

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D2081388	<b>(X3) Date Survey Completed</b>  02/10/2022
<b>Name of Provider or Supplier</b>  Wren Laboratories, Llc	<b>Street Address, City, State</b>  688 East Main St, Branford, CT	
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>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview the laboratory failed to document routine maintenance and function checks for laboratory equipment in the subspecialties of routine Chemistry and Virology. Findings include: 1. Surveyor observation on 02/10/2022 at approximately 9:30 AM of the laboratory's amplification room revealed four QuantStudio 7 (QS7) Flex Real-Time Polymerase Chain Reaction (PCR) systems by Applied Biosystems. 2. Record review on 02/10/2022 of the above instrumentation user guide Revision A, November 2013 revealed "The QuantStudio 6 and 7 Flex system require regular calibration and maintenance for proper operation. To ensure proper operation of your instrument, perform weekly, monthly, and semiannual maintenance..." 3. Record review on 02/10/2022 of the laboratory's Care &amp; Maintenance: PCR Machines - WRL-FM-010c procedure revealed the laboratory did not have maintenance protocols/schedules for the weekly and monthly required maintenance tasks. 4. Record review on 02/10/2022 of the QS7 maintenance/calibration binder revealed the laboratory did not have the required weekly and monthly maintenance records. 5. Staff interview with technical supervisor (TS) on 02/10/2022 at 2:20 PM confirmed the laboratory did not conduct weekly and monthly required maintenance tasks. TS revealed he/she was unaware of the weekly and monthly required maintenance.</p>
<b>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p>

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to document corrective action when temperatures exceeded established acceptable ranges in the subspecialty of Virology and Routine Chemistry for the period of March 2021 through August 2021. Findings include: 1. Record review on 2/10/2022 of the Laboratory Equipment Logs for the Six month period of March through August 2021 revealed the following: a. Acceptable temperature range for Equipment F10 was -25 to -15 Degrees Celsius (C). b. Corrective action was not documented for 75 of 130 working days when the freezer temperature was outside of the range in 1a above. c. Acceptable temperature range for Equipment F6 was 2 to 8 Degrees Celsius (C). d. Corrective action was not documented for 39 of 130 working days when the room temperature was outside of the range in 1c above. 2. Staff interview on 2/10/2022 at 02:45 PM with General Supervisor #2 verified the temperatures were out of range and documentation of corrective action was not recorded.