Attn: Lab Director, Lab Supervisor, Lab Personnel



WRITING YOUR PLAN OF CORRECTION FOR CLIA DEFICIENCIES

CLIA REGULATION AND DEFICIENCY STATEMENT FOR DEFICIENT PRACTICE

D-TAG EXAMPLE:

D5413 493.1252(b) TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following:

- (1) Water quality
- (2) Temperature
- (3) Humidity
- (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports

This STANDARD is not met as evidenced by:

Based on review of laboratory temperature logs and confirmed by laboratory supervisor, the laboratory failed to monitor and document the temperature of the chemistry reagent refrigerator for 9 of 31 days in January 2018.

The findings include:

- 1.
- 2.
- 3.

Pow't forget!

AN ACCEPTABLE PLAN OF CORRECTION (POC) MUST CONTAIN THE FOLLOWING:



MUST ADDRESS the processes that led to the deficiency



A PLAN for correcting the deficiency



A **PROCEDURE** for implementing the plan of correction



MONITOR procedure to ensure plan of correction is effective



DOCUMENT if patient results were affected and corrective action if affected



WHAT changes were made to prevent reoccurrence of deficiency



TITLE of person responsible for implementing Plan of Correction – DO NOT USE PROPER NAMES



DATE of corrective action completion

NOTE: You may write your POC on this form or you may submit a separate document as an attachment. If you choose to use a separate document please indicate "see attachments" on the POC form, and include the facility name and CLIA # on each document.



The CMS-2567 Form *MUST* remain in its *ORIGINAL* format.

REMEMBER TO HAVE THE LABORATORY DIRECTOR OR REPRESENTATIVE SIGN AND DATE THE PLAN OF CORRECTION (CMS-2567), INCLUDING THEIR TITLE!

