Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0860669	09/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mackey Family Practice Pa	1025 W Meeting St, Lancaster, 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 announced CLIA recertification survey was conducted at Mackey Family Practice on 09/18/2024 by the South Carolina Department of Public Health (SC DPH). The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The facility was found to be out of compliance with the CONDITIONS of the CLIA program. The following CONDITION and STANDARD LEVEL DEFICIENCES were found to be out of compliance.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: During an onsite recertification survey on 09/18/2024, based on the records review (from Certification And Survey Provider Enhanced Reports (CASPER) and Laboratory Personnel Report CMS 209), and staff interview, the laboratory failed to ensure that proficiency testing (PT) samples were rotated among all testing personnel (TP) who routinely performed chemistry testing for 4 of 4 PT events reviewed from 2023 to 2024 (2023 Event 1,2, and 3; 2024, Event 1). Findings included: 1. The laboratory listed 2 testing personnel on the CMS 209 performed non-waived testing in the specialty and subspeciality of chemistry on the day of the survey. 2. Review of American Proficiency Institute (API) records revealed Events 1, 2, and 3 in 2023 were performed by TP1. 3. Review of API records revealed for 2024 Events 1, and 2 were also performed by TP1. TP 2 also routinely performed patient chemistry test; however, did not perform any chemistry proficiency tests during 2023, or for 1 event of 2024. 4. In an interview with TP1 on 09/18/2024 at 1:30 pm in the office the above findings were confirmed.

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: Based on API proficiency testing records review, CASPER Report 0155D and staff interview, the laboratory failed to achieve 80% successful performance for specialty chemistry analyte aminotransferase (AST)/serum glutamic-oxaloacetic transaminase (SGOT) for two consecutive proficiency testing events reviewed (20203, Events 2; 2024, Event 1). See D2096
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on API proficiency testing records review, CASPER Report 0155D and staff interview, the laboratory failed to achieve satisfactory performance for chemistry analyte aspartate aminotransferase (AST)/ serum glutamic-oxaloacetic transaminase (SGOT) for two out of three events from 2023 to 2024. Findings included: 1. Review of laboratory records for American Proficiency Institute (API) revealed the following results: a. AST/SGOT, 2023, Event 2, score 40%, unacceptable b. AST/SGOT, 2024, Event 1, score 0%, unacceptable 2. Review of CASPER Report 0155D revealed unsuccessful proficiency testing for AST/SGOT. a. 2023 AST(SGOT), score 40% b. 2024 AST(SGOT), score 0% 3. In an interview with TP1 on 09/18/2024 at 3:56 pm in the office, the above findings were confirmed.
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 procedure manual review, testing personnel record review and staff interview, the laboratory failed to establish and follow written policies and procedures to assess employee competency for 7 out of 8 moderate complexity testing personnel listed on the CMS 209 3 years reviewed (2022, 2023 2024). Findings included: 1. The laboratory's procedure manual did not have a policy or procedure for the frequency of performing employee competency. 2. Review of testing personnel's file revealed that initial, semi-annual, or annual assessment could not be identified. 3. Review of "Personal Performance Checklist" revealed the following: a. 2022 lack documentation for 8 out of 8 TP No documentation available on the day of the survey. 4. In an interview with TP 1 on 09/18/2024 at 1:30 pm in the office the above 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 policy and procedures, records review and staff interview, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated correct problems identified in the general laboratory systems as specified at 493.1231 through 493.1236. Findings included: 1. Review of policy titled "Laboratory Quality Assurance Plan For Mackey Family Practice" revealed that evaluation and documentation of quality assurance activities would be performed monthly. 2. Review of Mackey Family Practice records revealed a lack of documentation monitoring the activities and standards as stated in the "Laboratory Quality Assurance Plan for Mackey Family Practice". 3. In an interview with TP1 on 09/18/2024 at 1:30 pm in the office the above findings were confirmed.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, manufacturer instructions and staff interview, the laboratory failed to indicate open and expiration dates of controls in use for chemistry and hematology analyzers. 1. During a tour of the laboratory on 09/18/2024 at 3:35 pm the surveyor observed quality control material Difftrol Tri-Level for the Horiba Medical Hematology Devices. a. Level 1, Lot # DX449L, expiration (exp) date 11/05

	/2024 b. Level 2, Lot # DX449N, exp. date 11/05/2024 c. Level 3, Lot# DX449H, exp. date 11/05/2024 No open or expiration dates written on bottles in use. 2. Review of manufacturer package insert under "Stability and storage", opened tubes are stable for 15 days provided they are handled properly. 3. The surveyor observed quality control material multi-analyte Thermo Scientific used for the Siemens analyzer. a. Liquid Assayed Chemistry Control MAS ChemTrak H, Level 1, Lot#24081A, exp. date 08/31/2024. b. Liquid Assayed Chemistry Control MAS ChemTrak H, Level 2, Lot# CHA 25122A, exp. date 12/31/2025 c. Liquid Assayed Chemistry Control MAS ChemTrak H, Level 3, Lot# CHA25043A, exp. date 04/30/2025 d. Liquid Assayed Immunoassay Control MAS Liquimmune, Lot# LIA24091A, exp. date 09/30/2024 e. Liquid Assayed Immunoassay Control MAS Liquimmune, Lot# LIA24092A, exp. date 09/30/2024 f. MAS CardioImmune XL, Level 3, Lot# CXL23063A, exp. date 06 /30/2023 No open or expiration dates written on bottles in use. 4. In an interview with testing personnel on 09/18/2024 at 3:35 pm in the laboratory, the above findings were confirmed.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on direct observations, and staff interviews, that laboratory failed to perform function checks on traceable timers used in the laboratory. Findings included: 1. During the laboratory tour on 09/18/2024 at 3:35 pm with testing personnel, the surveyor observed two Mckesson traceable timers with expired dates. 2. Review of label for timers reveal no information of calibrations. 3. In an interview with TP 1 on 09/18/2024 at 3:35 pm in the laboratory, the above findings were confirmed.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interviews with testing personnel the laboratory failed to document training provided to personnel prior to testing patients. Two personnel have

	been identified as new since the last survey. 2 out of 8 personnel records lack training documentation. Findings included: 1. Review of CMS 209 personnel report form, 7 personnel listed as testing personnel (TP) and one GS. 2. Competency forms provided a list of duties with no indication of initial training to date of hire for (TP3, TP7). 3. In an interview on 09/18/2024 at 1:30 pm in the office with TP 1, the above findings were confirmed.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of policy and procedures, records review, and staff interview, the laboratory failed to address all 6 components in the competency assessment policy. The laboratory lacks documentation of technical consultant (TC) assessment of TP problem solving skills, direct observations and proficiency testing samples. Findings included: 1. Review of policy and procedures lacks all six components and a timeline for personnel competency. 2. A review of policy titled "Laboratory Quality Assurance Plan for Mackey Family Practice" included section III. Areas of Quality Assurance Evaluation, E. Personnel assessment" lack semiannual assessment. 3. Review of competency records reveals "personal performance checklist" lack problem solving /troubleshooting skills and handling proficiency testing samples the same as patient samples. 4. In an interview on 09/18/2024 at 1:30 pm with TP 1 in the office, confirm the findings above.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of policy and procedures, records review, and staff interview, the laboratory failed to ensure that testing personnel were evaluated at least semiannually during the first year of testing patient specimens for 2 out of 2 new testing personnel (TP3, TP7) Findings included: 1. The laboratory listed 7 testing personnel on the CMS 209 on the day of the survey and 1 general supervisor. 2. Review of policy and procedure manual revealed a policy titled "Laboratory Quality Assurance Plan For Mackey Family Practice" included section III. Areas of Quality Assurance Evaluation, E. Personnel assessment" procedure did not include a semiannual evaluation for the first year of testing. 3. Documentation of initial training and evaluation at least seminannually during the first year of testing was unavailable for review on the day of the survey for 2 of 2 new employees (TP3, TP7). 4. In an interview on 09/18/2024 at 1:30 pm in the office with the testing personnel, the above findings were confirmed.