

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D0661011	<b>(X3) Date Survey Completed</b>  12/16/2019
<b>Name of Provider or Supplier</b>  Metropolitan Laboratory Services, Inc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An unannounced CLIA off-site proficiency testing desk review of Mira Scientific was conducted on December 13 and 16, 2019 by a Medical Facilities Inspector of the Virginia Department of Health's Office of Licensure and Certification. The laboratory was inspected under 42 CFR Part 493 CLIA regulations. Specific deficiencies cited are as follows:
<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: A. Based on an off-site desk review of the laboratory's 2019 proficiency testing (PT) records, a total of three (3) events, and interview, the laboratory failed to attain a score</p>

of at least eighty (80) percent of acceptable responses for Anti-Streptolysin O (ASO), Infectious Mononucleosis (Mono) and Rheumatoid Factor (RF) in two (2) consecutive General Immunology testing events resulting in unsuccessful PT performance. See D2077. B. Based on an off-site desk review of the laboratory's 2019 proficiency testing (PT) records, a total of three (3) events, and interview, the laboratory failed to attain a score of at one-hundred (100) percent of acceptable responses for Blood group typing (ABO and Rh) in two (2) consecutive events resulting in unsuccessful PT performance. See D2155.

**D2077**

**GENERAL IMMUNOLOGY**  
CFR(s): 493.837(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:  
Based on an off-site desk review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing (PT) records, CASPER Report 0153D and interview, the laboratory failed to submit PT results within the specified time frame for Anti-streptolysin O (ASO), Infectious Mononucleosis (IM), and Rheumatoid Factor (RF) in two (2) of three (3) General Immunology testing events in 2019. Findings include: 1. Review of the laboratory's AAB 2019 PT records, a total of three (3) events, revealed no results for ASO, IM, and RF for 2019 2nd Event and 2019 3rd Event resulting in an unsatisfactory PT performance. 2. Review of the laboratory's CASPER Report 0153D revealed the following 2019 General Immunology events with results of less than 80% for ASO, IM, and RF: 2019 2nd Event - ASO = 0%; IM = 0%; RF = 0%; 2019 3rd Event - ASO = 0%; IM = 0%; RF = 0%; resulting in unsatisfactory performance. 3. In a telephone interview with the interim laboratory manager (LM) on December 13, 2019 at 9:00 AM, the interim LM confirmed the findings and stated they were not performing ASO, IM, and RF testing since the 1st Event of 2019. The interim LM stated they did not use the "exception code " when submitting the results.

**D2155**

**ABO GROUP AND D(RHO) TYPING**  
CFR(s): 493.859(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on an off-site desk review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing (PT) records, CASPER Report 0153D and interview, the laboratory failed to submit PT results within the specified time frame for ABO and Rh (blood group typing) in two (2) of three (3) 2019 testing events in 2019. Findings include: 1. Review of the laboratory's AAB 2019 PT records, a total of three (3) events, revealed no results for ABO and Rh for 2019 2nd Event and 2019 3rd Event resulting in an unsatisfactory PT performance. 2. Review of the laboratory's CASPER Report 0153D revealed the following 2019 ABO and Rh events with results of less than 100%: 2019 2nd Event - ABO = 0%; Rh = 0%; 2019 3rd Event - ABO = 0%; Rh = 0%; resulting in unsatisfactory performance. 3. In a telephone interview with the interim laboratory manager (LM) on December 13, 2019 at 9:00 AM, the interim LM confirmed the findings and stated they were not performing ABO, and Rh testing since the 1st Event of 2019. The interim LM stated they did not use the "exception code " when submitting the results.