

# Laboratory Committee

## Meeting Report

***October 19<sup>th</sup>, 2021***

In Attendance: Andy Haines, Dana Dvoracek-Driksna, Joseph DeCrescenzo, Matthew Forester, Shelley Lankford, Jill MacLeod, Linda McFarland, Diane Regan, Wade Rourke, Mona Hochman, Jacob Madden, Shannara Lynn, Maggie Broadwater, Cheryl Lassitter, Stephanie Haynes, Johnna Fay, Gina Olson, Sara McGrath, Jonathan Deeds

Absent: Jennifer McDonald, Richard Burrow, Drew Sheehan, Steve Archer, Leanne Flewelling, Joel Hansel, Lizzie Farrell, Jessica Jones

Guests: None

Note Takers: Andy, Cheryl, Gina

## AGENDA

1. Roll Call
2. Meeting Minutes – September 2021
3. Meeting Report – September 2021
4. Response From New Manufacturer of Scotia Rapid Test
5. Proposal 15-112
6. Adding Reference to Proposal 19-136 Recommendation
7. Subcommittee Reports
  - a. Biotoxin
    - i. Neogen Project Plan Review
  - b. Microbiology
  - c. Checklist
    - i. Introduce Subcommittee Recommendation on Proposal 19-140
  - d. Method Validation
  - e. Method Portal
  - f. Engagement
  - g. Lab Evaluation
8. Review of Action Items
9. Other Business
  - a. December Meeting Date?
10. Adjourn

**\*\*NOTE CHANGE\*\* Next Meeting – Thursday, November 18<sup>th</sup>, 3:00 – 5:00 p.m. ET**

## **MEETING NOTES SUMMARY**

### **Roll Call:**

The meeting was called to order, followed by roll call and a review of the agenda. A quorum was present.

### **Meeting Minutes:**

The meeting minutes are designed for internal use, and contain more detail, names, notes on deliberations, action items, etc. The draft meeting minutes from the September 2021 Laboratory Committee Meeting were reviewed and discussed. There was a motion to approve the minutes as written, with a second, and the motion carried.

**Action Item: LC Chair will remove the watermark, finalize, and distribute to the LC.**

### **Meeting Report:**

The meeting report is designed for public use, including potential posting on ISSC website once approved. Names are removed, and the report is typically less detailed than what is included in the minutes. The draft meeting report from the September 2021 Laboratory Committee Meeting was reviewed and discussed. There was a motion to approve the report as written, with a second, and the motion carried.

**Action Item: LC Chair will remove the watermark, finalize, and distribute to the LC along with the Executive Office.**

### **Response From New Manufacturer of Scotia Rapid Test**

- The new manufacturer responded to the second letter, and requested more detail on the information we are requesting.
- If possible, a comparison between results generated using the new kits versus the old kits, although kits may have a limited shelf life, so this may not be an option.
- If no old kits are available, potentially ask to compare the current kit performance with the original validation data that was submitted to the LC.

### **Proposal 15-112**

- The sole supplier of the AP-labeled oligonucleotides necessary for this method has ceased manufacturing the product.
- Modifications necessary to adjust the method to a new probe are substantial enough to require a new validation, so the submitter will not be able to pursue this proposal any longer.
- There was a motion to recommend no action on Proposal 15-112, with a second, and the motion carried.

## **Adding Reference To Proposal 19-136 Recommendation**

- There was a motion to reopen discussion on Proposal 19-136, with second. The motion carried.
- This was followed by a second motion to amend 19-136 by adding the appended data as a reference within the checklist, and provided suggested text for that reference. This motion would also add citations to items 1.4.10 and 2.4.5 to point towards this reference. There was a second, and the motion carried.
- This information will be included within the summary of actions after the next biennial meeting, since it has been appended to this proposal. It will also be added to the Method Portal on the ISSC website.
- There was a third motion to recommend adoption of proposal 19-136 as amended, with a second, and the motion carried.

## **Subcommittee Reports:**

### **Biotoxin Subcommittee**

- The subcommittee has completed review of the Neogen Reveal 2.0 for DSP preproposal study design document, and compiled the subcommittee comments into one cohesive document for LC review.
- There was a motion to approve the letter as amended to send to Neogen through the Executive Office, with a second, and the motion carried.
- Began discussion on Beacon Analytical data submission, and also updated the subcommittee to-do list to include making recommendations to the Method Validation subcommittee on potential edits to the SOPs that were noted during previous proposal reviews, as well as working on the Platform Extension Guidelines once the Micro subcommittee has completed their work.

### **Microbiology Subcommittee**

- The subcommittee began discussion of the new data that was recently submitted in support of Proposal 15-114. During discussion, one edit to the lab evaluation checklist was made to help clarify collection temperature requirements.
- Work on the Platform Extension Guidelines continues.

### **Checklist Subcommittee**

- The subcommittee has completed their review of Proposal 19-140 and has made a recommendation to the LC to recommend adoption of this proposal as amended.
- During review, the subcommittee discussed method-related questions and concerns, made minor editorial and clarifying changes, and reviewed the references as well.
- Technical requirement changes include:
  - 3.11.3 (formerly 3.11.5) – Bottom agar storage time adjusted to 6 weeks, as reflected in the MSC SLV (13-120).

- 3.11.7 (formerly 3.11.9) – Remove requirement for cold growth broth to warm to ambient temperature before use; 3.14.13 was then modified to require room temperature growth broth for plating the negative control.
- 3.14.15 – Only require a negative control plate at the end, rather than beginning and end.
- Discussed updating the APHA Compendium reference to the most recent edition, but want to ensure there will not be any inadvertent impacts to the rest of the micro checklist by doing so. This review will be completed by the next LC meeting.
- Next on the list is Proposal 19-141, the RBA for PSP checklist.

#### Method Validation Subcommittee

- No new updates at this time.

#### Method Portal

- Next meeting scheduled for tomorrow (10/20).
- There is going to be a members only section on the ISSC website in the near future, and one topic of discussion at the next subcommittee meeting will be how to lay out the different lab resources between the public facing and the members only pages.

#### Engagement

- Still updating the Priorities document and making suggestions for updating the ISSC website for greater ease of navigation and for new method submitters to understand the process.
- The Biotoxins Committee is currently working on proposals 19-123 and 19-124.

#### Lab Evaluation

- No new updates at this time.

#### **Review Action Items:**

- LC Chair will finalize the September Meeting Minutes and Meeting Report and will distribute both to the LC and the Executive Office.
- LC Chair will prepare Meeting Minutes and a Meeting Report for the October meeting, and will also update the Tracker and Proposal Status documents to reflect recent activities.
- LC Chair will convey the additional questions from the LC to the new manufacturer of the Scotia Rapid Test.
- LC Chair will send the updated recommendation on Proposal 19-136 to the Executive Office with a request to present our recommendation to the Executive Board at the next available opportunity.
- LC Chair will work with the Executive Office to convey the plan review from the LC to Neogen.
- All LC members should review the recommendation from the Checklist Subcommittee on Proposal 19-140 in advance of the next meeting and come prepared to discuss.

#### **Other Business**

**Adjourn**

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