Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1024832	01/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Palmetto Family Medicine Of Chesterfield County	316 Second St, Cheraw, 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 CLIA recertification survey was conducted at Palmetto Family Medicine of Chesterfield County facility on January 6, 2025, by the South Carolina Department of Public Health's 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.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: During onsite recertification survey on 01/06/2025, based on records review, lack of documentation and staff interview, the laboratory failed to document corrective action for analyzer problems. Findings include: 1. Review of the laboratory's written QA plan titled Quality Assessment "the laboratory will monitor, identify, evaluate, investigate, manage, correct and document incidents and problems that occur as a result of non-compliance with laboratory policies and procedures or unexpected events". 2. There were no documented corrective action activities for 2022, 2023, 2024 available for review on the day of the survey. 3. In an interview with technical consultant (TC) in the office on 01/06/2025 at 3:00 pm that no corrective actions were documented from June and August 2023 of Sysmex POChi analyzer being down.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 package label for BD vacutainer tubes, review of environmental logs, and staff interview, the laboratory failed to maintain acceptable temperature ranges for 12 of 12 months reviewed. Findings include: 1. During a tour of Palmetto Family Medicine of Chesterfield County on 01/06/2025 at 12:05 pm the surveyor observed vacutainer tubes stored in the laboratory. 2. BD K2EDTA, Lavender tubes package label states acceptable temperature range for storage is 4 to 25 degrees Celsius (C)/39. 2 to 77 F. 3. Review of the laboratory's temperature records for 12 months of 2024 revealed room temperature range as 64 to 90 Fahrenheit (F)/17.777 to 32.22 C. 4. In an interview with TC in the office on 01/06/2025 at 3:00pm the above findings were confirmed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: During an onsite recertification survey on 01/06/2025, based on instruction manual, instrument maintenance record review and staff interview, the laboratory failed to document monthly maintenance on the Sysmex poch-100i instrument for eight of twelve months reviewed from January to December of 2024. Findings include: 1. Review of the Sysmex poch-100i hematology analyzer operator's manual on 01/06 /2025 at 1:00 pm revealed that maintenance is to be performed "Every 2 weeks or 150 samples". 2. Review of maintenance for complete blood count (CBC) analyzer poch-100i revealed a lack of documentation for Bi-weekly maintenance or every 150 samples for 8 out of 12 months in 2023 (January, February, March, April, May, June, July, August) reviewed. 3. In an interview with TC in the office on 01/06/2025 at 3:00 pm the above findings were confirmed.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on policy and procedure review, lack of documentation and staff interview, the laboratory failed to perform a quality assessment to ensure the electronic test results

	verification is performed. Findings include: 1. A review of the laboratory quality assurance plan titled Quality Assessment revealed the laboratory information system will be reviewed for quality assessment. 2. The laboratory QA plan did not include documentation that a review of an electronic test report was verified with the client or laboratory. No documentation provided on the day of survey 01/06/2025. 3. An interview with the TC in the office on 01/06/2025 at 3:00 pm confirmed the laboratory did not have documentation for electronic verification of patient results.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) (b)(8)(vi) Assessment of problem-solving skills; and This STANDARD is not met as evidenced by: Based on record review, the laboratory's policy and staff interview the Technical Consultant failed to assess all six competency elements for 2 of 2 testing personnel (TP) in 2022, 2023, and 2024. 1. A review of CMS 209 Laboratory Personnel Report revealed moderately complex testing is performed by TP 1 and TP 2. 2. A review of the laboratory's competency records revealed the competency assessment lacked a troubleshooting component for the two personnel reviewed for the three years reviewed. 3. An interview with the TC in the office on 01/06/2025 at 3:00 pm the above findings were confirmed.
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderate complexity testing must-- (a) possess a current license issued by the State in which the laboratory is located, if such licensing is required; and This STANDARD is not met as evidenced by: Based on records reviewed (CMS 209), lack of education documentation, and staff interview, the laboratory failed to ensure 1 of 2 testing personnel had documentation of their highest diploma (high school, GED, 50 weeks military training, Associates Degree, Bachelors Degree, Masters Degree, or Doctorate in a Biological, Chemical or Physical Science) as listed under 42 CFR Section 493.1423 to qualify as moderate complexity testing personnel. Findings include: 1. A review of laboratory personnel report (CMS 209) record reveals two testing personnel on the day of the survey 01/06 /2025. 2. No education records were present for review on day of survey for TP2 one of two testing personnel. 3. An interview with the TC in the office on 01/06/2025 at 3: 00 pm the above findings were confirmed.