Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0681245	02/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
A Dahhan Md Fccp	120 Professional Lane Ste 101, Harlan, KY	

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	Based on desk review of proficiency testing (PT) in 2022, the laboratory failed to meet the following conditions, resulting in an initial PT participation: D2016 - SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) D6000 - MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403
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 a desk review of proficiency testing (PT) records, the laboratory failed to successfully participate in a PT program approved by the Department of Health and Human Services (HHS), for each specialty, subspecialty, and analyte or test in which the laboratory is certified under Clinical Laboratory Improvement Amendments

	(CLIA). The laboratory failed to successfully participate in the specialty of Hematology for the Hemoglobin (HGB) and Red Blood Cell (RBC) analytes. (Refer to 2130 and 2131)
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 a proficiency testing (PT) desk review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 Report and American Proficiency Institute (API) 2021 records (2nd and 3rd event), the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two (2) of two (2) consecutive testing events in the specialty of Hematology for the Hemoglobin (HGB) and Red Blood Cell (RBC) analytes. The findings include: 1. Review of the Casper-0155 report revealed the following: Hematology 2021- 2nd Event Laboratory received an unsatisfactory score of 20% for the HGB analyte Hematology 2021- 3rd Event Laboratory received an unsatisfactory score of 20% for the HGB analyte Hematology 2021- 2nd Event Laboratory received an unsatisfactory score of 0% for the RBC analyte Hematology 2021- 3rd Event Laboratory received an unsatisfactory score of 20% for the RBC analyte 2. A proficiency testing desk review from API 2021 proficiency testing records confirmed the above findings.
D2131	HEMATOLOGY CFR(s): 493.851(g) 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. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 Report and American Proficiency Institute (API) 2021 records (2nd and 3rd event), the laboratory failed to achieve overall satisfactory performance (80% or greater) for two (2) of two (2) consecutive events in the specialty of Hematology. The findings include: 1. Review of the Casper-0155 report revealed the following: Hematology 2021- 2nd Event Laboratory received an unsatisfactory score of 60% for the Hematology. Hematology 2021- 3rd Event Laboratory received an unsatisfactory score of 63% for the Hematology. 2. A proficiency testing desk review from API 2021 proficiency testing records confirmed the above findings.
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 a desk review of laboratory proficiency testing (PT) performance, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing (PT) results, the laboratory director failed to ensure successful participation in an HHS approved PT program. Refer to D2130 and D2131.