

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0426602	(X3) Date Survey Completed 01/05/2021
Name of Provider or Supplier Northshore Clinical Laboratories,	Street Address, City, State 4751 N Kedzie Ave, Chicago, IL	
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	<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 CASPER Report 155D (Individual Laboratory Proficiency Testing Profile) and phone interview with an American Proficiency Institute (API) program representative; the laboratory failed to successfully participate in the PT program for the Specialty of Hematology during calendar year 2020. Findings include: 1. Review of the CASPER Report 155D on January 05, 2021 and communication with the PT vendor API at 1:40 PM, the initial unsuccessful PT performance was confirmed under the Specialty of Hematology for the analytes red blood cells and prothrombin time. See D2130.</p>

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 the CASPER Report 155D (Individual Laboratory Proficiency Testing Profile) and interview with the PT vendor American Proficiency Institute (API) confirmed the laboratory failed to successfully participate in the testing of proficiency testing samples under the Specialty of Hematology for the analytes Prothrombin Time and Red Blood Cells during the calendar year 2020. Findings include: 1. Review of the CASPER Report 155D on January 05, 2021 revealed that the initial unsuccessful PT performance occurred under the Specialty of Hematology for Prothrombin Time and Red Blood Cells during events 2 and 3 of 2020 as listed below: HEMATOLOGY Prothrombin Time EVENT -2, 2020 = 60% Unsuccessful Prothrombin Time EVENT -3, 2020 = 0% Unsuccessful Red Blood Cells EVENT -2, 2020 = 60% Unsuccessful Red Blood Cells EVENT -3, 2020 = 0% Unsuccessful 2. During a phone interview with the PT vendor API on January 05, 2021 at 1:40 PM, they confirmed the above PT scores for Prothrombin Time and Red Blood Cells for events 2 and 3 of 2020.