

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2077478	(X3) Date Survey Completed 11/20/2019
Name of Provider or Supplier Waynesboro Family Clinic, Pa	Street Address, City, State 1706 Wayne Memorial Drive, Goldsboro, NC	
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 desk review of CMS (Centers for Medicare and Medicaid Services) Casper reports 153D and 155D 9/5/19 and desk review of 2018 and 2019 AAB (American Association of Bioanalysts) proficiency testing results 11/20/19, the laboratory failed to achieve satisfactory performance for creatinine on 2 of 3 consecutive testing events. See the deficiency cited at D2096.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p>

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 desk review of CMS (Centers for Medicare and Medicaid Services) Casper reports 153D and 155D 9/5/19 and desk review of 2018 and 2019 AAB (American Association of Bioanalysts) proficiency testing results 11/20/19, the laboratory failed to achieve satisfactory performance for creatinine in 2 of 3 consecutive testing events, resulting in unsuccessful performance. Findings: 1. Desk review of CMS 155D and 2018 AAB proficiency testing results revealed the laboratory provided incorrect responses for 2 of 5 creatinine samples and received a score of 60% for creatinine on the 2018 Q3 Chemistry event. 2. Desk review of CMS 155D and 2019 AAB proficiency testing results revealed the laboratory provided incorrect responses for 2 of 5 creatinine samples and received a score of 60% for creatinine on the 2019 Q2 Chemistry event.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on desk review of CMS (Centers for Medicare and Medicaid Services) Casper reports 153D and 155D 9/5/19 and desk review of 2018 and 2019 AAB (American Association of Bioanalysts) proficiency testing results 11/20/19, the laboratory director failed to ensure satisfactory performance in proficiency testing as required in Subpart H. See the deficiency cited at D6089.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on desk review of CMS (Centers for Medicare and Medicaid Services) Casper reports 153D and 155D 9/5/19 and desk review of 2018 and 2019 AAB (American Association of Bioanalysts) proficiency testing results 11/20/19, the laboratory director failed to ensure successful participation in proficiency testing as required in Subpart H. Findings: 1. Desk review of CMS 155D and 2018 AAB proficiency testing results revealed the laboratory provided incorrect responses for 2 of 5 creatinine samples and received a score of 60% for creatinine on the 2018 Q3 Chemistry event. 2. Desk review of CMS 155D and 2019 AAB proficiency testing results revealed the laboratory provided incorrect responses for 2 of 5 creatinine samples and received a score of 60% for creatinine on the 2019 Q2 Chemistry event.