

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0463834	<b>(X3) Date Survey Completed</b>  06/21/2023
<b>Name of Provider or Supplier</b>  Arklatex Children's Clinic	<b>Street Address, City, State</b>  2400 Hospital Drive, Suite 120, Bossier City, LA	
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>D0000</b>	A Certification survey was performed on June 21, 2023 at ArkLaTex Children's Clinic, CLIA ID 19D0463834. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: ***REPEAT DEFICIENCY from previous survey 11/04/2021*** Based on review of CMS-209 (Laboratory Personnel Report), laboratory policy, personnel records, and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for Clinical Consultant were complete. Findings: 1. Review of the laboratory's CMS-209 form provided to surveyor revealed the following five (5) Clinical Consultants: a) Personnel 1 (Laboratory Director, Clinical Consultant and Technical Consultant) b) Personnel 2 (Clinical Consultant) c) Personnel 3 (Clinical Consultant) d) Personnel 4 (Clinical Consultant) e) Personnel 5 (Clinical Consultant) 2. Review of the laboratory's policy for competency assessment revealed "Competency assessment of all clinical consultants is performed by the Laboratory Director upon verification of CLIA requirements. This will be repeated only if the CLIA requirements or Policy/Procedure requirements change". 3. Review of personnel records from 2022 and 2023 revealed the laboratory did not perform a competency assessment for duties as Clinical Consultant for the following four (4) of five (5) consultants: Personnel 2 through Personnel 5 4. In interview on June 21, 2023 at 11:54 am, Personnel 6 stated that the laboratory added a policy for clinical</p>

consultant competency after the last survey but the laboratory director did not perform competencies for the identified personnel. Personnel 6 confirmed competency assessments were not performed for the above identified personnel.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have written procedures to include corrective actions to take when temperature and humidity do not meet the laboratory's acceptability criteria. 2. In interview on June 21, 2023 at 12:20 pm, Personnel 6 confirmed the laboratory did not include the identified procedure.

**D5785**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

I. Based on review of laboratory policy, temperature logs and interview with personnel, the laboratory failed to perform corrective actions for temperatures outside of the acceptability criteria for eighteen (18) of one hundred seven (107) days reviewed in 2023. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not include a policy for corrective actions performed when temperatures exceed the acceptability criteria. 2. Review of the laboratory's "Daily Temperature Control Form" from January 2023 through June 21, 2023 revealed the laboratory did not document the acceptable range (2 to 8 degrees celsius/35.6 to 46.4 degrees fahrenheit) for the refrigerator temperatures. 3. Further review of the laboratory's temperature logs revealed the laboratory did not document corrective

actions for the following eighteen (18) of one hundred seven (107) days that temperatures exceeded the acceptable range: a) January 30, 2023 - documented as 35 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) b) January 31, 2023 - documented as 35 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) c) March 6, 2023 - documented as 35 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) d) March 15, 2023 - documented as 35 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) e) March 22, 2023 - documented as 35 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit /2 to 8 degrees celsius) f) April 5, 2023 - documented as 35 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) g) April 6, 2023 - documented as 33 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) h) April 7, 2023 - documented as 34 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) i) April 10, 2023 - documented as 34 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) j) April 11, 2023 - documented as 34 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) k) April 12, 2023 - documented as 34 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) l) April 14, 2023 - documented as 35 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) m) April 15, 2023 - documented as 34 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) n) May 12, 2023 - documented as 22 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit /2 to 8 degrees celsius) o) May 13, 2023 - documented as 12 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) p) May 18, 2023 - documented as 18 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) q) June 9, 2023 - documented as 35 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) r) June 13, 2023 - documented as 35 degrees fahrenheit (acceptable range 35.5 to 46.4 degrees fahrenheit/2 to 8 degrees celsius) 4. In interview on June 21, 2023 at 12:20 pm, Personnel 6 confirmed the laboratory did not perform corrective actions for refrigerator temperatures on the above identified dates. II. Based on review of laboratory policy, temperature logs and interview with personnel, the laboratory failed to document room temperatures for three hundred seventy two (372) of three hundred seventy two (372) days reviewed in 2022 and 2023. Findings: 1. Review of the laboratory policy manual revealed the laboratory did not include a written policy for the documentation of daily temperatures with an acceptable range of 18 to 32 degrees celsius (64.4 to 89.6 degrees fahrenheit). 2. Review of the laboratory's temperature logs for January 2022 through June 21, 2023 revealed the laboratory did not document the room temperature for three hundred seventy two (372) of three hundred seventy two (372) days reviewed. 3. In interview on June 21, 2023 at 12:20 pm, Personnel 6 confirmed the laboratory did not document room temperatures for the above identified days.

**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 review of laboratory policy, temperature records and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Findings: 1. The laboratory failed to perform corrective actions for temperatures outside of the acceptability criteria for eighteen (18) of one hundred seven (107) days reviewed in 2023. Refer to D5785 I. 2. The laboratory failed to document room temperatures for three hundred seventy two (372) of three hundred seventy two (372) days reviewed in 2022 and 2023. Refer to D5785 II.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, personnel records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to ensure written policies and procedures to assess competency for Clinical Consultant were complete. Refer to D5209.

**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 review of laboratory policies and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5403.