Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2076055	03/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Khair Family Practice	125 Eagle Spring Dr, Stockbridge, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 25, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: A review of the current Procedure Manual confirmed that the Procedure Manual failed to contain written procedures. THE FINDINGS INCLUDE: 1. A review of the current Procedure Manual confirmed that there were no SOPs for the Waived Testing Procedures: Glucose Testing, Hemoccult Testing, HCG Urine Pregnancy Testing, Urinalysis Dipstick Testing, Rapid COVID-19 Testing, Rapid Influenza A/B Testing, and Rapid Strep Testing, 2. An interview with the Testing Personnel confirmed that package inserts were not used in lieu of written procedures for the Waived Testing Procedures: Glucose Testing, Hemoccult Testing, HCG Urine Pregnancy Testing, Urinalysis Dipstick Testing, Rapid COVID-19 Testing, Rapid Influenza A/B Testing, and Rapid Strep Testing, 3. An exit interview, with the Laboratory Director and Testing Personnel, in the conference room, on March 25, 2025, at 1:30pm, confirmed these findings to be accurate.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) (b)(2) The laboratory must test samples the same number of times that it routinely

	tests patient samples. This STANDARD is not met as evidenced by: A review of 2023 - 2024 WSLH Proficiency Testing Records confirmed that Testing Personnel (TP) failed to process proficiency specimens in the same manner as routinely tested patient samples. THE FINDINGS INCLUDE: 1. A review of the WSLH Proficiency Testing Records confirmed that the proficiency testing challenges included three (3) Hematology events per year for a biannual total of six (6) testing events in 2023 - 2024. Five (5) specimens were received per event evaluated six (6) indices per proficiency specimen that included: Cell ID, RBC, HCT, HGB, WBC COUNT, and PLATELETS. A biannual total of thirty (30) Proficiency specimens are evaluated, which included the evaluation of one hundred and eighty (180) indices. 2. A review of the raw testing data of the proficiency samples revealed that all testing personnel (listed on CMS 209 - TP#1, TP#2, TP#3, TP#4, and TP#5) performed testing for all five (5) proficiency specimens for the six (6) testing events in the 2023 - 2024 Hematology Proficiency Testing Events. 3. An interview with the TP staff confirmed that routine patient specimens are processed once (1X) by a single TP, unless confirmatory testing is indicated by the initial test results. 4. An exit interview with the LD and TPs, in the conference room, on March 25, 2025, at 1:30pm, confirmed that Testing Personnel (TP) failed to process proficiency samples in the manner as routinely tested patient samples.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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: A review of the Procedure Manual confirmed that the Procedure Manual failed to contain any written procedures for the patient testing currently performed at the laboratory. THE FINDINGS INCLUDE: 1. A review of the Procedure Manual confirmed that there were no SOPs for the following procedures: CBC Testing , Quality Control, Quality Assurance, or Downtime. 2. An exit interview, with the Laboratory Director and Testing Personnel, in the conference room, on March 25, 2025, at 1:30p, confirmed these findings to be accurate.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: A review of two (2) randomly presented patient reports for in-house testing (1 in-house CBC Report and 1 in-house COVID/ Influenza Report), confirmed that the patient test results report failed to contain reference ranges and/ or to identify where the testing was performed. THE FINDINGS INCLUDE: 1. A review of the in-house CBC test results confirmed that the reports did not identify the facility taht performed the testing. 2. A review of the in-house COVID and Influenza A/B confirmed that the test results reports did not contain reference ranges or identify the facility that performed the testing. 3. An exit interview with the Labortory Director and Testing Personnel, in the conference room, on March 25, 2025, at 1:30pm, confirmed that the in-house patient testing reports did not contain reference ranges or the identification of the testing facility.
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) (e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards; This STANDARD is not met as evidenced by: A tour of the Laboratory testing areas confirmed that the Laboratory Director (LD) failed to provide the required safety protections against accidental exposure to hazardous chemicals. THE FINDINGS INCLUDE: 1. A tour of the Hematology testing area revealed that the area did not contain a clean sink or eyewash station. 2. An exit interview with the Laboratory Director and Testing Personnel, on March 25, 2025, at 1:30pm, confirmed that the LD failed to provide the required safety protections against accidental exposure to hazardous chemicals.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: A review of 2023 - 2025 Personnel Competency Records, confirmed that the Laboratory Director (LD) failed to assure the competency of laboratory Testing Personnel (TP). THE FINDINGS INCLUDE: 1. The review of the 2023 - 2025 Personnel Competency Records confirmed that the LD did not perform the required personnel training and competencies on TP#1, TP#2, TP#3, TP#4, and TP#5 (as dentified on 2025- CMS 209 Personnel Form). Records indicate that TP conducted training and competencies on each other for the 2023, 2024, and 2025. 2. An exit interview, with the LD and TPs, on March 25, 2025, at 1:30pm, confirmed that the LD failed to assure the competency of laboratory Testing Personnel (TP).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify

	failures in quality as they occur; This STANDARD is not met as evidenced by: A review of 2023 - 2025 Quality Assurance (QA) Records confirmed that the Laboratory Director failed to provide appropriate oversight to assure the quality of laboratory services provided. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 QA Records confirmed that the LD did not perform QA reviews. QA documentation revealed that QA reviews were conducted by unqualified Testing Personnel (TP) - TP#1, TP#2, TP#3, TP#4, and TP#5 as identified on the 2025- CMS 209 Personnel Form. 2. A review of the 2023 - 2025 Refrigerator Temperature Logs confirmed that Refrigerator Temperature Logs for January 2024 - December 2024 were not reviewed by the LD until February 10, 2025. 3. A review of the 2023 - 2025 Levy Jennings QC charts from the Sysmex Hematology Analyzer revealed erratic patterns for testing parameters with no documented review, investigation, or corrective actions taken. 4. A review of the 2023 - 2025 Humidity Records for the Refrigerator/ Freezer Room area revealed a low-end humidity trend from January 2024 - June 2024 with six (6) out of range low values. No corrective actions were documented for failed humidity events. 5. An exit interview with the LD and TPs, on March 25, 2025, at 1:30pm, confirmed that the Laboratory Director failed to provide appropriate oversight to assure the quality of laboratory services provided.