Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1071164	11/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cardiovascular Clinic Of West Tn Pc	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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer operator's manual, review of laboratory calibration records, and staff interview, the laboratory failed to follow manufacturer requirements for calibration of the Cell-Dyn Emerald complete blood count (CBC) instrument at least every six months in 2023. The findings include: 1. Observation of the laboratory on 11/29/2023 at 9:10 am revealed the Cell-Dyn Emerald (Serial #8328) hematology instrument in use for patient testing for CBC. 2. Review of the Cell-Dyn Emerald Operator's Manual section six titled "When to Calibrate" revealed the Cell-Dyn Emerald was to be calibrated "At least every six months". 2. Review of the calibration records for the Cell-Dyn Emerald revealed the Cell-Dyn Emerald instrument was calibrated on 08/04/2022 and 08/03/2023. The calibration that was due on 02/04/2023 was not performed resulting in a 12 month period between calibrations. 4. Interview on 11/29/2023 at 11:25 am with the laboratory liaison confirmed the laboratory failed to follow the manufacturer's requirements for calibration of the Cell-Dyn Emerald CBC instrument in 2023.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Citation I. Based on observation of the laboratory, review of the laboratory's individualized quality control (QC) plan (IQCP) for the Piccolo Xpress chemistry instrument, QC records, lack of records, random patient final test report review, and staff interview, the laboratory failed to follow the IQCP for the external QC frequency and documentation of electronic QC in 2022 and 2023. The findings include: 1. Observation of the laboratory on 11/26/2023 at 9:10 am revealed a Piccolo Xpress (Serial #P08693) instrument in use for performing patient testing for chemistry analytes to include glucose, urea nitrogen, sodium, potassium, chloride, carbon dioxide, magnesium, calcium, creatinine, and lactate dehydrogenase. 2. Review of the laboratory's IQCP for the Piccolo Xpress revealed the following: Two levels of external QC to be performed with each new lot, new shipment of same lot, or every seven days. Electronic Quality Control must be documented as acceptable prior to patient testing. 3. Review of the QC records for the Piccolo Xpress revealed external quality control was not performed every seven days as required by the IQCP for 19 of 19 months reviewed (04/2022, 06/2022, 10/2022, 11/2022, 01/2023-11/2023) for 2022 and 2023. 4. Electronic QC was not documented from 08/2022 through the date of the survey (11/29/2023). 5. Random review of final patient test reports revealed the following patients that were performed on the Piccolo Xpress chemistry instrument: 07 /14/2022 Patient #18289 06/15/2023 Patient #17383 08/31/2023 Patient # 18733 09/07 /2023 Patient #24697 09/13/2023 Patient #29166 11/08/2023 Patient #29244 6. Interview on 11/29/2023 at 11:15 am with the laboratory liaison confirmed the laboratory failed to follow it's own IQCP for the Piccolo Xpress used for patient chemistry testing when the external QC was not performed every seven days and electronic QC was not documented in 2022 and 2023. Citation II. Based on observation of the laboratory, review of the laboratory's IQCP for the VerifyNow AccuMetrics hematology instrument, QC record review, random patient final test report review, and staff interview, the laboratory failed to follow the IQCP for the external QC frequency in 2022 and 2023. The findings include: 1. Observation of the laboratory on 11/26/2023 at 9:10 am revealed a VerifyNow AccuMetrics (Serial #3153) hematology instrument in use for performing patient testing for Platelet glycoprotein IIB/IIIA receptor blockade. 2. Review of the laboratory's IQCP for the VerifyNow instrument revealed two levels of external QC to be performed with each new lot, new shipment of the same lot, or every seven days. 3. Review of the QC records for the VerifyNow revealed external QC was not performed every seven days as required by the IQCP for 16 of 16 months reviewed (02/2022 through 04/2022, 08 /2022, 11/2022, 01/2023, 02/2023, 04/2023, 06/2023 through 11/2023) for 2022 and 2023. 4. Random review of final patient test reports revealed the following patients

	that were preformed on the VerifyNow hematology instrument: 07/13/2022 Patient #20767 07/14/2022 Patient #18289 09/13/2023 Patient #29166 5. Interview on 11/29 /2023 at 11:15 am with the laboratory liaison confirmed the laboratory failed to follow it's own IQCP for the VerifyNow used for patient hematology testing when the external QC was not performed every seven days in 2022 and 2023.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, calibration and QC record review, quality assessment record review, and staff interviews, the laboratory failed to have an effective quality assessment procedure to identify and correct calibration and quality control frequency failures in 2022 and 2023 for the specialties of hematology and chemistry patient testing. The findings include: 1. Review of the laboratory quality assessment policy revealed that bi-monthly reviews of QC, procedure manual, patient test management, and quality assessment would be performed by the technical consultant. 2.. Review of the laboratory's QC and calibration records revealed gaps in performance of external QC according to the laboratory's IQCP for both the Piccolo Xpress chemistry instrument and the VerifyNow Accumetrics hematology instrument, and gaps in the calibration according to the manufacturer requirements for the Cell-Dyn Emerald CBC instrument (Refer to D5437 and D5441). 3. Review of the quality assessment records for 2022 and 2023 revealed no indication that the gaps in calibrations and QC frequency had been identified or corrective action performed. 4. Interview on 11/29/2023 at 11:30 am with the laboratory liaison confirmed the laboratory failed to have an effective quality assessment process when the QC and calibration frequency requirements were not met or documented for the Piccolo Xpress chemistry instrument, VerifiyNow hematology instrument, and Cell-Dyn Emerald hematology instrument used for patient testing with no identification or correction of errors in 2022 and 2023.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory policy, QC records, and staff interview, the laboratory director failed to ensure the QC program for the Piccolo Xpress and VerifyNow was maintained in 2022 and 2023. (See D5441) The findings include: 1. Review of the

	laboratory's IQCP revealed two levels of external QC to be performed with each new lot, new shipment of the same lot, or every seven days for both the Piccolo Xpress chemistry instrument and the VerifyNow hematology instrument. 2. Review of the laboratory's QC records revealed the QC was not performed at the frequency required by the laboratory's IQCP for both the Piccolo Xpress chemistry instrument and the VerifyNow hematology instrument in 2022 and 2023. 3. Interview on 11/29/2023 at 11:30 am with the laboratory liaison confirmed the laboratory director failed to ensure the laboratory's QC program was maintained for the Piccolo Xpress and the VerifyNow hematology instruments in 2022 and 2023.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality assessment records, and staff interview, the laboratory director failed to ensure the quality assessment program identified failures for calibration and QC frequency for the chemistry and hematology specialties in 2022 and 2023. (See D5793) The findings include: 1. Review of the laboratory's quality assessment policy revealed bi-monthly reviews would occur to include QC, procedure manual, patient test management, and quality assessment. 2. Review of the quality assessment records for 2022 and 2023 revealed the quality assessments performed failed to identify or correct the quality control and calibration frequency failures (nine of nine assessments reviewed). (See D5793) 3. Interview on 11/29/2023 at 11:30 am with the laboratory liaison confirmed the laboratory director failed to ensure the quality assessment program was effective in identification and correction of errors in QC and calibration frequency requirements in 2022 and 2023.