Using the Data Acceptance White Paper and Checklist

January 25, 2017
Governmental Food and Feed Laboratories Accreditation Meeting
Introduction

- Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories (aka Data Acceptance White Paper)
  - White paper originally published October 2016
  - Available on the APHL website and through the partnering organizations that helped create the document
White Paper Objectives

• Assist laboratories in becoming compliant with ISO/IEC 17025
• Checklist tool, Appendix A, to review laboratory quality management system against key elements of white paper
  ▫ Will be using the checklist for our in depth review
Things to keep in mind

- Use of the checklist does not imply accreditation
- Not all items on the checklist may be applicable for all laboratory sections
- On going communication throughout any project is key to ensuring understanding of needs of customer and capability of laboratories
Mission of FDA

• Promote the public health by ensuring that
  ▫ Foods are safe, wholesome, sanitary, and properly labeled
  ▫ Human and veterinary drugs are safe and effective
  ▫ Medical devices intended for human use are safe and effective
  ▫ Cosmetics are safe and properly labeled
  ▫ Public health and safety are protected from electronic product radiation

• FDA is a regulatory agency
What Does FDA Regulate?

- **Biologics:** Viruses, Antitoxins, Vaccines, Blood/Blood Components
- **Cosmetics**
- **Foods:** Labeling, Safety of food products (except meat and poultry), Bottled water
- **Human Drugs:** Product Approvals, Over-the-Counter (OTC) and Prescription Drug Labeling, Drug Manufacturing Standards
- **Medical Devices**
- **Radiation-Emitting Electronic Products:** microwave ovens, TVs, diagnostic X-ray equipment, laser products, sun lamps, mammography facilities
- **Veterinary Products:** Livestock and Pet food, Veterinary drugs and devices.
What FDA Does Not Regulate

- Advertising for products other than drugs or medical devices. The Federal Trade Commission regulates advertising for all other products.
- Alcohol: Regulated by Bureau of Alcohol, Tobacco, Firearms and Explosives
- Meat and Poultry: Regulated by the US Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS)
- Pesticides: The Environmental Protection Agency (EPA) determines safety and effectiveness of pesticides and establishes tolerance levels
- Restaurants and Grocery Stores
- Municipal drinking water: Regulated by EPA
FDA Legal Considerations

- FDA authority is outlined in their regulations
- Compliance/Regulatory Action elements
- Jurisdiction
- Interstate Commerce
- Violation
- Responsibility
- This information is provided by developing evidence to support a legal case
- Regulatory samples are part of this evidence
Request for testing
Request for Testing

- Laboratory/Customer Agreement
  - Is there a system in place for services with the customer?
    - Rules, contracts, MOUs, grants, or procedures
    - Do any of these consider actionable levels and applicable laws?
    - Who is approving? Is management included?
    - This helps to ensure that everyone is on the same page regarding what is being asked, how samples will be handled and tested by the laboratory and if the customer has any specific requirements
Request for Testing

• Subcontracting of test services
  ▫ Are you able to perform all the tests for the customer? If not, which laboratories do you use to complete the request?
    • Is the subcontractor accredited or does the customer specify which laboratories to use?
    • Do you have records demonstrating that they are accredited or that the customer specified which laboratory to use?
      • If accredited, does the laboratory have the test on their scope of work?
      • If accredited, has the primary laboratory verified that the subcontracted laboratory is still accredited?
# Scope of Accreditation to ISO/IEC 17025:2005

**Arizona Department of Health Services, Bureau of State Laboratory Services**

220 N. 17th Avenue, Phoenix, Arizona 85007

Victor Waddell, Ph.D.  Phone: (602)342-1188

Kathryn Wangness  Phone: (602)342-1188

kathryn.wangness@azdhs.gov  www.azdhs.gov/lab

**TESTING**

Valid to: August 4, 2017  Certificate Number: AT-1973

---

## I. Chemical

<table>
<thead>
<tr>
<th>Item, Materials or Products Tested</th>
<th>Specific Tests or Properties Measured</th>
<th>Specification, Standard, Method, or Technique Used</th>
<th>Key Equipment or Technology*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food/Beverage Matrices</td>
<td>Trace Elements (metals)</td>
<td>FERN Method T039</td>
<td>ICPMS</td>
</tr>
<tr>
<td>Food/Beverage Matrices</td>
<td>Trace Elements (metals)</td>
<td>FDA Method EAM 4.7</td>
<td>ICPMS</td>
</tr>
<tr>
<td>Food/Beverage Matrices</td>
<td>Drugs and Poisons (Confidential List)</td>
<td>FERN Method CHF 0006</td>
<td>GCMS</td>
</tr>
<tr>
<td>Food/Beverage Matrices</td>
<td>Cyanide</td>
<td>Isotope Dilution Mass Spectrometry Determination of Cyanide by Headspace Gas Chromatography</td>
<td>GCMS</td>
</tr>
</tbody>
</table>

## II. Biological

<table>
<thead>
<tr>
<th>Item, Materials or Products Tested</th>
<th>Specific Tests or Properties Measured</th>
<th>Specification, Standard, Method, or Technique Used</th>
<th>Key Equipment or Technology*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food/Beverage Matrices, Environmental Samples (Swabs)</td>
<td><em>Salmonella</em> spp.</td>
<td>Detection of <em>Salmonella</em> spp. in Food and Environmental Samples by BAX System Real-Time PCR Assay</td>
<td>PCR</td>
</tr>
<tr>
<td>Food/Beverage Matrices, Environmental Samples (Swabs)</td>
<td><em>E. coli O157</em></td>
<td>Detection of <em>Escherichia coli</em> O157 in Food and Environmental Samples by BAX System Real-Time PCR Assay</td>
<td>PCR</td>
</tr>
</tbody>
</table>

---

*Note:*

1. *Key Equipment or Technology* is applicable.
2. This scope is formatted as part of a single document including Certificate No. AT-1973.
Sample Collection and Handling

• Sample handling
  ▫ Is your laboratory responsible for sampling?
    • If no, communicate closely with your customer on best practices for sampling (e.g. Sample Quality Criteria or GoodSamples).
    • If yes, then is the following in place:
      • Sampling protocols
      • Trained samplers – records of training
      • Traceability records for sample collection - clear
Sample Collection and Handling

- Are there procedures in place for:
  - Developing sampling plans with the sampling entity
  - Unique identifiers for samples and records
  - Recording any abnormalities or departures
  - Secure storage, handling, and preparation
  - Tracking of sample throughout process
  - Documenting chain of custody for samples
    - What is the level of chain of custody required?
Chain-of-Custody Definition

- The movement and location of physical evidence from the time it is obtained until the time it is presented in court.

Chain of Custody Elements

- What was collected?
- Who collected it?
- When did they collect it?
- How did they collect it?
- Where did they collect it?
- Who did they give it to?

- What did they do with it?
- Who else has had access to it?
- What is its current condition?
- Where is it now?
Things to Consider

• How is chain of custody documented?
  ▫ Are there specific forms or procedures that your customer uses for chain of custody?
• Physical security elements (locked storage, seals, etc.)
• Environmental storage conditions
• Other issues: Some products (controlled substances, select agent cultures, etc.) require additional security measures.
Things to Consider

• Chain of custody starts as soon as the sample is collected.
• These issues need to be sorted out **before** the sample is collected.
FDA Procedures

- Domestic Compliance Samples are sealed
- Chain-of custody maintained electronically in an internal system as well as by hard copy documentation (analytical worksheets).
- Sample reserves are re-sealed and securely stored pending final disposition determined by FDA District Compliance Office.
FDA Official Sample Seal
Sample Collection and Handling

- **Protocols continued**
  - Sampling records adequate to assure integrity and quality
  - Sampling protocols assure confidence to make relevant regulatory inference and decisions

- **Sampling data**
  - Is there adequate data and records to provide information on the sampling
    - Product lot identification, description, sampling methodology, traceability to manufacturer/grower/etc
## Appendix B
### Example of Collection Report

<table>
<thead>
<tr>
<th>ANALYST WORKSHEET</th>
<th>1. PRODUCT</th>
<th>2. SAMPLE NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. SEALS</td>
<td>4. DATE REC'D</td>
<td>5. RECEIVED FROM</td>
</tr>
<tr>
<td>□ INTACT</td>
<td>□ BROKEN</td>
<td>□ NONE</td>
</tr>
</tbody>
</table>

### 7. DESCRIPTION OF SAMPLE


### 8. NET CONTENTS

- □ NOT DETERMINED
- □ NOT APPLICABLE
- DECLARE/UNIT
- AMOUNT FOUND
- UNITS EXAMINED
- % OF DECLARED

### 9. LABELING

- ORIGINAL(S) SUBMITTED
- COPIES SUBMITTED
- □ NONE

### 10. SUMMARY OF ANALYSIS

- Container:
- Labeling:
- Code:
- Product:
- Analysis:
- Method:
- Results:

### 11. RESERVE SAMPLE

### 12. a. ANALYST SIGNATURE (Broke Seal □)

### 13. a. BY

- WORKSHEET CHECK
- DATE

### 14. DATE REPORTED

- ATTACHMENTS
  - PAGE _____ OF _____ PAGES
ANALYST WORKSHEET

1. PRODUCT
Avocados

2. SAMPLE NUMBER

3. SEALS
☑️ INTACT
☐ BROKEN
☐ NONE

4. DATE REC'D
07/01/2014

5. RECEIVED FROM
Robert Dockett

6. DISTRICT OR LABORATORY
Florida Department of Agriculture & Consumer Services

7. DESCRIPTION OF SAMPLE
One cardboard box with Styrofoam cooler containing 7 ice packs, officially sealed "INV 60/30/14 JPS" containing 25 whirl-pak bags containing product, each identified as "INV 60/30/14 JPS" with sub-numbers 1 through 25; one intact whirl-pak bag control identified as "INV 60/30/14 sub a JPS", one opened whirl-pak bag identified as "INV 60/30/14 sub b JPS", and one intact glove control identified as "INV 60/30/14 sub c JPS". Samples received in good condition at 18.3°C.

8. NET CONTENTS
☑️ NOT DETERMINED
☐ NOT APPLICABLE
DECLARE/UNIT
AMOUNT FOUND

9. LABELING
3 ORIGINAL(S) SUBMITTED
0 COPIES SUBMITTED
☐ NONE

10. SUMMARY OF ANALYSIS
Container: Whirl-pak type bags containing product have measurements approximately 34cm length x 26cm width.

Labeling: Manufacturer's multicolored sticker label "Hand Grown in California, USA 94225 Organic" on top of avocados for all subs, except subs 5, 13 and 14, which have no sticker label.

Code: Refer to CR

Product: Appearance of oval shaped, green product similar in appearance to avocados

Analysis: Microbiological examination on Subs 1-10 for Salmonella as two 5-sub composites.
Microbiological examination on Subs 11-20 for Listeria as two 5-sub composites.
Microbiological examination on both collector control samples (whirl-pak bag and gloves) for both Salmonella and Listeria.

Method: Refer to page(s) 2 for Salmonella and page(s) 3 for Listeria.

Results: Refer to page(s) 2 for Salmonella and page(s) 3-10 for Listeria.
No Salmonella spp. detected in subs 1-10 via VIDAS screen. All controls Performed Properly.
Listeria monocytogenes detected in subs 12, 15, 16, via VIDAS screen and confirmed. No Listeria monocytogenes detected in subs 11, 13, 14, 18-20 via VIDAS screen. All controls performed properly.
Per NPO Instructions, the open bag control was not tested.

11. RESERVE SAMPLE
No product reserve. Analyst used all product for analysis. Analyst destroyed all remaining product.
Official seal submitted as attachment E

12.a. ANALYST SIGNATURE (Broke Seal)
ANB

12.b.

13. WORKSHEET CHECK
a. BY
b. DATE
3/25/14 7/16/14

14. DATE REPORTED
7/11/14

ATTACHMENTS
A- F

GENERAL SAMPLE INFORMATION & CHAIN OF CUSTODY

GEN-COC-001 v.1 9/14/11
Official Avocado Sample
Preparing to test
Prior to Testing

- Prior to testing the laboratory should ensure that it has Management Guidelines in place
  - Does the laboratory’s quality system cover any multiple sites including secondary and/or temporary or mobile facilities?
  - Is there a document and records management and control procedure?
Prior to Testing

• Continued
  ▫ Are managerial and technical personnel with both authority and resources to identify departures from the quality system in place?
    • Can they initiate actions to prevent or minimize any departures?
  ▫ Are the following procedures in place
    • Corrective actions
    • Preventative actions
    • Complaint process
    • Control of non-conforming work
Management Review

- At least annually is the laboratory management reviewing (and documenting the review) the quality system
  - Suitability of polices and procedures
  - Reviewing internal and external audits
  - Corrective and preventative actions
  - Volume and type of work
  - Feedback from customers including complaints
  - Resources which include personnel and equipment
  - Other relevant factors that impact quality of testing
AGENDA (based on SOP QA-035 and ISO 17025, Section 4.15)

1. Review action items from previous meeting
   a. ISO Inspection completed by 08.2015
      i. ISO inspection in June 2015 – received accreditation on 08.04.2015
   b. Receiving Food Micro SOP to be revised for receiving samples without proper paperwork
   c. Section managers to create/send Survey Monkey for customer feedback by this meeting

2. Review of internal audits
   a. Internal audits scheduled in 2015 were started in the month scheduled (some took longer and were over a few months)
   b. Trends seen from internal audits

3. Review of external audits
   a. Over the last year we had EPA Chemistry and ISO 17025 (along with a few others)
      i. Inspections have gone well
   b. In the next year we expect CLIA and ISO 17025 Surveillance

4. Review of Preventative Actions
   a. The management staff will review proposed Preventative Actions and propose.
      See proposed projects below
      i. PA-2016-01221458 – Lab Chair replacement
      ii. PA-2016-02121329 – Hood Exhaust Alarms for A2 BSC
      iii. PA-2016-02170813 – RightFax ability to automate distribution of reports

5. Review of Corrective Actions - Trends in 2015

6. Reports from sections (Testing, Facilities, Purchasing, Receiving, APS, etc)
   a. Review of policies/procedures
   b. Review of customer feedback
   c. Review of resources (staffing, training, equipment, etc)
   d. Changes in volume and work

7. Review of Quality Policy Statement and Objectives (QAM)

8. Review of ISO 17025 Scope
   a. Current scope of accreditation

9. Goals/Recommendations/Improvements
Document Control

• Are all documents that form the quality system controlled, for example methods, software, instructions
  ▫ Is there a procedure for approval of all documents before use?
  ▫ Periodic review of documents
  ▫ Changes to documents recorded
    • Are these changes approved?
  ▫ Only current revision being used
  ▫ Clearly marked obsolete documents or segregated
  ▫ Documents are uniquely identified and cross-referenced
  ▫ External documents, regulations, standards and manuals
Document Control Examples

Arizona State Public Health Laboratory

Quality Assurance Manual
June 2016
Replaces: QAP, June 2015, Revision 17

Date Issued: 06.13.2016
Effective Date: 06.20.2016
Purchasing Items for Testing

• Is there a procedure or policy for the selection and purchasing of critical supplies, reagents, consumable materials and services?
  ▫ Is the laboratory verifying that supplies comply with standard specifications and requirements?
  ▫ Is the laboratory ensuring services and supplies meet specifications and will not adversely affect the quality of the results?
    • ATCC strain specified
    • Accredited vendors supplying calibration services on balances and weights
Purchasing Items for Testing

- Does the laboratory have an approved vendor list that is scheduled for regular review?
  - Are the reviews documented
  - Is the approved vendor list based on the laboratory’s own evaluation of the quality of goods and services (not just the government purchasing system of approved vendors)?
<table>
<thead>
<tr>
<th>VENDOR</th>
<th>PHONE #</th>
<th>CERT FOUND</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>VeRAD - New name is United Ad Label Brand</td>
<td>800-423-4643</td>
<td>F</td>
<td><a href="http://www.uailind.com/certification.php">http://www.uailind.com/certification.php</a> (Reviewed June 2016)</td>
</tr>
<tr>
<td>ABBOTT</td>
<td>1-800-322-9100</td>
<td>F</td>
<td><a href="http://www.abbottinformatics.com/us/about/certifications">http://www.abbottinformatics.com/us/about/certifications</a> (Reviewed June 2016)</td>
</tr>
<tr>
<td>ADAM DIAG LAB</td>
<td>1-800-276-2326</td>
<td>NF</td>
<td>Biz closed? (Reviewed June 2016)</td>
</tr>
<tr>
<td>AEROTECH</td>
<td>1-800-651-4602</td>
<td>F</td>
<td><a href="https://www.aerotech.com/about-aerotech/certifications.aspx">https://www.aerotech.com/about-aerotech/certifications.aspx</a> (Reviewed June 2016)</td>
</tr>
<tr>
<td>AGENT COURT</td>
<td>1-800-361-7780</td>
<td>NF</td>
<td></td>
</tr>
<tr>
<td>ALDRICH CHEM CO</td>
<td>1-800-553-9160</td>
<td>F</td>
<td>They had iso certificates with different states, and I did not know which to choose <a href="http://www.sigmaaldrich.com/customer-services/quality-systems/iso-certification.html">http://www.sigmaaldrich.com/customer-services/quality-systems/iso-certification.html</a></td>
</tr>
<tr>
<td>ALEXION TREND INC</td>
<td>1-800-265-6730</td>
<td>NF</td>
<td>does not appear in google search, even under a different name (Reviewed June 2016)</td>
</tr>
<tr>
<td>AMBIOS, INC (NOW THERMO FISHER)</td>
<td>1-800-988-8804</td>
<td>F</td>
<td><a href="https://www.thermofisher.com/content/dam/LifeTech/Global/Life-sciences/synthetic-biology/pdfs/FM%20566037.pdf">https://www.thermofisher.com/content/dam/LifeTech/Global/Life-sciences/synthetic-biology/pdfs/FM%20566037.pdf</a> (Reviewed June 2016)</td>
</tr>
<tr>
<td>AMER. B-CODE CONC</td>
<td>1-480-994-5595</td>
<td>NF</td>
<td>(Reviewed June 2016)</td>
</tr>
<tr>
<td>AMER WATER WORKS</td>
<td>1-303-794-7711</td>
<td>NF</td>
<td>(Reviewed June 2016)</td>
</tr>
<tr>
<td>AMERICAN HEALTHCARE</td>
<td>1-800-532-3999</td>
<td>F</td>
<td><a href="http://www.geinstruments.com/company/iso-9001-certification.html">http://www.geinstruments.com/company/iso-9001-certification.html</a> (Reviewed June 2016)</td>
</tr>
<tr>
<td>ANALYTICAL CONTROL SYS</td>
<td>317-941-0495</td>
<td>NF</td>
<td></td>
</tr>
<tr>
<td>ARIZONA AIR BALANCE</td>
<td>408-966-2001</td>
<td>NF</td>
<td>(Reviewed June 2016)</td>
</tr>
<tr>
<td>LIFE TECHNOLOGIES/APPLIED BIO-SYSTEMS</td>
<td>1-800-985-9077</td>
<td>NF</td>
<td>(Reviewed June 2016)</td>
</tr>
<tr>
<td>CONTROLLED ENVIRONMENTAL MANAGEMENT (CEM)</td>
<td>403-836-4144</td>
<td>NF</td>
<td>(Reviewed June 2016)</td>
</tr>
<tr>
<td>S. J. ANDERSON (General Contractor)</td>
<td></td>
<td>F</td>
<td><a href="http://www.anderson-nogale.com/us/certification/">http://www.anderson-nogale.com/us/certification/</a> They have it but I can't seem to open the pdf with the actual document (Reviewed June 2016)</td>
</tr>
<tr>
<td>ASM PRESS</td>
<td>1-800-546-2416</td>
<td>NF</td>
<td>(Reviewed June 2016)</td>
</tr>
<tr>
<td>A.T. C.</td>
<td>1-800-638-6697</td>
<td>NF</td>
<td>(Reviewed June 2016)</td>
</tr>
<tr>
<td>ATLANTA BIOLOGICAL</td>
<td>1-800-780-7798</td>
<td>NF</td>
<td>(Reviewed June 2016)</td>
</tr>
<tr>
<td>ATLAS BIOLOGICAL</td>
<td>1-988-8808</td>
<td>NF</td>
<td>(Reviewed June 2016)</td>
</tr>
<tr>
<td>ATR SOLUTIONS</td>
<td>1-602-242-2092</td>
<td>NF</td>
<td>(Reviewed June 2016)</td>
</tr>
<tr>
<td>AZNET</td>
<td>1-602-364-4444</td>
<td>NA</td>
<td>This is the phone vendor, so non-critical</td>
</tr>
</tbody>
</table>
CERTIFICATE

Certificate Number: 110067.00
Including two page addendum

The Quality System of:

Matheson Tri-Gas, Inc.

Headquarters:
150 Allen Road
Basking Ridge, NJ 07920
United States

and

909 Lake Carolyn Parkway, Suite 1300
Irving, TX 75039
United States

Including its implementation meets the requirements of the standard:

ISO 9001:2008

Scope:
The manufacture, purification, mixing, packaging, or distribution of electronic, specialty, industrial and medical gases along with their associated process gas handling equipment, such as gas detection, gas purification, clean air equipment, and pressure and flow components, which may include equipment design, supply and servicing.

This Certificate is valid until: September 15, 2018
This Certificate is valid as of: November 6, 2014

Dr. Cem O. Onur
Managing Director, Business Assurance
DERKA Certification, Inc.

*The partial reproduction for quality certification is subject to the DERKA Master Services Agreement. In any case publication of this certificate is allowed.

Accredited By:
ANAB
Purchasing Items for Testing

• Is the laboratory able to provide traceability for critical supplies, reagents and consumable materials?
  ▫ Can you trace a supply used in testing back to the purchase?
    • Purchase request and approval
    • Receipt of items (e.g. packing slips)
Facilities

• Accommodation and Environmental Conditions
  ▫ Does the laboratory have procedures to ensure that environmental conditions do not affect the quality of test results?
    • Separation between incompatible activities
    • Good housekeeping
    • Monitoring where critical temperature, lighting and humidity
Technical Requirements

• Are there procedures ensuring that observations, data and calculations used to generate this data are recorded at the time and identifiable to a specific task or person?
• Do the observations, data and calculations contain sufficient information to help facilitate identification factors that may affect the uncertainty?
• Is there sufficient information to recreate the testing (dates, personnel, equipment, materials, method used, etc)?
Technical Personnel

- Are there records available for all technical personnel generating testing data (training, education, experience)?
- Is a training program established and maintained?
- Is ongoing competency/continuing demonstration of assessments established and maintained?
Preparing Sample
Preparing Sample for Testing

• Selection and Validation of Sample Preparation Methods
  ▫ Are there policies and procedures that document the sample preparation methods are fit for purpose (this includes all mass reduction procedures)
  ▫ Are deviations addressed and what is considered acceptable (e.g. technically justified, authorized, validated/verified and documented)?
Preparing Sample for Testing

• Is there a policy or procedure in place to validate/verify the performance of sample preparation methods?
  ▫ Reference methods performance verified for use
  ▫ Laboratory developed methods validated
Testing
Testing

• Selection and Validation of Test Methods
  ▫ Are there procedures to ensure that test methods are fit for purpose?
    • That any deviation from the method only occurs when technically justified, authorized, validated/verified, and recorded.
  ▫ Are there procedures to ensure that test methods are validated/verified before use?
    • Reference methods verified for use
    • Laboratory methods validated/verified for use
Testing

- Equipment
  - Are there procedures to ensure equipment and software used is uniquely identified, capable of achieving accuracy required, complies with specifications relevant to tests prior to being used?
  - Are there procedures in place to ensure proper use of equipment is used to generate data?
  - Are there procedures for the calibration of equipment, including calibrations and verifications performed prior to being placed in service?
Testing

• Equipment continued
  ▫ Are records for equipment and software maintained and contain at least:
    • Identity and unique identification
    • Checks that the equipment complies with required specifications
    • Dates, results, and copies of reports and certificates of all maintenance, calibrations and adjustments, including any damage, malfunction, modifications or repairs
Testing

• Equipment continued
  ▫ Are there procedures for the use of reference standards and materials?
    • Instructions and records for use and traceability of reference standards and materials in order to prevent contamination, deterioration and to protect the integrity
    • Instructions for the safe handling, transport, storage of reference standards and materials
Quality Control of Test Results

- Are there quality control procedures with acceptance criteria for monitoring the accuracy of the test methods?
  - Regular use of certified reference materials, cultures, and/or internal quality controls
  - Participation in inter-laboratory comparison or proficiency testing programs or intra-laboratory proficiency testing program
  - Implement and assess quality control with each batch run
<table>
<thead>
<tr>
<th>SUPPLIES (check and record lot numbers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Stomacher bags</td>
</tr>
<tr>
<td>✓ Loops 12.0621597</td>
</tr>
<tr>
<td>✓ Needles</td>
</tr>
<tr>
<td>✓ Sterile forceps</td>
</tr>
<tr>
<td>✓ VIDAS® SLM Kit 7212 x 10/01/14</td>
</tr>
<tr>
<td>✓ VIDAS® EASY SLM Kit</td>
</tr>
<tr>
<td>✓ Other (describe)</td>
</tr>
<tr>
<td>✓ Pipettors 0.9 x 100mm</td>
</tr>
<tr>
<td>✓ Other (describe)</td>
</tr>
<tr>
<td>✓ Sterile Knife</td>
</tr>
<tr>
<td>Hockey Sticks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MEDIA &amp; REAGENTS (check and record lot numbers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Enrichment Broth: BPW 17D - H1 x 7/10/14</td>
</tr>
<tr>
<td>✓ Tryptone broth (TT) 153-CO x 7/12/14</td>
</tr>
<tr>
<td>✓ Butterfield's (10ml) 7232 02-28/16</td>
</tr>
<tr>
<td>✓ M broth 17S-16 x 8/14/14</td>
</tr>
<tr>
<td>✓ XLD Agar</td>
</tr>
<tr>
<td>✓ BS Agar</td>
</tr>
<tr>
<td>✓ LIA</td>
</tr>
<tr>
<td>✓ Sterile Water</td>
</tr>
<tr>
<td>✓ 0.35% Saline</td>
</tr>
<tr>
<td>✓ Oxidase reagent</td>
</tr>
<tr>
<td>✓ Crystal Violet</td>
</tr>
<tr>
<td>✓ Gram Decolorizer</td>
</tr>
<tr>
<td>✓ TSA</td>
</tr>
<tr>
<td>✓ TSI</td>
</tr>
<tr>
<td>✓ HE Agar</td>
</tr>
<tr>
<td>✓ Urea broth</td>
</tr>
<tr>
<td>✓ 0.1% BQ dye solution</td>
</tr>
<tr>
<td>✓ 0.85% saline</td>
</tr>
<tr>
<td>✓ Gram Iodine</td>
</tr>
<tr>
<td>✓ Safranin</td>
</tr>
<tr>
<td>✓ Mineral Oil</td>
</tr>
<tr>
<td>✓ Rappaport-Vassiadi medium (RV) 17D - E3 x 10/01/14</td>
</tr>
<tr>
<td>✓ KI solution 077-560 x 03/18/16</td>
</tr>
<tr>
<td>✓ HE Agar</td>
</tr>
<tr>
<td>✓ Urea broth</td>
</tr>
<tr>
<td>✓ 0.1% BQ dye solution</td>
</tr>
<tr>
<td>✓ 0.85% saline</td>
</tr>
<tr>
<td>✓ Gram Iodine</td>
</tr>
<tr>
<td>✓ Safranin</td>
</tr>
<tr>
<td>✓ Mineral Oil</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EQUIPMENT (check and record identification)</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Incubator 35°C MT-25</td>
</tr>
<tr>
<td>✓ Refrigerator 4°C</td>
</tr>
<tr>
<td>✓ Freezer</td>
</tr>
<tr>
<td>✓ Heat'n'Go (95-120°C) MW-03-21</td>
</tr>
<tr>
<td>✓ VIDAS® Vidas 1</td>
</tr>
<tr>
<td>✓ Other (describe)</td>
</tr>
<tr>
<td>✓ Pipettor (describe)</td>
</tr>
<tr>
<td>✓ Other (describe)</td>
</tr>
<tr>
<td>✓ Pipettor (describe)</td>
</tr>
<tr>
<td>✓ Other (describe)</td>
</tr>
<tr>
<td>✓ Other (describe)</td>
</tr>
<tr>
<td>✓ Other (describe)</td>
</tr>
<tr>
<td>✓ Other (describe)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ADDITIONAL COMMENTS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANALYST(S)</td>
</tr>
<tr>
<td>MVL</td>
</tr>
<tr>
<td>Vignarf</td>
</tr>
</tbody>
</table>

FERNS SALMONELLA QUALITY CONTROL WORKSHEET  FSW2  3/2014
Quality Control of Test Results

• Are there procedures to ensure that the results of tests or series of tests are reported accurately and in accordance with specified instructions to the test methods?
• Are there procedures in place to monitor the error (uncertainty) associated with each sample preparation and test procedure?
Out of Control Events

- Are there policies and procedures detailing acceptable handling of nonconforming work or any departure from the policies and procedures in quality or technical operations that:
  - Identify responsibilities
  - Identify actions to be taken (including halting work and who has authority to resume)
  - Corrective actions taken immediately
    - Notification of customer if needed
    - Monitoring of results to ensure effective actions were taken
  - Identify needed improvements and potential sources to reduce likelihood of reoccurrence
Records

- Before, during and after testing does the laboratory establish traceability by having procedures in place for technical and quality records?
  - These include original observations, derived data, test reports, calibration records, staff records, internal audit reports, management reviews, corrective and preventative actions, and other information
<table>
<thead>
<tr>
<th>ORGANISM ID</th>
<th>PRODUCT CONTINUATION SHEET</th>
<th>PRODUCT: Avocado</th>
<th>SAMPLE NUMBER:</th>
</tr>
</thead>
</table>

**L. monocytogenes and other Listeria spp. Controls Worksheet**

<table>
<thead>
<tr>
<th>INITIAL P/C</th>
<th>TEST RESULTS</th>
<th>IDENTIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>SATISFACTORY</td>
</tr>
</tbody>
</table>

**Summary**

- **Identification**: SATISFACTORY

**Plate Abbreviations**

- OK (OXOID), PAL (PALLCAMI), VMK, LPM, ALOA, RIM (RAMP), MONO, CAL (CHROMAGAR LISTERIA), BCM (IN R&I)

**Key**

- T: Typical
- AT: Atypical
- NT: Not Typical
- NG: No Growth
- POS: Positive
- NEG: Negative
- N/A: Not Applicable

**Additional Comments**

- *β-Lactam disc used & results entered in SA culture 9/14/19*
Records

• Do the procedures address
  ▫ Collection of the records
  ▫ Identification of the records
  ▫ Storage of these records (file cabinet, archives, frequency)
  ▫ Access to these records
  ▫ Inventory of these records
  ▫ Electronic data records verified for accuracy (e.g. eLEXNET data reporting)
Records

• Are they legible, held secure and in confidence for a defined period (customer or in house records retention policies)?
• Easily retrievable and retained in such a way as to prevent alteration, damage, deterioration and/or loss
• Prevention of unauthorized access to computers and data stored in computers and laboratory information systems
• Mistakes in records are not deleted or made illegible
4.13 CONTROL OF RECORDS

The laboratory has established and maintains procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions. Arizona State Library, Archives and Public Records, Records Retention Schedule is followed along with regulatory retention requirements.

All records shall be legible, stored and retained in such a way that they are easily retrievable and in a suitable environment that provides protection from damage, deterioration and/or loss. Retention times of records are established that are consistent with customer and laboratory requirements.

Records are stored onsite anywhere from six months or longer depending on specific program requirements. If records are stored offsite, they are moved to the state government records retention center for a specified period. The records retention center is a secure facility and records are available from the center within 24 hours of a request. After the specified program
required retention, the records are destroyed. For some programs, electronic records are required to be maintained from instruments and LIMS. These records are maintained on backup systems for the required time frame before being destroyed.

All records shall be held secure and in confidence.

Electronic records shall be protected and backed-up to prevent unauthorized access or amendment. ADHS ITS 004 Data Security

The laboratory retains records of original observations, derived data and sufficient information to establish to establish an audit trail, calibration records and identify testing personnel for each analysis performed for a defined period.

Observations, data and calculations are recorded at the time they are made and are identifiable with a specific task.

When mistakes occur in records, each mistake is crossed out and the correct value entered alongside, initialed and dated by the person making the correction. In cases other than typographical errors, a brief explanation may be required for correction.

Electronic data are safeguarded by access, rights, and audit trail (recording changes made in the database). Electronic reports are stored in a computer system with limited access, governed by Arizona Department of Health Services information technology (IT) procedures, which follow statewide policies. The state and agency IT Divisions maintains secured storage of electronic records.
Reporting
Reporting

• Reporting of Test Results
  ▫ Are there procedures in place to prevent the production of unauthorized reports or other documents?
  ▫ Are preliminary/interim or amended reports marked as such?
Reporting

- Do sample records contain at least the following or is information accessible to ensure traceability
  - Identification of personnel and employer who collected and shipped samples
  - Identification of personnel preparing samples
  - Identification of personnel performing tests
  - Unique sample identification given to sample
### Identification of individuals receiving, testing, and reviewing sample records

<table>
<thead>
<tr>
<th>Analyst (Print Name)</th>
<th>Analyst Initials</th>
<th>Analyst Signature</th>
<th>Task Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jason Crowe</td>
<td>JC</td>
<td></td>
<td>Manager review</td>
</tr>
<tr>
<td>Brian Caudle</td>
<td>BC</td>
<td></td>
<td>Logging in</td>
</tr>
<tr>
<td>Amy Bryant</td>
<td>AB</td>
<td></td>
<td>Logging in</td>
</tr>
<tr>
<td>Lindsey Caulkins</td>
<td>LC</td>
<td></td>
<td>Logging in, Salmonella transfer</td>
</tr>
<tr>
<td>VIJAYA MOLLETI</td>
<td>MVL</td>
<td></td>
<td>Salmonella analysis</td>
</tr>
<tr>
<td>Carl Franchini</td>
<td>CF</td>
<td></td>
<td>Later analysis</td>
</tr>
<tr>
<td>Tiffie Matthews</td>
<td>TM</td>
<td>Tiffie Mathew</td>
<td>Technical review</td>
</tr>
<tr>
<td>Sun Kim</td>
<td>SK</td>
<td></td>
<td>Complete W/KShit Review &amp; Reporting</td>
</tr>
</tbody>
</table>

Back of Page 1
Reporting

• Sample records contain continued:
  ▫ Name of laboratory where testing was carried out
    • If a subcontractor performed part of the test, is their report or a clear note indicating the laboratory’s name on or part of the report?
  ▫ Accurate and complete identification of sample
    • Description of sample, product, lot number(s), labeling, container, condition of custody seal, etc
  ▫ Status of sample – surveillance, violation, etc
  ▫ Verification of shipment lot, composition, and availability for sampling (if needed)
Reporting

- Sample records contain continued:
  - Identification of sample source/owner/traceback
  - Identification and detailed description of sampling procedure (date, sampler, equipment, containers, etc)
  - Clear description of sample receipt, condition and receiver
  - Complete and unbroken records of chain of custody from sample collection to discard
  - Accurate and complete identification and description of subsamples
## SAMPLE CONDITION AND ROUTING

### SAMPLE RECEIPT

<table>
<thead>
<tr>
<th>SAMPLE NO.</th>
<th>DATE RECEIVED</th>
<th>RECEIVED BY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7/1/14</td>
<td>RD</td>
</tr>
</tbody>
</table>

**TEMPERATURE**

- [x] Surface
- [ ] TCT
- [x] Electronic

**SHIPPING PACKAGE**

- [x] Styrofoam
- [ ] Styrofoam Box Cooler
- [ ] Cardboard Box
- [ ] Hard Cooler
- [ ] Hand Delivered
- [ ] Electronic
- [ ] Other

**SAMPLE MOVEMENT** (a list of samples may be attached when moving large numbers of samples)

<table>
<thead>
<tr>
<th>SAMPLE NO.</th>
<th>MOVED FROM</th>
<th>MOVED TO</th>
<th>MOVED BY</th>
<th>DATE</th>
<th>TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>LC</td>
<td>RD</td>
<td>7/1/14</td>
<td>9:50</td>
</tr>
</tbody>
</table>

**SAMPLE TRANSFER** (for recording transfers between laboratories, e.g. CR → FL and FL → CR)

<table>
<thead>
<tr>
<th>FROM</th>
<th>TO</th>
<th>DATE TRANSFERRED</th>
<th>DELIVERED BY</th>
<th>RECEIVED BY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**RAD- Neg (5m-oz)**
Reporting

- Sample records contain continued:
  - Identification/name/source of method used for testing, along with any deviation from or additions to the test method
  - Identification of equipment such as thermometers and balances for traceback
  - Any dates associated with the testing (sample receipt, testing date, etc)
  - Name, title, and signatures (or other equivalent approval stamp) of person(s) approving release of test data for reporting
### Listeria Analysis

#### Composite 3

<table>
<thead>
<tr>
<th>Sub-Samples</th>
<th>Date &amp; Initials</th>
<th>Composite</th>
<th>Date &amp; Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sub 11</td>
<td>7/1/14 11:44 CF</td>
<td>7/2/14 12:16 CF</td>
<td></td>
</tr>
<tr>
<td>Sub 12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sub 13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sub 14</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sub 15</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Composite made by transferring 2mL of pre-enrichment broth from each of the sub-samples listed above into 50mL of Fraser broth. A reserve of at least 100mL of each sub-sample pre-enrichment held in refrigeration.

#### Composite 4

<table>
<thead>
<tr>
<th>Sub-Samples</th>
<th>Date &amp; Initials</th>
<th>Composite</th>
<th>Date &amp; Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sub 16</td>
<td>7/1/14 11:44 CF</td>
<td>7/2/14 12:16 CF</td>
<td></td>
</tr>
<tr>
<td>Sub 17</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sub 18</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sub 19</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sub 20</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Composite made by transferring 2mL of pre-enrichment broth from each of the sub-samples listed above into 50mL of Fraser broth. A reserve of at least 100mL of each sub-sample pre-enrichment held in refrigeration.

#### Composite VIDAS Results

<table>
<thead>
<tr>
<th>Method(s)</th>
<th>Date: 7/3/14 Initials: CF</th>
<th>Attachment: 0 Page(s): 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Bacteriological Analytical Manual Online: Chapter 10: Listeria</td>
<td>Composite 4: Negative X Screened Positive*</td>
<td></td>
</tr>
<tr>
<td>□ AOAC Official Methods of Analysis, 2012.02 VITEK GP</td>
<td>Controls Performance: Satisfactory Ununsatisfactory</td>
<td></td>
</tr>
<tr>
<td>□ AOAC Official Methods of Analysis, 18th edition 992.18 MICRO-300</td>
<td>Collector &amp; System Controls: N/A</td>
<td></td>
</tr>
</tbody>
</table>

* If screened positive, continue with form FLW 4 for composite and sub-sample confirmation.
Reporting

• Does the report contain the error (uncertainty) associated with all the sample preparation and test procedures (combine repeatability or uncertainty)?
  ▫ If not reported, is the laboratory able to produce this information?
  ▫ Can the laboratory contribute sufficient information so that the customer/organization can calculate global estimation error?
THE END
IS NEAR
AND IT’S GOING TO BE
AWESOME

Retrieved from thehayride.com
Summarize

• Demonstrate how the checklist can be used to develop quality management system
  ▫ How the QMS relates to the data being produced and provided to customers
Examples of FDA Use of State Data

- 2014-2015: Large Scale Avocado Sampling Assignment
- 15 FERN microbiology laboratories assisted with analyzing samples from this assignment
- Samples were collected by FDA investigators and sent to state servicing labs
- Analytical documentation for positive samples submitted to FDA and reviewed by agency SMEs
Future Considerations

• FDA continued support of developing processes for accepting state data
• Finalize data acceptance criteria document to serve as a tool for state laboratories
• Major Challenge
  ▫ Electronic data sharing
References/Additional Information

• FDA/ORA Laboratory Manual, Chapter 2
  http://www.fda.gov/ScienceResearch/FieldScience/LaboratoryManual/default.htm

• FDA Investigations Operations Manual
  http://www.fda.gov/ICECI/Inspections/IOM/

• PFP Food/Feed Testing Laboratory Draft Best Practices
  http://www.fda.gov/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/default.htm
Comments

• Comments and suggested revisions for the white paper, [https://www.aphl.org/aboutAPHL/publications/Documents/FS-Best-Practices-Food-Feed-Data-102016.pdf](https://www.aphl.org/aboutAPHL/publications/Documents/FS-Best-Practices-Food-Feed-Data-102016.pdf), are encouraged and may be sent to [foodsafty@aphl.org](mailto:foodsafty@aphl.org)
Thank you

Kathryn Wangsness, MHA
Arizona State Public Health Laboratory
Office: 602-364-0724
Kathryn.wangsness@azdhs.gov

CDR Terri T. McConnell, USPHS
FDA, ORA, Office of Regulatory Science
60 8th St. NE
Atlanta, GA 30309
Office: 404-253-1217
e-mail: terri.mcconnell@fda.hhs.gov