

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2241394	(X3) Date Survey Completed 06/27/2024
Name of Provider or Supplier Southern Health And Wellness Clinic	Street Address, City, State 3519 Chere Carol Rd, Humboldt, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory policy, the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, and a staff interview, the laboratory failed to follow the proficiency testing policy for performing corrective action for unacceptable PT results for 2022 event two (one of six PT events reviewed). The findings include: 1. A review of the laboratory policy titled "Proficiency Testing Policy and Procedure" revealed that the medical director or designee would evaluate proficiency testing results, and any results less than 100% would have documented corrective action. 2. A review of the laboratory's API PT records revealed a score of 80% for the platelet analyte for 2022 event two with no documented corrective action. 3. An interview with the technical consultant on 06/27/2024 at 12:00 pm confirmed the survey findings. Word Key: % - percent</p>
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel</p>

meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on a review of the Aspen Web 116 database and the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), Laboratory Personnel Report CLIA (Form CMS-209), lack of documentation, and staff interview, the laboratory director failed ensure compliance with 493.51 (a)(4) when the state agency was not notified of change in laboratory director within 30 days of the change which occurred in May 2023. The findings include: 1. A review of the Aspen Web 116 database, Form CMS-116, and Form CMS-209 revealed the laboratory director listed on the survey forms (CMS-116 and CMS-209) was different from the laboratory director in the Aspen Web 116 database. 2. The laboratory could not provide evidence that the state agency was notified of the change in laboratory director within 30 days of the change that occurred in May 2023. 2. An interview with the technical consultant on 06/27/2024 at 10:30 am confirmed that the laboratory director failed to ensure the state agency was notified of the change in laboratory director within 30 days of the change that occurred in May 2023.