

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0976442	(X3) Date Survey Completed 03/11/2022
Name of Provider or Supplier Steward Internal Medicine Center Taunton	Street Address, City, State 1 Washington Street, Taunton, MA	
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
D0000	A CLIA paper desk review of proficiency testing was conducted for the SMG Taunton Medical laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Based on evidence of unsuccessful proficiency testing performance for the specialty of Hematology, the following Condition level deficiency was deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. .
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 an off-site proficiency testing desk review for calendar year 2021, the laboratory failed to successfully participate (achieve a score of 80 percent or more) in</p>

the American Proficiency Institute (API) proficiency testing program for the specialty of Hematology resulting in unsuccessful proficiency testing performance for the specialty of Hematology. Refer to D2123 and D2131. .

D2123

HEMATOLOGY
CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on proficiency testing record review of American Proficiency Testing (API) proficiency testing results for calendar year 2021, the laboratory failed to participate in the second and third testing event of 2021 for the specialty of Hematology (complete blood count) resulting in a score of zero (0) percent for each of the testing events and unsuccessful performance for the specialty area. The nonparticipation in the testing events was confirmed in a telephone interview with the office manager on 3/4/22 at 3:35 PM.

D2131

HEMATOLOGY
CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for 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 American Proficiency Institute (API) proficiency testing performance review for calendar year 2021, the laboratory failed to achieve an overall testing event score of satisfactory performance for two out of two testing events for the specialty area of Hematology leading to unsuccessful performance as evidenced by the following scores obtained: The specialty of Hematology: 1. 2021 API testing event 2 - score of 0 % (failure to participate - refer to D2123). 2. 2021 API testing event 3 - score of 0 % (failure to participate - refer to D2123).. The overall hematology scores were confirmed in a telephone interview with the office manager on 3/4/22 at 3:30 PM. .