

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0466470	(X3) Date Survey Completed 09/29/2021
Name of Provider or Supplier St Vincent Morrilton Lab	Street Address, City, State #4 Hospital Drive, Morrilton, 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 the 2020 and 2021 CMS Casper Reports 155D, 153D and the American Proficiency Institute(API) proficiency testing results, it was determined the laboratory failed to have successful participation in proficiency testing for ABO/RH and D(Rho) Type testing as evidenced by: Failure to attain a testing event score of at least 100 percent in ABO/RH and D(Rho) type testing is unsatisfactory performance as cited at 2153.</p>
D2153	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a)</p>

Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

. Based on review of 2020 and 2021 CMS Casper Reports 155D, 153D and the American Proficiency Institute(API) proficiency testing results, it was determined the laboratory failed to have successful participation in proficiency testing for ABO/RH and D(Rho) type testing as evidenced by: A. A review of the proficiency testing results revealed the laboratory received a score of 80% for the test of D(Rho) type testing and 90% for ABO/RH testing in the third proficiency testing event of 2020. B. A review of the proficiency testing results revealed the laboratory failed to participate in the second proficiency testing event of 2021 resulting in a score of 0 % for the test of ABO/RH and D(Rho) type testing.

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 2020 and 2021 proficiency testing results, it was determined the laboratory director failed to ensure that the proficiency testing samples are tested as required under Subpart H of this part. Refer to D6016

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

. Based on review of 2020 and 2021 proficiency testing event results, it was determined the laboratory director failed to ensure the laboratory successfully participated in proficiency testing for the test D(Rho) type. Refer to D2153