

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0895823	(X3) Date Survey Completed 08/31/2020
Name of Provider or Supplier Tennessee Valley Regional Laboratory Inc	Street Address, City, State 619 W Grand Ave, Rainbow City, 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 for proficiency testing), a review of the American Association of Bioanalysts (AAB) proficiency testing evaluations for 2019 and 2020, and an interview with an AAB representative, the surveyor determined the laboratory failed three consecutive testing events [Events #2 and #3 of 2019 and Event #1, 2020 for BUN (Blood Urea Nitrogen)]. These consecutive failures resulted in a non-initial unsuccessful proficiency testing participation for the laboratory. The findings include: 1. A review of the CASPER reports revealed the laboratory failed three consecutive testing events for BUN. For Chemistry Event #2 and #3 of 2019, the laboratory scored 20 % for BUN; and 40 %</p>

for Event #1, 2020. These failures resulted in a non-initial unsuccessful proficiency testing participation for the laboratory. 2. In a telephone interview on 5/15/2020, the AAB representative confirmed the repeat failures, and sent the evaluation reports to the surveyor. From January's failure report: In an interview with an AAB representative on 1/13/2020 at 2:57 PM, the representative confirmed the two failures (2019) for the laboratory. The representative also stated these were the only events the laboratory were enrolled with the company for 2019. 3. A review of the proficiency testing evaluations for Chemistry 2019 and 2020, Events #2 and #3, and #1, respectively, provided by AAB via email, confirmed the above mentioned failures by the laboratory.

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 a review of the CMS CASPER reports (#153 and #155 for proficiency testing), a review of the American Association of Bioanalysts (AAB) proficiency testing evaluations for 2019 and 2020, and interviews with an AAB representative, the surveyor determined the laboratory failed two perform satisfactorily for three consecutive testing events [Events #2 and #3, 2019 and Event #1, 2020 for BUN (Blood Urea Nitrogen)]. These consecutive failures resulted in a non-initial unsuccessful proficiency testing participation for the laboratory. The findings include: Refer to D2016.

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(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 for proficiency testing), a review of the American Association of Bioanalysts (AAB) proficiency testing evaluations for 2019 and 2020, and interviews with an AAB representative, the surveyor determined the laboratory failed two perform satisfactorily for three consecutive testing events [Events #2 and #3, 2019 and Event #1, 2020 for BUN (Blood Urea Nitrogen)]. These consecutive failures resulted in a non-initial unsuccessful proficiency testing participation for the laboratory. The findings include: Refer to D2016.

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 a review of the CMS CASPER reports (#153 and #155 for proficiency testing), a review of the American Association of Bioanalysts (AAB) proficiency testing evaluations for 2019 and 2020, and an interview with an AAB representative, the surveyor determined the Laboratory Director failed to ensure the laboratory staff successfully performed in proficiency testing for three consecutive testing events [Events #2 and #3 of 2019 and Event #1, 2020] for BUN (Blood Urea Nitrogen). These consecutive failures resulted in a non-initial unsuccessful proficiency testing participation for the laboratory. The findings include: 1. See also D2016 (493.803). Unsuccessful Proficiency Testing.