

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0968759	(X3) Date Survey Completed 05/11/2022
Name of Provider or Supplier Southern Family Health	Street Address, City, State 201 Old Highway 25 East, Columbiana, 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 CMS (Centers for Medicaid and Medicare Services) CASPER reports and API (American Proficiency Institute) Proficiency Testing (PT) Evaluations, and a telephone interview with laboratory staff, the surveyor determined the laboratory failed to successfully participate in PT for RBC (Red Blood Cell) testing for two of three consecutive testing events. These failures resulted in an initial unsuccessful PT participation. The findings include: Refer to 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 a review of CMS (Centers for Medicaid and Medicare Services) CASPER reports and API (American Proficiency Institute) Proficiency Testing (PT) Evaluations, and a telephone interview with laboratory staff, the surveyor determined the laboratory failed to successfully participate in PT for RBC (Red Blood Cell) testing for two of three consecutive testing events, Event #2, 2021 and Event #1, 2022. These failures resulted in an initial unsuccessful PT participation. The findings include: 1. A review of the CASPER reports and API PT evaluations revealed the following scores: a) RBC Event #2, 2021 0 % b) RBC Event #1, 2022 60 % These failures resulted in an initial unsuccessful PT participation. 2. In a telephone interview on 5/10/2022 at 4:40 PM, the laboratory staff confirmed the zero score for Event #2, 2021, explaining the staff failed to enter the results. The laboratory staff was unaware of the 60 % failing score for RBC.