

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0457919	(X3) Date Survey Completed 03/13/2020
Name of Provider or Supplier Jefferson Pediatric Clinic	Street Address, City, State 1111 Medical Center Blvd Suite N813, Marrero, LA	
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	A Certification Survey was performed on March 13, 2020 at Jefferson Pediatric Clinic, CLIA ID # 19D0457919. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include the following: a) Written instructions related to actions to take for Complete Blood Count (CBC) flags on the Sysmex CBC analyzer. b) Corrective actions for temperatures and humidity readings outside of acceptable limits 2. In interview on March 13, 2020, the Testing Personnel and Laboratory Director confirmed the laboratory did not include the identified policies/procedures.</p>
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</p>

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.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to continuously monitor the room temperature and humidity of the laboratory where testing is performed. Findings: 1. Review of the laboratory's Temperature and Humidity Log for JPC Lab" forms for 2019 and 2020 revealed the laboratory did monitor the temperature and humidity for the following months: January 2019 February 2019 March 2019 April 1-5, 2019 2. In interview on March 13, 2020 at 3:22 pm, the Laboratory Director and Testing Personnel stated the thermometer in the laboratory was missing and took a while to get replaced. The Laboratory Director and Testing Personnel confirmed the laboratory did not monitor the temperature and humidity of the laboratory for the identified dates.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(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 interview with personnel, the laboratory failed to document corrective actions performed when the laboratory's room temperature was not maintained between 72 degrees Fahrenheit to 78 degrees Fahrenheit. Findings: 1. Review of the laboratory's "Temperature and Humidity Log for JPC Lab" revealed the room temperature acceptable range was "72-78 degrees Fahrenheit." 2. Review of the laboratory's temperature logs for 2019 and 2020 revealed the following fifty-two (52) dates the room temperature exceeded acceptable limits without documented corrective actions: a) April 9, 2019: recorded temperature 70.9 degrees Fahrenheit (F) b) April 10, 2019: recorded temperature 71.1 degrees F c) April 12, 2019: recorded temperature 71.8 degrees F d) April 16, 2019: recorded temperature 71.8 degrees F e) April 23, 2019: recorded temperature 71.8 degrees F f) April 25, 2019: recorded temperature 70.9 degrees F g) April 29, 2019: recorded temperature 71.4 degrees F h) May 1, 2019: recorded temperature 71.6 degrees F i) May 3, 2019: recorded temperature 71.4 degrees F j) May 6, 2019: recorded temperature 70.3 degrees F k) May 7, 2019: recorded temperature 70.9 degrees F l) May 8, 2019: recorded temperature 71.4 degrees F m) May 9, 2019: recorded temperature 71.4 degrees F n) May 10, 2019: recorded temperature 70.7 degrees F o) May 13, 2019: recorded temperature 71.6 degrees F p) May 14, 2019: recorded temperature 70.9 degrees F q) May 17, 2019: recorded temperature 71.4 degrees F r) May 20, 2019: recorded temperature 71.6 degrees F s) May 22, 2019: recorded temperature 71.2 degrees F t) May 23, 2019: recorded temperature 71.6 degrees F u) May 28, 2019: recorded

temperature 71.6 degrees F v) May 29, 2019: recorded temperature 71.8 degrees F w) May 30, 2019: recorded temperature 71.6 degrees F x) May 31, 2019: recorded temperature 71.6 degrees F y) June 3, 2019: recorded temperature 71.2 degrees F z) June 4, 2019: recorded temperature 71.2 degrees F aa) June 6, 2019: recorded temperature 71.6 degrees F bb) June 7, 2019: recorded temperature 71.5 degrees F cc) June 11, 2019: recorded temperature 71.2 degrees F dd) June 12, 2019: recorded temperature 71.8 degrees F ee) June 25, 2019: recorded temperature 71.8 degrees F ff) June 27, 2019: recorded temperature 71.4 degrees F gg) July 10, 2019: recorded temperature 71.8 degrees F hh) July 11, 2019: recorded temperature 71.6 degrees F ii) July 12, 2019: recorded temperature 71.6 degrees F jj) July 15, 2019: recorded temperature 71.2 degrees F kk) July 16, 2019: recorded temperature 71.6 degrees F ll) July 26, 2019: recorded temperature 71.8 degrees F mm) July 31, 2019: recorded temperature 71.2 degrees F nn) August 30, 2019: recorded temperature 71.4 degrees F oo) September 4, 2019: recorded temperature 71 degrees F pp) September 13, 2019: recorded temperature 71.6 degrees F qq) September 16, 2019: recorded temperature 71.8 degrees F rr) September 24, 2019: recorded temperature 71.4 degrees F ss) October 14, 2019: recorded temperature 71.8 degrees F tt) October 18, 2019: recorded temperature 71 degrees F uu) October 22, 2019: recorded temperature 71.6 degrees F vv) November 5, 2019: recorded temperature 71.8 degrees F ww) November 6, 2019: recorded temperature 71.8 degrees F xx) November 8, 2019: recorded temperature 71.8 degrees F yy) November 11, 2019: recorded temperature 71.8 degrees F zz) November 12, 2019: recorded temperature 71.6 degrees F 3. In interview on March 13, 2020 the Testing Personnel confirmed the laboratory did not perform corrective actions when the laboratory's room temperature was outside of acceptable range for the identified dates.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413.

D6024

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(7)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Refer to D5401.