

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2050413	(X3) Date Survey Completed 09/13/2023
Name of Provider or Supplier Cook Hospital Tower Lab	Street Address, City, State 415 North 2nd Street Suite #2, Tower, 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	<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 proficiency testing (PT) reports from the Center for Medicare and Medicaid Services (CMS) and the American Proficiency Institute (API), the laboratory failed to successfully participate in Prothrombin Time PT under the specialty of Hematology in 2023. Finding are as follows: 1. The CMS CASPER Report 0155D and the API 2023 Hematology/Coagulation - 2nd Event Performance Summary and Comparative Evaluation were reviewed on September 13, 2023. The reports indicated the laboratory failed to achieve satisfactory performance for Prothrombin Time in two consecutive testing events in 2023 resulting in unsuccessful performance. 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 proficiency testing (PT) reports from the Center for Medicare and Medicaid Services (CMS) and the American Proficiency Institute (API), the laboratory failed to achieve successful PT performance for Prothrombin Time testing in two consecutive PT events in 2023. Findings include: 1. The CMS CASPER Report 0155D, reviewed on September 13, 2023, indicated the laboratory failed to obtain a Prothrombin Time PT successful score of at least 80 percent in two consecutive testing events in 2023. 2. The API 2023 Hematology/Coagulation - 2nd Event Performance Summary confirmed the laboratory failed to obtain a Prothrombin Time PT score of at least 80 percent in two consecutive testing events in 2023. -2023 1st event 60% -2023 2nd event 60%