

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0669427	(X3) Date Survey Completed 07/19/2022
Name of Provider or Supplier Muhammed I Khokar Md	Street Address, City, State 608 New Hope Road Suite 3, Princeton, WV	
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 unannounced, off site, proficiency testing (PT) desk review was conducted at Muhammed I Khokar MD on July 19, 2022, by the West Virginia Office of Laboratory Services. The laboratory proficiency testing evaluations with the Medical Laboratory Evaluation (MLE) were reviewed and evaluated with the laboratory CMS 0153D Unsuccessful PT Report for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are cited below.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Medical Laboratory Evaluation (MLE) proficiency testing</p>

	<p>(PT) records and the CLIA 155D Individual Laboratory Profile report for Muhammed I Khokar MD, the laboratory failed to successfully participate in a program approved by CMS for 6 analytes in the specialty of Hematology (#0760) for 2 of 2 events in 2022. Findings: 1. Hematology (#0760) 1st event 2022- 0% Failure to Participate: 0% scores for analytes Cell ID/WBC Diff (#0765), RBC (#0775), HCT (#0785), HGB (#0795), WBC (#0805), Platelets (#0815) 2. Hematology (#0760) 2nd event 2022- 0% Failure to Participate: 0% scores for analytes Cell ID/WBC Diff (#0765), RBC (#0775), HCT (#0785), HGB (#0795), WBC (#0805), Platelets (#0815)</p>
<p>D2127</p>	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) evaluations and the CASPER 155D report, the laboratory failed to participate in 2 of 2 PT events for 2022 in Hematology. Findings: 1. Hematology (#0760) 2022 Event 1- 0% 2022 Event 2 - 0%</p>
<p>D2131</p>	<p>HEMATOLOGY CFR(s): 493.851(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CASPER 155D Report and the Medical Laboratory Evaluation (MLE) proficiency testing (PT) evaluations the laboratory failed to achieve a satisfactory performance for the speciality of Hematology in 2 of 2 consecutive 2022 testing events. Findings: 1. Review of CASPER 155D Report identified the following for the specialty #0760 Hematology: 1st event 2022- 0% 2nd event 2022- 0% 2. Review of MLE PT evaluations for the laboratory confirmed the unsuccessful performance of 0% for Hematology in 2 of 2 testing events of 2022.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory proficiency testing (PT) records from Medical Laboratory Evaluation (MLE) evaluations and CMS reports, the laboratory director failed to: 1) ensure successful participation for the specialty of Hematology for the regulated analytes on the laboratory test menu. Refer to D2016 2) ensure and monitor</p>

process to return results to the PT Provider before the deadline. Refer to D2127 and D2131.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records from CMS and Medical Laboratory Evaluation (MLE), the laboratory director failed to assure compliance with the regulation requiring successful participation in PT for the analytes Cell ID /WBC Diff, RBC, HCT, HGB, WBC, and Platelets in 2 of 2 testing events in 2022. Findings: 1. Hematology (#0760) 1st event 2022- 0% Failure to Participate: 0% scores for analytes Cell ID/WBC Diff (#0765), RBC (#0775), HCT (#0785), HGB (#0795), WBC (#0805), Platelets (#0815) 2. Hematology (#0760) 2nd event 2022- 0% Failure to Participate: 0% scores for analytes Cell ID/WBC Diff (#0765), RBC (#0775), HCT (#0785), HGB (#0795), WBC (#0805), Platelets (#0815)