

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1015208	(X3) Date Survey Completed 05/31/2019
Name of Provider or Supplier Southlake Pediatrics	Street Address, City, State 5000 Southlake Parkway Suite 250, Birmingham, AL	
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 a review of the CMS Casper reports (#153/155), and a review of the API (American Proficiency Institute) proficiency testing records, the surveyor determined the laboratory failed White Blood Cell (WBC) Differential, two consecutive testing events (Event #3, 2018 and #1 of 2019), resulting in an initial unsuccessful participation. The findings include: 1. A review of the Casper reports revealed the laboratory scored 67 % (percent) for the WBC Differential for Event #3, 2018 and 33 % for Event #1, 2019, two consecutive testing event failures. 2. A review of the API proficiency testing records confirmed the 67 % score (60 % for Granulocytes and 40</p>

% for Lymphocytes) for Event #3, 2018 and the 33 % score (20 % for Granulocytes and Monocytes and 60 % for Lymphocytes) for Event #1, 2019. 3. The two consecutive event failures resulted in the laboratory's initial unsuccessful proficiency testing participation.

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 a review of the CMS Casper reports (#153/155), and a review of the API (American Proficiency Institute) proficiency testing records, the surveyor determined the laboratory failed to perform satisfactorily in White Blood Cell (WBC) Differential testing for two consecutive testing events (Event #3, 2018 and #1 of 2019), resulting in an initial unsuccessful participation. The findings include: 1. A review of the Casper reports revealed the laboratory scored 67 % (percent) for the WBC Differential for Event #3, 2018 and 33 % for Event #1, 2019, two consecutive testing event failures. 2. A review of the API proficiency testing records confirmed the 67 % score (60 % for Granulocytes and 40 % for Lymphocytes) for Event #3, 2018 and the 33 % score (20 % for Granulocytes and Monocytes and 60 % for Lymphocytes) for Event #1, 2019. 3. The two consecutive event failures resulted in the laboratory's initial unsuccessful proficiency testing participation.