Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0883465	(X3) Date Survey Completed 09/05/2024
Name of Provider or Supplier Mcleod Pediatrics - Dillon	**Street Address, City, State** 705 N 8th Ave Suite 3a, Dillon, 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	An onsite announced CLIA recertification survey was conducted on September 5, 2024, at the clinical laboratory of McLeod Pediatrics-Dillon by the South Carolina Department of Public Health's (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a description of the Standard Level deficiencies cited:
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on laboratory personnel documented on the CMS 209 form, review of policy and procedures, and staff interview, the laboratory failed to have a written procedure for evaluating personnel competency. Findings included: 1. Review of laboratory personnel documented on the CMS 209 form reveals the lack competency assessments for 6 out of 6 testing personnel. 2. Review of the laboratory's policy and procedure manual reveals a lack of a written procedure for asessing the competency of employees. 3. In a staff interview with testing personnel (TP1) on September 5, 2024 in the laboratory conference room at 1:00pm, the findings were confirmed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231

	through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedures and staff interview, the laboratory failed to have a written policy and procedeure for quality assessments. Findings included: 1. Review of laboratory documents reveals a form entitled "Monthly Quality Assessment Review". 2. Review of laboratory policy and procedure reveals a lack of a written procedure for conducting Quality Assessments. 3. In a staff interview with TP1on September 5, 2024 at 12:00pm in the laboratory conference room, the findings were confirmed.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the review of Attestation forms from the College of American Pathology's (CAP) proficiency testing (PT) and staff interview, 2 out of 9 Attestation forms were not signed by testing personnel and the Laboratory Director. Findings included: 1. Review of CAP Attestation Forms reveals: a. CAP survey FH1 dated February 15, 2022, was not signed by testing personnel and laboratory director. b. CAP survey D6 dated December 26, 2023, was not signed by testing personnel and laboratory director. 2. In a staff interview with TP1 on September 5, 2024 at 12:00pm in the laboratory conference room, the findings were confirmed.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the lack laboratory personnel competency documentation and staff interview, The laboratory director failed to ensure personnel competency assessments in 6 out of 6 testing personnel. Finding included: 1. Review of laboratory

	documentation reveals a lack personnel competency evaluations for initial, 6 months, and annual competency assessments. 2. Laboratory document review reveals testing performance authorization forms. These forms do not fullfill the requirement for personnel competency assessments to include the 6 different competency standards. 3. In a staff interview on September 5, 2024 at 12:00pm with TP1 in the laboratory conference room, the findings were confirmed.