

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2175316	(X3) Date Survey Completed 10/20/2022
Name of Provider or Supplier Infinity Health	Street Address, City, State 219 W Washington Street, Osceola, IA	
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 review of proficiency records and reports, the laboratory fails to successfully participate in a proficiency testing program for the specialty, hematology and the analytes: white blood cell count, white blood cell automated differential, red blood cell count, hematocrit, hemoglobin and platelet count for two out of three consecutive testing events: 2021 event 3 and 2022 event 1 (refer to D2130 and D2131).
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 review of proficiency testing (PT) reports and records, the laboratory failed to achieve satisfactory performance for the analytes: white blood cell count, white blood cell automated differential, red blood cell count, hematocrit, hemoglobin, and platelet count, for two out of three consecutive PT events for unsuccessful participation. The laboratory received unsatisfactory performance scores of zero for 2021 testing event 3 and 2022 testing event 2.

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 review of proficiency testing reports and records, the laboratory failed to achieve an overall testing event score of satisfactory performance for two out of three consecutive testing events for the specialty, hematology. The laboratory received unsatisfactory performance scores of zero for 2021 testing event 3 and 2022 testing event 2.