Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0461155	08/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Crowley Walkin Clinic Corporation	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 performed on August 5, 2021 at Crowley Walk-In Clinic, CLIA ID # 19D0461155. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to document remedial action for unacceptable Hematology scores. Findings: 1. Review of the laboratory's 2020 and 2021 Proficiency Testing (PT) results revealed the laboratory received the following unacceptable results: a) 2020 Event 3: Score for Red Blood Cell (RBC) - 80% b) 2021 Event 1: Score for Red Blood Cell (RBC) - 80% c) 2021 Event 1: Score for Platelets - 80% 2. Further review revealed no documentation of corrective action, investigation or remedial action of these unacceptable scores. 3. In interview on August 6, 2021 at 11:06 am, testing personnel confirmed the laboratory did not investigate proficiency testing unless the event or analyte was less that 80%.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	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. This STANDARD is not met as evidenced by: Based on observation, review of laboratory policy and interview with personnel, the laboratory failed to ensure the laboratory policy detailed the frequency of calibration for Hematology testing. 1. Observation during the laboratory tour revealed the laboratory performed complete blood count (CBC) testing on a Sysmex POCH 100-i. 2. Review of the laboratory policy & procedure manual revealed the frequency of calibration testing was not specified. 3. Interview with laboratory personnel confirmed the laboratory performed calibration annually, but frequency was not detailed in the policy and procedure manual.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of manufacturer's temperature requirements, and interview with personnel, the laboratory failed to monitor the room temperature where reagents and supplies are stored per manufacturer requirements. Findings: 1. Observation by surveyors during the laboratory tour on August 6, 2021 at 11:30 am revealed the laboratory did not monitor the temperature of the storage room where the following supplies were stored: a) 5 Pack-D pocH pack b) 8 bottles of Multistix 10SG c) 5 boxes of Icon urine HcG d) pediatric EDTA collection tubes 2. Review of the manufacturer's storage requirements for the above supplies revealed the following: 15-25 degrees celsius. 3. In interview on August 6, 2021 at 11:44 am, the laboratory testing personnel confirmed the laboratory did not monitor the temperature of the storage closet where extra laboratory supplies were stored.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Refer to D5413.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to document remedial action for unacceptable Hematology scores. Refer to D2128.
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.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review and interview with personnel, the Technical Consultant failed to monitor the room temperature where reagents and supplies are stored per manufacturer requirements. Refer to D5413.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in

	an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to document remedial action for unacceptable Hematology scores. D2128.