

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 09D0968273	(X3) Date Survey Completed 06/05/2024
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
D0000	Federal Jurisdictional Survey The laboratory is not in compliance with 42 CFR part 493 with standard level deficiencies cited:
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, manufacturer's instructions, review of laboratory's testing records, interview with Laboratory Director and interview with the processing department staff, the laboratory failed to follow their written policies for conditions for specimen transportation and acceptability for 3 of 24 specimens reviewed from January 1, 2024 to the date of the survey as evidenced by: SARS-COV-2 Specimen 1. In review of the laboratory's policy states, "Specimens should be stored at 2 to 8 degrees C prior to testing and during transport." 2. In review of the Panther Fusion manufacturer's instructions Rev 006 states, "Specimens in the Panther Lysis Tube may be stored under one of the following conditions: 15 to 30 degrees C up to 6 days or 2 to 8 degrees C up to 3 months." 3. In review of the laboratory's testing records, the following specimen temperature condition was recorded as -22 degrees C during transportation: patient #24040090005 was received on 4/8/2024 and reported on 4/9/2024. 4. In review of the laboratory's testing records, the following specimen temperature condition was recorded as -65 degrees C during transportation: patient #24042230001 was received on 4/23/2024 and reported on 4/23/2024. Mumps Specimen 1. In review of the laboratory's policy states, "Specimens should be stored at</p>

2 to 8 degrees C prior to testing and transport." 2. In review of the laboratory's testing records, the following specimen temperature condition was recorded as -10 degrees C degrees during transportation: patient #2405150016 was received on 5/15/2024 and reported on 5/16/2024. 4. In interview with the processing department staff on June 5, 2024 at 1024 stated that they are not sure why the temperatures were recorded out of range. 5. In interview with the Laboratory Director on June 5,2024 at 1415 stated that she would look into the issue.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, laboratory maintenance records (3/1/24 - 5/31/24), test volume records, and interview with the General Supervisor (GS) - 3 (as per the Form CMS-209), the laboratory failed to follow the operator's manual for the Hologic Panther Fusion System for daily maintenance requirements and cleaning for 3 of 3 months. Findings included: Mag Wash Clean 1. The manufacturer's instructions for the Hologic Panther Fusion System (AW-20220-001 Rev. 001) listed the following maintenance requirements: "As part of system maintenance, it is required that this task be performed after each testing day. For example, if processing test orders on Monday-Friday, schedule the Mag Wash Clean task to be run after working hours on Monday-Friday." 2. A review of the laboratory's maintenance record titled, "DC Dept of Forensic Sciences Panther Fusion Maintenance Log Report" from March 1, 2024 through May 31, 2024 revealed the laboratory failed to follow manufacturer's instructions to perform daily Mag Wash Clean maintenance after testing, for the following months testing was performed on the Hologic Panther Fusion Analyzers: (Serial Number 01720) - March, April, May (Serial Number 02113) - March, April, May 3. A review of the laboratory's test volume records between January 1, 2024 and May 31, 2024 showed daily Mag Wash Clean maintenance was not performed after testing for 17 SARS-COV-2 specimens (Serial Number 01720), 37 CT/GC specimens (Serial Number 01720) and 237 SARS-COV-2 specimens (Serial Number 02113). 4. In an interview within the IVU room on 6/04/24 at 12:35pm, the General Supervisor - 3 (As per the Form CMS-209) confirmed the settings were from when the laboratory was testing SARS-COV-2 24 hours a day, and further confirmed the Mag Wash settings were not set to run after each testing day. Word Key: GC- Neisseria gonorrhoea CT-Chlamydia trachomatis SARS-COV-2- Severe Acute Respiratory Syndrome Coronavirus 2 IVU-Immunology Virology Unit