARASITOLOGY – DOMESTIC

Specimen PA-2

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	3	100%	Acceptable

Parasite present in specimen PA-2: Negative for parasites.

Specimen PA-3

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba histolytica	4	80%	Acceptable
Iodamoeba butschlii	1	20%	

Parasite present in specimen PA-3: *Entamoeba histolytica*.

Specimen PA-4

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. eggs	3	50%	Not graded
Blastocystis hominis	2	33.3%	
Ascaris lumbricoides eggs	1	16.67%	

Parasite present in specimen PA-4: *Taenia sp. eggs*. This is an ungraded challenge due to less than 80% participant consensus.

Specimen PA-5

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Plasmodium vivax	2	50%	Acceptable
Plasmodium sp., not falciparum	2	50%	Acceptable

Parasite present in specimen PA-5: *Plasmodium vivax*.

SUMMARY OF ISOLATES FOUND IN THE 2006 MLE-M1 CULTURE SPECIMENS

Organism	ATCC Strain
<i>Streptococcus pyogenes</i>	19615
<i>Staphylococcus epidermidis</i>	14990
<i>Streptococcus pneumoniae</i>	6305
<i>Haemophilus influenzae</i>	10211
<i>Escherichia coli</i>	25922
<i>Pseudomonas aeruginosa</i>	27853
<i>Staphylococcus aureus</i>	25923
<i>Enterococcus faecium</i>	35667
<i>Corynebacterium species</i>	49528
<i>Proteus mirabilis</i>	12453
<i>Lactobacillus casei</i>	393
<i>Neisseria gonorrhoeae</i>	19424
<i>Klebsiella pneumoniae</i>	13883
<i>Streptococcus agalactiae</i>	12386
<i>Gardnerella vaginalis</i>	14018

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