

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1071164	(X3) Date Survey Completed 02/01/2022
Name of Provider or Supplier Cardiovascular Clinic Of West Tn Pc	Street Address, City, State 2968 North Highland Ave, Jackson, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and interview with the laboratory liaison, the laboratory failed to verify the accuracy of the activated clotting time (ACT) twice a year in 2021. The findings include: 1. Review of the laboratory's PT performance summary records revealed the following: a. 2021 second event score: 50%. b. 2021 third event score: 0%. 2. Interview on February 1, 2022 at approximately 5:00 pm with the laboratory liaison confirmed the laboratory failed to verify the accuracy of ACT twice a year when it failed two PT events in 2021. The laboratory liaison further confirmed no additional studies had been done after the two failed PT events to verify accuracy.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the laboratory liaison, the laboratory failed to label controls with open and close dates in 2022. The findings</p>

include: 1. Observation of the laboratory on February 1, 2022 at approximately 8:30 am revealed quality control (QC) material for the Cell-DYN Emerald complete blood count (CBC) analyzer that were in use. They were not labeled with open date or corrected expiration date. 2. Interview with the laboratory liaison on February 1, 2022 at approximately 5:00 pm confirmed the laboratory failed to label controls with open date and corrected expiration date in 2022.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's individualized quality control plan (IQCP) for fibrin degradation product (D-Dimer), the laboratory's quality control (QC) logs, patient test records, and interview with the laboratory liaison, the laboratory failed to follow the quality assessment section of the IQCP for D-Dimer in 2021. The findings include: 1. Review of the laboratory's IQCP for D-Dimer revealed the following: External quality control would be performed with each new lot, new shipment or every 30 days. The quality assessment section of the IQCP stated that monthly review of the QC records would occur to determine if QC is acceptable and correction action performed if unacceptable. If an interruption of the QC frequency occurs, the electronic QC followed by two levels of wet QC must be run before any patients are performed. 2. Review of the laboratory's QC log sheet revealed the D-Dimer QC due on May 1, 2021 was not performed. The 30 day requirement for external QC was not met. The error was noted on the quality control log, however, there were no documents showing corrective action to prevent the reoccurrence of the error. 3. Review of patient test records revealed five patients were reported between May 1, 2021 and June 23, 2021 (date the next external QC was performed) (patient chart numbers 11438, 25282, 25289, 26737, 27159). 4. Interview with the laboratory liaison on February 1, 2022 at approximately 5:00 pm confirmed the laboratory failed to follow the quality assessment and error correction part of the D-dimer IQCP on the Alere Triage meter in 2021 when no evidence of corrections to prevent reoccurrence were noted.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), testing personnel records, and interview with the laboratory liaison, the laboratory director failed to ensure that three of three testing persons had the appropriate documentation of education prior to performing moderately complex patient testing in 2022. The findings include: 1. Review of the Form CMS-209 revealed moderately complex testing performed by three testing personnel. 2. Review of testing personnel records revealed no evidence of highest level of education for any of the three testing personnel. 3. Interview on February 1, 2022 at approximately 5:00 pm with the laboratory liaison confirmed there was no evidence of highest level of education for all testing personnel prior to performing moderate complex testing. The laboratory director failed to ensure three of three testing personnel had the appropriate documentation of education prior to performing moderately complex patient testing.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on observations of the laboratory, review of the laboratory's policy for testing personnel (TP), the form used for recording TP competency, and interview with the laboratory liaison, the technical consultant (TC) failed to either perform competency or performed incomplete competency for all testing personnel in 2020 and 2021. The findings include: 1. Observation of the laboratory on February 1, 2022 at approximately 8:30 am revealed the following moderately complex test systems in use for patient testing: a. Cell-DYN Emerald analyzer for complete blood count (CBC). b. Alere Triage meter (Cardiac Panel) for creatine kinase MB (CK-MB), myoglobin, troponin I, and fibrin degradation product (D-dimer). c. Abbott Piccolo Xpress for chemistry testing using the Basic Metabolic Panel Plus (BMP+) reagent. d. Verify Now system (P2Y12) for platelet function. e. Abbott I-Stat meter for activated clotting time (ACT). 2. Review of the laboratory's competency of TP policy revealed that training/competency will be performed and documented by the technical consultant initially, at six months, and annually thereafter. 3. Review of the forms used for recording TP competency revealed either no competency performed, or incomplete competency as follows: A. TP number one: a. I-Stat ACT- no blind testing in 2020, no 2021 competency. b. Triage meter - no blind testing in 2020, no 2021 competency. c. Verify Now system - no blind testing in 2020. d. Cell-DYN Emerald - no 2020 or 2021 competency. B. TP number two: a. I-Stat ACT- no problem solving 2020 and 2021, No blind testing 2020 and 2021. b. Piccolo BMP+ - no blind testing in 2020 and 2021. c. Triage meter - no problem solving in 2020 and 2021. d. Verify Now system - no blind testing in 2020 and 2021. C. TP number three: a. I-Stat ACT- no problem solving 2021. 4. Interview with the laboratory liaison on February 1, at approximately 5:00 pm confirmed the technical consultant failed to maintain competency for all testing personnel in 2020 and 2021.