

MEDICAL LABORATORY EVALUATION

PARTICIPANT SUMMARY

2 • 0 • 1 • 5

Microbiology
MLE-M3



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

Table of Contents

| | |
|--------------------------|---|
| Evaluation Criteria..... | 2 |
|--------------------------|---|

Microbiology

| | | | |
|--|----|---|----|
| Throat Culture | 3 | GC (Antigen Detection) | 23 |
| Strep A Antigen Detection..... | 4 | Cryptosporidium Antigen Detection | 24 |
| General Bacteriology | 8 | Giardia lamblia Antigen Detection..... | 25 |
| MRSA Screening | 9 | RSV Antigen Detection..... | 26 |
| Urine Culture | 10 | Influenza A/B Antigen Detection..... | 27 |
| Gram Stain..... | 10 | Influenza A Antigen Detection | 28 |
| Antimicrobial Susceptibility Testing | 12 | Influenza B Antigen Detection | 30 |
| Genital Culture | 13 | Legionella Antigen Detection..... | 32 |
| Gram Stain..... | 13 | Clostridium Difficile Toxin Antigen Detection | 33 |
| Colony Count/Presumptive ID | 15 | Rotavirus Antigen Detection..... | 34 |
| Gram Stain..... | 15 | Streptococcus pneumoniae Antigen Detection | 35 |
| Dermatophyte Screen | 17 | Parasitology | 36 |
| Gram Stain..... | 17 | | |
| Affirm VP III | | | |
| Trichomonas vaginalis..... | 19 | | |
| Gardnerella vaginalis | 20 | | |
| Candida sp. | 20 | | |
| Chlamydia (Antigen Detection)..... | 21 | | |

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 | Influenza A Antigen Detection | 80% Consensus |
| Affirm VP III Gardnerella Ag Detection | 80% Consensus | Influenza A/B Antigen Detection | 80% Consensus |
| Affirm VP III Trichomonas Ag Detection | 80% Consensus | Influenza B Antigen Detection | 80% Consensus |
| Antimicrobial Susceptibility Testing | 80% Consensus | Legionella Antigen Detection | 80% Consensus |
| Bacterial Identification | 80% Consensus | Parasite Identification | 80% Consensus |
| C. difficile Toxin/Antigen Detection | 80% Consensus | Rotavirus Antigen Detection | 80% Consensus |
| Chlamydia (EIA, DNA) | 80% Consensus | RSV Antigen Detection | 80% Consensus |
| Colony Count | 80% Consensus | Strep A Antigen Detection | 80% Consensus |
| Cryptosporidium Antigen Detection | 80% Consensus | Streptococcus pneumoniae Antigen Detection | 80% Consensus |
| Dermatophyte Screen | 80% Consensus | Urine Presumptive Identification | 80% Consensus |
| GC (EIA, DNA) | 80% Consensus | | |
| Giardia lamblia Antigen Detection | 80% Consensus | | |
| Gram Stain | 80% Consensus | | |
| Gram Stain Morphology | 80% Consensus | | |

THROAT CULTURE

Specimen TC-11

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|------------------------------|-------------|----------------|--------------------|
| Positive for Group A. Strep | 69 | 47.26% | Acceptable |
| Presump. Pos. Group A. Strep | 53 | 36.30% | Acceptable |
| Streptococcus pyogenes | 17 | 11.64% | Acceptable |
| Staphylococcus sp. | 3 | 2.05% | Acceptable |
| Staph – coagulase negative | 1 | 0.68% | Acceptable |

Organisms present in specimen TC-11: *Streptococcus pyogenes* and *Staphylococcus epidermidis*.

Specimen TC-12

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|----------------------------|-------------|----------------|--------------------|
| Negative for Group A Strep | 119 | 85.00% | Acceptable |
| Moraxella catarrhalis | 15 | 10.71% | Acceptable |
| Normal flora | 1 | 0.71% | Acceptable |

Organisms present in specimen TC-12: *Moraxella catarrhalis* and *Neisseria mucosa*.

Specimen TC-13

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------------|-------------|----------------|--------------------|
| Presump. Pos. Group A Strep | 43 | 52.44% | Acceptable |
| Positive for Group A Strep | 36 | 43.90% | Acceptable |
| Streptococcus pyogenes | 1 | 1.22% | Acceptable |

Organism present in specimen TC-13: *Streptococcus pyogenes*.

Specimen TC-14

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|----------------------------|-------------|----------------|--------------------|
| Negative for Group A Strep | 65 | 94.20% | Acceptable |
| Streptococcus pneumoniae | 1 | 1.45% | Acceptable |

Organism present in specimen TC-14: *Streptococcus pneumoniae*.

Specimen TC-15

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|----------------------------|-------------|----------------|--------------------|
| Negative for Group A Strep | 65 | 92.86% | Acceptable |
| Haemophilus influenzae | 1 | 1.43% | Acceptable |

Organisms present in specimen TC-15: *Haemophilus influenzae* and *Neisseria mucosa*.

STREP A ANTIGEN DETECTION

Specimen RS-11

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|--|-------------|-----------------|-----------------|
| ALL METHODS | 540 | 9 | 531 |
| Abbott Signify Strep A-waived | 3 | - | 3 |
| Alere Acceava Strep A Test | 12 | - | 12 |
| Alere Signify Strep A Dipstick | 1 | 1 | - |
| BD Chek Strep A | 4 | - | 4 |
| BD Veritor - waived | 3 | - | 3 |
| Beckman Coulter ICON DS | 2 | - | 2 |
| Beckman Coulter ICON SC | 4 | - | 4 |
| Binax NOW Strep A | 7 | - | 7 |
| Cardinal Health Strep A - waived | 14 | - | 14 |
| Consult Diagnostic Strep A Dipstick - Waived | 85 | - | 85 |
| Fisher HealthCare Sure-Vue - waived | 2 | - | 2 |
| Henry Schein One Step+ - waived | 39 | 1 | 38 |
| Immunostics Detector Strep A Direct | 6 | - | 6 |
| McKesson Strep A Dipstick | 14 | - | 14 |
| Other Moderately Complex Method | 1 | - | 1 |
| Other Waived Method | 12 | - | 12 |
| Polymedco Poly Stat Strep A - moderate | 1 | - | 1 |
| Polymedco Poly Stat Strep A - waived | 7 | - | 7 |
| PSS Select Diag. Strep A Dipstick - waived | 3 | - | 3 |
| Quidel QuickVue Dipstick Strep | 78 | 1 | 77 |
| Quidel QuickVue In-Line | 65 | 3 | 62 |
| Quidel QuickVue+ | 17 | - | 17 |
| Quidel Sofia Strep A - moderate | 4 | - | 4 |
| Quidel Sofia Strep A+ - waived | 4 | - | 4 |
| Sekisui OSOM | 93 | 1 | 92 |
| Sekisui OSOM Ultra Strep A | 53 | 2 | 51 |
| Stanbio QuStick Strep A | 1 | - | 1 |

STREP A ANTIGEN DETECTION

Specimen RS-12

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|--|-------------|-----------------|-----------------|
| ALL METHODS | 534 | 519 | 15 |
| Abbott Signify Strep A-waived | 3 | 3 | - |
| Alere Acceava Strep A Test | 12 | 11 | 1 |
| Alere Signify Strep A Dipstick | 1 | - | 1 |
| BD Chek Strep A | 4 | 4 | - |
| BD Veritor - waived | 3 | 3 | - |
| Beckman Coulter ICON DS | 2 | 2 | - |
| Beckman Coulter ICON SC | 4 | 4 | - |
| Binax NOW Strep A | 7 | 7 | - |
| Cardinal Health Strep A - waived | 14 | 14 | - |
| Consult Diagnostic Strep A Dipstick - Waived | 84 | 84 | - |
| Fisher HealthCare Sure-Vue - waived | 2 | 2 | - |
| Henry Schein One Step+ - waived | 39 | 37 | 2 |
| Immunostics Detector Strep A Direct | 6 | 6 | - |
| McKesson Strep A Dipstick | 13 | 12 | 1 |
| Other Moderately Complex Method | 1 | 1 | - |
| Other Waived Method | 11 | 11 | - |
| Polymedco Poly Stat Strep A - moderate | 1 | 1 | - |
| Polymedco Poly Stat Strep A - waived | 7 | 7 | - |
| PSS Select Diag. Strep A Dipstick - waived | 3 | 3 | - |
| Quidel QuickVue Dipstick Strep | 77 | 76 | 1 |
| Quidel QuickVue In-Line | 65 | 59 | 6 |
| Quidel QuickVue+ | 15 | 15 | - |
| Quidel Sofia Strep A - moderate | 4 | 4 | - |
| Quidel Sofia Strep A+ - waived | 4 | 4 | - |
| Sekisui OSOM | 93 | 92 | 1 |
| Sekisui OSOM Ultra Strep A | 53 | 51 | 2 |
| Stanbio QuStick Strep A | 1 | 1 | - |

STREP A ANTIGEN DETECTION

Specimen RS-13

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|--|-------------|-----------------|-----------------|
| ALL METHODS | 103 | 103 | - |
| Alere Acceava Strep A Test | 2 | 2 | - |
| BD Chek Strep A | 1 | 1 | - |
| BD Veritor - waived | 1 | 1 | - |
| Beckman Coulter ICON DS | 1 | 1 | - |
| Beckman Coulter ICON SC | 1 | 1 | - |
| Binax NOW Strep A | 1 | 1 | - |
| Consult Diagnostic Strep A Dipstick - Waived | 17 | 17 | - |
| Henry Schein One Step+ - waived | 8 | 8 | - |
| McKesson Strep A Dipstick | 1 | 1 | - |
| Other Waived Method | 2 | 2 | - |
| Polymedco Poly Stat Strep A - moderate | 1 | 1 | - |
| PSS Select Diag. Strep A Dipstick - waived | 1 | 1 | - |
| Quidel QuickVue Dipstick Strep | 15 | 15 | - |
| Quidel QuickVue In-Line | 20 | 20 | - |
| Quidel QuickVue+ | 10 | 10 | - |
| Quidel Sofia Strep A - moderate | 4 | 4 | - |
| Quidel Sofia Strep A+ - waived | 2 | 2 | - |
| Sekisui OSOM | 3 | 3 | - |
| Sekisui OSOM Ultra Strep A | 11 | 11 | - |

STREP A ANTIGEN DETECTION**Specimen RS-14**

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|--|--------------------|------------------------|------------------------|
| ALL METHODS | 92 | 91 | 1 |
| Alere Acceava Strep A Test | 2 | 2 | - |
| BD Chek Strep A | 1 | 1 | - |
| BD Veritor - waived | 1 | 1 | - |
| Beckman Coulter ICON DS | 1 | 1 | - |
| Beckman Coulter ICON SC | 1 | 1 | - |
| Binax NOW Strep A | 1 | 1 | - |
| Consult Diagnostic Strep A Dipstick - Waived | 17 | 17 | - |
| Henry Schein One Step+ - waived | 7 | 7 | - |
| Other Waived Method | 2 | 2 | - |
| PSS Select Diag. Strep A Dipstick - waived | 1 | 1 | - |
| Quidel QuickVue Dipstick Strep | 14 | 14 | - |
| Quidel QuickVue In-Line | 20 | 19 | 1 |
| Quidel QuickVue+ | 9 | 9 | - |
| Quidel Sofia Strep A - moderate | 4 | 4 | - |
| Quidel Sofia Strep A+ - waived | 1 | 1 | - |
| Sekisui OSOM | 1 | 1 | - |
| Sekisui OSOM Ultra Strep A | 8 | 8 | - |

Specimen RS-15

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|--|--------------------|------------------------|------------------------|
| ALL METHODS | 92 | 1 | 91 |
| Alere Acceava Strep A Test | 2 | - | 2 |
| BD Chek Strep A | 1 | - | 1 |
| BD Veritor - waived | 1 | - | 1 |
| Beckman Coulter ICON DS | 1 | - | 1 |
| Beckman Coulter ICON SC | 1 | - | 1 |
| Binax NOW Strep A | 1 | - | 1 |
| Consult Diagnostic Strep A Dipstick - Waived | 17 | - | 17 |
| Henry Schein One Step+ - waived | 7 | - | 7 |
| Other Waived Method | 2 | - | 2 |
| PSS Select Diag. Strep A Dipstick - waived | 1 | - | 1 |
| Quidel QuickVue Dipstick Strep | 14 | - | 14 |
| Quidel QuickVue In-Line | 20 | 1 | 19 |
| Quidel QuickVue+ | 9 | - | 9 |
| Quidel Sofia Strep A - moderate | 4 | - | 4 |
| Quidel Sofia Strep A+ - waived | 1 | - | 1 |
| Sekisui OSOM | 1 | - | 1 |
| Sekisui OSOM Ultra Strep A | 8 | - | 8 |

GENERAL BACTERIOLOGY

Specimen BA-7 – Blood Culture

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Serratia marcescens | 9 | 69.23% | Acceptable |
| Serratia sp. | 3 | 23.08% | Acceptable |

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

Specimen BA-8 – Stool Culture

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-------------------------|-------------|----------------|--------------------|
| Escherichia coli | 8 | 42.11% | Acceptable |
| Yersinia enterocolitica | 6 | 31.58% | Acceptable |
| Yersinia sp. | 4 | 21.05% | Acceptable |

Organisms present in specimen BA-8: *Yersinia enterocolitica* and *Escherichia coli*.

Specimen BA-9 – Wound Culture

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Staphylococcus aureus | 14 | 56.00% | Acceptable |
| Corynebacterium sp. | 9 | 36.00% | Acceptable |
| Gram positive bacilli | 1 | 4.00% | Acceptable |

Organisms present in specimen BA-9: *Staphylococcus aureus* and *Corynebacterium sp.*

METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS SCREEN

Specimen MSA-11

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

Organisms present in specimen MSA-11: *Staphylococcus aureus* and *Neisseria sicca*.

Specimen MSA-12

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

Organisms present in specimen MSA-12: *Staphylococcus aureus* and *Streptococcus pyogenes*.

Specimen MSA-13

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

Organisms present in specimen MSA-13: *Staphylococcus aureus* – Methicillin resistant and *Neisseria sicca*.

Specimen MSA-14

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

Organisms present in specimen MSA-14: *Staphylococcus aureus* – Methicillin resistant and *Staphylococcus epidermidis*.

Specimen MSA-15

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

Organisms present in specimen MSA-15: *Staphylococcus epidermidis* and *Corynebacterium sp.*

URINE CULTURE

Specimen UC-11

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-------------------------------------|-------------|----------------|--------------------|
| Pseudomonas aeruginosa | 42 | 60.87% | Acceptable |
| Growth, referred for identification | 9 | 13.04% | Acceptable |
| Pseudomonas sp. | 7 | 10.14% | Acceptable |
| Gram negative bacilli | 6 | 8.70% | Acceptable |
| Presump. Pseudomonas sp. | 4 | 5.80% | Acceptable |
| Presump. Gram negative | 1 | 1.45% | Acceptable |

Gram Stain

| | | | |
|---------------|----|------|------------|
| Gram negative | 47 | 100% | Acceptable |
|---------------|----|------|------------|

Gram Stain Morphology

| | | | |
|--------------|----|------|------------|
| Rods/bacilli | 46 | 100% | Acceptable |
|--------------|----|------|------------|

Organism present in specimen UC-11: *Pseudomonas aeruginosa*.

Specimen UC-12

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-------------------------------------|-------------|----------------|--------------------|
| Staphylococcus saprophyticus | 27 | 45.76% | Acceptable |
| Growth, referred for identification | 14 | 23.73% | Acceptable |
| Gram positive cocci | 6 | 10.17% | Acceptable |
| Staphylococcus sp. | 5 | 8.47% | Acceptable |
| Staph – coagulase negative | 3 | 5.08% | Acceptable |
| Presump. Staphylococcus sp. | 2 | 3.39% | Acceptable |
| Presump. Gram positive | 1 | 1.69% | Acceptable |
| Staphylococcus epidermidis | 1 | 1.69% | Acceptable |

Organisms present in specimen UC-12: *Staphylococcus saprophyticus* and *Staphylococcus epidermidis*.

Specimen UC-13

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-------------------------------------|-------------|----------------|--------------------|
| Citrobacter freundii | 18 | 48.65% | Acceptable |
| Growth, referred for identification | 10 | 27.03% | Acceptable |
| Gram negative bacilli | 4 | 10.81% | Acceptable |
| Citrobacter sp. | 3 | 8.11% | Acceptable |
| Presump. Gram negative | 2 | 5.41% | Acceptable |

Organism present in specimen UC-13: *Citrobacter freundii*.

URINE CULTURE

Specimen UC-14

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-------------------------------------|-------------|----------------|--------------------|
| Enterococcus sp. | 6 | 42.86% | Acceptable |
| Growth, referred for identification | 4 | 28.57% | Acceptable |
| Enterococcus (Strep) faecium | 2 | 14.29% | Acceptable |
| Gram positive cocci | 1 | 7.14% | Acceptable |
| Presump. Gram positive | 1 | 7.14% | Acceptable |

Organism present in specimen UC-14: *Enterococcus (Strep) faecium*.

Specimen UC-15

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-------------------------------------|-------------|----------------|--------------------|
| Staphylococcus aureus | 8 | 57.14% | Acceptable |
| Growth, referred for identification | 4 | 28.57% | Acceptable |
| Presump. Gram positive | 1 | 7.14% | Acceptable |
| Gram positive cocci | 1 | 7.14% | Acceptable |

Organisms present in specimen UC-15: *Staphylococcus aureus* and *Corynebacterium* species.

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Specimen UC-11, CC-11 (SUS-11) The organism present is: *Pseudomonas aeruginosa*.

| <u>Antimicrobial</u> | <u>-----Disk Diffusion-----</u> | | | | <u>-----MIC-----</u> | | | | <u>Acceptable (%)</u> |
|-------------------------------|-------------------------------------|----------|----------|----------|-------------------------------------|----------|----------|----------|---------------------------------|
| | <u>Interpretative category data</u> | | | | <u>Interpretative category data</u> | | | | |
| | <u>Labs</u> | <u>S</u> | <u>I</u> | <u>R</u> | <u>Labs</u> | <u>S</u> | <u>I</u> | <u>R</u> | |
| Amikacin | 4 | 3 | 1 | - | 3 | 2 | 1 | - | 100.00% |
| Amoxicillin/Clavulanate | 1 | - | - | 1 | 2 | - | - | 2 | Inappropriate drug ¹ |
| Ampicillin | 2 | - | - | 2 | 1 | - | - | 1 | Inappropriate drug ¹ |
| Ampicillin/Sulbactam | - | - | - | - | 1 | - | - | 1 | Inappropriate drug ¹ |
| Aztreonam | 3 | 2 | 1 | - | 2 | 2 | - | - | 83.33% |
| Carbenicillin | 1 | 1 | - | - | - | - | - | - | Inappropriate drug ¹ |
| Cefazolin | - | - | - | - | 2 | - | - | 2 | Inappropriate drug ¹ |
| Cefepime | 1 | 1 | - | - | 5 | 4 | 1 | - | 83.33% |
| Cefotaxime | - | - | - | - | 1 | - | - | 1 | Inappropriate drug ¹ |
| Ceftazidime | 12 | 12 | - | - | 5 | 4 | - | 1 | 95.65% |
| Ceftriaxone | 2 | 1 | 1 | - | 1 | - | - | 1 | Inappropriate drug ¹ |
| Cefuroxime | 1 | - | - | 1 | - | - | - | - | Inappropriate drug ¹ |
| Ciprofloxacin | 42 | 13 | 26 | 3 | 10 | 8 | 2 | - | 94.91% |
| Doxycycline | 1 | - | - | 1 | - | - | - | - | Inappropriate drug ¹ |
| Gentamicin | 31 | 10 | 4 | 17 | 10 | - | 5 | 5 | 86.00% ² |
| Imipenem | 5 | 5 | - | - | 4 | 4 | - | - | 100.00% |
| Levofloxacin | 24 | - | 6 | 18 | 8 | 1 | 6 | 1 | 97.36% |
| Meropenem | - | - | - | - | 3 | 3 | - | - | Not graded ³ |
| Nitrofurantoin | 5 | - | - | 5 | 2 | - | - | 2 | Inappropriate drug ¹ |
| Piperacillin | 5 | 5 | - | - | 4 | 4 | - | - | 100.00% |
| Piperacillin/Tazobactam | 5 | 5 | - | - | 4 | 4 | - | - | 100.00% |
| Tetracycline | 1 | - | - | 1 | 1 | - | - | 1 | Inappropriate drug ¹ |
| Tobramycin | 7 | 7 | - | - | 10 | 10 | - | - | 100.00% |
| Trimethoprim | 1 | - | - | 1 | - | - | - | - | Inappropriate drug ¹ |
| Trimethoprim/Sulfamethoxazole | 5 | - | - | 5 | 3 | - | - | 3 | Inappropriate drug ¹ |

NOTE: Please be aware that CLSI may issue a new edition of the supplement to the standards used by all proficiency testing programs for grading of susceptibilities as often as annually. Please contact CLSI to ensure that you are using the most recent version of these standards when reporting your susceptibilities. MLE has observed significant changes to which drugs are considered appropriate for various organisms with each subsequent supplement editions.

¹ This is an inappropriate drug for organism and/or source.
² This is challenge graded by referee consensus.
³ This is an ungraded challenge due to lack of comparison group.

GENITAL CULTURE

Specimen GC-11

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|---|-------------|----------------|--------------------|
| Negative for <i>N. gonorrhoeae</i> | 31 | 59.62% | Acceptable |
| <i>Enterococcus</i> sp. | 16 | 30.77% | Acceptable |
| <i>Enterococcus</i> (Strep) <i>faecalis</i> | 3 | 5.77% | Acceptable |
| Gram positive cocci | 1 | 1.92% | Acceptable |

Gram Stain

| | | | |
|---------------|----|------|------------|
| Gram positive | 26 | 100% | Acceptable |
|---------------|----|------|------------|

Gram Stain Morphology

| | | | |
|------------|----|--------|------------|
| Cocci | 25 | 96.15% | Acceptable |
| Diplococci | 1 | 3.85% | |

Organisms present in specimen GC-11: *Enterococcus* (Strep) *faecalis* and *Streptococcus viridans*.

Specimen GC-12

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|---------------------------------------|-------------|----------------|--------------------|
| Presumptive for <i>N. gonorrhoeae</i> | 8 | 80.00% | Acceptable |
| <i>Neisseria gonorrhoeae</i> | 2 | 20.00% | Acceptable |

Organisms present in specimen GC-12: *Neisseria gonorrhoeae* and *Corynebacterium* species.

Specimen GC-13

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-------------------------------------|-------------|----------------|--------------------|
| Presumptive for <i>N. gonorrhea</i> | 7 | 70.00% | Acceptable |
| <i>Neisseria gonorrhoeae</i> | 3 | 30.00% | Acceptable |

Organism present in specimen GC-13: *Neisseria gonorrhoeae*.

GENITAL CULTURE

Specimen GC-14

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------------|-------------|----------------|--------------------|
| Negative for N. gonorrhoeae | 10 | 100% | Acceptable |

Organism present in specimen GC-14: *Streptococcus agalactiae* and *Staphylococcus epidermidis*.

Specimen GC-15

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------------|-------------|----------------|--------------------|
| Negative for N. gonorrhoeae | 10 | 100% | Acceptable |

Organism present in specimen GC-15: *Lactobacillus casei*.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-11

| <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 | 76 | 1 | - | 10 | 65 |
| Calibrated Loop | 26 | - | - | 1 | 25 |
| HealthLink | 3 | - | - | - | 3 |
| Troy Bacti-Urine, Plate | 1 | - | - | - | 1 |
| Uri-Check | 10 | - | - | 3 | 7 |
| Uricult | 32 | 1 | - | 6 | 25 |

Identification–Specimen CC-11

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-------------------------------------|-------------|----------------|--------------------|
| Presump. Gram negative | 8 | 36.36% | Acceptable |
| Growth, referred for identification | 7 | 31.82% | Acceptable |
| Presump. Pseudomonas sp. | 4 | 18.18% | Acceptable |
| Pseudomonas aeruginosa | 2 | 9.09% | Acceptable |
| Pseudomonas sp. | 1 | 4.55% | Acceptable |

Organism present in specimen CC-11: >100,000 CFU/mL of *Pseudomonas aeruginosa*.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Specimen CC-12

| <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 | 76 | 3 | 2 | 8 | 63 |
| Calibrated Loop | 26 | - | - | 1 | 25 |
| HealthLink | 3 | - | - | - | 3 |
| Troy Bacti-Urine, Plate | 1 | - | - | - | 1 |
| Uri-Check | 10 | - | 1 | - | 9 |
| Uricult | 32 | 2 | 1 | 7 | 22 |

Identification–Specimen CC-12

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-------------------------------------|-------------|----------------|--------------------|
| Presump. Gram positive | 9 | 40.91% | Acceptable |
| Growth, referred for identification | 8 | 36.36% | Acceptable |
| Presump. Staphylococcus sp. | 1 | 4.55% | Acceptable |
| Staph – coagulase negative | 1 | 4.55% | Acceptable |
| Staphylococcus saprophyticus | 1 | 4.55% | Acceptable |
| Gram positive cocci | 1 | 4.55% | Acceptable |

Organisms present in specimen CC-12: >100,000 CFU/mL of *Staphylococcus saprophyticus* and <10,000 CFU/mL of *Staphylococcus epidermidis*.

COLONY COUNT/PRESUMPTIVE IDENTIFICATION

Identification–Specimen CC-13

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-------------------------------------|-------------|----------------|--------------------|
| Presump. Gram negative | 7 | 43.75% | Acceptable |
| Growth, referred for identification | 5 | 31.25% | Acceptable |
| Citrobacter freundii | 1 | 6.25% | Acceptable |

Organism present in specimen CC-13: 50,000 - 75,000 CFU/mL of *Citrobacter freundii*.

Identification–Specimen CC-14

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-------------------------------------|-------------|----------------|--------------------|
| Growth, referred for identification | 6 | 37.50% | Acceptable |
| Presump. Gram positive | 6 | 37.50% | Acceptable |
| Presump. Enterococcus sp. | 3 | 18.75% | Acceptable |
| Enterococcus (Strep) faecium | 1 | 6.25% | Acceptable |

Organism present in specimen CC-14: >100,000 CFU/mL of *Enterococcus (Strep) faecium*.

Identification–Specimen CC-15

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-------------------------------------|-------------|----------------|--------------------|
| Presump. Gram positive | 7 | 43.75% | Acceptable |
| Growth, referred for identification | 5 | 31.25% | Acceptable |
| Staphylococcus aureus | 2 | 12.50% | Acceptable |
| Presump. Staphylococcus sp. | 2 | 12.50% | Acceptable |

Organisms present in specimen CC-15: 50,000 - 75,000 CFU/mL of *Staphylococcus aureus* and <10,000 CFU/mL of *Corynebacterium* species.

DERMATOPHYTE SCREEN

Specimen DM-5

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Dermatophyte absent | 15 | 95.75% | Acceptable |

Organism present in specimen DM-5: *Staphylococcus epidermidis*.

Specimen DM-6

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Dermatophyte present | 16 | 100% | Acceptable |

Organism present in specimen DM-6: *Trichophyton tonsurans*.

GRAM STAIN

Specimen GS-11

| <u>Reaction</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------|-------------|----------------|--------------------|
| Gram positive | 19 | 100% | Acceptable |

Gram Stain Morphology

| | | | |
|--------------|----|--------|------------|
| Cocci | 15 | 88.24% | Acceptable |
| Coccobacilli | 2 | 11.76% | |

Organism present in specimen GS-11: *Staphylococcus epidermidis*.

Specimen GS-12

| <u>Reaction</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------|-------------|----------------|--------------------|
| Gram positive | 17 | 89.47% | Acceptable |
| Gram negative | 2 | 10.53% | |

Gram Stain Morphology

| | | | |
|--------------|----|--------|------------|
| Cocci | 12 | 70.59% | Acceptable |
| Diplococci | 2 | 11.76% | Acceptable |
| Coccobacilli | 3 | 17.65% | |

Organism present in specimen GS-12: *Streptococcus pneumoniae*.

GRAM STAIN

Specimen GS-13

| <u>Reaction</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------|-------------|----------------|--------------------|
| Gram negative | 18 | 100% | Acceptable |

Gram Stain Morphology

| | | | |
|--------------|----|--------|----------|
| Coccobacilli | 4 | 23.53% | Ungraded |
| Diplococci | 10 | 58.82% | |
| Cocci | 3 | 17.65% | |

Organism present in specimen GS-13: *Haemophilus influenzae*. The Gram Stain Morphology is not graded due to lack of referee consensus. Vendor assay value is: Coccobacilli.

Specimen GS-14

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

Gram Stain Morphology

| | | | |
|--------------|----|------|------------|
| Rods/bacilli | 17 | 100% | Acceptable |
|--------------|----|------|------------|

Organism present in specimen GS-14: *Serratia marcescens*.

Specimen GS-15

| <u>Reaction</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------|-------------|----------------|--------------------|
| Gram positive | 17 | 89.47% | Acceptable |
| Gram negative | 2 | 10.53% | |

Gram Stain Morphology

| | | | |
|------------|----|--------|------------|
| Cocci | 14 | 82.35% | Acceptable |
| Diplococci | 3 | 17.65% | Acceptable |

Organism present in specimen GS-15: *Staphylococcus aureus*.

AFFIRM VP III–*Trichomonas vaginalis*

Specimen VP-11

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Negative | 31 | 100% | Acceptable |

Organism present in specimen VP-11: *Gardnerella vaginalis*.

Specimen VP-12

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Positive | 31 | 100% | Acceptable |

Organisms present in specimen VP-12: *Candida albicans* and *Trichomonas vaginalis*.

Specimen VP-13

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Positive | 31 | 100% | Acceptable |

Organism present in specimen VP-13: *Trichomonas vaginalis*.

Specimen VP-14

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Negative | 31 | 100% | Acceptable |

Organism present in specimen VP-14: *Candida albicans*.

Specimen VP-15

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Negative | 31 | 100% | Acceptable |

Organism present in specimen VP-15: *Gardnerella vaginalis*.

AFFIRM VP III–Gardnerella vaginalis

Specimen VP-11

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Positive | 30 | 96.77% | Acceptable |
| Negative | 1 | 3.23% | |

Specimen VP-12

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Negative | 31 | 100% | Acceptable |

Specimen VP-13

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Negative | 31 | 100% | Acceptable |

Specimen VP-14

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Negative | 30 | 96.77% | Acceptable |
| Positive | 1 | 3.23% | |

Specimen VP-15

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Positive | 30 | 96.77% | Acceptable |
| Negative | 1 | 3.23% | |

AFFIRM VP III–Candida sp.

Specimen VP-11

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Negative | 31 | 100% | Acceptable |

Specimen VP-12

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Positive | 30 | 96.77% | Acceptable |
| Negative | 1 | 3.23% | |

AFFIRM VP III–Candida sp.**Specimen VP-13**

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Negative | 31 | 100% | Acceptable |

Specimen VP-14

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Positive | 30 | 96.77% | Acceptable |
| Negative | 1 | 3.23% | |

Specimen VP-15

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Negative | 31 | 100% | Acceptable |

CHLAMYDIA (ANTIGEN DETECTION)**Specimen CY-11**

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|----------------------|-------------|-----------------|-----------------|
| ALL METHODS | 16 | - | 16 |
| BD ProbeTec | 3 | - | 3 |
| Cepheid GeneXpert | 1 | - | 1 |
| Gen-Probe APTIMA | 2 | - | 2 |
| Quidel QuickVue | 6 | - | 6 |
| Roche COBAS Amplicor | 3 | - | 3 |

Organism present in specimen CY-11: No organism present.

Specimen CY-12

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|----------------------|-------------|-----------------|-----------------|
| ALL METHODS | 17 | 17 | - |
| BD ProbeTec | 3 | 3 | - |
| Cepheid GeneXpert | 2 | 2 | - |
| Gen-Probe APTIMA | 2 | 2 | - |
| Quidel QuickVue | 6 | 6 | - |
| Roche COBAS Amplicor | 3 | 3 | - |

Organism present in specimen CY-12: *Chlamydia trachomatis*.

CHLAMYDIA (ANTIGEN DETECTION)

Specimen CY-13

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|----------------------|-------------|-----------------|-----------------|
| ALL METHODS | 15 | 15 | - |
| BD ProbeTec | 3 | 3 | - |
| Cepheid GeneXpert | 2 | 2 | - |
| Gen-Probe APTIMA | 2 | 2 | - |
| Quidel QuickVue | 4 | 4 | - |
| Roche COBAS Amplicor | 3 | 3 | - |

Organisms present in specimen CY-13: *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

Specimen CY-14

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|----------------------|-------------|-----------------|-----------------|
| ALL METHODS | 14 | 1 | 13 |
| BD ProbeTec | 3 | - | 3 |
| Cepheid GeneXpert | 1 | 1 | - |
| Gen-Probe APTIMA | 2 | - | 2 |
| Quidel QuickVue | 4 | - | 4 |
| Roche COBAS Amplicor | 3 | - | 3 |

Organism present in specimen CY-14: *Neisseria gonorrhoeae*.

Specimen CY-15

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|----------------------|-------------|-----------------|-----------------|
| ALL METHODS | 15 | 15 | - |
| BD ProbeTec | 3 | 3 | - |
| Cepheid GeneXpert | 2 | 2 | - |
| Gen-Probe APTIMA | 2 | 2 | - |
| Quidel QuickVue | 4 | 4 | - |
| Roche COBAS Amplicor | 3 | 3 | - |

Organism present in specimen CY-15: *Chlamydia trachomatis*.

GC (ANTIGEN DETECTION)

Specimen CY-11

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|----------------------|-------------|-----------------|-----------------|
| ALL METHODS | 10 | - | 10 |
| BD ProbeTec | 3 | - | 3 |
| Cepheid GeneXpert | 1 | - | 1 |
| Gen-Probe APTIMA | 2 | - | 2 |
| Roche COBAS Amplicor | 3 | - | 3 |

Specimen CY-12

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|----------------------|-------------|-----------------|-----------------|
| ALL METHODS | 11 | - | 11 |
| BD ProbeTec | 3 | - | 3 |
| Cepheid GeneXpert | 2 | - | 2 |
| Gen-Probe APTIMA | 2 | - | 2 |
| Roche COBAS Amplicor | 3 | - | 3 |

Specimen CY-13

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|----------------------|-------------|-----------------|-----------------|
| ALL METHODS | 11 | 11 | - |
| BD ProbeTec | 3 | 3 | - |
| Cepheid GeneXpert | 2 | 2 | - |
| Gen-Probe APTIMA | 2 | 2 | - |
| Roche COBAS Amplicor | 3 | 3 | - |

Specimen CY-14

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|----------------------|-------------|-----------------|-----------------|
| ALL METHODS | 10 | 10 | - |
| BD ProbeTec | 3 | 3 | - |
| Cepheid GeneXpert | 1 | 1 | - |
| Gen-Probe APTIMA | 2 | 2 | - |
| Roche COBAS Amplicor | 3 | 3 | - |

Specimen CY-15

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|----------------------|-------------|-----------------|-----------------|
| ALL METHODS | 11 | - | 11 |
| BD ProbeTec | 3 | - | 3 |
| Cepheid GeneXpert | 2 | - | 2 |
| Gen-Probe APTIMA | 2 | - | 2 |
| Roche COBAS Amplicor | 3 | - | 3 |

CRYPTOSPORIDIUM ANTIGEN DETECTION

Specimen LC-11

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| ALL METHODS | 1 | 1 | - |

Antigen present in specimen LC-11: *Cryptosporidium*.

Specimen LC-12

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| ALL METHODS | 1 | - | 1 |

Antigen present in specimen LC-12: *Giardia lamblia*.

Specimen LC-13

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| ALL METHODS | 1 | 1 | - |

Antigens present in specimen LC-13: *Cryptosporidium* and *Giardia lamblia*.

Specimen LC-14

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| ALL METHODS | 1 | - | 1 |

Antigen present in specimen LC-14: No antigens present.

Specimen LC-15

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| ALL METHODS | 1 | 1 | - |

Antigen present in specimen LC-15: *Cryptosporidium*.

GIARDIA LAMBLIA ANTIGEN DETECTION

Specimen LC-11

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| ALL METHODS | 1 | - | 1 |

Specimen LC-12

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| ALL METHODS | 1 | 1 | - |

Specimen LC-13

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| ALL METHODS | 1 | 1 | - |

Specimen LC-14

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| ALL METHODS | 1 | - | 1 |

Specimen LC-15

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| ALL METHODS | 1 | - | 1 |

RSV ANTIGEN DETECTION

Specimen V-11

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|------------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 66 | 66 | - |
| Alere Binax NOW - waived | 40 | 40 | - |
| Alere Clearview RSV - waived | 5 | 5 | - |
| Quidel QuickVue RSV - waived | 10 | 10 | - |
| Quidel Sofia - waived | 8 | 8 | - |
| Remel Xpect - waived | 1 | 1 | - |

Antigen present in specimen V-11: RSV.

Specimen V-12

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|------------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 66 | 1 | 65 |
| Alere Binax NOW - waived | 40 | - | 40 |
| Alere Clearview RSV - waived | 5 | - | 5 |
| Quidel QuickVue RSV - waived | 10 | 1 | 9 |
| Quidel Sofia - waived | 8 | - | 8 |
| Remel Xpect - waived | 1 | - | 1 |

Antigen present in specimen V-12: Influenza B.

Specimen V-13

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|------------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 16 | 15 | 1 |
| Alere Binax NOW - waived | 3 | 3 | - |
| Alere Clearview RSV - waived | 3 | 2 | 1 |
| Quidel QuickVue RSV - waived | 4 | 4 | - |
| Quidel Sofia - waived | 6 | 6 | - |

Antigen present in specimen V-13: RSV.

Specimen V-14

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|------------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 16 | - | 16 |
| Alere Binax NOW - waived | 3 | - | 3 |
| Alere Clearview RSV - waived | 3 | - | 3 |
| Quidel QuickVue RSV - waived | 4 | - | 4 |
| Quidel Sofia - waived | 6 | - | 6 |

Antigen present in specimen V-14: Influenza A.

RSV ANTIGEN DETECTION

Specimen V-15

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|------------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 16 | - | 16 |
| Alere Binax NOW - waived | 3 | - | 3 |
| Alere Clearview RSV - waived | 3 | - | 3 |
| Quidel QuickVue RSV - waived | 4 | - | 4 |
| Quidel Sofia - waived | 6 | - | 6 |

Antigen present in specimen V-15: No antigen present.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-11

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 38 | 1 | 37 |
| Quidel QuickVue Influenza | 30 | - | 30 |

Antigen present in specimen V-11: RSV.

Specimen V-12

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 36 | 33 | 3 |
| Quidel QuickVue Influenza | 29 | 27 | 2 |

Antigen present in specimen V-12: Influenza B.

Specimen V-13

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 12 | - | 12 |
| Quidel QuickVue Influenza | 11 | - | 11 |

Antigen present in specimen V-13: RSV.

Specimen V-14

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 12 | 12 | - |
| Quidel QuickVue Influenza | 11 | 11 | - |

Antigen present in specimen V-14: Influenza A.

INFLUENZA A/B ANTIGEN DETECTION

Specimen V-15

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 12 | - | 12 |
| Quidel QuickVue Influenza | 11 | - | 11 |

Antigen present in specimen V-15: No antigen present.

INFLUENZA A ANTIGEN DETECTION

Specimen V-11

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 335 | 1 | 334 |
| Alere Binax NOW - waived | 106 | - | 106 |
| Alere i Instrument Influenza | 1 | - | 1 |
| Alere Influenza A&B | 11 | - | 11 |
| BD Veritor - waived | 30 | - | 30 |
| Cepheid GeneXpert | 1 | - | 1 |
| Henry Schein OneStep+ Flu A&B | 3 | - | 3 |
| Labsco Advantage Flu A&B | 1 | - | 1 |
| Medline Influenza A&B | 3 | - | 3 |
| Other Moderately Complex Method | 1 | - | 1 |
| Quidel QuickVue Influenza A+B | 40 | - | 40 |
| Quidel Sofia - waived | 76 | 1 | 75 |
| Remel Xpect | 2 | - | 2 |
| Sekisui OSOM Influenza A&B | 44 | - | 44 |

Antigen present in specimen V-11: RSV.

Specimen V-12

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 334 | 2 | 332 |
| Alere Binax NOW - waived | 106 | 2 | 104 |
| Alere i Instrument Influenza | 1 | - | 1 |
| Alere Influenza A&B | 10 | - | 10 |
| BD Veritor - waived | 30 | - | 30 |
| Cepheid GeneXpert | 1 | - | 1 |
| Henry Schein OneStep+ Flu A&B | 3 | - | 3 |
| Labsco Advantage Flu A&B | 1 | - | 1 |
| Medline Influenza A&B | 3 | - | 3 |
| Other Moderately Complex Method | 1 | - | 1 |
| Quidel QuickVue Influenza A+B | 39 | - | 39 |
| Quidel Sofia - waived | 77 | - | 77 |
| Remel Xpect | 2 | - | 2 |
| Sekisui OSOM Influenza A&B | 44 | - | 44 |

Antigen present in specimen V-12: RSV.

INFLUENZA A ANTIGEN DETECTION

Specimen V-13

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 111 | - | 111 |
| Alere Binax NOW - waived | 20 | - | 20 |
| Alere Influenza A&B | 2 | - | 2 |
| BD Veritor - waived | 2 | - | 2 |
| Cepheid GeneXpert | 1 | - | 1 |
| Labsco Advantage Flu A&B | 1 | - | 1 |
| Other Moderately Complex Method | 1 | - | 1 |
| Quidel QuickVue Influenza A+B | 6 | - | 6 |
| Quidel Sofia - waived | 41 | - | 41 |
| Remel Xpect | 1 | - | 1 |
| Sekisui OSOM Influenza A&B | 35 | - | 35 |

Antigen present in specimen V-13: RSV.

Specimen V-14

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 111 | 111 | - |
| Alere Binax NOW - waived | 20 | 20 | - |
| Alere Influenza A&B | 2 | 2 | - |
| BD Veritor - waived | 2 | 2 | - |
| Cepheid GeneXpert | 1 | 1 | - |
| Labsco Advantage Flu A&B | 1 | 1 | - |
| Other Moderately Complex Method | 1 | 1 | - |
| Quidel QuickVue Influenza A+B | 6 | 6 | - |
| Quidel Sofia - waived | 41 | 41 | - |
| Remel Xpect | 1 | 1 | - |
| Sekisui OSOM Influenza A&B | 35 | 35 | - |

Antigen present in specimen V-14: Influenza A.

Specimen V-15

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 111 | 1 | 110 |
| Alere Binax NOW - waived | 20 | - | 20 |
| Alere Influenza A&B | 2 | - | 2 |
| BD Veritor - waived | 2 | - | 2 |
| Cepheid GeneXpert | 1 | - | 1 |
| Labsco Advantage Flu A&B | 1 | - | 1 |
| Other Moderately Complex Method | 1 | - | 1 |
| Quidel QuickVue Influenza A+B | 6 | - | 6 |
| Quidel Sofia - waived | 41 | - | 41 |
| Remel Xpect | 1 | - | 1 |
| Sekisui OSOM Influenza A&B | 35 | 1 | 34 |

Antigen present in specimen V-15: No antigen present.

INFLUENZA B ANTIGEN DETECTION

Specimen V-11

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 333 | 7 | 326 |
| Alere Binax NOW - waived | 105 | 1 | 104 |
| Alere i Instrument Influenza | 1 | - | 1 |
| Alere Influenza A&B | 10 | - | 10 |
| BD Veritor - waived | 30 | - | 30 |
| Cepheid GeneXpert | 1 | - | 1 |
| Henry Schein OneStep+ Flu A&B | 3 | - | 3 |
| Labsco Advantage Flu A&B | 1 | - | 1 |
| Medline Influenza A&B | 3 | - | 3 |
| Other Moderately Complex Method | 1 | - | 1 |
| Quidel QuickVue Influenza A+B | 38 | - | 38 |
| Quidel Sofia - waived | 74 | - | 74 |
| Remel Xpect | 2 | - | 2 |
| Sekisui OSOM Influenza A&B | 47 | 6 | 41 |

Antigen present in specimen V-11: RSV.

Specimen V-12

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 339 | 330 | 9 |
| Alere Binax NOW - waived | 105 | 103 | 2 |
| Alere i Instrument Influenza | 1 | 1 | - |
| Alere Influenza A&B | 11 | 10 | 1 |
| BD Veritor - waived | 30 | 30 | - |
| Cepheid GeneXpert | 1 | 1 | - |
| Henry Schein OneStep+ Flu A&B | 3 | 3 | - |
| Labsco Advantage Flu A&B | 1 | 1 | - |
| Medline Influenza A&B | 3 | 2 | 1 |
| Other Moderately Complex Method | 1 | 1 | - |
| Quidel QuickVue Influenza A+B | 40 | 39 | 1 |
| Quidel Sofia - waived | 75 | 74 | 1 |
| Remel Xpect | 2 | 2 | - |
| Sekisui OSOM Influenza A&B | 48 | 45 | 3 |

Antigen present in specimen V-12: Influenza B.

INFLUENZA B ANTIGEN DETECTION

Specimen V-13

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 111 | 9 | 102 |
| Alere Binax NOW - waived | 20 | - | 20 |
| Alere Influenza A&B | 2 | - | 2 |
| BD Veritor - waived | 2 | - | 2 |
| Cepheid GeneXpert | 1 | - | 1 |
| Labsco Advantage Flu A&B | 1 | - | 1 |
| Other Moderately Complex Method | 1 | - | 1 |
| Quidel QuickVue Influenza A+B | 6 | - | 6 |
| Quidel Sofia - waived | 40 | - | 40 |
| Remel Xpect | 1 | - | 1 |
| Sekisui OSOM Influenza A&B | 37 | 9 | 28 |

Antigen present in specimen V-13: RSV.

Specimen V-14

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 111 | 4 | 107 |
| Alere Binax NOW - waived | 20 | - | 20 |
| Alere Influenza A&B | 2 | - | 2 |
| BD Veritor - waived | 2 | - | 2 |
| Cepheid GeneXpert | 1 | - | 1 |
| Labsco Advantage Flu A&B | 1 | - | 1 |
| Other Moderately Complex Method | 1 | - | 1 |
| Quidel QuickVue Influenza A+B | 6 | - | 6 |
| Quidel Sofia - waived | 40 | - | 40 |
| Remel Xpect | 1 | - | 1 |
| Sekisui OSOM Influenza A&B | 37 | 4 | 33 |

Antigen present in specimen V-14: Influenza A.

Specimen V-15

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 111 | 9 | 102 |
| Alere Binax NOW - waived | 20 | - | 20 |
| Alere Influenza A&B | 2 | - | 2 |
| BD Veritor - waived | 2 | - | 2 |
| Cepheid GeneXpert | 1 | - | 1 |
| Labsco Advantage Flu A&B | 1 | - | 1 |
| Other Moderately Complex Method | 1 | - | 1 |
| Quidel QuickVue Influenza A+B | 6 | - | 6 |
| Quidel Sofia - waived | 40 | 1 | 39 |
| Remel Xpect | 1 | - | 1 |
| Sekisui OSOM Influenza A&B | 37 | 8 | 29 |

Antigen present in specimen V-15: No antigen present.

LEGIONELLA ANTIGEN DETECTION

Specimen L-11

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| Binax NOW | 21 | - | 21 |

Specimen L-11: Negative for Legionella antigen.

Specimen L-12

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| Binax NOW | 21 | 21 | - |

Specimen L-12: Positive for Legionella antigen.

Specimen L-13

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| Binax NOW | 21 | 21 | - |

Specimen L-13: Positive for Legionella antigen.

Specimen L-14

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| Binax NOW | 21 | - | 21 |

Specimen L-14: Negative for Legionella antigen.

Specimen L-15

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| Binax NOW | 21 | - | 21 |

Specimen L-15: Negative for Legionella antigen.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-11

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|-------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 7 | - | 7 |
| Alere C. diff Quik Chek | 5 | - | 5 |
| Meridian Illumigene | 1 | - | 1 |
| Meridian Premier | 1 | - | 1 |

Antigen present in specimen AG-11: No antigen present.

Specimen AG-12

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|-------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 7 | 7 | - |
| Alere C. diff Quik Chek | 5 | 5 | - |
| Meridian Illumigene | 1 | 1 | - |
| Meridian Premier | 1 | 1 | - |

Antigen present in specimen AG-12: *Clostridium difficile*.

Specimen AG-13

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|-------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 7 | - | 7 |
| Alere C. diff Quik Chek | 5 | - | 5 |
| Meridian Illumigene | 1 | - | 1 |
| Meridian Premier | 1 | - | 1 |

Antigen present in specimen AG-13: Rotavirus.

Specimen AG-14

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|-------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 7 | 7 | - |
| Alere C. diff Quik Chek | 5 | 5 | - |
| Meridian Illumigene | 1 | 1 | - |
| Meridian Premier | 1 | 1 | - |

Antigens present in specimen AG-14: *Clostridium difficile* and Rotavirus.

CLOSTRIDIUM DIFFICILE TOXIN ANTIGEN DETECTION

Specimen AG-15

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|-------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 7 | 7 | - |
| Alere C. diff Quik Chek | 5 | 5 | - |
| Meridian Illumigene | 1 | 1 | - |
| Meridian Premier | 1 | 1 | - |

Antigen present in specimen AG-15: *Clostridium difficile*.

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-11

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|----------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 5 | - | 5 |
| Fisher HealthCare Sure-Vue | 5 | - | 5 |

Specimen AG-12

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|----------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 5 | - | 5 |
| Fisher HealthCare Sure-Vue | 5 | - | 5 |

Specimen AG-13

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|----------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 5 | 5 | - |
| Fisher HealthCare Sure-Vue | 5 | 5 | - |

Specimen AG-14

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|----------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 5 | 5 | - |
| Fisher HealthCare Sure-Vue | 5 | 5 | - |

ROTAVIRUS ANTIGEN DETECTION

Specimen AG-15

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|----------------------------|-------------|-----------------|-----------------|
| ALL METHODS | 5 | - | 5 |
| Fisher HealthCare Sure-Vue | 5 | - | 5 |

STREPTOCOCCUS PNEUMONIAE ANTIGEN

Specimen SP-11

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| Binax NOW | 19 | - | 19 |

Specimen SP-11: Negative for *Streptococcus pneumoniae* antigen.

Specimen SP-12

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| Binax NOW | 19 | 19 | - |

Specimen SP-12: Positive for *Streptococcus pneumoniae* antigen.

Specimen SP-13

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| Binax NOW | 19 | 19 | - |

Specimen SP-13: Positive for *Streptococcus pneumoniae* antigen.

Specimen SP-14

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| Binax NOW | 19 | 19 | - |

Specimen SP-14: Positive for *Streptococcus pneumoniae* antigen.

Specimen SP-15

| <u>Method</u> | <u>Labs</u> | <u>Positive</u> | <u>Negative</u> |
|---------------|-------------|-----------------|-----------------|
| Binax NOW | 19 | - | 19 |

Specimen SP-15: Negative for *Streptococcus pneumoniae* antigen.

PARASITOLOGY

Specimen PA-11

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Dientamoeba fragilis | 1 | 100% | Acceptable |

Parasite present in specimen PA-11: *Dientamoeba fragilis*.

Specimen PA-12

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

Parasites present in specimen PA-12: *Endolimax nana* and *Blastocystis hominis*.

Specimen PA-13

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| No parasite seen | 1 | 100% | Ungraded |

Specimen PA-13 is an ungraded challenge due to less than 80% participant consensus.

Parasite present in specimen PA-13: *Strongyloides stercoralis*.

Specimen PA-14

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Taenia sp. eggs | 1 | 100% | Acceptable |

Parasite present in specimen PA-14: *Taenia sp. eggs*.

Specimen PA-15

| <u>Identification</u> | <u>Labs</u> | <u>Percent</u> | <u>Performance</u> |
|-----------------------|-------------|----------------|--------------------|
| Plasmodium ovale | 1 | 100% | Acceptable |

Parasite present in specimen PA-15: *Plasmodium ovale*.

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