

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1071164	(X3) Date Survey Completed 01/16/2025
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
D0000	During a recertification survey conducted on 01/16/2025, the laboratory was found out of compliance with 493.1210 Condition: Routine Chemistry.
D5016	<p>ROUTINE CHEMISTRY CFR(s): 493.1210</p> <p>If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on laboratory observation, a review of the laboratory's Individualized Quality Control Plan for the Abaxis Piccolo Express chemistry instrument, quality control records, patient test records, and staff interview, the laboratory failed to follow the Quality Control procedure for the Abaxis Piccolo Express instrument (Refer to D5401) and failed to verify the control ranges used for evaluating quality control data for the Abaxis Piccolo Express instrument (Refer to D5469).</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's Individualized Quality Control Plan (IQCP) for the Abaxis Piccolo Express, a review of the</p>

laboratory's quality control (QC) records, patient test results and staff interview, the laboratory failed to follow the QC plan for the Abaxis Piccolo Express chemistry instrument in 2024 when the system was not re-validated during gaps in QC performance, the laboratory failed to perform two levels of QC on 01/24/2024, and QC for the Lactic Dehydrogenase (LDH) analyte was not repeated when level two QC was unacceptable on 06/17/2024, with four patients reported after the unacceptable QC run and the next acceptable QC run. Approximately 35 patient chemistry panels were reported during the 2024 calendar year when the QC Plan for the Abaxis Piccolo Express was not followed. 1. Observation of the laboratory on 01/16/2025 at 8:15 a.m. revealed the Abaxis Piccolo Express instrument used for patient testing for Sodium (Na+), Potassium (K+), Chloride (Cl-), Total Carbon Dioxide (CO2), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Crea), Calcium (Ca+), Lactate Dehydrogenase (LDH), and Magnesium (Mg) analytes using the Basic Metabolic Plus test disc. 2. A review of the laboratory's IQCP for the Abaxis Piccolo revealed the following statements under the section titled "Liquid QC": "2 levels of QC must be performed, with every new lot #, new shipment or every 30 days. Document the assay ranges and ensure all QC was in acceptable ranges. If a level should fail it must be repeated and in acceptable range before patient testing is performed. If over 30 days pass before QC is run, a validation must be performed. Validation is performed by running 2 levels of QC, 3 times each and all in acceptable ranges. This validation must be completed before patient testing may be done." 3. A review of the laboratory's QC records for the Abaxis Piccolo revealed the following: Level one QC was performed on 01/24/2024. QC was not performed again until 03/26/2024. There was no documentation that the re-validation was performed when there was a gap in QC performance. Level two QC was not performed on 01/24/2024. QC was performed on 04/25/2024. QC was not performed again until 06/17/2024. There was no documentation that the re-validation was performed when there was a gap in QC performance. QC was performed on 06/17/2024. QC was not performed again until 07/22/2024. There was no documentation that the re-validation was performed when there was a gap in QC performance. QC was performed on 08/29/2024. QC was not performed again until 12/02/2024. There was no documentation that the re-validation was performed when there was a gap in QC performance. The level two quality control for LDH performed on 06/17/2024 was outside the acceptable QC range compared to the QC package insert. The range in the QC package insert was 395 - 569 U/L. The QC value for the level two control was 358 U/L. The level two QC was not repeated. 4. A review of patient reports revealed that the LDH analyte was reported on 06/26/2024 for patient number 25739, on 07/01/2024 for patient number 26760, on 07/10/2024 for patient number 28700, and on 07/15/2024 for patient 13589, after the level two QC was unacceptable on 06/17/2024, and before acceptable QC was obtained on 07/22/2024. 6. The laboratory liaison confirmed the survey findings during a phone interview on 01/24/2025 at 4:35 p.m.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control

materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:

Based on laboratory observation, a review of the laboratory's quality control (QC) records, a review of patient test results, and staff interview, the laboratory failed to ensure the QC ranges used were verified for eight of eight QC lots used from 01/04/2024 to 01/07/2025 for the tests performed on the Abaxis Piccolo Express instrument, with 38 patients reported during the period when the incorrect QC ranges were used. 1. Observation of the laboratory on 01/16/2025 at 8:15 a.m. revealed the Abaxis Piccolo Express instrument used for patient testing for Na⁺, K⁺, CL⁻, CO₂, Glu, BUN, Crea, Ca⁺, LDH, and Mg analytes using the Basic Metabolic Plus test disc. 2. A review of the laboratory's QC records (package inserts and QC printouts) for the Abaxis Piccolo Express chemistry tests revealed incorrect quality control ranges used for the evaluation of quality control results as follows: QC lot number 2307009 (level one and level two): The QC ranges programmed into the instrument for QC lot number 2307009, level one, were incorrect for the Na⁺, K⁺, Cl⁻, CO₂, Glu, BUN, Ca⁺, LDH, and Mg analytes (nine of ten analytes). The level one QC lot was used for performing QC on 01/04/2024 and 01/24/2024. The QC ranges programmed into the instrument for QC lot number 2307009, level two, were incorrect for the Na⁺, K⁺, Cl⁻, CO₂, Crea, BUN, Glucose, and LDH analytes (eight of ten analytes). The level two QC lot was used for performing QC on 01/24/2024. QC lot number 2309018 (level one and level two): The QC ranges programmed into the instrument for QC lot number 2309018, level one, were incorrect for the Na⁺, Cl⁻, CO₂, Crea, Glu, BUN, Ca⁺, and LDH analytes (eight of ten analytes). The level one QC lot was used for performing QC on 03/25/2024 and 04/25/2024. The QC ranges programmed into the instrument for QC lot number 2309018, level two, were incorrect for the Na⁺, K⁺, Cl⁻, Crea, BUN, Glucose, Mg, and LDH analytes (eight of ten analytes). The level two QC lot was used for performing QC on 03/25/2024 and 04/25/2024. QC lot number 2402008 (level one and level two): The QC ranges programmed into the instrument for QC lot number 2402008, level one, were incorrect for the Na⁺, K⁺, Cl⁻, CO₂, Crea, BUN, Glucose, Ca⁺, Mg, and LDH analytes (ten of ten analytes). The level one QC lot programmed with the incorrect QC ranges was used for performing QC on 06/17/2024. The QC ranges programmed into the instrument for QC lot number 2402008, level two, were incorrect for the Na⁺, K⁺, Cl⁻, CO₂, Crea, BUN, Glucose, Ca⁺, Mg, and LDH analytes (ten of ten analytes). The level two QC lot programmed with the incorrect QC ranges was used for performing QC on 06/17/2024. The QC range programmed into the instrument for QC lot number 2402008, level one, was incorrect for the Glucose analyte when QC was performed on 07/22/2024, 08/08/2024, and 08/29/2024 (one of ten analytes). QC lot number 2404034 (level one and level two): The QC ranges programmed into the instrument for QC lot number 2404034, level one, were incorrect for the Na⁺, K⁺, Cl⁻, CO₂, Crea, Glu, BUN, Ca⁺, and LDH analytes (nine of ten analytes). The level one QC lot was used for performing QC on 12/02/2024 and on 01/07/2025. The QC ranges programmed into the instrument for QC lot number 2404034, level two, were incorrect for the Na⁺, K⁺, Cl⁻, CO₂, Crea, BUN, Glucose, Ca⁺, Mg, and LDH analytes (ten of ten analytes). The level two QC lot was used for performing QC on 12/02/2024 and on 01/07/2025. 3. A review of patient results revealed that 38 patients were reported from 01/04/2024 to 01/16/2025 (survey date) during the period when the incorrect QC ranges were used. Analytes reported included the Na⁺, K⁺, CL⁻, CO₂, Glu, BUN, Crea, Ca⁺, LDH, and Mg analytes. 4. The laboratory liaison confirmed the survey findings during a phone interview on 01/24/2025 at 04:35 p.m.