

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0717499	(X3) Date Survey Completed 09/08/2023
Name of Provider or Supplier Harbir S Makin Md	Street Address, City, State 3300 Providence Drive 114, Anchorage, AK	
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
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 review of the laboratory's 2023 American Proficiency Institute (API) proficiency testing (PT) records and an interview with the Testing Personnel, it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for the White Blood Cell Differential in two (2) out of three (3) Hematology testing events resulting in unsuccessful PT performance. See D2130
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 review of the laboratory's 2023 American Proficiency Institute (API) proficiency testing (PT) records, and an interview with the Testing Personnel it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for the White Blood Cell Differential in two (2) out of three (3) Hematology events. Findings include: 1. A review of the laboratory's 2023 API PT records revealed White Blood Cell Differential scores of less than eighty percent for the following hematology events: a. 2023-1: score of 0% b. 2023-2: score of 4% 2. A telephone interview conducted on 9/8/23 at approximately 12:00 PM with the Testing Personnel confirmed the laboratory was unsuccessful in the PT events listed above.