

NEW YORK STATE DEPARTMENT OF HEALTH
Wadsworth Center
Clinical Laboratory Evaluation Program
Empire State Plaza, PO Box 509
Albany, NY 12201-0509

Email: CLEPPOC@health.ny.gov
Fax number: (518) 485-5414

Plan of Correction

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 each of 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. You can return your Plan of Correction to the address, email address or fax number listed above.

Important: Please be sure to sign the Attestation Statement below (include owner signature only when requested on the original Survey Findings form).

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.

Please be reminded that failure to correct a deficiency after having attested that it would be corrected may be construed as misrepresentation. Article V, Title 5 of the NYS Public Health Law Section 577 stipulates that misrepresentation in obtaining a laboratory permit or in the operation of a laboratory may be used as grounds to revoke, suspend, or limit the permit or as grounds to censure, reprimand, or otherwise discipline the permit holder. Such misrepresentation may also violate NYS Penal Law Article 175 and subject parties who file a false instrument to criminal prosecution.

By signing below, you attest that this plan of correction has been/or will be implemented by the date(s) indicated.

Owner's Signature

Date

Director's Signature

Date