

Laboratory Evaluation Report

PFI: _____

LABORATORY NAME AND ADDRESS:

SURVEYED BY:

SURVEY BEGIN DATE:

SURVEY TYPE:

Survey Findings

Instructions: Review the findings supporting the deficiency and prepare a detailed plan of correction. Your plan of correction must address all the elements of response specified below for the cited sustaining standards, or it will be returned as incomplete. You may use additional sheets if needed. Do not send supporting documentation unless requested.

Sustaining Standard Tag and Title _____

1) Outline the root-cause for the substandard practices. Root cause analysis must include consideration of the following conditions: a) Did the laboratory have documented requirements, procedures and policies that are compliant with the cited standard of practice? b) Did the director delegate in writing the responsibility for ensuring compliance with pertinent procedures and policies? c) Were personnel trained and found competent in the performance of delegated responsibilities? d) Were monitors used to audit ongoing compliance with the documented requirements? e) Did laboratory management review audit documents and taken action to improve compliance, where indicated?

2) Describe the plan of action to correct the substandard practices, and the implementation date.

3) Provide a statement that the laboratory has evaluated relevant procedures and practices in all sections of the laboratory for compliance.

4) Describe the quality systems practices that will be used to monitor the effectiveness of corrective action.