Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1020567	(X3) Date Survey Completed 10/16/2024
Name of Provider or Supplier Chop A Division Of Rcca- Md	**Street Address, City, State** 9715 Medical Center Dr Ste 221, Rockville, 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
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 and interview, the laboratory did not provide the lot number and expiration date of the lyse and wash solutions used for testing on the hematology analyzer for 1 of 4 records requested, to ensure that an event such as a reagent recall may be investigated. Findings: 1. The laboratory did not provide the lot number and expiration dates for the hematology reagents for November 2022, to show that the records are maintained for the required two year retention. 2. During interview with the technical consultant at 11:00 am on 10/16/2024, the technical consultant stated that the analyzer will not operate without registering the in date reagents lot numbers, and that the analyzer stored the records for at least two years, but was unable to provide the November 2022 records to confirm this.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system

	performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not document weekly reviews of Levey-Jennings charts from the hematology analyzer to monitor shifts and trends, as stated in the laboratory's written procedure. Findings: 1. The laboratory written procedure states that Levey-Jennings charts are reviewed weekly to detect shifts or trends of test results for each of the three levels of quality control reagents in use to check accuracy of the test system. The laboratory did not document these weekly reviews. 2. This was confirmed during interview with the technical consultant at 11:00 am on 10/16/2024.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview, the hematology laboratory did not perform a random review of five patient charts annually as stated in the written procedure. Findings: 1. The laboratory written procedure states that the laboratory conducts an annual review of five random patient charts to check the reliability of patient hematology test result entry and orders. The laboratory did not perform the annual reviews for 2023. 2. This was confirmed during interview with the technical consultant on 10/16/2024 at 11;00 am.