

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0661011	(X3) Date Survey Completed 08/02/2019
Name of Provider or Supplier Metropolitan Laboratory Services, Inc	Street Address, City, State 12011 Lee Jackson Memorial Hwy Suite 200, Fairfax, VA	
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	An unannounced, off-site CLIA proficiency testing (PT) desk review was conducted for Tristar Medical Labs, Inc on August 2, 2019 by a Medical Facilities Inspector of the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
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 an off-site desk review of the laboratory's to date 2019 proficiency testing (PT) records, a total of two (2) events, and interview with the Laboratory Manager,</p>

the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for Lithium in two (2) consecutive Toxicology events resulting in unsuccessful PT performance. See 2118.

D2118

TOXICOLOGY
CFR(s): 493.845(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 the off-site review of the CASPER 0153D Unsuccessful proficiency testing (PT) report, PT scores (the first and second events in 2019), and telephone interview with the Laboratory Manager (LM), the laboratory failed to achieved satisfactory performance of at least 80% for two (2) consecutive PT events for the analyte Lithium (Li), resulting in an unsuccessful performance. Findings include: 1. Review of the CASPER 0153D Unsuccessful PT report and the College of American Pathologists (CAP) PT scores for the first and second events in 2019 revealed the following Lithium scores: CAP-C-A Event 1 Li-0% CAP-C-B Event 2 Li-0% The laboratory has received 2 consecutive unsatisfactory CAP PT scores for the analyte listed above. 2. A telephone interview with the LM at approximately 10:00 AM confirmed that the laboratory received 2 consecutive unsatisfactory performance scores for the Li analyte.