

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0645348	(X3) Date Survey Completed 05/15/2024
Name of Provider or Supplier Fdoh Bureau Of Public Health Laboratories - Miami	Street Address, City, State 1325 Nw 14th Ave, Miami, FL	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's policy, review of rapid plasma reagin (RPR) testing records, and interview with Testing person #5 (pg.2), the laboratory failed to following manufacturer's instructions for Becton Dickinson (BD) macro- vue RPR temperature testing requirements for 4 of 4 months in 2024 as evidenced by: 1. In review of the manufacturer's instructions for the BD macro-vue RPR under reagents states, " Upon removal from refrigeration allow reagents to warm to room temperature (23-29 degree C)" 2. In review of the laboratory policy, states under temperature, "The temperature of the room is critical and daily temperatures should be recorded daily and monitored all day. The outcome of the test is dependent on room temperature (RT). RT must be maintained at 23 to 29 degrees C " 3. In review of the RPR testing records from January 2024 to the date of testing, the temperature range was recorded as 20-30 degrees C on their testing worksheet for the manual BD RPR manual titers. 4. The laboratory was outside the temperature testing range for titer testing for 4 of 4 months. No days of the 4 months were recorded within the 23 to 29 degree range. Random examples are as follows: a. January 3, 2024 temperature was recorded as 21 degree C. b. January 16, 2024 temperature was recorded as 22.5 degrees C. c. January 25,2024 temperature was recorded as 20.9 degrees C. d. February 8, 2024 temperature was recorded as 20.5 degrees C. e. February 14,2024 temperature was recorded as 20.9 degrees C. f. March 4, 2024 temperature was recorded as 20.7 degrees C. g. March 12,2024 temperature was recorded as 20.9 degrees C. h. March 14,2024 temperature was recorded as 21.1</p>

degrees C. i. March 22,2024 temperature was recorded as 21.2 degrees C. j. April 15, 2024 temperature was recorded as 20.7 degrees C. k. April 16,2024 temperature was recorded as 21.5 degrees C. l. April 17, 2024 temperature was recorded as 21.7 degrees C. m. April 18, 2024 temperature was recorded as 20.9 degrees C. n. April 19, 2024 temperature was recorded as 21 degrees C. o. April 22, 2024 temperature was recorded as 20.9 degrees C. p. April 23, 2024 temperature was recorded a 21.5 degrees C. 5. In a random sample of April 19, 2024 the following patients were manually re-tested for titers. a. MSS24012675 b. MSS24012677 c. MSS24012691 d. MSS24012697 e. MSS24012700 f. MSS24012708 6. In interview with testing personnel # 5 (pg.2) on 5/14/2024 at 1356 she stated that she takes the temperature during the beginning of the day rather than when they begin the test.

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 (1/1/24 - 4/30/24), test volume records, and interview with the Testing Person (TP) - 1 (as per the Form CMS-209), the laboratory failed to follow the manufacturer's instructions for the Hologic Panther System for daily and quarterly maintenance requirements and cleaning for 4 of 4 months. Findings included: Mag Wash Clean 1. The manufacturer's instructions for the Hologic Panther 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, "Panther Maintenance (Updated 0.1.2021 ARP)" from January 1, 2024 through April 30, 2024 revealed the laboratory failed to perform daily Mag Wash Clean maintenance after the following days testing was performed on the Hologic Panther System Analyzers: (Serial Number 02768) - 1/3/24, 1/8/24, 1/12/24, 1/19/24, 1/24/24, 1/29/24, 2/2/24, 2/7/24, 2/12/24, 2/16/24, 3/1/24, 3/11/24, 3/15/24, 3/29/24, 4/8/24, 4/15/24, 4/22/24, 4/26/24 (Serial Number 00814) - 3/5/24, 3/11/24, 4/2/24, 4/8/24 (Serial Number 02801) - 1/8/24, 1/22/24, 1/26/24, 1/29/24, 2/5/24, 2/12/24, 2/19/24, 2/26/24, 3/4/24, 3/11/24, 3/18/24, 3/25/24, 4/1/24, 4/8/24, 4/11/24, 4/15/24, 4/22/24, 4/26/24, 4/29/24 3. A review of the laboratory's test volume records between January 1, 2024 and April 30, 2024 showed daily Mag Wash Clean maintenance was not performed after testing for 504 HCV specimens (Serial Number 02768), 79 HIV specimens (Serial Number 00814) and 3,724 GC/CT specimens (Serial Number 02801). 4. In an interview within the conference room on 5/14/24 at 1:52pm, the Testing Personnel (TP) - 9 (As per the Form CMS-209) confirmed that the service technician from the manufacturer had pre-set the settings for the Mag Wash, and their staff did not know it was pre-set to incorrect settings to the manufacturer's instructions. Thermocycler Cleaning 1. The manufacturer's instructions for the Hologic Panther System (AW-20220-001 Rev. 001) listed the following cleaning requirements of the thermocycler: "Clean Thermocycler - Perform the Thermocycler Clean Maintenance task at least every 3 months and as needed to remove debris that may be inside the thermocycler wells." 2. A review of the laboratory's maintenance log report titled "Panther Maintenance Log Report" from January 1, 2024 to April 30,

2024 revealed the laboratory failed to perform quarterly thermocycler cleaning for two Hologic Panther analyzers (Serial Numbers 02801 and 00814). 3. A review of the laboratory's test volume records titled "Test Count Report" between January 1, 2024 and April 30, 2024 showed a total of 13,538 CT/GC specimens (Serial Number 02801) and 180 HIV specimens (Serial Number 00814) run. 4. In an interview within the conference room on 5/14/24 at 2:00pm, the Testing Personnel (TP) - 9 (As per the Form CMS-209) confirmed that the service technician from the manufacturer had not notified staff of thermocycler cleaning and was not a part of their maintenance documentation; additionally, the manufacturer representative would be contacted.

Daily Maintenance 1. The manufacturer's instructions for the Hologic Panther System (AW-20220-001 Rev. 001) listed the following daily maintenance task requirements: "Laboratory Check and Cleaning - Perform preparatory cleaning and environmental checks every 24 hours during routine operation. Verify the following environmental specifications are met before initiating testing: Temperature (C) 15-30C, Relative Humidity (%) 20% - 85%." 2. A review of the laboratory's maintenance log report titled "Panther Maintenance (Updated 0.1.2021 ARP)" from January 1, 2024 to April 30, 2024 revealed the laboratory failed to perform and document daily maintenance of room temperature, humidity check and cleaning of external surface for 64 of 86 days of routine operation days (Serial Number 02768). 3. A review of the laboratory's test volume records titled "Test Count Report" between January 1, 2024 and April 30, 2024 showed a total of 767 qHCV specimens (Serial Number 02768) run. 4. In an interview within the Hepatitis testing area on 5/15/24 at 10:39am, the Testing Personnel (TP) - 1 (As per the Form CMS-209) confirmed that the staff was not completing and recording daily maintenance tasks on days they did not test, but are still operating the lab. Word Key: GC - Neisseria gonorrhoea CT - Chlamydia trachomatis HCV - Hepatitis C Viral Load qHCV - Quantitative Hepatitis C Viral Load HIV - Human Immunodeficiency Virus C - Celsius

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's maintenance records for 2024, and interview with Testing Personnel (TP) - 9 (as per Form CMS-209), the laboratory failed to document all required weekly maintenance for 12 of 17 weeks and daily maintenance for 66 of 82 days on the Hologic Panther analyzer (Serial Number 02801) for CT/GC specimen testing. Findings include: Weekly Sample Shield Cleaning 1. A review of the laboratory's maintenance records titled "Panther Maintenance (Panther #2)" [Serial Number 02801] from January 1, 2024 to April 30, 2024 revealed the laboratory failed to document weekly sample shield cleaning on the following weeks: (Serial Number 02801) - 1/8/24-1/12/24, 1/22/24-1/26/24, 1/29-2/2/24, 2/5/24-2/9/24, 2/19/24-2/23/24, 3/4/24-3/8/24, 3/11/24-3/15/24, 3/18/24-3/22/24, 3/25/24-3/29/24, 4/1/24-4/5/24, 4/8/24-4/12/24, 4/22/24-4/26/24. 2. In an interview within the conference room with Testing Personnel (TP)- 9 (As per the Form CMS-209) on 5/14/24 at 1:52pm, the TP

confirmed the missing of the recording of this weekly maintenance task. Daily Maintenance Bench Cleaning 1. A review of the laboratory's maintenance records titled "Panther Maintenance (Panther #2)" [Serial Number 02801] from January 1, 2024 to April 30, 2024 revealed the laboratory failed to document daily "Panther External surface" cleaning for the following days: (Serial Number 02801) - 1/3/24-1/25/24, 2/1/24-2/8/24, 2/12/24-2/15/24, 2/19/24-2/20/24, 2/22/24-2/29/24, 3/1/24-3/15/24, 3/20/24-3/29/24, 4/1/24-4/12/24, 4/16/24-4/17/24, 4/24/24-4/25/24, 4/30/24 2. In an interview within the conference room with Testing Personnel (TP) - 9 (As per the Form CMS-209) on 5/14/24 at 1:52pm, the TP confirmed the missing of the recording of this daily maintenance task.