

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2076055	(X3) Date Survey Completed 10/16/2018
Name of Provider or Supplier Khair Family Practice	Street Address, City, State 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) complaint survey was completed on October 16, 2018. The laboratory was found not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of laboratory records and an interview with the Laboratory Director (LD), the laboratory failed to enroll in a CMS-approved proficiency test (PT) program or peer review as required by Clinical Laboratory Improvement Amendments (CLIA) for the specialty of Hematology from January 2018 through October 2018. The findings include: 1. Review of laboratory PT records revealed the laboratory was not enrolled in a PT program or peer review for the specialty of Hematology from January 2018 through October 2018. 2. The Laboratory Director confirmed on 10/16 /18 at 10:30 AM in the office, that the facility was not enrolled in a CMS- approved PT program or peer review for the specialty of Hematology.</p>
D6015	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p>

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and an interview with the Laboratory Director (LD), the laboratory director failed to ensure the laboratory was enrolled in a CMS-approved proficiency testing (PT) program for the specialty of Hematology for 2018. The findings include: 1. A review of laboratory records revealed that the facility was not performing PT or enrolled in a PT program for the specialty of Hematology for 2018. 2. The Laboratory Director confirmed on 10/16/18 at 10:30 AM in the office, that the facility was not enrolled in a CMS- approved PT program or peer review for the specialty of Hematology.