Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0461155	06/27/2023
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 June 27, 2023 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.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 (Laboratory Personnel Report) form, proficiency testing records, and the laboratory's policy and procedure manual, as well as interview with personnel, the laboratory failed to ensure that proficiency testing (PT) was performed by personnel who routinely perform laboratory testing for five (5) of five (5) events reviewed. Findings: 1. Review of the laboratory's CMS 209 form revealed the laboratory listed the following Testing Personnel: Testing Personnel 1 Testing Personnel 2 2. Review of the laboratory's American Academy of Family Physicians (AAFP) and American Proficiency Institute (API) proficiency testing records revealed Testing Personnel 2 tested all PT samples for the following events: a) AAFP 2021 Event C b) AAFP 2022 Event A c) AAFP 2022 Event B d) AAFP 2022 Event C e) API 2023 1st Event 4. Review of the laboratory's policy "Proficiency Testing" revealed "Proficiency testing will be rotated among all licensed laboratory personnel." 5. In interview on June 27, 2023 at 10:04 a.m., the Technical Consultant confirmed proficiency testing samples were not rotated between all testing personnel for the events identified above.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)

	The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with laboratory personnel, the laboratory failed to test proficiency testing (PT) samples the same number of times as patients are routinely tested for five (5) of five (5) events reviewed. Findings: 1. Review of the laboratory's American Academy of Family Physicians (AAFP) and American Proficiency Institute (API) records with raw data revealed the laboratory tested PT samples multiple times as follows: a) AAFP 2021 Event C: Sample 11- tested two (2) times Sample 12- tested two (2) times Sample 13- tested two (2) times Sample 14- tested two (2) times Sample 15- tested two (2) times b) AAFP 2022 Event A: Sample 2 - tested two (2) times Sample 4 - tested three (3) times Sample 5 - tested two (2) times c) AAFP 2022 Event B: Sample 6 - tested three (3) times Sample 8 - tested two (2) times Sample 10 - tested two (2) times d) AAFP 2022 Event C: Sample 11- tested two (2) times Sample 12- tested two (2) times Sample 13- tested two (2) times Sample 14- tested two (2) times Sample 15- tested two (2) times e) API 2023 1st Event: Sample 3 - tested two (2) times 2. In interview on June 27, 2023 at 10:04 a.m., the Technical Consultant stated the Laboratory Director reviews all patient results and decides if a rerun is needed. He further stated the Laboratory Director had testing personnel repeat the proficiency testing identified above. The Technical Consultant confirmed the laboratory did not have a policy stating the Laboratory Director reviews all results. He also confirmed the proficiency testing samples identified above were tested multiple times.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with personnel, the laboratory failed to retain proficiency testing records for one (1) of five (5) events reviewed for at least two (2) years. Findings: 1. Review of the laboratory's American Academy of Family Physicians (AAFP) and American Proficiency Institute (API) proficiency testing records revealed the performance evaluation report for the platelet count of AAFP 2022 Event B sample SYX-8 had "Fail" in the "Comments" column. 2. Further review of the performance evaluation revealed the laboratory documented "Passed on repeat" next to the "Fail" comment. 3. Review of the laboratory's American Academy of Family Physicians (AAFP) proficiency testing records with raw data for AAFP 2022 Event B revealed the laboratory did not retain documentation of repeat testing for the platelet count of sample SYX-8. 4. In interview of June 27, 2023 at 10:54 a.m., the Technical Consultant confirmed the laboratory did not have the raw data to support the documentation of repeat testing for the PT sample identified above.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish a complete written policy for competency assessment that included problem solving. Findings: 1. Review of the laboratory's policy and procedure manual revealed a "Personnel Competency" policy that did not include assessment of problem solving skills as part of the competency assessment requirements for testing personnel. 2. In interview on June 27, 2023 at 11:50 a.m., the Technical Consultant confirmed the laboratory's competency assessment policy did not include assessment of problem solving skills.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and proficiency testing (PT) records as well as interview with laboratory personnel, the laboratory failed to follow their proficiency testing policy for review of proficiency testing evaluations for four (4) of five (5) events. Findings: 1. Review of the laboratory's policy "Proficiency Testing" revealed "The technical consultant and the laboratory director will review and sign all surveys." 2. Review of the laboratory's American Academy of Family Physicians (AAFP) and American Proficiency Institute (API) records with raw data revealed the laboratory director did not document review of the following proficiency testing evaluations: a) AAFP 2022 Event A b) AAFP 2022 Event B b) AAFP 2022 Event C d) API 2023 1st Event 3. In interview June 27, 2023 at 10:29 a.m., the Technical Consultant confirmed the proficiency testing evaluations were not reviewed by the laboratory director.
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 the laboratory's policy and procedure manual and quality control records, as well as interview with personnel, the laboratory failed to follow their policy for new lots of hematology quality control for three (3) of three (3) lots reviewed. Findings: 1. Observation by surveyors during the laboratory tour on June 27, 2023 at 8:49 a.m. revealed the laboratory utilized Eightcheck-3WP X-TRA hematology quality controls on the Sysmex pocH-100i. 2. Review of the laboratory's

	"Complete Blood Count Policy" revealed "Starting a New Lot of Controls...Parallel test new controls by analyzing the three (3) levels of control a minimum of twice a day for 5 days, prior to expiration of the previous lot. After a minimum of 10 data points are accumulated, enter the new targets using the mean of the analyzed points (optional)."" 3. Review of quality control records for the following lots of Eightcheck-3WP X-TRA hematology quality control revealed the laboratory did not test new lots of quality control per laboratory policy for the following lots of quality control: a) Lot 23610710 Low Abnormal, Lot 23610711 Normal, 23610712 High Abnormal; Expiration Date April 5, 2023: Ten (10) runs on January 10, 2023 b) Lot 30800710 Low Abnormal, Lot 30800711 Normal, 30800712 High Abnormal; Expiration Date June 8, 2023: Ten (10) runs on March 31, 2023 c) Lot 31640710 Low Abnormal, Lot 31640711 Normal, 31640712 High Abnormal; Expiration Date September 20, 2023: Ten (10) runs on June 20, 2023 4. In interview on June 27, 2023 at 11:28 a.m., the Technical Consultant confirmed the laboratory was not following their policy for parallel testing new lots of quality control.
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 observation; review of the laboratory's policy and procedure manual, patient test records, and the manufacturer's instructions for use; as well as interview with laboratory personnel, the laboratory failed to establish a complete policy for complete blood count testing. Findings: 1. Observation by surveyors during the laboratory tour on June 27, 2023 at 8:49 a.m. revealed the laboratory utilized the Sysmex pocH-100i for complete blood count testing. 2. Review of the laboratory's policy "Complete Blood Count (CBC) on the Sysmex pocH-100i" under the section "Limitations of Procedure" revealed "Any flags will be reviewed by physician and slide review performed at his/her request." 3. Review of patient test records revealed asterisk flags on three (3) of six (6) patient records reviewed: a) Chart 18588 - Asterisk flag on platelet result b) Chart 14376 - Asterisk flag on platelet result c) Chart 3269 - Asterisk flag on platelet result 4. Further review of the laboratory's policy and procedure manual revealed the laboratory did not identify all flags to include, but not limited to, the asterisk flag. 5. Review of the manufacturer's instructions for use revealed the

	asterisk flag interpretation is "Result is unreliable." 6. In interview on June 27, 2023 at 2:30 p.m., Testing Personnel 2 confirmed the laboratory's policy did not identify all manufacturer result flags and the action to take if such flags occur.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's requirements, and interview with personnel, the laboratory failed to document the open and expiration date for hematology quality control (QC) material as required. Findings: 1. Observation by surveyors during the laboratory tour on June 27, 2023 at 8:49 am revealed the laboratory utilized Sysmex Eightcheck-3WP X-TRA quality control material for hematology testing on the Sysmex Poch 100-I. 2. Further observation revealed the following open quality control vials with June 12, 2023 written on them: X-TRA-L - LOT 30800710, Manufacturer's expiration date: June 28, 2023 X-TRA-N - LOT 30800711, Manufacturer's expiration date: June 28, 2023 X-TRA-H - LOT 30800712, Manufacturer's expiration date: June 28, 2023 3. In interview on June 27, 2023 at 9:09 a.m., Testing Personnel 1 stated the date written on the quality control vials identified above was the open date of the vials. 4. Review of the Sysmex Eightcheck-3WP X-TRA package insert revealed "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8 degrees Celsius after being re-capped." 5. In interview on June 27, 2023 at 9:09 a.m., Testing Personnel 1 confirmed the open expiration date was not written on the quality control vials identified above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's requirements and patient test records, as well as interview with personnel, the laboratory failed to ensure hematology quality control material is not used beyond its expiration date. Findings: 1. Observation by surveyors during the laboratory tour on June 27, 2023 at 8:49 am revealed the laboratory utilized Sysmex Eightcheck-3WP X-TRA quality control material for hematology testing on the Sysmex Poch 100-I. 2. Further observation revealed the following open quality control vials with June 12, 2023 written them: X-TRA-L - LOT 30800710, Manufacturer's expiration date: June 28, 2023 X-TRA-N - LOT 30800711, Manufacturer's expiration date: June 28, 2023 X-TRA-H - LOT 30800712, Manufacturer's expiration date: June 28, 2023 3. Review of the Sysmex Eightcheck-3WP X-TRA package insert revealed "Opened and recapped vials and vials whose

	caps have been pierced will retain stability for 14 days if stored at 2-8 degrees Celsius after being re-capped." 4. In interview on June 27, 2023 at 9:09 a.m., Testing Personnel 1 stated the date written on the quality control vials identified above was the open date of the vials. She also confirmed the open expiration date of the vials was June 26, 2023 and the vials were expired. 5. Review of patient test records revealed one patient was tested (chart 3269) on June 27, 2023 after expired quality control material was utilized on the hematology instrument.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation, review of maintenance records, and 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 seventeen (17) months reviewed for 2022 and 2023. Findings: 1. Observation by surveyors during the laboratory tour on June 27, 2023 at 8:49 a.m. revealed the laboratory utilized the Sysmex pocH-100i for complete blood count testing. 2. Review of maintenance records for the Sysmex pocH-100i revealed the laboratory was required to perform and document "Clean transducer" every two weeks. 3. Further review of maintenance records revealed the laboratory failed to perform and document maintenance every two weeks for the following months: a) June 2022: One (1) of two (2) cleanings not performed b) July 2022: One (1) of two (2) cleanings not performed c) December 2022: One (1) of two (2) cleanings not performed d) January 2023: Two (2) of two (2) cleanings not performed e) April 2023: One (1) of two (2) cleanings not performed 4. In interview on June 27, 2023 at 1:45 p.m., the Technical Consultant confirmed the maintenance identified above was not performed and documented.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's policy and procedure manual and calibration records, as well as interview with personnel, the laboratory failed to perform calibration of the Sysmex pocH-100i annually as required by the laboratory for one (1) of two (2) years reviewed. Findings: 1. Observation by surveyors during

	the laboratory tour on June 27, 2023 at 8:49 a.m. revealed the laboratory utilized the Sysmex pocH-100i for complete blood count testing. 2. Review of the laboratory's policy "POCH-100I CALIBRATION FREQUENCY" revealed "Calibrations on the POCH-100i analyzer will be performed annually following the instructions provided in the analyzer operating manual." 3. Review of the Sysmex pocH-100i calibration records revealed the laboratory did not perform a calibration in 2022. 4. In interview June 27, 2023 at 2:42 p.m., Testing Personnel 2 confirmed the laboratory did not perform a calibration on the Sysmex pocH-100i in 2022.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to have Quality Assurance monitors in place to identify and correct quality issues in Analytic Systems. Findings: 1. The laboratory failed to follow the laboratory's policy for new lots of hematology quality control for three (3) of three (3) lots reviewed. Refer to D5401. 2. The laboratory failed to establish a complete policy for complete blood count testing. Refer to D5403. 3. The laboratory failed to document the open expiration date for hematology quality control (QC) material as required. Refer to D5415. 4. The laboratory failed to ensure hematology quality control material is not used beyond its expiration date. Refer to D5417. 5. The laboratory failed to ensure maintenance for the Sysmex pocH-100i was performed and documented every two weeks for five (5) of seventeen (17) months reviewed for 2022 and 2023. Refer to D5429. 6. The laboratory failed to perform annual calibration of the Sysmex pocH-100i annually as required by the laboratory for one (1) of two (2) years reviewed. Refer to D5437.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the Laboratory Director failed to provide overall direction and management to the laboratory. Refer to D3037.

D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) 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. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 (Laboratory Personnel Report) form, personnel records, and interview with laboratory personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of Technical Consultant. Findings: 1. Review of the laboratory's CMS 209 form revealed Personnel 4 was listed as the Technical Consultant. 2. Review of personnel records for Personnel 4 revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Technical Consultant to Personnel 4. 3. In interview on June 27, 2023 at 10:36 a.m., Personnel 4 confirmed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Technical Consultant to him.
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 for accurate and reliable results. Refer to D5437.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Findings: 1. The laboratory failed

	to ensure that proficiency testing (PT) was performed by personnel who routinely perform laboratory testing for five (5) of five (5) events reviewed. Refer to D2007. 2. The laboratory failed to test proficiency testing (PT) samples the same number of times as patients are routinely tested for five (5) of five (5) events reviewed. Refer to D2010.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to follow the laboratory's policy for new lots of hematology quality control for three (3) of three (3) lots reviewed. Refer to D5401. 2. The laboratory failed to document the open expiration date for hematology quality control (QC) material as required. Refer to D5415.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5791 and D5793.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5417.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5429.
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 record review 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 establish a complete written policy for competency assessment that included problem solving. Refer to D5209. 2. The Technical Consultant failed to ensure testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples for one (1) of two (2) testing personnel. Refer to D6051. 3. The Technical Consultant failed to ensure competency assessments for two (2) of two (2) laboratory testing personnel included assessment of problem solving skills for moderate complexity testing in 2022 and 2023. Refer to D6052.
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 observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.
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 surveyors, 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 retain proficiency testing records for one (1) of five (5) events reviewed for at least two (2) years. Refer to D3037. 2. The laboratory failed to follow the laboratory's policy for new lots of hematology quality control for three (3) of three (3) lots reviewed. Refer to D5401. 3. The laboratory failed to establish a complete policy for complete blood count testing. Refer to D5403. 4. The laboratory failed to document the open expiration date for hematology quality control (QC) material as required. Refer to D5415. 5. The laboratory failed to ensure hematology quality control material is not used beyond its expiration date. Refer to D5417. 6. The laboratory failed to ensure maintenance for the Sysmex pocH-100i was performed and documented every two weeks for five (5) of seventeen (17) months reviewed for 2022 and 2023. Refer to D5429. 7. The laboratory failed to perform calibration of the Sysmex pocH-100i annually as required by the laboratory for one (1) of two (2) years reviewed. Refer to D5437.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review the laboratory's CMS-209 (Laboratory Personnel Report) form and personnel records as well as interview with personnel, the Technical Consultant failed to ensure testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples for one (1) of two (2) testing personnel. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the following testing personnel: Testing Personnel 1 Testing Personnel 2 2. Review of the laboratory's personnel records revealed the following documentation on the laboratory's competency assessment forms for

	Testing Personnel 1: 2022 - Unknown Sample - March 18, 2022 2023 - Unknown Sample - March 21, 2023 3. Further review of personnel records revealed the laboratory did not have documents to support the performance of blind sample testing by Testing Personnel 1for 2022 and 2023. 4. In interview on June 27, 2023 at 2:01 p. m., the Technical Consultant confirmed the laboratory did not have raw data to support blind testing performance by Testing Personnel 1 for 2022 and 2023.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 (Laboratory Personnel Report) form and personnel records as well as interview with laboratory personnel, the Technical Consultant failed to ensure competency assessments for two (2) of two (2) laboratory testing personnel included assessment of problem solving skills for moderate complexity testing in 2022 and 2023. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the following testing personnel: Testing Personnel 1 Testing Personnel 2 2. Review of 2022 and 2023 personnel records revealed competency assessment forms documenting problem solving for the following testing personnel: a) Testing Personnel 1: - Problem solving February 11, 2022 - Problem solving March 16, 2023 b) Testing Personnel 2: - Problem solving February 11, 2022 - Problem solving March 16, 2023 3. Further review of the personnel records revealed no documentation to support competency assessment of problem solving skills. 4. In interview on June 27, 2023 at 11:50 a.m., the Technical Consultant confirmed the laboratory did not have records to support the assessment of problem solving skills for the testing personnel identified above.