Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0661011	05/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Metropolitan Laboratory Services, Inc	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-cite CLIA proficiency testing (PT) desk review was conducted for Mira Scientific on May 5, 2020 by 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 and includes the following: 493.803 Condition: Successful participation.
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: A. Based on an off-site desk review of the laboratory's 2019 and 2020 American Association of Bioanalysts (AAB) proficiency testing (PT) records (2019 2nd Event,

	2019 3rd Event and 2020 1st Event), a total of three (3) events, CASPER Report 155D and interview, the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for Anti-Streptolysin O (ASO), Infectious Mononucleosis (Mono) and Rheumatoid Factor (RF) in three (3) consecutive General Immunology testing events resulting in a repeat unsuccessful PT performance. See D2077. B. Based on an off-site desk review of the laboratory's 2019 and 2020 American Association of Bioanalysts (AAB) proficiency testing (PT) records (2019 2nd Event, 2019 3rd Event and 2020 1st Event), a total of three (3) events, CASPER Report 155D and interview, the laboratory failed to attain a score of one-hundred (100) percent of acceptable responses for ABO and Rh in three (3) consecutive events resulting in repeat unsuccessful PT performance. See D 2155. C. Based on an off-site desk review of the laboratory's 2019 American Association of Bioanalysts (AAB) proficiency testing (PT) records (2019 2nd Event, 2019 3rd Event and 2020 1st Event), a total of three (3) events, CASPER Report 155D and interview, the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for Rapid Plasma Reagin (RPR) in two (2) consecutive Syphilis Serology testing events resulting in unsuccessful PT performance. See 2067. D. Based on an off-site desk review of the laboratory's 2019 American Association of Bioanalysts (AAB) proficiency testing (PT) records (2019 2nd Event, 2019 3rd Event and 2020 1st Event), a total of three (3) events, CASPER Report 155D and interview, the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for Human Chorionic Gonadotropin (HCG) in two (2) consecutive Endocrinology testing events resulting in unsuccessful PT performance. See 2100.
D2067	SYPHILIS SEROLOGY CFR(s): 493.835(b) 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 0155D and interview, the laboratory failed to submit PT results within the specified time frame for Syphilis Serology (Rapid Plasma Reagin-RPR) in two (2) consecutive Syphilis Serology testing events in 2019 and 2020. Findings include: 1. Review of the laboratory's AAB 2019 2nd, 2019 3rd Event and 2020 1st Event PT records, a total of three (3) events, revealed no results for RPR for 2019 3rd Event and 2020 1st Event resulting in an unsatisfactory PT performance. 2. Review of the laboratory's CASPER Report 0155D revealed the following 2019 and 2020 General Immunology events with results of less than 80% for RPR: 2019 3rd Event=0%; and 2020 1st Event=0%; resulting in unsatisfactory performance. 3. In a telephone interview with the interim laboratory manager (LM) on May 5, 2020 at 2:05 PM, the interim LM confirmed the findings and stated they were not performing RPR testing since the 1st Event of 2019.

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 0155D 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 three (3) of three (3) General Immunology testing events in 2019 and 2020. Findings include: 1. Review of the laboratory's AAB 2019 2nd Event, 2019 3rd Event and 2020 1st Event PT records, a total of three (3) events, revealed no results for ASO, IM, and RF for 2019 2nd Event, 2019 3rd Event and 2020 1st Event resulting in a repeat unsatisfactory PT performance. 2. Review of the laboratory's CASPER Report 0155D revealed the following 2019 and 2020 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%; 2020 1st Event- ASO=0%; IM=0%; RF=0%, resulting in unsatisfactory performance. 3. In a telephone interview with the interim laboratory manager (LM) on May 5, 2020 at 2:05 PM, the interim LM confirmed the findings and stated they were not performing ASO, IM, and RF testing since the 1st Event of 2019.
D2100	ENDOCRINOLOGY CFR(s): 493.843(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 0155D and interview, the laboratory failed to submit PT results within the specified time frame for Human Chorionic Gonadotropin (HCG) in two (2) consecutive Endocrinology testing events in 2019 and 2020. Findings include: 1. Review of the laboratory's AAB 2019 2nd Event, 2019 3rd Event and 2020 1st Event PT records, a total of three (3)

	events, revealed no results for RPR for the 2019 3rd Event and 2020 1st Event resulting in an unsatisfactory PT performance. 2. Review of the laboratory's CASPER Report 0155D revealed the following 2019 and 2020 General Immunology events with results of less than 80% for HCG: 2019 3rd Event=0%; and 2020 1st Event=0%, resulting in unsatisfactory performance. 3. In a telephone interview with the interim laboratory manager (LM) on May 5, 2020 at 2:05 PM, the interim LM confirmed the findings and stated they were not performing HCG since the 1st Event of 2019.
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 0155D and interview, the laboratory failed to submit PT results within the specified time frame for ABO and Rh (Blood group typing) in three (3) of three (3) ABO/Rh testing events in 2019 and 2020. Findings include: 1. Review of the laboratory's AAB 2019 2nd Event, 2019 3rd Event and 2020 1st Event PT records, a total of three (3) events, revealed no results for ABO/Rh for 2019 2nd Event, 2019 3rd Event and 2020 1st Event resulting in a repeat unsatisfactory PT performance. 2. Review of the laboratory's CASPER Report 0155D revealed the following 2019 and 2020 ABO and Rh events with results of less than 100%: 2019 2nd Event - ABO = 0%; Rh = 0%; 2019 3rd Event - ABO = 0%; Rh = 0%; 2020 1st Event - ABO=0%; Rh=0%, resulting in unsatisfactory performance. 3. In a telephone interview with the interim laboratory manager (LM) on May 5, 2020 at 2:05 PM , the interim LM confirmed the findings and stated they were not performing ABO, and Rh testing since the 1st Event of 2019.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. 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 0155D and interview, the laboratory director failed to ensure PT results for Anti-Streptolysin O

	(ASO), Infectious Mononucleosis (Mono), Rheumatoid Factor (RF) and ABO/Rh were submitted within the specified time frame for three (3) of three (3) events in 2019 and 2020 resulting in repeat unsuccessful PT performance. See D2077 and D2155.