

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0955789	(X3) Date Survey Completed 04/11/2022
Name of Provider or Supplier Lister Labs, Llc	Street Address, City, State 2805 D West Mall Drive, Florence, AL	
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	<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 reviews of CMS (Centers for Medicare and Medicaid Services) CASPER reports and API (American Proficiency Institute) Proficiency Testing Evaluations, the laboratory failed T4 (Thyroxine) for two of three consecutive testing events, Event #2, 2021 and Event #1, 2022. These failures resulted in an initial unsuccessful proficiency testing participation. The findings include: Refer to D2107.</p>
D2107	<p>ENDOCRINOLOGY CFR(s): 493.843(f)</p>

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 reviews of CMS (Centers for Medicare and Medicaid Services) CASPER reports and API (American Proficiency Institute) Proficiency Testing Evaluations, the laboratory failed T4 (Thyroxine) for two of three consecutive testing events, Event #2, 2021 and Event #1, 2022. These unsatisfactory performances for T4 resulted in an initial unsuccessful proficiency testing participation. The findings include: 1. A review of the CASPER reports revealed the laboratory scored sixty percent (60 %) for T4 for Event #2, 2021 and Event #1, 2022. 2. A review of the API Proficiency Evaluations confirmed the above noted findings.