

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0461155	(X3) Date Survey Completed 03/27/2019
Name of Provider or Supplier Crowley Walkin Clinic Corporation	Street Address, City, State 621 N Avenue K, Crowley, 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 Recertification survey was conducted at Crowley Walk-In Clinic-CLIA ID # 19D0461155 on March 27, 2019. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to take corrective action when quality control (QC) values were unacceptable for Complete Blood Count (CBC) testing per laboratory policy. Findings: 1. Review of the laboratory's QC records for CBC testing revealed the laboratory performs the following three (3) levels of QC: Sysmex Eight Check-3WP X-TRA Low Abnormal, Normal, and High Abnormal 2. Review of the laboratory's "AWIC Quality Control Procedures" under the "Quality Control Process section revealed the following: a) "C. At least two controls will be used for any analyte whenever possible. These controls should be levels representing the normal and abnormal range of the assay." b) "D. Three levels of controls will be performed in assays where controls should be analyzed in the low, medium, and high levels of reportable range." 3. Review of the laboratory's "AWIC Quality Control Procedures" under the "Quality Control Evaluation" section revealed the following: a) "A. When all control observations results are within manufacture's ranges, results will be reported." b) "B. When one of</p>

the control observations is out of the manufacturer's range, the analytical run must be repeated prior to patient testing." 4. In interview on March 27, 2019 at 2:42 pm, Personnel 1 stated all three levels of CBC controls must be within acceptable range. 5. Review of 2017 QC records for CBC testing for October, November, and December revealed QC was unacceptable for the following two (2) of sixty five (65) days reviewed: a) November 6, 2017: QC Level 01 (Low) MXD%: value reported: + 70.2% (acceptable range: 4.7-13.9 %) NEUT%: value reported: - 3.6 % (acceptable range: 60.7-71.1 %) MXD #: value reported: + 2.1 x 10³/uL (acceptable range: 0.1-0.5 x 10³/uL) NEUT#: value reported: - 0.1 x10³/uL (acceptable range: 1.5-2.3 x 10³/uL) W-LMV: value reported: + 266.2 fL (acceptable range: 178.3-219.3 fL) b) December 21, 2017: QC Level 01 (Low) MXD%: value reported: + 39.1% (acceptable range: 4.7-13.9 %) NEUT%: value reported: - 37.1 % (acceptable range: 60.7-71.1 %) MXD #: value reported: + 1.1 x 10³/uL (acceptable range: 0.1-0.5 x 10³/uL) NEUT#: value reported: - 1.1 x10³/uL (acceptable range: 1.5-2.3 x 10³/uL) W-LMV: value reported: + 228.0 fL (acceptable range: 178.3-219.3 fL) 6. In further interview on March 27, 2019 at 2:42 pm, Personnel 1 stated the identified controls should have been repeated and was unsure why they were not. Personnel 1 further stated she was unable to determine at the time of the survey the patients with reported CBC results for the identified dates. 7. In interview via phone on March 27, 2019 at approximately 4:15 pm, Personnel 2 stated only two (2) control levels for CBC testing needed to be within acceptable range. Personnel 2 stated the laboratory did not repeat the identified controls since the two (2) remaining levels were within acceptable range.

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 D5783.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director

review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to provide written job descriptions for all Laboratory Personnel. Findings: 1. Review of the laboratory's policy and procedure manual and personnel records revealed the laboratory did not have a written job description for the Laboratory Director, who also serves as the Clinical Consultant. 2. In interview on March 27, 2019 at 2:41 pm, Personnel 1 stated she was unsure where the written job description was located in the manual. Personnel 1 confirmed she the laboratory did not have a written job description for the Laboratory Director.

D6044

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(6)

(b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5783.