MFRPS Laboratory CAP Successes

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Virginia’s State Laboratory
Division of Consolidated Laboratory Services (DCLS)

- Serve as the state’s public health, environmental, agriculture and consumer protection laboratory for the Commonwealth of Virginia
- Serve hundreds of local, state and federal agencies
- Conduct over **9 million tests/year** with over **650 different types of analyses**
- Comprehensive testing services:
  - Newborn screening
  - Clinical testing
    - Microbiology
    - Immunology
    - Virology
    - Molecular
  - Motor fuels and commodities
  - Organic/inorganic chemical analyses for food, fertilizer, feed and water
  - Drugs of abuse
  - Food microbiology and food emergency responses
  - Water microbiology
  - Biomonitoring
  - Metal and pesticide analyses
  - Radiochemistry
  - Biological and chemical terrorism response
Our start with ISO/IEC 17025

• Met major milestones within the 5 year cooperative agreement
• Applied for accreditation in the 5th year
  • 3 microbiological methods
  • 3 chemistry methods
• Accredited in 2017 to ISO/IEC 17025:2005 Standard
  • Accredited in 2019 to ISO/IEC 17025:2017 Standard
Before ISO/IEC 17025

- QMS was focused on CLIA and TNI
- Document management
  - Then: Used network drive with minimal document control
  - Now: Qualtrax QMS Document Control Database
- Temperature monitoring system
  - Then: Manually recording temperatures twice a day (including weekends)
  - Now: LABGUARD® Temperature Monitoring System
- Non-standardized data packets and worksheets
  - Traceability
  - Chain of custody
- Training
  - Non-existent for ISO/IEC 17025
Before ISO/IEC 17025

• Harmonized SOPs with reference methods
• No dedicated Quality Assurance Officer for ISO/IEC 17025
• No sampling agreement with Virginia Department of Agriculture and Consumer Services (VDACS)
• Interested in ISO/IEC 17025 but no resources to implement before the FDA Cooperative Agreement
  • Aware of benefits but due to lack of samples and funds was not a priority
Improvements to Scope of Accreditation

- Enhancing/expanding scope of accreditation yearly
  - Adding new methods on scope as needs arise
    - MALDI-TOF for confirmation of foodborne Isolates (Added 2019)
    - Plan to add hemp to scope in 2020/2021
  - Currently have nine methods on scope with intent to add yearly
    - Began with six methods in 2017
  - Received renewal accreditation under ISO/IEC 17025:2017 Jan. 31, 2019

<table>
<thead>
<tr>
<th>Test Method</th>
<th>In-House Method(s)</th>
<th>Reference Method(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confirmation of the Following Organisms</td>
<td>26242</td>
<td>AOAC Official Methods: AOAC Official Method of Analysis 2017.09 and 2017.10</td>
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<tr>
<td>Using MALDI-TOF MS:</td>
<td></td>
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<tr>
<td>Listeria monocytogenes</td>
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<tr>
<td>Listeria spp.</td>
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<tr>
<td>Salmonella spp.</td>
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<tr>
<td>Shiga Toxin Producing <em>Escherichia coli</em></td>
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Success Stories from ISO/IEC 17025 Accreditation

- From a state perspective
  - Improved working relationship between VDACS and DCLS
    - Interested and engaged in our success
    - Communication
    - Mutually beneficial
  - Have a well-established, risk-based surveillance program with VDACS
    - This has led to increased investigations and recalls
    - Prior to sampling agreements, received just over 100 samples a year
    - After sampling agreement, received over 1,500 samples a year
  - Renewed investment in quality from VDACS
    - Improvements in collections and submissions of samples
Success Stories from ISO/IEC 17025 Accreditation

• From a federal perspective
  • Data packets are accepted and flow seamlessly through FDA’s Compliance Management System (CMS)
    • Use of standard FDA forms and documents
  • Data is added seamlessly to outbreak response data
  • Accreditation and FDA’s Mutual Reliance go hand-in-hand
Key Players Who Added to Our Success

• North Carolina Department of Agriculture (Mentor Lab)
• APHL
• FDA ORA (Project Officer)
• DCLS’ Quality Assurance Group
  • DCLS ISO/IEC 17025 QA Officer,
• DCLS’ Food Laboratories
• VDACS MFRPS Coordinator
• A2LA
Contact Information

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