Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0691847	(X3) Date Survey Completed 12/20/2023
Name of Provider or Supplier East Tn Childrens Hospital Primary Care Corp	**Street Address, City, State** 502 Winfield Dunn Parkway, Sevierville, 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	The following deficiencies are the result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing]
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 proficiency testing desk review of Certification and Survey Provider Enhancement Reporting (CASPER)-0155 report and American Proficiency Institute

	(API) Proficiency Testing program 2023 records, the laboratory had not successfully participated 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 participate in the specialty of Bacteriology. (Refer to D2028)
D2028	BACTERIOLOGY CFR(s): 493.823(e) 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 a Proficiency Testing (PT) desk review of the CMS CASPER Report 0155D and the laboratory's 2023 Proficiency Testing (PT) performance summary records from the American Proficiency Institute (API) Proficiency Testing program, the laboratory failed to maintain satisfactory performance for Bacteriology in the 2nd and 3rd events 2023, resulting in the initial unsuccessful PT occurrence. The findings include: 1. A review of the CMS 0155D report revealed the following unsatisfactory Bacteriology analyte scores: -2nd event 2023= 0% -3rd event 2023= 50% 2. A review of the laboratory's API Proficiency Testing records revealed unsatisfactory Microbiology (Group C/G Strep (molecular)) scores of 0% for the 2nd event 2023 and 50% for the 3rd event 2023, resulting in the intial unsuccessful PT occurrence.