

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0468144	(X3) Date Survey Completed 01/28/2019
Name of Provider or Supplier Five Rivers Medical Center	Street Address, City, State 2801 Medical Center Drive, Pocahontas, AR	
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 review of 2018 CMS Casper Reports 0155D, 0153D, and the American Proficiency Institute(API) proficiency testing results, it was determined the laboratory failed to have successful participation in proficiency testing for the analyte of Blood Urea Nitrogen (BUN) as evidence by: Failure to achieve satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance as cited at D2087.</p>
D2017	<p>REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b)</p>

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

This CONDITION is not met as evidenced by:
. Based on review of 2018 CMS Casper Reports 155D, 153D and American Proficiency Institute (API) testing results, it was determined the laboratory had a subsequent unsuccessful performance for the analyte Blood Urea Nitrogen (BUN). Failure to achieve satisfactory performance for the analyte BUN in three consecutive testing events, as cited at D2087.

D2087

ROUTINE CHEMISTRY
CFR(s): 493.841(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:
. Based on review of 2018 CMS Casper Reports 153d and 155D and the American Proficiency Institute (API) proficiency testing results, it was determined the laboratory had a subsequent unsuccessful performance for the analyte of Blood Urea Nitrogen (BUN) as evidenced by: A. The laboratory received a score of 0% for the analyte BUN in the first proficiency testing event of 2018. B. The laboratory received a score of 60% for the analyte BUN in the second proficiency testing event of 2018. C. The laboratory received a score of 0% for the analyte BUN in the third proficiency testing event of 2018.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
. Based on review of 2018 Proficiency Reports, it was determined the laboratory director failed to ensure that corrective action was effective, and failed to provide overall management and directions as cited at: D6019: Failure to ensure that corrective action was effective.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

. Based on review of 2018 proficiency testing results, it was determined the laboratory director failed to ensure that corrective action was effective for the unsatisfactory performance of BUN as cited at: D2087.