

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1079372	(X3) Date Survey Completed 12/14/2021
Name of Provider or Supplier Springer Medical Associates	Street Address, City, State 16615 Hwy 104 N Ste B, Lexington, TN	
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: The laboratory failed to maintain satisfactory proficiency testing (PT) performance for the hematocrit analyte in 2020 event three, 2021 event one, and 2021 event three, resulting in the second unsuccessful PT occurrence. (Refer to D2130)</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p>

This STANDARD is not met as evidenced by:
 Based on a desk review of the Center for Medicare and Medicaid Services Casper Report 155 (CMS 155) and the laboratory's 2020 and 2021 proficiency testing (PT) records, the laboratory failed to maintain satisfactory performance in three out of four PT events for the hematocrit analyte, resulting in the second unsuccessful PT occurrence. The findings include: 1. Review of the CMS 155 revealed the following unsatisfactory hematocrit scores: 2020 event three = 0% 2021 event one = 20% 2021 event three = 0% 2. Review of the laboratory's American Academy of Family Physicians (AAFP) PT evaluation reports revealed the following: 2020 event three: Sample numbers HD-11, HD-12, HD-13, HD-14 and HD-15 scored as 'Fail' for 'No Results Received' resulting in an overall score of 0% for the hematocrit analyte. 2021 event one: Sample numbers HD-1, HD-2, HD-4 and HD-5 scored as 'Fail' resulting in an overall score of 20% for the hematocrit analyte. 2021 event three: Sample numbers HD-11, HD-12, HD-13, HD-14 and HD-15 scored as 'Fail' resulting in an overall score of 0% and the second unsuccessful PT occurrence for the hematocrit analyte.

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:
 The laboratory director failed to ensure the laboratory performed proficiency testing in such a manner as to achieve and maintain satisfactory performance with successful proficiency testing (PT) for the hematocrit analyte, resulting in the second unsuccessful PT occurrence. (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 a desk review of the Centers for Medicare and Medicaid Services Casper report 155 (CMS 155), the laboratory's 2020 and 2021 proficiency testing (PT) evaluation reports, and laboratory communication, the laboratory director failed to ensure the laboratory performed proficiency testing in such a manner as to achieve and maintain satisfactory performance, resulting in unsatisfactory performance for three out of four consecutive proficiency testing events for the hematocrit analyte and the second unsuccessful PT occurrence. The findings include: 1. Review of the CMS 155 and the laboratory's American Academy of Family Physicians (AAFP) PT evaluation reports revealed the following unsatisfactory hematocrit scores: 2020 event

three = 0% 2021 event one = 20% 2021 event three = 0% 2. Review of email communication received on December 3, 2021 at 9:11 am from the laboratory liaison confirmed the laboratory failed 2021 PT event three for hematocrit, which resulted in the 2nd unsuccessful PT occurrence. The email also indicated the laboratory stopped patient testing on December 2, 2021 and are "working on the cause of this failure."