

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0365956	<b>(X3) Date Survey Completed</b>  05/10/2022
<b>Name of Provider or Supplier</b>  Steven D Trombly Md	<b>Street Address, City, State</b>  5195 15 Mile Rd, Sterling Heights, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<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 record review of the CMS database and the American Proficiency Institute (API) proficiency testing reports and phone interview with the Technical Consultant, it was determined the laboratory failed to successfully participate in a CMS-approved proficiency testing program for hematology white blood cell identification and differential testing. Findings include: Review of the CMS database and the API proficiency testing reports and phone interview with the Technical Consultant revealed the laboratory failed to achieve satisfactory performance for hematology white blood cell identification and differential testing. Refer to D2121.</p>

**D2121**

**HEMATOLOGY**

CFR(s): 493.851(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

. Based on record review of the CMS database and the American Proficiency Institute (API) proficiency testing reports and phone interview with the Technical Consultant, the laboratory failed to achieve at least 80 percent for white blood cell identification and differential for 2 (3rd event of 2021 and 1st event of 2022) out of 2 consecutive testing events. Findings include: 1. A record review of the CMS database and API proficiency testing reports revealed the following scores for 2 out of 2 consecutive testing events: White Blood Cell Differential PT Event Score 1st event 2022 20% 3rd event 2021 47% 2. A phone interview on 5/10/22 at 11:39 am with the Technical Consultant confirmed the laboratory received the scores listed above for white blood cell identification and differential.