Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2119640	08/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Frederick P Smith, Md, Pc, Division Of Rcca	5530 Wisconsin Avenue Suite 1640, Chevy Chase, MD	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the testing person (TP), the laboratory failed to ensure that PT results were reviewed by the laboratory director (LD) or designee for two of five PT events. Findings: 1. The records for five PT events were reviewed. 2. The results evaluations were not signed as reviewed by the LD or designee for two of five PT events (2024 2nd and 3rd). 3. During the exit interview on 07/11/2025 at 1:50 PM, the TP confirmed that two of five PT results were not reviewed by the LD or designee.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the testing person (TP), the new laboratory director failed to approve, sign, and date the procedure manual. Findings: 1. The new laboratory director began at the end of 02/2025. 2. During the exit interview on 07/11/2025 at 1:50 PM, the TP confirmed that the new laboratory director had not reviewed, approved, and signed the procedure manual.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (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. This STANDARD is not met as evidenced by: Based on review of the procedure manual, temperature logs, quality assessment (QA) forms, and monthly maintenance logs, and interview with the testing person (TP), the laboratory failed to consistently document and monitor room temperature (RT), humidity, and refrigerator temperatures (FT) in 8 of 23 months reviewed. Findings: 1. The "Quality Assessment" procedure stated that the "Temperatures will be recorded for room temperature (RT), room humidity, and for all refrigerators and freezers used by the laboratory for storage of reagents, controls, and calibration materials. This information and any corrective actions needed for out-of-range results will be documented on a log." 2. The laboratory monitored temperatures monthly using the "QA Tracking Sheet Temperature and Humidity Logs" (QA form). The QA forms included the questions "Were room temperature and humidity recorded each day of testing" and "Were refrigerator temperatures recorded each day of testing" with a section to check "Yes," "No," or "N/A." 3. Temperature logs and QA forms were reviewed for 08/2023-06/2025 for a total of 23 months. 4. In 10/2023, RT, humidity, and FT were not documented on 16 of 22 days instrument maintenance was recorded. The 10/2023 QA form indicated that RT, humidity, and FT were recorded each day of testing. 5. In 11/2023, RT, humidity, and FT were not documented on 18 of 20 days instrument maintenance was recorded. The 11/2023 QA form indicated that RT, humidity, and FT were recorded each day of testing. 6. In 12/2023, RT, humidity, and FT were not documented on 5 of 20 days instrument maintenance was recorded. The 12/2023 QA form was missing. 7. In 02/2024, RT, humidity, and FT were not documented on 13 of 21 days instrument maintenance was recorded. The 02/2024 QA form indicated that RT, humidity, and FT were recorded each day of testing. 8. In 03 /2024, humidity was not documented on 20 of 21 days that RT and FT were recorded. The 03/2024 QA form indicated that humidity was recorded each day of testing. 9. In 06/2024, humidity was not documented on 5 of 20 days that RT and FT were recorded. The 06/2024 QA form indicated that humidity was recorded each day of testing. 10. In 09/2024, humidity was not documented on 3 of 21 days that RT and FT were recorded. The 09/2024 QA form indicated that humidity was recorded each day of testing. 11. In 01/2025, FT was not documented on five of 22 days that RT and humidity were recorded. The 01/2025 QA form indicated that FT was recorded each day of testing. 12. During the exit interview on 07/11/2025 at 1:50 PM, the TP confirmed that RT, humidity, and FT were not consistently documented.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (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. This STANDARD is not met as evidenced by: Based on review of the quality control (QC) procedure, QC records, and quality assessment (QA) review forms, and interview with the testing person (TP), the laboratory failed to document corrective actions taken when QC results did not meet acceptability criteria in one of six months reviewed. Findings: 1. The "Quality Control" procedure stated that: a. "All QC results will be reviewed by the Technical Consultant or Lab Director on a monthly basis. This review will be documented by the completion of the QA Tracking Sheet for Quality Control." b. "A minimum of 3 levels of QC will be run each day for hematology testing on the Sysmex XS1000i system in the laboratory." c. "Remedial action(s) for all out-of-range control values will be documented prior to testing patient samples or reporting patient results." d. "If 2 of the 3 controls are within acceptable limits, it is permissible to report patient values." e. "Document all corrective actions taken to resolve the problems." 2. The QA Tracking Sheet for QC was to be completed monthly and included sections to document that "QC was performed each day of patient testing, or as dictated by alternative QC procedures, and within acceptable range prior to testing patients" and "Corrective action was taken and documented if problems occurred." 3. The QC "Levey-Jennings Report" (L-J report) was reviewed for a total of six months (January-March in 2024 and 2025). The L-J reports for 03/2024 were missing. 4. There was a separate L-J report for each level of QC (low, normal, and high) for each analyte tested. 5. The L-J reports for 01/2024 showed that the QC for white blood cells (WBC) and neutrophils (Neut) did not meet acceptability criteria for two out of three QC (normal and high levels) tested on 01/23/2024 (one of 20 days in 01/2024). The QC was not repeated on 01/23/2024 and there were no documented remedial actions. 6. The QA Tracking Sheet for QC was missing for 01/2024 and 01/2025 to document review by the laboratory director (LD) or technical consultant (TC) and the reviews for 02/2025 and 03/2025 were not performed by the LD or TC. 7. There were no documented remedial actions for all out-of-range QC values, as stated in the procedure, when only a single level didn't meet acceptability criteria. For example, the high level QC did not meet acceptability criteria for WBC, hemoglobin, hematocrit, platelets, and Neut on 01/29/2024. The high level QC was not repeated on 01/29 /2025. The other two levels of controls were acceptable either initially or on repeat testing, however, this was not documented on the L-J report. 8. During the exit interview on 07/11/2025 at 1:50 PM, the TP confirmed that corrective actions were not documented when two out of three QC results did not meet acceptability criteria on 01/23/2024.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (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; This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) records and interview with the testing

person (TP), the laboratory director (LD) failed to ensure that monthly QA forms were completed and maintained and were able to identify failures in quality as they occurred. Findings: 1. The "Quality Assessment" procedure stated: a. "The major processes or systems to be evaluated are organized by month. The frequency of QA reviews will vary depending on the area of review. Areas that are particularly problematic or have a greater potential to affect the quality of patient test results will be reviewed at a greater frequency. Monthly checklists are provided for each of these reviews." b. "The following criteria will be reviewed using the QA Tracking Sheet for Proficiency Testing: 1. Receipt of specimens 2. PT reports assessment" c. "The laboratory must evaluate the quality control program monthly." d. "The lab must ensure that temperature requirements for instrument and testing are met, that storage temperatures for reagents and controls and calibrators are maintained within range, and that humidity levels are within acceptable limits for operation of any instrumentation." 2. The QA binder included the "Quality Assurance Monitoring Schedule 2022" that listed which area was due for review each month. a. The "Complaints/Problem Log review," "QC," and "Temp. Humidity Logs" were due each month. b. "Proficiency Test Evaluations" were due in April, August, and December. c. "Instrument Maintenance Records" were due in March and September. d. "Personnel Testing Evaluation" was due in July. e. "Calibrations" were due in January and August but were "Subject to change due to maintenance/service." 3. Monthly QA logs were reviewed for 08/2023-06/2025 for a total of 23 months. 4. A new LD began at the end of 02/2025. There was no documentation that the new LD reviewed any QA forms since starting in the role. 5. Beginning in 10/2024, the logs were reviewed by TP #2 (11/2024, 12/2024, 01/2025, 02/2025, 03/2025, and 05/2025). 6. All QA logs were missing for 04/2025 and 06/2025. 7. The monthly QA Tracking Sheets for Temperature and Humidity Logs were missing in two of 23 months reviewed (08 /2023 and 12/2023). 8. The QA Tracking Sheet for Temperature and Humidity Logs indicated that room temperature, humidity, and refrigerator temperatures were recorded each day of testing for seven of eight months where the temperature logs were missing entries and was missing for the remaining one of eight months. Cross-refer to tag D5413 for details. 9. The monthly QA Tracking Sheets for Quality Control were missing in three of 23 months reviewed (01/2024, 08/2024, and 01/2025) including when corrective actions were not documented when QC results didn't meet acceptability criteria. Cross-refer to tag D5783 for details. 10. The following QA Tracking Sheets were present in the QA binder, but were signed as reviewed when the form was not filled out. a. 12/2023: Quality Control was not completed and was signed by the previous LD on 01/09/2024 b. 03/2024: Instrument Maintenance was not completed and was signed by the previous LD on 04/01/2024 c. 05/2024: Two copies of the Temperature and Humidity Logs were not completed and were signed by the previous LD on 06/05/2024 and 06/07/2025 d. 10/2024: Temperature and Humidity Logs was not completed and was signed by TP #2 on 11/04/2024 e. 11 /2024: Quality Control and Calibration Review were not completed and were signed by TP #2 on 12/06/2024 f. 12/2024: Temperature and Humidity Logs, Complaints /Problem Log Review, and Quality Control were not completed and were signed by TP #2 on 01/06/2025 11. The QA Tracking Sheet for "Personnel Testing Evaluation" was missing in 07/2024. There were no records that competency assessments were performed for the testing personnel in 2024 or 2025. 12. There was a section in the QA Tracking Sheet for "Proficiency Testing" to confirm that "All proficiency testing reports were reviewed and the review was documented by testing personnel and Lab Director." Two out of five PT events were not documented as reviewed by the LD or designee. Cross-refer to tag D5211 for details. 13. During the exit interview on 07/11 /2025 at 1:50 PM, the TP confirmed that monthly QA forms were missing and were signed when not filled out.

D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of personnel credentials and interview with the testing person, the laboratory could not provide documentation demonstrating that any personnel qualified as the technical consultant for the specialty of hematology (D6035).
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December

	28, 2024. This STANDARD is not met as evidenced by: Based on review of personnel credentials and interview and email communication with the testing person, the laboratory could not provide documentation demonstrating that any personnel qualified as the technical consultant (TC) for the specialty of hematology. Findings: 1. The Laboratory Personnel Report (form CMS-209) listed the laboratory director (LD) as the clinical consultant and the TC and then four testing personnel (TP). 2. The laboratory changed laboratory directors at the end of 02/2025. 3. The previous LD signed a letter on 01/03/2024 delegating responsibilities that can be delegated to the TC to TP #2 and TP #4 including performing quality control reviews, enrolling the laboratory in approved proficiency testing (PT) programs, and ensuring that PT results were reviewed and corrective actions taken for any unacceptable results. 4. Credentials available in the laboratory at the time of the onsite survey on 07/11/2025 could not determine whether the LD, TP #2, and TP #4 could qualify to be the TC. 5. During the exit interview on 07/11/2025 at 1:50 PM, the TP confirmed that personnel records could not determine whether personnel were qualified as the TC. 6. Emails were sent on 07/15/2025, 07/25/2025, and 08/05/2025 to request the transcripts for TP #2 and TP #4 and documentation that the LD had at least one year of clinical laboratory training or experience, or both, in nonwaived testing for hematology. 7. As of 08/15/2025, the documentation had not been received.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the testing person, the technical consultant failed to ensure that all testing personnel (TP) were evaluated for competency annually. Findings: 1. The Laboratory Personnel Report (form CMS-209) listed four TP. 2. The last competency assessment performed for all four TP was documented on 03/16/2023. There was no documentation of competency assessments performed in 2024 or 2025. 3. During the exit interview on 07/11/2025 at 1:50 PM, the testing persone confirmed that competency assessments were not performed for 2024 and 2025.