

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2136897	(X3) Date Survey Completed 12/03/2018
Name of Provider or Supplier Lifescan Labs Of Illinois, Llc	Street Address, City, State 10148 South Western 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	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 surveyor review of CASPER Report 155 Proficiency Testing (PT) records, and communication with the PT vendor Wisconsin State Laboratory of Hygiene (WSLH); it was confirmed that the laboratory failed to successfully participate in the testing of PT samples under the Specialty of Hematology for events 1 and 3 of 2018. Findings include: 1. Review of the CASPER Report 155 on November 01, 2018 and communication with the PT vendor WSLH on 12/03/18 at 1:40 PM, the initial unsuccessful PT performance was confirmed under the Specialty of Hematology Hematocrit (HCT) See D-2130.

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 surveyor review of CASPER Report 155 Proficiency Testing (PT) records, and communication with the PT vendor Wisconsin State Laboratory of Hygiene (WSLH); it was confirmed that the laboratory failed to successfully participate in the testing of PT samples under the Specialty of Hematology for events 1 and 3 of 2018. Findings include: 1. Review of the CASPER Report 155 on December 03, 2018 revealed that the initial unsuccessful PT performance occurred under the Specialty of Hematology Hematocrit (HCT) as listed below: HEMATOLOGY Hematocrit HCT EVENT -1, 2018 = 60% Unsuccessful Hematocrit HCT EVENT -3, 2018 = 60% Unsuccessful 2. During a phone communication with the PT vendor WSLH on December 02, 2018 at 1:40 PM, confirmed the PT failing scores.