

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0923891	<b>(X3) Date Survey Completed</b>  12/22/2021
<b>Name of Provider or Supplier</b>  Cookeville Medical Center, Pllc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 participation in three out of four events for Chloride (CL), resulting in the SECOND Unsuccessful Proficiency Testing (PT) occurrence. (Refer to D2096) =====</p>
<b>D2096</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

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 proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER report 155 (CMS 0155D) and American Proficiency Institute (API) Testing performance summary, the laboratory failed to maintain satisfactory performance in three out of four events for the Chloride (CL) analyte, 3rd event 2020, 1st and 3rd events 2021, resulting in the SECOND unsuccessful PT performance occurrence. The findings include: 1. A review of the CMS 0155D report for 2020 revealed the CL score for event three = 40%. 2. A review of the CMS 0155D report for 2021 revealed the CL scores for event one = 60% and event three = 20%. 3. A review of the 2020 API PT Performance Summary for event three revealed CL was graded as unsatisfactory with a score of 40%. 4. A review of the 2021 API PT Performance Summary for event one revealed the CL was graded as unsatisfactory with a score of 60%, and event three was graded as unsatisfactory with a score of 20% resulting in the SECOND Unsuccessful PT occurrence. =====

**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 provide direction for successful Proficiency Testing (PT) Participation in Three of Four Events for Chemistry in 2020 and 2021 resulting in the SECOND Unsuccessful PT occurrence (Reference 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 desk review of the Centers for Medicare and Medicaid Services Casper report 155 (CMS 155) and the laboratory's 2020 and 2021 American Proficiency Institute (API) Testing proficiency testing (PT) evaluation reports, 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 Chloride analyte and the second unsuccessful PT

occurrence. The findings include: 1. A review of the CMS 0155D evaluation reports revealed the following unsatisfactory Chloride scores: 2020 event three = 40% 2021 event one = 60% 2021 event three = 20% 2. A review of the laboratory's API PT evaluation reports revealed the following unsatisfactory Chloride scores: 2020 event three = 40% 2021 event one = 60% 2021 event three = 20%

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