Request for Proposals: Validation of the MALDI-TOF for the Identification of Neisseria gonorrhoeae

1) Please describe the laboratory’s current MALDI-TOF testing practices including pathogens detected.
   a. Describe how many years the MALDI-TOF has been in use, which MALDI-TOF is in use, how often testing is performed, pathogens tested, and amount of experience laboratory staff have in using the methodology (years, training, and consistency performing method).

   The DC PHL implemented the Bruker MALDI Biotyper system in 2014. The instrument has been used for identification of isolates submitted from local hospitals (ex. Campylobacter, Salmonella) and for identification of isolates from autopsy cultures (variety of Gram positive and Gram negative bacteria). The instrument has generally been used 2-3 times per week. Three technologists were trained to use the system upon implementation and two additional technologists were trained in July 2017. The Microbiology Unit manager has extensive experience with the Bruker MALDI Biotyper and employed it as the primary means of microorganism identification in a high volume clinical laboratory for 3 years. The Laboratory Director also has extensive experience with both the Bruker and bioMérieux MALDI-TOF MS systems for over 4 years. Both the Microbiology Unit Manager and Laboratory Director have published on MALDI-TOF MS technology so are very familiar with its use.

   Additionally, the Laboratory Director has conducted successful validations of MALDI-TOF MS for the identification of Neisseria gonorrhoeae at another public health laboratory so that routine identification of gonorrhea could be done with this new technology instead of traditional identification methodologies (e.g., sugar fermentation, agglutination tests, and probe-based assays).

2) Please describe the laboratory’s experience in testing for N. gonorrhoeae including methodologies.
   a. Describe how many years each method has been in use, how often testing is performed (times per week), annual volume, and amount of experience laboratory staff have in using the methodology (years, training, and consistency performing method).

   Neisseria gonorrhoeae isolates have not been routinely requested by the DC PHL. Isolates are identified using the VITEK 2 Compact automated system. Although very few isolates are received by the DC PHL, our two newest technologists, microbiology unit manager, and laboratory director have extensive clinical and public health laboratory backgrounds (3-15+ years’ experience) and have frequently cultured Neisseria species. Methods utilized in previous laboratories, which could be applied in the DC PHL include: Specimen transport in E-swab or JEMBEC system, direct specimen or colony Gram stains, culture on chocolate agar and modified Thayer Martin agar, identification with BactiCard Neisseria, VITEK NH, or MALDI TOF MS, sugar fermentation, Phadebact Monoclonal GC test, and Accuprobe (as needed, all methods supplemented with additional biochemical tests).

   The DC PHL is in a current state of growth and will be bringing back STD testing this year. Currently, all STD testing is privatized through a contract with LabCorp. With the initiation of this testing in-house, volumes will grow at the DC PHL and it is currently moving forward with conducting some studies with the Centers for Disease Control and Prevention (CDC) for GC culture in addition to testing of chlamydia and gonorrhea via molecular methods on the Hologic Panther system. The laboratory has the capacity
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and capabilities to validate N. gonorrhoeae for MALDI-TOF MS. The laboratory can easily obtain N. gonorrhoeae isolates from other public health laboratories to help expedite the validation process.

3) Please describe the current methodologies for testing non-gonococcal Neisseria species.
   a. Describe how many years each method has been in use, how often testing is performed (times per week), pathogens detected, and amount of experience laboratory staff have in using the methodology (years, training, and consistency performing method).
   b. Describe current strategies to mitigate biosafety risk of working with Neisseria meningitidis.
      a. Neisseria (non-gonococcal) submissions (i.e., Neisseria meningitidis) are routinely requested from clinical hospitals in the District. Isolates are identified using the VITEK 2 Compact automated system. The two newest technologists, microbiology unit manager, and laboratory director have extensive clinical and public health laboratory backgrounds (3-15+ years’ experience) and have frequently cultured Neisseria species. Methods utilized in previous laboratories, which could be applied in the DC PHL include: Specimen transport in E-swab or JEMBEC system, direct specimen or colony Gram stains, culture on chocolate agar and modified Thayer Martin agar, identification with BactiCard Neisseria, VITEK NH, or MALDI TOF (as needed, all methods supplemented with additional biochemical tests).
      b. Potential Neisseria meningitidis isolates are worked with inside of a certified Class II Biosafety cabinet. Staff handling potential Neisseria meningitides isolates are offered the meningococcal conjugate vaccine and serogroup B meningococcal vaccine. The DC PHL also conducts risk assessments prior to any test implementation to assess any threats to the staff and laboratory. Any risks that are found have action steps conducted to mitigate the risks to as minimal level as possible.
      c. Please describe the current collection of non-gonococcal Neisseria species.
         a. Provide an Excel list of commensal Neisseria species as well as M. catarrhalis and K. denitrificans your lab currently have on hand, when possible include the number of isolates for each species, and describe the storage method (frozen, lyophilize).

The DC PHL has the following frozen isolates:

Neisseria meningitidis- 16 isolates
M. catarrhalis- 0 isolates
K. denitrificans- 0 isolates

   d. Include a completed and signed copy of Appendix B as an attachment.
Appendix B: Minimum Requirements for the Validation of the MALDI-TOF for the Identification of Neisseria gonorrhoeae RFP

<table>
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<tr>
<th>YES</th>
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Signature: [Signature]  
Printed Name:  
Date: 8/6/17  

Please send the Letter of Intent (Due 7/31/17) and completed application (Due 8/16/17) to Anne Gaynor, anne.gaynor@aphl.org