

Laboratory Committee

Meeting Report

September 21st, 2021

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

Absent: Jennifer McDonald, Drew Sheehan, Mona Hochman, Joel Hansel, Maggie Broadwater, Lizzie Farrell, Jessica Jones

Guests: Steve Crupi (Alaska)

Note Takers: Andy, Cheryl, Gina

AGENDA

1. Roll Call
2. Meeting Minutes – August 2021
3. Meeting Report – August 2021
4. Strategy for Addressing Lack of Response From New Manufacturer of Scotia Rapid Test
5. Subcommittee Reports
 - a. Biotoxin
 - b. Microbiology
 - c. Checklist
 - d. Method Validation
 - e. Method Portal
 - f. Engagement
 - g. Lab Evaluation
6. Review of Checklist Subcommittee Recommendation on Proposal 19-136
7. Review of Action Items
8. Other Business
9. Adjourn

Next Meeting – Tuesday, October 19th, 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 August 2021 Laboratory Committee Meeting were reviewed and discussed. A motion was made to approve the minutes as written, with a second, and the motion carried.

Action Item: The 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 August 2021 Laboratory Committee Meeting was reviewed and discussed. A motion was made to approve the minutes as written, with a second, and the motion carried.

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

Strategy for Addressing Lack of Response From New Manufacturer of Scotia Rapid Test

- The LC reviewed the history on this situation, and summarized the discussion from the last meeting on potential responses. A draft response letter was reviewed and approved.
- The LC Chair will work with the Executive Office to review and mail the letter following this meeting.

Subcommittee Reports:

Biotoxin Subcommittee

- The subcommittee has completed review of the Neogen Reveal 2.0 for DSP preproposal, and is in the process of compiling and organizing the comments into a cohesive format to send to the submitters.
- The subcommittee received an update from the submitters of proposal 13-114 that they are preparing to do the work necessary to address LC comments that were provided.
- A letter from Beacon Analytical was received indicating that they were submitting a new data package in response to LC comments on proposal 17-108. See "Other Business" section of report for further discussion.

Microbiology Subcommittee

- The subcommittee continues work on the Platform Extension Guidelines, and has circulated an updated draft with a request for subcommittee comment.

Checklist Subcommittee

- The subcommittee is continuing review of proposal 19-140.
- There was a lot of discussion at the last meeting about the 24-hour hold time requirement, and issues different states were having recently with shipping of samples that exceeds those hold times.

Method Validation Subcommittee

- No new updates at this time.

Method Portal

- Plan to start meeting again in October, and have a number of edits to the Portal to review at that time.
- Once the Portal work is complete, next on the agenda is to look at updating Table 14 from the Guidance Documents of the NSSP Guide.

Engagement

- No new updates at this time.

Lab Evaluation

- No new updates at this time.

Review of Checklist Subcommittee Recommendation on Proposal 19-136:

- After a review of progress from the last few meetings, discussion on the proposal was untabled.
- A set of proposed edits were introduced that were intended to address the concerns expressed in previous meetings. These edits introduced two potential options for confirming that the calibration has not significantly drifted, including one that utilizes bracketing calibration curves, and another that uses a continuing calibration verification standard.
- A motion was made to introduce these edits as a substitute amendment to the previous one. Several additional edits were made to this substitute language, and after discussion was completed, the motion carried.
- Discussion returned to the working draft of the full checklist. One additional edit to item 2.6.2 was made.
- There was no further discussion, and a vote was held on the original motion to recommend adoption of the checklist as amended. The motion carried.

Review Action Items:

- The LC Chair will finalize the August Meeting Minutes and Meeting Report and will distribute both to the LC and the Executive Office.
- The LC Chair will prepare Meeting Minutes and a Meeting Report for the September meeting, and will also update the Tracker and Proposal Status documents to reflect recent activities.
- The LC Chair will forward the prepared letter to the Executive Office for review and delivery to the new manufacturer of the Scotia Rapid Test.
- All LC members will review the updated version of the 19-136 checklist to be sure all edits are properly captured within the final document.
- The LC Chair will contact Beacon Analytical to notify them that they need to include a lab evaluation checklist in order for their most recent data submission to be considered complete.

Other Business

- The LC has received a new submission from Beacon Analytical in support of Proposal 17-108, the Domoic Acid Plate Kit. These materials will be circulated to the full LC within the next LC email, and initial review of this submission will be assigned to the Biotoxin Subcommittee. A lab evaluation checklist was not included with the submission, so we will be contacting Beacon to indicate that they will need to submit one in order for their submission to be considered complete.

Adjourn

Next Meeting – Tuesday, October 19th, 3:00 – 5:00 p.m. ET