

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1061078	(X3) Date Survey Completed 06/15/2018
Name of Provider or Supplier Northfield Hospital & Clinics-Northfield Clinic	Street Address, City, State 2000 North Avenue, Northfield, MN	
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 proficiency testing reports from the American Proficiency Institute (API), the laboratory failed to successfully participate in proficiency testing for Cell ID or WBC Differential testing under the specialty of Hematology. Findings are as follows: D2122 - the laboratory failed to obtain a PT score for Cell ID or WBC Differential testing of at least 80 percent in two testing events D2131 - the laboratory failed to achieve satisfactory performance for Cell ID or WBC Differential testing in two of three testing events
D2122	HEMATOLOGY

CFR(s): 493.851(b)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

. Based on a review of proficiency testing (PT) reports from the American Proficiency Institute (API), the laboratory failed to obtain a PT score for Cell ID or WBC Differential testing of at least 80 percent which resulted in unsatisfactory performance for the analyte. Unsatisfactory PT performance of Cell ID or WBC Differential testing was obtained in the following events. - 2017 2nd event: 67% - 2018 1st event: 0% .

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 proficiency testing scores from the American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for Cell ID or WBC Differential in two out of three consecutive testing events, constituting unsuccessful performance for the analyte. Review of results from API revealed that the laboratory had unsatisfactory performance for Cell ID or WBC Differential in two out of three consecutive events, leading to unsuccessful performance. Unsatisfactory PT performance of the Cell ID or WBC Differential was obtained in the following events. - 2017 2nd event: 67% - 2018 1st event: 0% .