

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2081388	(X3) Date Survey Completed 07/16/2018
Name of Provider or Supplier Wren Laboratories, Llc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow manufacturer instructions for proper storage of reagents in the specialty of clinical cytogenetics. Findings include: 1. Surveyor observation of the FF4 laboratory refrigerator contents on 7/16/18 at 1:30 PM revealed: a. 1 bottle from Applied Biosystems (ABI) labeled DNA wipe test, lot# 1611035, expiration date 9/2/18. b. 6 bottles of ABI TaqMan Universal MMII with UNG used for QPCR for the NETest, lot# 1706037, expiration date 5/23/19. c. Manufacturer instructions on these bottles revealed proper storage is 2 to 8 degrees Celsius. 2. Record review on 7/16/18 of the FF4 laboratory refrigerator temperature logs from 10/12/16 through 5/31/18 revealed: a. The temperature logs from October and November 2016 do not have an acceptable range written on them. b. The acceptable range from December 2016 through May 2018 is listed as 1 to 9 degrees Celsius. c. The temperatures were out of range for the storage of the above reagents on 103 of 406 working days. d. Corrective action was not documented for the days the temperatures were out of range because the range was incorrectly listed. 3. Staff interview with the general supervisor on 7/16/18 at 2:00 PM confirmed the above findings. 4. The laboratory performs 5,200 tests annually in the specialty of clinical cytogenetics.</p>

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate 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 verify the accuracy of test results interpretations when introducing a new laboratory information system (LIS). Findings include: 1. Record review on 7/16/18 of the laboratory's LIS validation documentation revealed the laboratory failed to check the test result interpretation on the final patient test reports for normal patient results. 2. Record review on 7/16/18 of a final patient test report revealed: a. The test result was reported as 6.7%. b. The result was interpreted as intermediate. c. The corresponding test result graph revealed the result falls in the normal range. 3. Record review of a 'Non-Conformance Corrective Action Form' on 7/16/18 revealed, "It only happens to the scores that fell into the "normal range"." 4. Staff interview with the general supervisor (GS) and laboratory director on 7/16/18 at 1:00 PM confirmed the above findings. The GS stated, "We never get patients that are normal, so we did not use normal patients in our validation." 5. The laboratory performs 5,200 tests annually in the specialty of clinical cytogenetics.

D5821

TEST REPORT

CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to notify the authorized person ordering the test of reporting errors. Findings include: 1. Record review of an amended patient NETest report on 7/16/18 revealed, notification documentation of amended results was not available. 2. Staff interview with the laboratory director (LD) on 7/16/18 at 11:30 AM confirmed the above findings. The LD stated the patient was called instead of the ordering physician. 3. The laboratory performs 5,200 tests annually in the specialty of clinical cytogenetics.