Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0923891	(X3) Date Survey Completed 09/02/2025
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
D0000	Based on desk review of 2025 proficiency testing (PT) scores, the laboratory failed to meet the following conditions, resulting in an initial unsuccessful PT participation: D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director .
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 a desk review of proficiency testing (PT) records from the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report and American Proficiency Institute (API) proficiency testing records, the laboratory failed to

	successfully participate in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully perticipate in the Free Thyroxine (FREE TY) analyte. Refer to D2107. .
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) (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 a proficiency testing desk review of the CASPER 0155 report and the API 2025 PT records (Events 1 and 2), the laboratory failed to achieve satisfactory performance (80% or better) for the same analyte in two consecutive testing events in the specialty of Endocrinology for the Free Thyroxine (FREE TY) analyte. The findings include: 1. A review of the CASPER 0155 report revealed the following results: 2025 Event One: The laboratory received a 60% score for Free Thyroxine. 2025 Event Two: The laboratory received a 20% score for Free Thyroxine. 2. A review of the API 2025 PT records (2025 Chemistry - Core - 1st and 2nd Events) confirmed that the laboratory received the above results. .
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 proficiency testing desk review of CASPER 0155 report and American Proficiency Institute 2025 records, the laboratory director failed to provide overall management and direction of the laboratory services. The laboratory director failed to ensure the overall quality of the laboratory services provided. Refer to D6016. .
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) 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 proficiency testing desk review of CASPER 0155 report and American Proficiency Institute 2025 records, the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2107.