BACTERIOLOGY PROFICIENCY TESTING PROGRAM

Comprehensive Category

April 25, 2016

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Bacteriology Proficiency Testing Program
GENERAL INFORMATION

The Bacteriology Proficiency Testing Program. Three proficiency testing events are given annually, each consisting of a minimum of five specimens. In order to successfully complete a test event, participating laboratories must achieve a score of 80% or greater. Unsuccessful performance in the testing program is defined as a score of less than 80% on two of three consecutive test events.

Authentication. The presence and identity of the organism(s) in each specimen must be confirmed by at least 80% of the referee or participating laboratories. Referee laboratories are selected from New York State participating laboratories (located throughout the State) with acceptable and reproducible levels of performance.

Grading System. Laboratories are to process proficiency test specimens in the same manner as patient specimens. Thus, laboratories are responsible for identifying test isolates to the same level as performed on patient isolates. If your laboratory speciates an organism on special request, then you must also speciate it in the proficiency test; consider speciation to have been requested on all reportable isolates. In addition, laboratories are not responsible for culturing any test samples from specimen sources which they do not process. Information regarding your laboratory's reporting protocol was provided to us in the questionnaire previously distributed to all laboratories. Any changes in reporting protocol must be received by our office prior to the mailout date for proficiency testing for that information to be considered in grading.

Our testing format is in compliance with Center for Medicare & Medicaid Services guidelines as specified in the regulations of CLIA '88. One-half of our samples require identification of all organisms present. The other half requires that only the pathogenic organism(s) be reported. We recognize the potential for any organism to be pathogenic depending on the clinical condition of the patient. However, our samples are designed so that only well-established pathogens should be reported. Tests are graded in adherence to CMS guidelines, as specified in the regulations of CLIA '88. Each of the specimens receives a score as determined by the following formula:

$$(a + b)/(c + d + e) \times 100\%$$

a = # correct identifications
b = # correct antibiotic susceptibility results (if applicable)
c = # possible identifications
d = # possible antibiotic susceptibility results (if applicable)
e = # additional organisms reported
Grades for each sample are then averaged to determine the final grade for this testing event.

Disclaimer
The use of brand and/or trade names in this report does not constitute an endorsement of the products on the part of the Wadsworth Center or the New York State Department of Health.

Notes of Interest

Proficiency Testing Participation
Beginning with the first proficiency test event of 2016 laboratories holding NYS permits were allowed to participate in either the NYS PT program or an equivalent PT program administered by another provider.

Reminder
Proficiency test samples must be handled just like patient samples, to the extent possible. If you perform testing using one system on patient samples DO NOT use additional systems on proficiency samples. Several laboratories are reporting the use of multiple systems/methods to identify organisms or perform susceptibility tests. Unless you are using multiple systems on patient samples you must not do so on proficiency samples.

Online Instructions and Worksheets
The instructions and worksheets for Bacteriology proficiency testing are available at the New York State Department of Health, Wadsworth Center website at http://www.wadsworth.org/regulatory/clep/pt/categories. This address has changed so be sure to bookmark it for future use.

Contact information
Please make sure that CLEP has the correct email addresses for your laboratory contact people. On occasion we need to notify you of an issue with a sample and this is done by email.

Bacteriology Questionnaires
Please update your questionnaire whenever there is a change in your laboratory's reporting policy. Proficiency test results are graded in accordance with information on the questionnaire so be certain that this information is accurate. If your questionnaire indicates that your laboratory reports an organism to the species level then you must report to the species level on the proficiency test to receive credit. If you need a copy of your questionnaire for review, please contact our office at 518-474-4177 or email us at BactiPTP@health.ny.gov. **Grades will not be revised due to incorrect information on the questionnaire.**

Clinical Laboratory Standards Institute
Please review the new CLSI recommendations to optimize detection and reporting of antimicrobial resistance. The latest guidelines were published in January 2016.

Samples for Remediation
We maintain a limited number of samples for remediation purposes. If your laboratory had difficulty isolating or identifying the organisms in a sample you can contact us after the event for additional samples. Contact us either by email or phone and provide your PFI number and the sample(s) needed. They will be shipped to you within a week.

New email address
The Bacteriology proficiency testing program has a new email address – BactiPTP@health.ny.gov

April 2016 Test Event

Number of Participating Laboratories: 78

Grade Distribution		
Score	**Number**	**Percent**
100%	48	62
90 – 99%	1	1
80 – 89%	27	35
<80%	2	3

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ANSWER KEY

Specimen Number 1 - Stool (Pathogens only)
Shigella sonnei, group D (*Shigella* species accepted)

Specimen Number 2 – Throat (Pathogens only)
Streptococcus, group A (*S. pyogenes*)

Specimen Number 3 – Tissue (Necrotizing fasciitis - Aerobic / Anaerobic (All organisms)
Clostridium perfringens

Specimen Number 4 –Urine (Pathogens only) and Antibiotic Susceptibility
Staphylococcus saprophyticus
Susceptibility to: Norfloxacin – susceptible
Nitrofurantoin – susceptible

Specimen Number 5 – Cervix (Pathogens only)
Neisseria gonorrhoeae

***Chlamydia* Direct Detection – Urine/Cervix**
Negative for *Chlamydia trachomatis*

Group A *Streptococcus* Direct Antigen Detection - Throat
Positive for Group A *Streptococcus*

Specimen Number 1 - Stool (Pathogens Only)

Accepted responses – *Shigella sonnei*, group D, *Shigella* species
Other organisms included: *Escherichia coli, Citrobacter freundii*

100% of the participating laboratories (& referee laboratories) reported either *Shigella sonnei*, group D or *Shigella* species.

Results reported for specimen # 1

Result	Method	# Labs
Shigella sonnei, group D	Siemens (Dade Behring) Negative Combo - any panel	20
	bioMerieux Vitek 2 GN	19
	bioMerieux API 20E	8
	Wellcolex Colour Shigella	2
	BD Phoenix Gram Negative ID	1
	BD Difco Shigella Latex	1
	bioMerieux VITEK MS	1
Shigella species	Siemens (Dade Behring) Negative Combo - any panel	9
	bioMerieux Vitek 2 GN	6
	bioMerieux API 20E	3
	bioMerieux API Rapid 20E	1
Specimen source not tested		7

Specimen Number 2 – Throat (Pathogens only)

Accepted response – *Streptococcus,* group A (*S. pyogenes*)
Other organisms included: *Staphylococcus epidermidis, Streptococcus mitis*

100% of participating laboratories (& referee laboratories) reported *Streptococcus,* group A (*S. pyogenes*).

Results reported for specimen # 2

Result	Method	# Labs
Streptococcus, group A (*S. pyogenes*)	Remel Streptex	20
	Conventional biochemicals	18
	BD BBL Streptocard	12
	DPC PathoDX Strep Grouping	10
	bioMerieux Vitek 2 GP	7
	Siemens (Dade Behring) Positive Combo - any panel	5
	bioMerieux VITEK MS	2
	Phadebact Strep A	1
	bioMerieux API 20 Strep	1
	OSOM Ultra Strep. A Test	1
	Hardy Diagnostic Streppro	1

Specimen Number 3 – Tissue – necrotizing fasciitis - Aerobic/Anaerobic (All organisms)

Accepted response - *Clostridium perfringens*

97% of the participating laboratories and 100% of the referee laboratories reported *Clostridium perfringens.*

Results reported for specimen # 3

Result	**Method**	**# Labs**
Clostridium perfringens	Remel RapID ANA II	34
	bioMerieux Vitek 2 ANC	11
	Siemens (Dade Behring) MicroScan Rapid Anaerobe	11
	bioMerieux API 20A	8
	bioMerieux VITEK MS	3
Clostridium species	bioMerieux Vitek 2 ANC	1
	Conventional biochemicals	1
	Remel RapID ANA II	2
	bioMerieux API 20A	1
No growth		1
No aerobic organisms		1
Specimen source not tested		4

Specimen Number 4 – Urine (Pathogens only) and Antibiotic susceptibility

Accepted response – *Staphylococcus saprophyticus*
Norfloxacin – susceptible
Nitrofurantoin – susceptible

97% of the participating laboratories and 90% of the referee laboratories reported *Staphylococcus saprophyticus.*

Results reported for specimen # 4

Result	**Method**	**# Labs**
Staphylococcus saprophyticus	Siemens (Dade Behring) Positive Combo - any panel	34
	bioMerieux Vitek 2 GP	23
	Conventional biochemicals	9
	bioMerieux API Staph	4
	bioMerieux VITEK MS	3
	bioMerieux Vitek 1 GPI	1
	BD Phoenix Gram Positive ID	1
Staphylococcus, coagulase negative	Conventional biochemicals	1
Staphylococcus saccharolyticus	bioMerieux Vitek 2 GP	2

Susceptibility testing results

Norfloxacin				
Result	**Method**	**# Labs**	**Zone**	**MIC**
Susceptible	MicroScan	3		<=4
		1		<4
	bioMerieux Vitek 2	1		<=16
	Disk diffusion	1	31	
		1	26	
		1	25	
Resistant	Disk diffusion	1	8	
Test not performed		69		
Nitrofurantoin				
Result	**Method**	**# Labs**	**Zone**	**MIC**
Susceptible	MicroScan	30		<=32
		2		<32
	bioMerieux Vitek 2	16		<=16
		1		Not given
	BD Phoenix	1		<=16
	Not given	1		<=16
	Disk diffusion	3	25	
		2	33	
		1	32	
		1	22	
		1	23	
		1	30	
		1	34	
		1	24	
		1	21	
		1	35	
Test not performed		14		

Specimen Number 5 – Cervix (Pathogens only)

Accepted response – *Neisseria gonorrhoeae*
Other organisms included: *Lactobacillus rhamnosus, Neisseria mucosa*

64% of participating laboratories reported *Neisseria gonorrhoeae.* 90% of referee laboratories reported *Neisseria gonorrhoeae.* Therefore, this sample was authenticated using referee laboratory responses.

Results reported for specimen # 5

Result	**Method**	**# Labs**
Neisseria gonorrhoeae	Remel RapID NH	19
	bioMerieux Vitek 2 NH	8
	bioMerieux API NH	8
	Siemens (Dade Behring) MicroScan HNID	8
	bioMerieux VITEK MS	3
	Remel BactiCard Neisseria	2
	bioMerieux Vitek 2 GN	1
No pathogens isolated	bioMerieux API NH	26
Gardnerella vaginalis	Siemens (Dade Behring) MicroScan HNID	2
Specimen source not tested		1

Chlamydia – Urine/cervical swab for Direct Detection Methods

This sample could be tested as a urine or a cervical swab in transport media. It was provided to laboratories that test for *Chlamydia* using molecular detection methods. This sample was not suitable for laboratories performing antigen detection for *Chlamydia* or *Chlamydia* culture.

This sample was negative for *Chlamydia trachomatis* and was reported as such by 100% of the participating laboratories that tested this specimen.

Test kits used by laboratories processing this specimen

Method	**# Labs**
Gen-Probe Aptima Combo 2	13
Cepheid Xpert CT/NG	10
BD ProbeTec ET CT or CT/GC	8
BD Viper System	1
Roche Diagnostics COBAS AMPLICOR CT/NG	1
Abbott RealTime CT/NG assay	1

Group A Streptococcus – Throat Swab for Direct Detection Methods

This simulated throat swab was provided to all laboratories that process specimens for Group A *Streptococcus* using direct detection techniques.

This specimen was reported as positive for Group A *Streptococcus* by 100% of the participating laboratories that processed it.

Test kits used by laboratories processing this specimen

Method	**# Labs**
Sekisui (Genzyme) OSOM Ultra Strep A	9
Acceava Strep A	8
BD Chek Group A Strep	7
Cardinal Health SP Brand Strep A Dipstick	6
Fisher Sure-Vue Strep A Lateral Flow Test	3
BD Directigen EZ Strep A	3
Clearview Exact Strep A Dipstick	3
Meridian Bioscience ImmunoCard STAT Strep A	2
Fisher Sure-Vue Signature Strep A Test	2
Signify Strep A Dipstick	2
Quidel QuickVue + Strep A	1
Alere BinaxNow Strep A Card	1
Beckman Coulter Icon DS Strep A	1
Beckman Coulter Icon SC Strep A	1
Stanbio QuStick Strep A Rapid Strip Test	1
BD Veritor System For Rapid Detection of Group A Strep	1
Sekisui (Genzyme) OSOM Strep A Test	1

BACTERIAL IDENTIFICATION BY PARTICIPATING LABORATORIES

Sample/Report	**# Labs**	**%**
SPECIMEN NUMBER 1 (Stool)		
Shigella sonnei, group D	52	73.2
Shigella species	19	26.8
Specimen source not tested	7	
SPECIMEN NUMBER 2 (Throat)		
Streptococcus, group A (*S. pyogenes*)	78	100
SPECIMEN NUMBER 3 (Tissue)		
Clostridium perfringens	67	90.5
Clostridium species	56	6.8
No growth	1	1.4
No aerobic organisms	1	1.4
Specimen source not tested	5	
SPECIMEN NUMBER 4 (Urine)		
Staphylococcus saprophyticus	75	96.2
Staphylococcus, coagulase negative	1	1.3
Staphylococcus saccharolyticus	2	2.6
SPECIMEN NUMBER 5 (Cervix)		
Neisseria gonorrhoeae	49	66.6
No pathogens isolated	26	33.8
Gardnerella vaginalis	2	2.6
Specimen source not tested	1	

***CHLAMYDIA* – DIRECT DETECTION (Urine/cervical swab)**		
Result	**# Labs**	**%**
Negative for *Chlamydia trachomatis*	34	100
GROUP A *STREPTOCOCCUS* - DIRECT DETECTION (Throat)		
Positive for Group A *Streptococcus*	52	100