

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0670422	(X3) Date Survey Completed 10/22/2019
Name of Provider or Supplier Selma Doctors Clinic	Street Address, City, State 509 Parkman Avenue, Selma, 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 the CMS CASPER reports (#153 and #155), API (American Proficiency Institute) proficiency testing records, and telephone interviews with the technical consultant, the surveyor determined the laboratory failed to successfully participate in proficiency testing for Free Thyroxine (Free T4) for two of three consecutive testing events. This affected Events #1 and #3 of 2019. The findings include: 1. A review of the Casper reports revealed the laboratory scored sixty percent (60 %) for the Free T4 on Event #1, 2019 and 0 % for the Free T4 on Event #3. 2. The API proficiency testing evaluation revealed the laboratory scored zero percent for the failure to participate in testing for Chemistry Event #3, 2019 (0 % for Free T4),</p>

resulting in the failure of two of three consecutive testing events, unsuccessful participation. The laboratory scored 60% for Free T4 for the first Event of 2019. 3. The surveyor contacted the technical consultant via telephone on October 21, 2019 at 12:44 PM to inquire of the proficiency testing failure and unsuccessful participation. The technical consultant stated she was not aware of the last failure but would be in contact with the laboratory to determine the circumstances. 4. On October 22, 2019 at 11:21 AM, via telephone, the technical consultant stated the patient testing had been suspended for routine Chemistry, due to the trained technician being out-of-the office, and the Endocrinology (performed on the FrenD) would require further investigation to determine the cause of the Free T4 failure.

D2107

ENDOCRINOLOGY
CFR(s): 493.843(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing 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 the CMS CASPER reports (#153 and #155), API (American Proficiency Institute) proficiency testing records, and telephone interviews with the technical consultant, the surveyor determined the laboratory failed to perform satisfactorily in Free Thyroxine (Free T4) testing for two of three consecutive events. These failures affected Events #1 and #3 of 2019 and resulted in unsuccessful proficiency testing participation for the laboratory. The findings include: 1. Refer to D2016.