

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0923891	(X3) Date Survey Completed 05/05/2023
Name of Provider or Supplier Cookeville Medical Center, Pllc	Street Address, City, State 225 North Willow Ave Ste 3, Cookeville, 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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on an off-site desk review of the laboratory's Centers for Medicare and Medicaid Services Casper Report 155 (CMS 155) and the laboratory's American Proficiency Institute (API) Proficiency Testing (PT) evaluation reports, the laboratory failed to maintain satisfactory performance for two consecutive PT events for the Total Bilirubin analyte, resulting in the first unsuccessful PT occurrence for the Total Bilirubin analyte. (Refer to D2096)
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 an off-site desk review of the laboratory's Centers for Medicare and Medicaid Services Casper Report 155 (CMS 155) and the laboratory's American Proficiency Institute (API) Proficiency Testing (PT) evaluation reports, the laboratory failed to maintain satisfactory performance for two consecutive PT events for the Total Bilirubin analyte, resulting in the first unsuccessful PT occurrence for the Total Bilirubin analyte. The findings include: 1. Review of the report CMS 155 revealed the following scores for the Total Bilirubin analyte: 2022 event three = 40% 2023 event one = 60% 2. Review of the laboratory's API PT evaluation reports revealed the following: Total Bilirubin scored as 40% for 2022 event three and 60% for 2023 event one, resulting in the first unsuccessful PT occurrence for the Total Bilirubin analyte.