

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 09D0968273	(X3) Date Survey Completed 08/12/2026
Name of Provider or Supplier Dc Dfs Public Health Laboratory	Street Address, City, State 401 E Street Sw, Washington, DC	
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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, a review of the manufacturer's instructions and the laboratory's temperature records, and interviews with the staff, the laboratory failed to ensure the room temperature and humidity range was consistent with the manufacturer's instructions for 1 of 1 months reviewed. Findings Include: a. 1 EZ Advanced XL was observed on 08/12/2026 at 10:22 AM in the BSL 3 room. b. A review of the manufacturer's instructions "EZ1 Advanced XL User Manual" revealed "Appendix A ...Operating Conditions ...Air Temperature ...15-30C [degrees Celsius] ... Relative humidity ...15-75% (noncondensing)." c. A review of the laboratory's June 2026 temperature and humidity monitoring records for the room revealed "BTU 4194 Storage-Temperature C ...Out of Range Values ...Low Point=10 ...High Point=40" and "BTU 4203 Extract-Humidity%...Out of Range Values ...Low Point=1 ...High Point=90". d. During an interview on 08/12/2026 at 12:30 PM, Technical Supervisor (TS) #3, as listed on the CMS-209, stated that for the BSL 3, the laboratory's room temperature range was 11-28C, and the humidity was 24-85%. The "Out of Range Values" are alarm values set by the laboratory. e. During an interview on 08/12/2026 at 12:40 PM, the Laboratory Director and TS #3 confirmed that the laboratory's defined room temperature and humidity range exceeded the manufacturer's

requirements, and the alarm values were set too wide and would not immediately alert the laboratory when temperature and humidity exceeded the defined range.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on direct observations, a review of the laboratory's procedures and the manufacturer's instructions, and interviews with staff, the laboratory failed to label 22 of 22 aliquots with expiration dates. Findings Include: a. 1 Box of Measles Synthetic RNA [ribonucleic acid] containing 22 aliquots labeled "Measles SyntheTic [sic] RNA ...Lot: 70059022 ...Prep: 9/15/2023 ...Exp: N/A" was observed on 08/12/2026 at 10:53 AM in the -80C [degrees Celsius] freezer. b. A review of the laboratory's procedure "MDU17-SOP for Measles Virus Real-Time Polymerase Chain Reaction Assay", revision 5, revealed "Preparation of concentrated Measles Synthetic RNA (MeV-N) control RNA stocks ...Prepare 10 ?l [microliters] aliquots and store at ? [less than or equal to] -70°C. Each aliquot should be thawed no more than 3 times." c. During an interview on 08/12/2026 at 10:53 AM, Testing Personnel (TP) #21, as listed on the CMS-209, stated the control did not have an expiration date. d. A review of the manufacturer's instructions "Measles Synthetic RNA (MeV-N3in)" catalog: GR-1381, Lot: 70059022, revealed, "For Research Use Only ...Performance Characteristics Have Not Been Established". The laboratory did not establish an expiration date. e. A review of an email provided by Technical Supervisor (TS) #3, as listed on the CMS-209, from the manufacturer to TS #3 revealed "did some additional checking on your request for expiration dates for GR-1379 Lot: 70059020 and GR-1381 Lot: 70059022. I can tell you that I was mistaken with the date I provided on the phone as being 4/8 /2028. I have been informed that neither of these products have an expiration date." f. During an interview on 08/12/2026 at 12:55 PM, TS #3 stated the reagent was received without an expiration date, and each aliquot can be thawed a maximum of 3 times. An additional interview with TP #21 on 08/12/2026 at 1:03 PM revealed that a dot is placed on the aliquot lid to indicate whether the vial is open, and a tick mark is placed on the label to indicate the number of freeze-thaw cycles. The last patient test performed was ID: 26107150010 on 07/15/2026.