STATE OF TENNESSEE DEPARTMENT OF HEALTH

CMS

CENTERS FOR MEDICARE & MEDICAID SERVICES

# *IMPORTANT PLEASE READ*

## HOW TO COMPLETE AN ACCEPTABLE PLAN OF CORRECTION

1. The Laboratory Director must sign and date the plan of correction on the first page.

2. Each DTAG (D0000) and each component in the deficiency must have a DETAILED response.

3. **Each deficiency response must include the following information:**

*a. The laboratory plan for correcting the specific deficiency cited and actions taken for patients affected by the deficient practice;*
*b. How the laboratory identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) have been taken;*
*c. What changes the laboratory made to ensure that the deficient practice does not recur; and,*
*d. How the laboratory corrective action(s) are monitored to ensure the deficient practice does not recur.*
*e. The job title of the person responsible to ensure the deficient practice does not recur.*

4. The completion date (MM/DD/VV) for each deficiency must be documented and reasonable for the correction.

5. The response must be written or typed on the CM5-2567 form and not on an attached sheet of paper. You may attach documents to support the correction but a response must be on the form. "See attached" only is NOT acceptable.

6. The plan of correction must be returned to your state Regional Office within 10 days of the fax letter date. You may e-mail, fax or send via regular postal service your response (address at top).

NOTE: *If your plan of correction is not completed properly, it will be returned to you as unacceptable. Not receiving a plan of correction in the appropriate time frame or receiving an unacceptable plan of correction could result in enforcement actions taken against your laboratory. If you need advice when completing the plan of correction you may contact* your regional surveyor by email or phone.

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 44D | A. BUILDING _____ B. WING _____ | 09/12/2014 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| | |

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETION DATE |
|---|---|---|---|---|
| D5413 | 493.1252(b) TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br><br>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:<br>(1) Water quality.<br>(2) Temperature.<br>(3) Humidity.<br>(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory temperature logs and confirmed by the laboratory supervisor, the laboratory failed to monitor and document the temperature of the chemistry reagent refrigerator for 9 out of 31 days in October 2008 (10/01, 10/05, 10/06, 10/07, 10/10, 10/12, 10/13, 10/14 and 10/15).<br><br>The findings include:<br><br>1.<br><br>2.<br><br>3.<br><br>4.<br><br>5. | D5413 | EXAMPLE PLAN OF CORRECTION:<br><br>1. HOW THE DEFICIENT PRACTICE WILL BE CORRECTED?<br>The tech assigned to the chemistry section each day is responsible for taking the temperature of the reagent refrigerator. The task will be added to the daily maintenance log. This will be completed by October 1, 2014.<br><br>2. WHAT CORRECTIVE ACTION/S HAVE BEEN TAKEN FOR PATIENTS FOUND TO BE AFFECTED BY THE DEFICIENT PRACTICE?<br>The laboratory determined that no patient test results were affected after review of chemistry controls and calibration results. All QC results were acceptable for the dates when temperatures were not taken.<br><br>3. HOW THE LABORATORY HAS IDENTIFIED OTHER PATIENTS HAVING POTENTIAL TO BE AFFECTED BY THE DEFICIENT PRACTICE AND WHAT CORRECTIVE ACTION/S HAVE BEEN TAKEN?<br>No other patients have been affected. Refer to #4 and # 5 for corrective actions.<br><br>4. WHAT MEASURE HAS BEEN PUT INTO PLACE OR WHAT SYSTEMIC CHANGES HAVE BEEN MADE TO ENSURE THAT THE DEFICIENT PRACTICE DOES NOT RECUR?<br>A memo was sent to all techs in the chemistry section explaining the additional daily task. Each tech is responsible to read and return a signed copy to the supervisor. This will be completed by October 1, 2014.<br><br>5. HOW THE CORRECTIVE ACTION/S IS BEING MONITORED TO ENSURE THE DEFICIENT PRACTICE DOES NOT RECUR?<br>The laboratory supervisor added review of all temperature logs to the laboratory quality assessment plan. Each month the logs will be reviewed for completeness. Corrective action will be taken for omissions and out of range temps. The process will be implemented October 1, 2014. | 10/01/2014 |

| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE |
|---|---|---|
| *Al Albumin, M.D.* | *Laboratory Director* | 09/22/2014 |

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.