

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0371580	(X3) Date Survey Completed 12/06/2019
Name of Provider or Supplier Sterling Heights Medical Center	Street Address, City, State 11600 15 Mile Road, Sterling Heights, MI	
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 review of the CMS database and review of the American Association of Bioanalysts final proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS approved proficiency testing program for the analyte: Hematocrit. Refer to D2130
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 CMS database and review of the American Association of Bioanalysts (AAB) final proficiency testing reports, the laboratory failed to achieve satisfactory performance in 2 (1st and 3rd events 2019) of 3 consecutive proficiency testing events for the following hematology analyte: Hematocrit (HCT). Findings include: 1. Unsatisfactory performance in 2 of 3 consecutive proficiency testing events constitutes unsuccessful proficiency testing performance. The initial unsuccessful performance for HCT occurred in the 1st and 3rd events in 2016. The subsequent unsuccessful performance for HCT occurred in the 1st and 3rd events in 2019. HCT PT Event Score 1st event 2016 0% 3rd event 2016 0% 1st event 2019 60% 3rd event 2019 60%