

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0252234	(X3) Date Survey Completed 09/27/2023
Name of Provider or Supplier Poinsett Family Practice	Street Address, City, State 2 Innovation Drive, Suite 120, Greenville, SC	
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	A Recertification Survey was initiated on 09/27/2023 and concluded on 09/27/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on documentation review and interview, the laboratory failed to maintain copies of proficiency testing (PT) records for 2 (2021 and 2022) of 2 years reviewed. Findings included: A review on 09/27/2023 at 11:00 AM revealed the laboratory could not produce PT records (graded reports, attestations, submitted results, instrument printouts) from American Proficiency Institute for all specialties when requested. During an interview on 09/27/2023 at 2:00 PM, Testing Personnel #1 stated she believed the records in question were misplaced.</p>
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on record review, hematology and chemistry analyzer manual review, and interview, the laboratory failed to monitor and document humidity readings for 2 (2022 and 2023) of 2 years reviewed. Findings included: On 09/27/2023 at 11:00 AM, temperature records intended to contain documentation of humidity readings from January 2022 through September 2023 were not available for review. Review of a manufacturer's manual for the hematology analyzer revealed the humidity range to operate the analyzer was 80%-88%. Additional review revealed the manufacturer's manual for the chemistry analyzer recommended a humidity range of 35%-55%. During an interview on 09/27/2023 at 2:00 PM, Testing Personal (TP) #1 stated the laboratory never documented the humidity for the laboratory room. TP #1 stated there was a humidity monitor installed in March of 2023, but they had not documented the humidity on any of their temperature or maintenance logs.