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Title: Proficiency Test Samples				
Revision: 04	Replaces: 09/25/09	Effective: 10/01/10		

1. Purpose

To provide guidance for the analysis of Proficiency Test (PT) samples by laboratories participating in the Microbiological Data Program (MDP).

2. Scope

This Standard Operating Procedure (SOP) shall be followed by all laboratories conducting microbiological studies for MDP, including support laboratories conducting non-routine activities that may impact the program.

3. References

- 3.1. Current MDP Semi-Annual Program Plan
- 3.2. Current MDP SOPs

4. Procedures

4.1. Proficiency Testing Round

- 4.1.1. MPO reserves the right to accept or reject results of MDP laboratories participating in PTs administered by outside Federal agencies such as FERN or the FDA. Once MPO agrees to accept a round of outside PT results, MDP laboratories will adhere to procedures set forth by the administering federal agency for that PT round. If MPO does not agree to accept outside PT results, the MDP laboratories will proceed with the following steps of this SOP.
- 4.1.2. If required, PT samples shall be inoculated by the laboratory Quality Assurance Officer (QAO) or designee and transferred to the Technical Program Manager (TPM) or designee for analysis.
- 4.1.3. PT samples shall be analyzed by the technical group according to the latest MDP Semi-annual Program Plan and the MDP SOPs currently in use in the same manner as regular MDP samples.

4.2. Test Sample Analysis

4.2.1. Sample analysis shall begin as stated per provided PT protocol(s).

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- 4.2.2. Samples shall be analyzed according to MDP SOP(s) currently in use.
- 4.2.3. Routine media and cultural controls shall accompany the analysis and be processed per applicable MDP SOPs.
- 4.2.4. Laboratories shall attempt confirmation of any presumptive positive samples according to the appropriate cultural procedures for that test organism. Cultural confirmation will not be required for any MPO supplied competing background organism(s).

4.3. Reporting PT Results

- 4.3.1. Analysts are responsible for recording test results on the reporting form(s) supplied with each PT round. These results shall be reported to the QAO or designee in sufficient time for the QAO/designee to add inoculation concentrations, review/verify results, and meet MPO's reporting deadline.
- 4.3.2. QAO or designee shall report PT results to MPO by the specified reporting date.

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1 September 2010

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Revision 04 August 2010 Monitoring Programs Office

- Deleted Old Section 4.1.1., "PT samples shall be analyzed according to the latest MDP Semi-Annual Program Plan and the MDP SOPs currently in use" **and replaced with** "MPO reserves the right to accept or reject results of MDP laboratories participating in PTs administered by outside Federal agencies such as FERN or the FDA. Once MPO agrees to accept a round of outside PT results, MDP laboratories will adhere to procedures set forth by the administering federal agency for that PT round. If MPO does not agree to accept outside PT results, the MDP laboratories will proceed with the following steps of this SOP."
- Added the words "If required...", Section 4.1.2.
- Revised Section 4.1.3. to read as "PT samples shall be analyzed by the technical group according to the latest MDP Semi-annual Program Plan and the MDP SOPs currently in use in the same manner as regular MDP samples."

Revision 03 September 2009 Monitoring Programs Office

- Revised Section 1, Purpose
- Revised Section 4, Procedures

Revision 02 February 20008 Monitoring Programs Office

Revised to allow technical group or QAU to purchase produce for PT rounds

Revision 01 December 2005 Monitoring Programs Office

• Updated to reflect current PT practices and requirements.