Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1000024	05/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Family Medical Center Of Blackville	130 N Baker Street, Blackville, 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 annouced on-site CLIA Initial survey was conducted at the Blackville Medical Center's clinical laboratory on May 16, 2024, by SC DHEC Bureau of Healthcare Systems and Services. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The laboratory was found to be non-compliant with CLIA requirements. Specific Condition and Standard level deficienies cited as follows:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on document review and staff interview, the laboratory failed to have the Laboratory Director sign Attestation statements for performed PT. Findings included: 1. All API surveys reviewed from 2021 to 2024 (72 out of 72) were not signed by the laboratory director. 2. In an interview on 05/16/2024 at 12:30 pm in the laboratory break room, the findings were confirmed by the laboratory supervisor (TP1).
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)

	(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: D2016 493.803 a Condition: Failure to successfully participate in CMS approved PT. Based on document review and staff interview, the laboratory failed to successfully participate in a CMS approved proficiency program. Findings included: 1. API Hematology 2021 2nd event and API Hematology 2022 1st event scored 50% for Hemoglobin (waived). 2. API Hematology 2022 1st event and API Hematology 2022 3rd event scored 50% for Hemoglobin (waived). 3. API Hematology 2022 3rd event and API Hematology 2023 1st event scored 50% for Hemoglobin (waived). 4. In an interview on 05/16/2024 at 12:30 pm in the laboratory break room, TP1 confirmed the survey findings.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on document review and staff interview, the laboratory failed 2 out of 3 PT events for the same analyte. 1. API Hematology 2021 2nd event and API Hematology 2022 1st event scored 50% for Hemoglobin (waived). 2. API Hematology 2022 1st event and API Hematology 2022 3rd event scored 50% for Hemoglobin (waived). 3. API Hematology 2022 3rd event and API Hematology 2023 1st event scored 50% for Hemoglobin (waived). 4. In an interview on 05/16/2024 at 12:30 pm in the laboratory break room, TP1 confirmed the survey findings.
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 document review and staff interview, the laboratory failed to follow its own policy for employee competency evaluations. 1. According to policy "Competency: Competency Evaluation for Personnel Performing Clinical Testing Effective" the interval for competency evaluation is "Initial training and competency must be documented prior to the reporting of any patient results. Six months follow the initial competency assessment. Twelve months following the initial assessment. Annually thereafter." 2. No initial or 6 months competency assessments were available for TP2. 3. No competency assessments were available for TP1. 4. In an interview on 05/16 /2024 at 11:30 am in the laboratory office, TP1 confirmed the survey findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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. This STANDARD is not met as evidenced by: Based on document review and staff interview, the laboratory failed to have written policies and procedures for all tests, assays, and examinations. 1. There was no written policy or procedure for the handling and performance of PT samples. 2. In an interview on 05/16/2024 at 12:30 pm in the laboratory break room, TP 1 confirmed the findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on document review and staff interview, the Laboratory Director failed to approve, sign and date the laboratory's procedure manual. 1. The laboratory's procedure manual had no evidence of review, or signature of approval by the LD. 2. In an interview on 05/16/2024 at 11:00 am in the laboratory break room, TP1 confirmed the finding.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on document review and staff interview, the LD failed to fulfill his responsibilities as LD. 1. The laboratory's procedure manual had no evidence of review, or signature of approval by the LD. 2. Based on document review, the LD

	failed to ensure the laboratory's successful participation a CMS approved proficiency program. 3. Based on document review, the LD failed monitor PT performance. 4. No evidence of active participation in the oversite and direction of the laboratory.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on document review and staff interview, the verification of the Sysmex instrument validation lacked evidence of review or signature of approval by the LD or laboratory supervisor. 1. No LD signature on the Sysmex instrument validation. 2. In an interview on 05/16/2024 in the laboratory break room at 1:00pm, TP1 confirmed the findings.
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 document review and staff interview, there is no evidence that the LD reviewed PT results and corrective actions. 1. No LD signature on 72 of 72 PT results 2. In an interview on 05/16/2024 at 12:00pm in the laboratory break room, TP1 confirmed the findings.