

# **MEDICAL LABORATORY EVALUATION**

## **PARTICIPANT SUMMARY**

**2 • 0 • 0 • 7**



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

Microbiology  
MLE – M2

# Table of Contents

**2007 Evaluation Criteria** ..... 2

## Microbiology

Throat Culture .....	3	Cryptosporidium Antigen Detection .....	24
Strep A Antigen Detection.....	4	Giardia lamblia Antigen Detection.....	25
General Bacteriology .....	8	RSV Antigen Detection.....	26
Urine Culture .....	10	Influenza A/B Antigen Detection.....	28
Gram Stain.....	10	Influenza A Antigen Detection .....	29
Antimicrobial Susceptibility Testing .....	12	Influenza B Antigen Detection .....	31
GC Culture .....	13	Legionella Antigen Detection.....	32
Gram Stain.....	13	Clostridium Difficile Toxin Antigen Detection .....	33
Colony Count .....	15	Rotavirus Antigen Detection.....	35
Gram Stain.....	15	Streptococcus pneumoniae Antigen Detection .....	36
Dermatophyte Screen .....	17	Parasitology .....	37
Gram Stain.....	18		
Affirm VP III			
Trichomonas vaginalis.....	19		
Gardnerella vaginalis .....	20		
Candida sp. ....	21		
Chlamydia (Antigen Detection).....	22		
GC (Antigen Detection).....	23		

---

## 2007 Evaluation Criteria

The evaluation criteria used in the 2007 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-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	116	54.72%	Acceptable
Presump. Pos. Group A Strep	86	40.57%	Acceptable
Streptococcus pyogenes	6	2.83%	Acceptable

Organism present in specimen TC-6: *Streptococcus pyogenes*.

### Specimen TC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	200	93.46%	Acceptable
Branhamella catarrhalis	4	1.87%	Acceptable
Growth, referred for identification	2	0.93%	Acceptable
Moraxella sp.	2	0.93%	Acceptable
Gram positive cocci	1	0.47%	Acceptable

Organisms present in specimen TC-7: *Branhamella catarrhalis* and *Streptococcus viridans*.

### Specimen TC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive for Group A Strep	49	53.26%	Acceptable
Presump. Pos. Group A Strep	41	44.57%	Acceptable

Organisms present in specimen TC-8: *Streptococcus pyogenes* and *Corynebacterium species*.

### Specimen TC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	81	96.43%	Acceptable

Organisms present in specimen TC-9: *Neisseria mucosa* and *Streptococcus viridans*.

### Specimen TC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for Group A Strep	78	92.86%	Acceptable

Organism present in specimen TC-10: *Streptococcus pneumoniae*.

## STREP A ANTIGEN DETECTION

### Specimen RS-6

<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	662	644	18	497	95	17
Abbott Signify Strep A-waived	22	22	-	13	8	-
Acon Laboratories	1	1	-	1	-	-
Applied Biotech Signify	4	3	1	2	-	-
BD Directigen	8	8	-	8	-	-
BD Directigen EZ	4	4	-	2	2	-
BD QTest	2	2	-	2	-	-
Beckman Coulter ICON DS	11	11	-	8	3	-
Beckman Coulter ICON SC	5	5	-	3	1	1
Binax NOW Strep A	3	3	-	1	-	-
BioStar Aceava Strep A Test	59	59	-	44	14	1
BioStar OIA	1	1	-	1	-	-
BioStar Strep A MAX OIA	21	21	-	14	3	2
Cardinal Health Strep A - moderate	8	8	-	8	-	-
Cardinal Health Strep A - waived	11	11	-	7	3	-
Fisher HealthCare Sure-Vue	2	2	-	-	1	-
Fisher HealthCare Sure-Vue - waived	3	3	-	3	-	-
Genzyme OSOM	36	34	2	30	3	-
Genzyme OSOM Ultra Strep A	65	65	-	51	11	-
Henry Schein One Step	8	8	-	4	1	1
Instant Technologies i Strep	7	7	-	6	-	-
Inverness Signify Strep A Dipstick	27	26	1	18	7	-
LifeSign Status Strep A	1	1	-	1	-	-
Mainline Confirms	3	3	-	3	-	-
Mainline Confirms Strep A Dots	1	1	-	1	-	-
McKesson Strep A Cassette	10	10	-	8	2	-
McKesson Strep A Dipstick	6	6	-	2	2	-
McKesson Strep A Test - Twist	1	1	-	1	-	-
Polymedco Poly Stat Strep A - moderate	7	7	-	3	1	-
Polymedco Poly Stat Strep A - waived	19	19	-	11	6	2
Polymedco Strep A Liquid Test	1	1	-	-	1	-
Quidel QuickVue Dipstick Strep	95	93	2	80	4	1
Quidel QuickVue In-Line	70	59	11	49	4	7
Quidel QuickVue+	101	101	-	87	10	-
Stanbio QuStick Strep A	4	4	-	3	-	-
Wampole Clearview	1	1	-	1	-	-

## STREP A ANTIGEN DETECTION

### Specimen RS-7

<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	641	625	16	469	110	12
Abbott Signify Strep A-waived	22	22	-	12	8	1
Acon Laboratories	1	1	-	1	-	-
Applied Biotech Signify	4	3	1	1	-	-
BD Directigen	8	8	-	4	4	-
BD Directigen EZ	4	4	-	2	2	-
BD QTest	2	2	-	2	-	-
Beckman Coulter ICON DS	11	11	-	9	2	-
Beckman Coulter ICON SC	5	5	-	4	1	-
Binax NOW Strep A	3	3	-	1	-	-
BioStar Aceava Strep A Test	57	57	-	40	16	1
BioStar OIA	1	1	-	1	-	-
BioStar Strep A MAX OIA	21	21	-	15	4	-
Cardinal Health Strep A - moderate	8	8	-	8	-	-
Cardinal Health Strep A - waived	11	11	-	8	2	-
Fisher HealthCare Sure-Vue	1	1	-	-	1	-
Fisher HealthCare Sure-Vue - waived	1	1	-	1	-	-
Genzyme OSOM	35	34	1	30	2	-
Genzyme OSOM Ultra Strep A	64	64	-	53	6	2
Henry Schein One Step	7	7	-	5	1	-
Instant Technologies i Strep	8	8	-	5	2	-
Inverness Signify Strep A Dipstick	26	25	1	16	9	-
LifeSign Status Strep A	1	1	-	1	-	-
Mainline Confirms	1	1	-	1	-	-
Mainline Confirms Strep A Dots	1	1	-	1	-	-
McKesson Strep A Cassette	10	10	-	7	3	-
McKesson Strep A Dipstick	6	6	-	1	3	-
McKesson Strep A Test - Twist	1	1	-	1	-	-
Polymedco Poly Stat Strep A - moderate	7	7	-	2	1	1
Polymedco Poly Stat Strep A - waived	19	19	-	12	5	2
Polymedco Strep A Liquid Test	1	1	-	-	1	-
Quidel QuickVue Dipstick Strep	93	93	-	74	9	1
Quidel QuickVue In-Line	69	56	13	43	10	4
Quidel QuickVue+	97	97	-	83	11	-
Stanbio QuStick Strep A	3	3	-	2	-	-
Wampole Clearview	1	1	-	1	-	-

## STREP A ANTIGEN DETECTION

### Specimen RS-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	356	2	354
Abbott Signify Strep A-waived	9	-	9
Acon Laboratories	1	-	1
Applied Biotech Signify	4	-	4
BD Directigen	8	-	8
BD Directigen EZ	4	-	4
BD QTest	2	-	2
Beckman Coulter ICON DS	9	-	9
Beckman Coulter ICON SC	2	-	2
Binax NOW Strep A	3	-	3
BioStar Aceava Strep A Test	18	-	18
BioStar OIA	1	-	1
BioStar Strep A MAX OIA	21	-	21
Cardinal Health Strep A - moderate	7	-	7
Cardinal Health Strep A - waived	7	-	7
Fisher HealthCare Sure-Vue - waived	1	-	1
Genzyme OSOM	13	-	13
Genzyme OSOM Ultra Strep A	33	-	33
Henry Schein One Step	3	-	3
Instant Technologies i Strep	3	-	3
Inverness Signify Strep A Dipstick	11	1	10
Mainline Confirms	1	-	1
Mainline Confirms Strep A Dots	1	-	1
McKesson Strep A Cassette	8	-	8
McKesson Strep A Dipstick	3	-	3
Polymedco Poly Stat Strep A - moderate	5	-	5
Polymedco Poly Stat Strep A - waived	3	-	3
Quidel QuickVue Dipstick Strep	28	-	28
Quidel QuickVue In-Line	29	-	29
Quidel QuickVue+	96	1	95
Stanbio QuStick Strep A	2	-	2
Wampole Clearview	1	-	1

## STREP A ANTIGEN DETECTION

### Specimen RS-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	295	1	294
Abbott Signify Strep A-waived	9	-	9
Applied Biotech Signify	4	-	4
BD Directigen	8	-	8
BD Directigen EZ	4	-	4
BD QTest	1	-	1
Beckman Coulter ICON DS	9	-	9
Beckman Coulter ICON SC	2	-	2
Binax NOW Strep A	2	-	2
BioStar Aceava Strep A Test	14	-	14
BioStar OIA	1	-	1
BioStar Strep A MAX OIA	21	-	21
Cardinal Health Strep A - moderate	6	-	6
Cardinal Health Strep A - waived	7	-	7
Fisher HealthCare Sure-Vue - waived	1	-	1
Genzyme OSOM	11	-	11
Genzyme OSOM Ultra Strep A	27	-	27
Henry Schein One Step	2	-	2
Instant Technologies i Strep	1	-	1
Inverness Signify Strep A Dipstick	11	-	11
Mainline Confirms	1	-	1
Mainline Confirms Strep A Dots	1	-	1
McKesson Strep A Cassette	5	-	5
McKesson Strep A Dipstick	3	-	3
Polymedco Poly Stat Strep A - moderate	4	-	4
Polymedco Poly Stat Strep A - waived	2	-	2
Quidel QuickVue Dipstick Strep	18	-	18
Quidel QuickVue In-Line	24	-	24
Quidel QuickVue+	79	1	78
Stanbio QuStick Strep A	2	-	2
Wampole Clearview	1	-	1

## STREP A ANTIGEN DETECTION

### Specimen RS-10

<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	295	288	7	199	60	8
Abbott Signify Strep A-waived	9	9	-	5	4	-
Applied Biotech Signify	4	4	-	2	-	-
BD Directigen	8	8	-	5	2	1
BD Directigen EZ	4	4	-	2	2	-
BD QTest	1	1	-	1	-	-
Beckman Coulter ICON DS	9	9	-	5	4	-
Beckman Coulter ICON SC	2	2	-	2	-	-
Binax NOW Strep A	2	2	-	1	-	-
BioStar Aceava Strep A Test	14	14	-	10	4	-
BioStar OIA	1	1	-	1	-	-
BioStar Strep A MAX OIA	21	21	-	14	5	-
Cardinal Health Strep A - moderate	6	6	-	5	1	-
Cardinal Health Strep A - waived	7	7	-	6	1	-
Fisher HealthCare Sure-Vue - waived	1	1	-	-	1	-
Genzyme OSOM	11	11	-	10	-	-
Genzyme OSOM Ultra Strep A	27	27	-	21	3	2
Henry Schein One Step	2	2	-	1	1	-
Instant Technologies i Strep	1	1	-	1	-	-
Inverness Signify Strep A Dipstick	11	11	-	4	7	-
Mainline Confirms	1	1	-	1	-	-
Mainline Confirms Strep A Dots	1	1	-	-	1	-
McKesson Strep A Cassette	5	5	-	3	1	1
McKesson Strep A Dipstick	3	3	-	-	1	-
Polymedco Poly Stat Strep A - moderate	4	4	-	1	1	-
Polymedco Poly Stat Strep A - waived	2	2	-	1	-	-
Quidel QuickVue Dipstick Strep	18	18	-	13	3	-
Quidel QuickVue In-Line	24	19	5	14	3	1
Quidel QuickVue+	79	77	2	60	12	1
Stanbio QuStick Strep A	2	2	-	1	-	-
Wampole Clearview	1	1	-	1	-	-

## GENERAL BACTERIOLOGY

### Specimen UC-6 – Urine Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Escherichia coli	7	87.50%	Acceptable
Gram positive cocci	1	12.50%	Acceptable
<b><u>Gram Stain</u></b>			
Gram negative	6	100%	Acceptable
<b><u>Gram Stain Morphology</u></b>			
Rods/bacilli	6	100%	

Organism present in specimen UC-6: *Escherichia coli*.

## GENERAL BACTERIOLOGY

### Specimen GC-6 – GC Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Neisseria gonorrhoeae	6	75%	Acceptable
Growth, referred for identification	2	25%	Acceptable

Organism present in specimen GC-6: *Neisseria gonorrhoeae*.

### Specimen BA-4 – Wound Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus aureus	7	77.78%	Acceptable
Staphylococcus sp.	1	11.11%	Acceptable
Staph – coagulase negative	1	11.11%	Acceptable

Organisms present in specimen BA-4: *Staphylococcus aureus* and *Staphylococcus epidermidis*.

### Specimen BA-5 – Blood Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Escherichia coli	7	100%	Acceptable

Organism present in specimen BA-5: *Escherichia coli*.

### Specimen BA-6 – Respiratory Culture

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Pseudomonas aeruginosa	7	77.78%	Acceptable
Staph – coagulase negative	1	11.11%	Acceptable
Staphylococcus epidermidis	1	11.11%	Acceptable

Organisms present in specimen BA-6: *Pseudomonas aeruginosa* and *Staphylococcus epidermidis*.

## URINE CULTURE

### Specimen UC-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Escherichia coli	55	40.74%	Acceptable
Growth, referred for identification	24	17.78%	Acceptable
Presump. Gram negative	21	15.56%	Acceptable
Presump. Escherichia coli	18	13.33%	Acceptable
Gram negative bacilli	14	10.37%	Acceptable
Bacturcult Group I	1	0.74%	Acceptable

### Gram Stain

Gram negative	60	98.36%	Acceptable
---------------	----	--------	------------

### Gram Stain Morphology

Rods/bacilli	59	100%	
--------------	----	------	--

Organism present in specimen UC-6: *Escherichia coli*.

### Specimen UC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Staphylococcus aureus	41	24.40%	Acceptable
Growth, referred for identification	38	22.62%	Acceptable
Presump. Gram positive	22	13.10%	Acceptable
Gram positive cocci	20	11.90%	Acceptable
Staphylococcus sp.	14	8.33%	Acceptable
Staph – coagulase negative	12	7.14%	Acceptable
Presump. Staphylococcus sp.	10	5.95%	Acceptable
Staphylococcus epidermidis	4	2.38%	Acceptable

Organisms present in specimen UC-7: *Staphylococcus aureus* and *Staphylococcus epidermidis*.

## URINE CULTURE

### Specimen UC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Growth, referred for identification	25	26.88%	Acceptable
Presump. Gram negative	19	20.43%	Acceptable
Pseudomonas aeruginosa	17	18.28%	Acceptable
Pseudomonas sp.	12	12.90%	Acceptable
Presump. Pseudomonas sp.	8	8.60%	Acceptable
Gram negative bacilli	6	6.45%	Acceptable
Bacturcult Group II	1	1.08%	Acceptable
Gram positive bacilli	1	1.08%	Acceptable

Organisms present in specimen UC-8: *Pseudomonas aeruginosa* and *Corynebacterium species*.

### Specimen UC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No growth (sterile)	49	92.45%	Acceptable

Organism present in specimen UC-9: Negative culture.

### Specimen UC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	19	34.55%	Acceptable
Growth, referred for identification	17	30.91%	Acceptable
Staphylococcus saprophyticus	5	9.09%	Acceptable
Gram positive cocci	3	5.45%	Acceptable
Staphylococcus sp.	2	3.64%	Acceptable
Staph – coagulase negative	1	1.82%	Acceptable
Lactobacillus sp.	1	1.82%	Acceptable
Presump. Staphyococcus sp.	1	1.82%	Acceptable
Contaminated specimen	5	9.09%	

Organisms present in specimen UC-10: *Staphylococcus saprophyticus* and *Lactobacillus casei*.

**ANTIMICROBIAL SUSCEPTIBILITY TESTING**

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

<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	-	-	6	6	-	-	100%
Amoxicillin/Clavulanate	13	13	-	-	7	7	-	-	100%
Ampicillin	65	60	4	1	15	13	1	1	92.79%
Ampicillin/Sulbactam	1	1	-	-	8	8	-	-	100%
Aztreonam	-	-	-	-	3	2	1	-	Not graded <sup>1</sup>
Carbenicillin	18	18	-	-	1	1	-	-	100%
Cefamandole	1	1	-	-	-	-	-	-	100%
Cefazolin	8	8	-	-	10	9	-	1	92.31%
Cefepime	-	-	-	-	4	3	-	1	83.33%
Cefixime	6	6	-	-	-	-	-	-	100%
Cefotaxime	2	2	-	-	2	1	-	1	83.33%
Cefotetan	-	-	-	-	2	2	-	-	100%
Cefoxitin	2	2	-	-	2	2	-	-	100%
Cefpodoxime	-	-	-	-	1	1	-	-	100%
Ceftazidime	2	2	-	-	7	6	-	1	92.31%
Ceftriaxone	4	4	-	-	9	9	-	-	100%
Cefuroxime	3	3	-	-	6	6	-	-	100%
Cephalexin	1	1	-	-	-	-	-	-	100%
Cephalothin	56	32	17	7	10	5	3	2	Not graded <sup>1</sup>
Cinoxacin	3	3	-	-	-	-	-	-	100%
Ciprofloxacin	64	63	-	1	14	13	-	1	98.18%
Doxycycline	2	2	-	-	-	-	-	-	100%
Ertapenem	-	-	-	-	1	1	-	-	100%
Fosfomycin	1	1	-	-	-	-	-	-	100%
Gatifloxacin	-	-	-	-	2	1	-	1	Not graded <sup>1</sup>
Gemifoxacin	-	-	-	-	1	1	-	-	Inappropriate drug <sup>2</sup>
Gentamicin	33	32	-	1	10	9	1	-	96.97%
Imipenem	1	1	-	-	5	5	-	-	100%
Levofloxacin	15	15	-	-	10	9	-	1	97.37%
Lomefloxacin	1	1	-	-	2	2	-	-	100%
Loracarbef	1	1	-	-	-	-	-	-	100%
Mezlocillin	1	1	-	-	-	-	-	-	100%
Nalidixic Acid	3	3	-	-	1	1	-	-	100%
Nitrofurantoin	76	75	1	-	14	13	-	1	98.43%
Norfloxacin	18	18	-	-	5	5	-	-	100%
Ofloxacin	23	23	-	-	4	4	-	-	100%
Piperacillin	-	-	-	-	4	3	-	1	83.33%
Piperacillin/Tazobactam	-	-	-	-	6	5	-	1	88.89%
Sulfisoxazole	6	6	-	-	1	1	-	-	92.86%
Sulfonamides	1	1	-	-	-	-	-	-	100%
Tetracycline	32	32	-	-	8	8	-	-	100%
Ticarcillin/Clavulanate	1	1	-	-	4	4	-	-	100%
Tobramycin	2	2	-	-	8	8	-	-	100%
Trimethoprim	6	6	-	-	5	5	-	-	100%
Trimethoprim/Sulfamethoxazole	72	72	-	-	14	14	-	-	100%

Organism present in specimen UC-6, CC-6 (SUS-6): *Escherichia coli*.

<sup>1</sup> This is an ungraded challenge due to less than 80% participant consensus.

<sup>2</sup> This drug is an inappropriate drug for this organism and/or source.

## GC CULTURE

### Specimen GC-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	23	54.76%	Acceptable
Neisseria gonorrhoeae	18	42.86%	Acceptable
Growth select media, referred	1	2.38%	Acceptable

#### Beta-lactamase Testing

Negative	5	83.33%
Positive	1	16.67%

#### Gram Stain

Gram negative	32	100%	Acceptable
---------------	----	------	------------

#### Gram Stain Morphology

Diplococci	36	100%
------------	----	------

Organism present in specimen GC-6: *Neisseria gonorrhoeae*.

### Specimen GC-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	18	81.82%	Acceptable
Gram negative bacilli	1	4.55%	Acceptable
Gram positive cocci	1	4.55%	Acceptable
Growth select media, referred	1	4.55%	Acceptable

Organisms present in specimen GC-7: *Escherichia coli* and *Enterococcus faecalis*.

### Specimen GC-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative for N. gonorrhoeae	14	70%	Not graded
No growth (sterile)	6	30%	Not graded

Organism present in specimen GC-8: *Lactobacillus casei*. This is an ungraded challenge due to less than 80% referee consensus.

## GC CULTURE

### Specimen GC-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	14	70%	Acceptable
Neisseria gonorrhoeae	5	25%	Acceptable

#### Beta-lactamase Testing

Negative	2	66.67%
Positive	1	33.33%

Organisms present in specimen GC-9: *Neisseria gonorrhoeae* and *Enterobacter cloacae*.

### Specimen GC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. GC, referred for ID	15	75%	Acceptable
Neisseria gonorrhoeae	4	20%	Acceptable

#### Beta-lactamase Testing

Negative	2	66.67%
Positive	1	33.33%

Organisms present in specimen GC-10: *Neisseria gonorrhoeae* and *Lactobacillus casei*.

**COLONY COUNT/PRESUMPTIVE IDENTIFICATION**

**Specimen CC-6**

<u>Method</u>	<u>Labs</u>	<u>No growth</u>	<u>&lt;10,000 organisms/mL</u>	<u>10,000-100,000 organisms/mL</u>	<u>&gt;100,000 organisms/mL</u>
ALL METHODS	102	-	-	3	99
Bacti-Star	1	-	-	-	1
Bacturcult	1	-	-	-	1
Bulls Eye	6	-	-	-	6
Calibrated Loop	29	-	-	2	27
Uri-Check	13	-	-	-	13
Uricult	46	-	-	1	45
Uri-Three	1	-	-	-	1

**Identification—Specimen CC-6**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Escherichia coli	16	48.48%	Acceptable
Presump. Gram negative	9	27.27%	Acceptable
Growth, referred for identification	5	15.15%	Acceptable
Escherichia coli	2	6.06%	Acceptable

**Gram Stain**

Gram negative	4	100%	Acceptable
---------------	---	------	------------

**Gram Stain Morphology**

Rods/bacilli	5	100%
--------------	---	------

Organism present in specimen CC-6: >100,000 CFU/mL of *Escherichia coli*.

**COLONY COUNT/PRESUMPTIVE IDENTIFICATION**

**Specimen CC-7**

<u>Method</u>	<u>Labs</u>	<u>No growth</u>	<u>&lt;10,000 organisms/mL</u>	<u>10,000-100,000 organisms/mL</u>	<u>&gt;100,000 organisms/mL</u>
ALL METHODS	101	2	4	36	59
Bacti-Star	1	-	-	-	-
Bacturcult	1	-	-	1	-
Bulls Eye	6	-	-	3	3
Calibrated Loop	29	1	1	3	24
Uri-Check	13	-	2	3	8
Uricult	46	1	1	23	21
Uri-Three	1	-	-	1	-

**Identification–Specimen CC-7**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	12	36.36%	Acceptable
Growth, referred for identification	7	21.21%	Acceptable
Presump. Staphylococcus sp.	5	15.15%	Acceptable
Staphylococcus aureus	3	9.09%	Acceptable
Staphylococcus sp.	1	3.03%	Acceptable
Bacturcult Group II	1	3.03%	Acceptable

Organisms present in specimen CC-7: >100,000 CFU/mL *Staphylococcus aureus* and approximately 9,500 CFU/mL of *Staphylococcus epidermidis*.

**Identification–Specimen CC-8**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Pseudomonas sp.	12	48%	Acceptable
Presump. Gram negative	7	28%	Acceptable
Pseudomonas aeruginosa	3	12%	Acceptable
Growth, referred for identification	2	8%	Acceptable
Pseudomonas sp.	1	4%	Acceptable

Organisms present in specimen CC-8: >100,000 CFU/mL of *Pseudomonas aeruginosa* and approximately 25,000 CFU/mL of *Corynebacterium sp.*

**Identification–Specimen CC-9**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No growth (sterile)	25	100%	Acceptable

Organism present in specimen CC-9: Negative culture.

## COLONY COUNT/PRESUMPTIVE IDENTIFICATION

### Identification–Specimen CC-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Presump. Gram positive	11	44%	Acceptable
Growth, referred for identification	4	16%	Acceptable
Presump. Staphylococcus sp.	3	12%	Acceptable
Staph – coagulase negative	2	8%	Acceptable
Staphylococcus saprophyticus	1	4%	Acceptable
Staphylococcus sp.	1	4%	Acceptable

Organisms present in specimen CC-10: >100,000 CFU/mL of *Staphylococcus saprophyticus* and approximately 2,000 CFU/mL of *Lactobacillus casei*.

## DERMATOPHYTE SCREEN

### Specimen DM-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte present	12	66.67%	Not graded
Dermatophyte absent	6	33.33%	

Organism present in specimen DM-6: *Microsporium audouinii*. This specimen is ungraded due to the lack of 80% participant consensus.

### Specimen DM-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Dermatophyte absent	18	100%	Acceptable

Organisms present in specimen DM-7: *Escherichia coli* and *Lactobacillus casei*.

## GRAM STAIN

### Specimen GS-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	53	100%	Acceptable

#### Gram Stain Morphology

Cocci	29	65.91%
Cocci in pairs	11	25.00%
Diplococci	4	9.09%

Organism present in specimen GS-6: *Staphylococcus epidermidis*.

### Specimen GS-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	53	100%	Acceptable

#### Gram Stain Morphology

Rods/bacilli	42	95.45%
Cocci	1	2.27%
Cocco-bacilli	1	2.27%

Organism present in specimen GS-7: *Serratia marcescens*.

### Specimen GS-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram positive	48	90.57%	Acceptable
Gram negative	5	9.43%	

#### Gram Stain Morphology

Cocci in chains	34	77.27%
Cocci	8	18.18%
Cocci in pairs	1	2.27%
Dipococci	1	2.27%

Organism present in specimen GS-8: *Streptococcus pyogenes*.

## GRAM STAIN

### Specimen GS-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	53	100%	Acceptable

#### Gram Stain Morphology

Rods/bacilli	41	93.18%
Cocci-bacilli	2	4.55%
Cocci	1	2.27%

Organism present in specimen GS-9: *Pseudomonas aeruginosa*.

### Specimen GS-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Gram negative	47	88.68%	Acceptable
Gram positive	6	11.32%	

#### Gram Stain Morphology

Diplococci	31	70.45%
Cocci	6	13.64%
Cocco-bacilli	4	9.09%
Cocci in pairs	3	6.82%

Organism present in specimen GS-10: *Neisseria gonorrhoeae*.

## AFFIRM VP III–Trichomonas vaginalis

### Specimen VP-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	23	82.14%	Acceptable
Negative	5	17.86%	

Organisms present in specimen VP-6: *Trichomonas vaginalis* and *Candida albicans*.

### Specimen VP-7

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	28	100%	Acceptable

Organism present in specimen VP-7: *Gardnerella vaginalis*.

**AFFIRM VP III–Trichomonas vaginalis****Specimen VP-8**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	28	100%	Acceptable

Organism present in specimen VP-8: *Candida albicans*.

**Specimen VP-9**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	28	100%	Acceptable

Organism present in specimen VP-9: *Gardnerella vaginalis*.

**Specimen VP-10**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	26	92.86%	Acceptable
Negative	2	7.14%	

Organism present in specimen VP-10: *Trichomonas vaginalis*.

**AFFIRM VP III–Gardnerella vaginalis****Specimen VP-6**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	28	100%	Acceptable

**Specimen VP-7**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	27	96.43%	Acceptable
Negative	1	3.57%	

**Specimen VP-8**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	28	100%	Acceptable

**AFFIRM VP III–Gardnerella vaginalis****Specimen VP-9**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	26	92.86%	Acceptable
Negative	2	7.14%	

**Specimen VP-10**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	28	100%	

**AFFIRM VP III–Candida sp.****Specimen VP-6**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive`	27	96.43%	Acceptable
Negative	1	3.57%	

**Specimen VP-7**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	27	96.43%	Acceptable
Positive	1	3.57%	

**Specimen VP-8**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Positive	28	100%	Acceptable

**Specimen VP-9**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	27	96.43%	Acceptable
Positive	1	3.57%	

**Specimen VP-10**

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Negative	28	100%	Acceptable

## CHLAMYDIA (ANTIGEN DETECTION)

### Specimen CY-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	20	1	19
BD ProbeTec	5	1	4
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	2	-	2
Gen-Probe	2	-	2
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	8	-	8

Organism present in specimen CY-6: *Neisseria gonorrhoeae*.

### Specimen CY-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	20	20	-
BD ProbeTec	5	5	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	2	2	-
Gen-Probe	2	2	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	8	8	-

Organism present in specimen CY-7: *Chlamydia trachomatis*.

### Specimen CY-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	-	16
BD ProbeTec	5	-	5
bioMerieux Vitek, Mini Vidas	2	-	2
BioStar OIA	2	-	2
Gen-Probe	2	-	2
Gen-Probe APTIMA	1	-	1
Quidel QuickVue	4	-	4

Organism present in specimen CY-8: *Neisseria gonorrhoeae*.

## CHLAMYDIA (ANTIGEN DETECTION)

### Specimen CY-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	16	-
BD ProbeTec	5	5	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	2	2	-
Gen-Probe	2	2	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	4	4	-

Organism present in specimen CY-9: *Chlamydia trachomatis*.

### Specimen CY-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	16	-
BD ProbeTec	5	5	-
bioMerieux Vitek, Mini Vidas	2	2	-
BioStar OIA	2	2	-
Gen-Probe	2	2	-
Gen-Probe APTIMA	1	1	-
Quidel QuickVue	4	4	-

Organism present in specimen CY-10: *Chlamydia trachomatis*.

## GC (ANTIGEN DETECTION)

### Specimen CY-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	10	10	-
BD ProbeTec	5	5	-
BioStar OIA	2	2	-
Gen-Probe	2	2	-
Gen-Probe APTIMA	1	1	-

### Specimen CY-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	10	-	10
BD ProbeTec	5	-	5
BioStar OIA	2	-	2
Gen-Probe	2	-	2
Gen-Probe APTIMA	1	-	1

## GC (ANTIGEN DETECTION)

### Specimen CY-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	10	10	-
BD ProbeTec	5	5	-
BioStar OIA	2	2	-
Gen-Probe	2	2	-
Gen-Probe APTIMA	1	1	-

### Specimen CY-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	10	-	10
BD ProbeTec	5	-	5
BioStar OIA	2	-	2
Gen-Probe	2	-	2
Gen-Probe APTIMA	1	-	1

### Specimen CY-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	10	1	9
BD ProbeTec	5	-	5
BioStar OIA	2	1	1
Gen-Probe	2	-	2
Gen-Probe APTIMA	1	-	1

## CRYPTOSPORIDIUM ANTIGEN DETECTION

### Specimen LC-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	-	4
Remel Xpect	4	-	4

Antigen present in specimen LC-6: *Giardia lamblia*.

### Specimen LC-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	4	-
Remel Xpect	4	4	-

Antigen present in specimen LC-7: *Cryptosporidium*.

## CRYPTOSPORIDIUM ANTIGEN DETECTION

### Specimen LC-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	4	-
Remel Xpect	4	4	-

Antigen present in specimen LC-8: *Cryptosporidium*.

### Specimen LC-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	-	4
Remel Xpect	4	-	4

Antigen present in specimen LC-9: *Giardia lamblia*.

### Specimen LC-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	4	-	4
Remel Xpect	4	-	4

Antigens present in specimen LC-10: No antigens present.

## GIARDIA LAMBLIA ANTIGEN DETECTION

### Specimen LC-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	6	-
Alexon (Hycor)	1	1	-
Remel Xpect	5	5	-

### Specimen LC-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	-	6
Alexon (Hycor)	1	-	1
Remel Xpect	5	-	5

## GIARDIA LAMBLIA ANTIGEN DETECTION

### Specimen LC-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	-	6
Alexon (Hycor)	1	-	1
Remel Xpect	5	-	5

### Specimen LC-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	6	-
Alexon (Hycor)	1	1	-
Remel Xpect	5	5	-

### Specimen LC-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	-	6
Alexon (Hycor)	1	-	1
Remel Xpect	5	-	5

## RSV ANTIGEN DETECTION

### Specimen V-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	33	-	33
BD Directigen	1	-	1
Binax NOW - waived	18	-	18
BioStar OIA	4	-	4
Quidel QuickVue	4	-	4
Remel Xpect - waived	2	-	2
Wampole Clearview RSV - waived	3	-	3

Specimen V-6: Negative for RSV antigen.

## RSV ANTIGEN DETECTION

### Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	33	-	33
BD Directigen	1	-	1
Binax NOW - waived	18	-	18
BioStar OIA	4	-	4
Quidel QuickVue	4	-	4
Remel Xpect - waived	2	-	2
Wampole Clearview RSV - waived	3	-	3

Specimen V-7: Negative for RSV antigen.

### Specimen V-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	22	22	-
BD Directigen	1	1	-
Binax NOW - waived	10	10	-
BioStar OIA	4	4	-
Quidel QuickVue	2	2	-
Remel Xpect - waived	2	2	-
Wampole Clearview RSV - waived	2	2	-

Specimen V-8: Positive for RSV antigen.

### Specimen V-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	22	22	-
BD Directigen	1	1	-
Binax NOW - waived	10	10	-
BioStar OIA	4	4	-
Quidel QuickVue	2	2	-
Remel Xpect - waived	2	2	-
Wampole Clearview RSV - waived	2	2	-

Specimen V-9: Positive for RSV antigen.

## RSV ANTIGEN DETECTION

### Specimen V-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	22	-	22
BD Directigen	1	-	1
Binax NOW - waived	10	-	10
BioStar OIA	4	-	4
Quidel QuickVue	2	-	2
Remel Xpect - waived	2	-	2
Wampole Clearview RSV - waived	2	-	2

Specimen V-10: Negative for RSV antigen.

## INFLUENZA A/B ANTIGEN DETECTION

### Specimen V-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	72	72	-
BioStar OIA	5	5	-
Quidel QuickVue Influenza	64	64	-

Specimen V-6: Positive for Influenza A/B antigen.

### Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	72	68	4
BioStar OIA	5	5	-
Quidel QuickVue Influenza	64	61	3

Specimen V-7: Positive for Influenza A/B antigen.

### Specimen V-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	-	25
BioStar OIA	5	-	5
Quidel QuickVue Influenza	19	-	19

Specimen V-8: Negative for Influenza A/B antigen.

## INFLUENZA A/B ANTIGEN DETECTION

### Specimen V-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	-	25
BioStar OIA	5	-	5
Quidel QuickVue Influenza	19	-	19

Specimen V-9: Negative for Influenza A/B antigen.

### Specimen V-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	25	25	-
BioStar OIA	5	5	-
Quidel QuickVue Influenza	19	19	-

Specimen V-10: Positive for Influenza A/B antigen.

## INFLUENZA A ANTIGEN DETECTION

### Specimen V-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	86	2	84
BD Directigen	1	-	1
Binax NOW - waived	25	-	25
BioStar Flu OIA A/B	4	-	4
Quidel QuickVue Influenza A+B	45	2	43
Remel Xpect	5	-	5

Specimen V-6: Negative for Influenza A antigen.

### Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	91	89	2
BD Directigen	1	1	-
Binax NOW - waived	26	26	-
BioStar Flu OIA A/B	4	4	-
Quidel QuickVue Influenza A+B	47	45	2
Remel Xpect	5	5	-

Specimen V-7: Positive for Influenza A antigen.

## INFLUENZA A ANTIGEN DETECTION

### Specimen V-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	40	-	40
BD Directigen	1	-	1
Binax NOW - waived	9	-	9
BioStar Flu OIA A/B	4	-	4
Quidel QuickVue Influenza A+B	17	-	17
Remel Xpect	5	-	5

Specimen V-8: Negative for Influenza A antigen.

### Specimen V-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	40	-	40
BD Directigen	1	-	1
Binax NOW - waived	9	-	9
BioStar Flu OIA A/B	4	-	4
Quidel QuickVue Influenza A+B	17	-	17
Remel Xpect	5	-	5

Specimen V-9: Negative for Influenza A antigen.

### Specimen V-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	40	40	-
BD Directigen	1	1	-
Binax NOW - waived	9	9	-
BioStar Flu OIA A/B	4	4	-
Quidel QuickVue Influenza A+B	17	17	-
Remel Xpect	5	5	-

Specimen V-10: Positive for Influenza A antigen.

## INFLUENZA B ANTIGEN DETECTION

### Specimen V-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	91	89	2
BD Directigen	1	1	-
Binax NOW - waived	26	25	1
BioStar Flu OIA A/B	4	4	-
Quidel QuickVue Influenza A+B	47	46	1
Remel Xpect	5	5	-

Specimen V-6: Positive for Influenza B antigen.

### Specimen V-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	86	3	83
BD Directigen	1	-	1
Binax NOW - waived	25	-	25
BioStar Flu OIA A/B	4	1	3
Quidel QuickVue Influenza A+B	45	1	44
Remel Xpect	5	-	5

Specimen V-7: Negative for Influenza B antigen.

### Specimen V-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	40	-	40
BD Directigen	1	-	1
Binax NOW - waived	9	-	9
BioStar Flu OIA A/B	4	-	4
Quidel QuickVue Influenza A+B	17	-	17
Remel Xpect	5	-	5

Specimen V-8: Negative for Influenza B antigen.

## INFLUENZA B ANTIGEN DETECTION

### Specimen V-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	40	-	40
BD Directigen	1	-	1
Binax NOW - waived	9	-	9
BioStar Flu OIA A/B	4	-	4
Quidel QuickVue Influenza A+B	17	-	17
Remel Xpect	5	-	5

Specimen V-9: Negative for Influenza B antigen.

### Specimen V-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	40	-	40
BD Directigen	1	-	1
Binax NOW - waived	9	-	9
BioStar Flu OIA A/B	4	-	4
Quidel QuickVue Influenza A+B	17	-	17
Remel Xpect	5	-	5

Specimen V-10: Negative for Influenza B antigen.

## LEGIONELLA ANTIGEN DETECTION

### Specimen L-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	66	1	65

Specimen L-6: Negative for Legionella antigen.

### Specimen L-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	66	65	1

Specimen L-7: Positive for Legionella antigen.

### Specimen L-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	66	65	1

Specimen L-8: Positive for Legionella antigen.

## LEGIONELLA ANTIGEN DETECTION

### Specimen L-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	66	65	1

Specimen L-9: Positive for Legionella antigen.

### Specimen L-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	66	-	66

Specimen L-10: Negative for Legionella antigen.

## CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

### Specimen AG-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	16	-
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	1	1	-
Biosite Triage	4	4	-
BioStar OIA	5	5	-
Meridian ImmunoCard	2	2	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-

Antigen present in specimen AG-6: *Clostridium difficile*.

### Specimen AG-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	16	-
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	1	1	-
Biosite Triage	4	4	-
BioStar OIA	5	5	-
Meridian ImmunoCard	2	2	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-

Antigens present in specimen AG-7: *Clostridium difficile* and Rotavirus.

## CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

### Specimen AG-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	-	16
Alexon (Hycor)	1	-	1
bioMerieux Vitek, Mini Vidas	1	-	1
Biosite Triage	4	-	4
BioStar OIA	5	-	5
Meridian ImmunoCard	2	-	2
Meridian Premier	1	-	1
Remel Xpect	1	-	1

Antigen present in specimen AG-8: Rotavirus.

### Specimen AG-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	-	16
Alexon (Hycor)	1	-	1
bioMerieux Vitek, Mini Vidas	1	-	1
Biosite Triage	4	-	4
BioStar OIA	5	-	5
Meridian ImmunoCard	2	-	2
Meridian Premier	1	-	1
Remel Xpect	1	-	1

Antigen present in specimen AG-9: No antigens present.

### Specimen AG-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	16	16	-
Alexon (Hycor)	1	1	-
bioMerieux Vitek, Mini Vidas	1	1	-
Biosite Triage	4	4	-
BioStar OIA	5	5	-
Meridian ImmunoCard	2	2	-
Meridian Premier	1	1	-
Remel Xpect	1	1	-

Antigen present in specimen AG-10: *Clostridium difficile*.

## ROTAVIRUS ANTIGEN DETECTION

### Specimen AG-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	-	9
bioMerieux Vitek, Mini Vidas	1	-	1
Fisher HealthCare Sure-Vue	2	-	2
Meridian ImmunoCard	1	-	1
Remel Xpect	1	-	1
SA Scientific Rota Test	1	-	1

### Specimen AG-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	9	-
bioMerieux Vitek, Mini Vidas	1	1	-
Fisher HealthCare Sure-Vue	2	2	-
Meridian ImmunoCard	1	1	-
Remel Xpect	1	1	-
SA Scientific Rota Test	1	1	-

### Specimen AG-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	9	-
bioMerieux Vitek, Mini Vidas	1	1	-
Fisher HealthCare Sure-Vue	2	2	-
Meridian ImmunoCard	1	1	-
Remel Xpect	1	1	-
SA Scientific Rota Test	1	1	-

### Specimen AG-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	-	9
bioMerieux Vitek, Mini Vidas	1	-	1
Fisher HealthCare Sure-Vue	2	-	2
Meridian ImmunoCard	1	-	1
Remel Xpect	1	-	1
SA Scientific Rota Test	1	-	1

### Specimen AG-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	9	-	9
bioMerieux Vitek, Mini Vidas	1	-	1
Fisher HealthCare Sure-Vue	2	-	2
Meridian ImmunoCard	1	-	1
Remel Xpect	1	-	1
SA Scientific Rota Test	1	-	1

## STREPTOCOCCUS PNEUMONIAE ANTIGEN

### Specimen SP-6

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	65	63	2

Specimen SP-6: Positive for *Streptococcus pneumoniae* antigen.

### Specimen SP-7

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	65	64	1

Specimen SP-7: Positive for *Streptococcus pneumoniae* antigen.

### Specimen SP-8

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	65	-	65

Specimen SP-8: Negative for *Streptococcus pneumoniae* antigen.

### Specimen SP-9

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	64	-	64

Specimen SP-9: Negative for *Streptococcus pneumoniae* antigen.

### Specimen SP-10

<u>Method</u>	<u>Labs</u>	<u>Positive</u>	<u>Negative</u>
Binax NOW	65	64	1

Specimen SP-10: Positive for *Streptococcus pneumoniae* antigen.

## PARASITOLOGY

### Specimen PA-6

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Entamoeba histolytica	4	80%	Acceptable

Parasite present in specimen PA-6: *Entamoeba histolytica*. Rare *Blastocystis hominis* seen.

### Specimen PA-7

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

Parasite present in specimen PA-7: *Endolimax nana*. Rare *Blastocystis hominis* seen.

### Specimen PA-8

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
No parasite seen	6	100%	Acceptable

Parasite present in specimen PA-8: No parasites present.

### Specimen PA-9

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Taenia sp. Eggs	5	83.33%	Acceptable

Parasite present in specimen PA-9: *Taenia sp. Eggs*. Small numbers of *Giardia lamblia* cysts are also present.

### Specimen PA-10

<u>Identification</u>	<u>Labs</u>	<u>Percent</u>	<u>Performance</u>
Ascaris lumbricoides eggs	6	75%	Acceptable
Blastocystis hominis	1	12.50%	Acceptable
Cryptosporidium sp., oocysts	1	12.50%	Acceptable

Parasites present in specimen PA-10: *Ascaris lumbricoides* eggs, *Blastocystis hominis*, *Endolimax nana* and *Cryptosporidium* sp.

**Medical Laboratory Evaluation**  
2011 Pennsylvania Avenue, NW, Suite 800  
Washington, DC 20006-1813  
800-338-2746 • 202-261-4500 • Fax: 202-835-0440