

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1026155	(X3) Date Survey Completed 05/16/2022
Name of Provider or Supplier Christian Family Medicine, Inc	Street Address, City, State 79 Hwy 51 South, Ripley, TN	
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: The laboratory failed to maintain satisfactory participation in two consecutive proficiency testing (PT) events for the White Blood Cell Count Differential (WBC Diff) resulting in the first unsuccessful PT occurrence for the WBC Diff analyte. (Refer to D2130)</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive</p>

events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of the Centers for Medicare and Medicaid Casper Report 155 (CMS 155) and the laboratory's 2021 and 2022 proficiency testing (PT) evaluation reports, the laboratory failed to maintain satisfactory performance for two consecutive PT events for the White Blood Cell Differential (WBC Diff) analyte. The findings include: 1. Review of the CMS 155 report revealed the following unsatisfactory White Blood Cell Differential (WBC Diff) scores: 2021 Event three = 20% 2022 Event three = 10% 2. Review of the laboratory's 2021 PT event three hematology evaluation report revealed the following: a. Lymphocyte: sample numbers SXT-12 and SXT-14 scored as failed resulting in a score of 60%. b. Monocyte: sample numbers SXT-11, SXT-12, SXT-13, SXT-14 scored as failed resulting in a score of 20%. c. Neutrophil: sample numbers SXT-11, SXT-13, SXT-14 and SXT-15 scored as failed resulting in a score of 20%. d. Eosinophil: all samples scored as failed resulting in a score of 0%. e. Basophil: sample numbers SXT-11, SXT-12, SXT-13, and SXT-14 scored as failed, resulting in a score of 20%. f. Immature Granules: all samples scored as fail resulting in a score of 0%, resulting in an overall score for the WBC Diff of 20% 3. Review of the laboratory's 2022 PT event one hematology evaluation report revealed the following: a. Lymphocyte: all samples scored as failed resulting in a score of 0%. b. Monocyte: sample numbers SXT-3, SXT-5 scored as failed resulting in a score of 60%. c. Neutrophil: all samples scored as failed resulting in a score of 0%. d. Eosinophil: all samples scored as failed resulting in a score of 0%. e. Basophil: all samples scored as failed resulting in a score of 0%. f. Immature Granules: all samples scored as fail resulting in a score of 0%, resulting in an overall score for the WBC Diff of 10% and the first unsuccessful PT occurrence.