| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 19D0461155 | 02/11/2025 |
| **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 |
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| **D0000** | A Recertification survey was performed on February 11, 2025 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. |
| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies and proficiency testing (PT) records as well as interview with personnel, the laboratory failed to ensure the Laboratory Director and/or designee reviewed the PT performance evaluation results for one (1) of five (5) events. Findings: 1. Review of the laboratory's "Proficiency Testing" policy revealed "The technical consultant and/or laboratory director will review and sign all surveys and all related documentation will be retained for at least two years." 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed the Laboratory Director and/or Technical Consultant did not document review of the 2023 Hematology/Coagulation 2nd Event. 3. In interview on February 11, 2025 at 9:56 a.m., the Technical Consultant confirmed the evaluation was not signed as identified above. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>(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 |

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| | applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, review of manufacturer's storage requirements and laboratory temperature records, as well as interview with personnel, the laboratory failed to monitor refrigerator temperatures for one (1) of one (1) refrigerators where laboratory supplies were stored. Findings: 1. Observation by surveyor during the laboratory tour on February 11, 2025 at 9:20 a.m. revealed the laboratory stored Sysmex Eightcheck-3WP X-TRA quality control materials in a refrigerator located in the laboratory. 2. Review of the manufacturer's package insert for the Sysmex Eightcheck-3WP X-TRA revealed "EIGHTCHECK - 3WP X - TRA is to be stored closed at 2 - 8 degrees Celsius." 3. Review of the laboratory's temperature monitoring records revealed the laboratory did not monitor the temperature of the refrigerator containing the quality control materials identified above. 4. In interview on February 11, 2025 at 10:15 a.m., the Technical Consultant confirmed the laboratory did not monitor the temperature of the refrigerator as identified above. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>**Repeat deficiency from previous survey June 27, 2023** Based on observation, review of the manufacturer's operator's manual and the laboratory's maintenance records, as well as interview with personnel, the laboratory failed to ensure maintenance for the Sysmex pocH-100i was performed and documented every two weeks for five (5) of eleven (11) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on February 11, 2025 at 9:20 a.m. revealed the laboratory utilized the Sysmex pocH-100i for complete blood count testing. 2. Review of the manufacturer's operator's manual for the Sysmex pocH-100i section "Routine Maintenance Procedures" revealed "Every 2 Week Maintenance (or every 150 samples): Clean Tranducer." 3. Review of the laboratory's maintenance logs revealed "Every 2 weeks: Clean transducer." 4. Further review of the laboratory's maintenance records from March 2024 through January 2025 revealed the laboratory failed to perform and document maintenance every two weeks for the following months: a) March 2024: One (1) of two (2) cleanings not performed b) April 2024: One (1) of three (3) cleanings not performed c) August 2024: One (1) of two (2) cleanings not performed d) September 2024: One (1) of three (3) cleanings not performed e) November 2024: One (1) of two (2) cleanings not performed 5. In interview on February 11, 2025 at 10:28 a.m., the Technical Consultant confirmed the maintenance was not performed as identified above. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an |

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| | ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the laboratory failed to establish complete procedures to monitor, assess, and correct problems identified with the analytic system. Findings: 1. The laboratory failed to monitor refrigerator temperature for one (1) of one (1) refrigerators where laboratory supplies were stored. Refer to D5413. 2. The laboratory failed to ensure maintenance for the Sysmex pocH-100i was performed and documented every two weeks for five (5) of eleven (11) months reviewed. Refer to D5429. |
| **D6014** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(iii)<br><br>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, review of manufacturer's instructions, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413. |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<br><br>(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to ensure the proficiency testing evaluations were reviewed. Refer to D5211. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control and quality assessment program was maintained to assure the quality of laboratory testing. Refer to D5791. |
| **D6023** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(6) |

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| | (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429. |
| **D6036** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413<br><br>The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to monitor refrigerator temperatures for one (1) of one (1) refrigerators where laboratory supplies were stored. Refer to D5413. 2. The laboratory failed to ensure maintenance for the Sysmex pocH-100i was performed and documented every two weeks for five (5) of eleven (11) months reviewed. Refer to D5429. |