

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0989506	(X3) Date Survey Completed 11/17/2020
Name of Provider or Supplier Oakleaf Clinics Sc	Street Address, City, State 3802 W Oakwood Mall Dr, Eau Claire, WI	
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 surveyor review of the federal Certification and Survey Provider Enhancement Reports (CASPER) Proficiency Testing (PT) and the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) records, the laboratory failed to successfully participate in PT for the White Blood Cell (WBC) Differential (Diff) analyte in the Specialty of Hematology for events 2020-2 and 2020-3. See D2130</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p>

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 the federal Certification and Survey Provider Enhancement Reports (CASPER) Proficiency Testing (PT) and the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) records, the laboratory failed to successfully participate in PT for the White Blood Cell (WBC) Differential (Diff) analyte in the Specialty of Hematology for events 2020-2 and 2020-3. Findings include: 1. Review of PT records in the CASPER reporting system showed that the laboratory failed two consecutive PT events for the WBC Diff analyte in the Specialty of Hematology: Event 2020-2, score 53% and Event 2020-3, score 50% 2. Surveyor review of the WSLH PT evaluation reports on November 17, 2020 confirmed the failed PT scores for the WBC Diff analyte. This results in a failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events which is an unsuccessful PT performance.