

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0457593	(X3) Date Survey Completed 02/18/2020
Name of Provider or Supplier Pediatric Clinic - Westbank	Street Address, City, State 151 Ochsner Blvd, Suite F, Gretna, 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 at Pediatric Clinic Westbank, CLIA ID 19D0457593 on February 18, 2020. 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 establish complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not establish complete policies for record retention requirements. 2. In interview on February 18, 2020 at 12:48 pm, the Business Manager/Testing Personnel 1 stated the lab does not statement or information concerning record retention in their policies.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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</p>

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 record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6046.

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 laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Technical Consultant failed to ensure the procedures to assess personnel competency were complete. Findings: 1. In interview on February 18, 2020, the Business Manager/Testing Personnel 1 stated Testing Personnel 6 was hired in October 2018. 2. Review of Personnel 6's six month competency assessment for Complete Blood Counts (CBC) revealed the laboratory utilized the "DxH 600 Training Checklist Basic Operator" which included the following tasks: a) System Manager b) Countertop c) Perform Daily Checks /Shutdown d) Run 6c, N/A, Latron-X, N/A e) Run patient samples" 3. Further review of the identified six month competency assessment revealed it did not include at a minimum the following six (6) procedures: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving

skills. 4. In interview on February 18, 2020, the Business Manager/Testing Personnel 1 stated the Laboratory Director (also serves as Technical Consultant) used the identified Basic Operator form for Personnel 6's six month competency assessment. The Business Manager stated the Laboratory Director performed the assessment on March 13, 2019. The Business Manager further stated she was unaware the identified six (6) procedures were required for semi-annual competency assessments.