Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1020567	04/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Chop A Division Of Rcca- Md	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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to retain the attestation worksheets for one of four PT events reviewed. Findings: 1. The PT records for 2022 and 2023 were reviewed for a total of four PT events. 2. The signed attestation statement documenting that PT samples were tested in the same manner as patient specimens was missing for one of the four PT events reviewed (2023 1st event). 3. During the survey on 04/28/2023 at 1:15 PM, the TC confirmed that the signed attestation statement was missing for one of four PT events reviewed.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the recertification survey completed on 10/08/2021 for not retaining all hematology quality control (QC) results. The laboratory's plan of correction stated that this would be corrected by 10/29 /2021. Based on review of the procedure manual, review of quality control (QC) records, and interview with the technical consultant (TC), the laboratory failed to retain hematology QC package inserts and QC results for a minimum of two years. Findings: 1. The "Quality Control" procedure stated that "The package insert which comes with the controls contains all the values for each level of control, and is set up for barcoded entry of values into the Medonic M-series analyzer ...The Quality Control package insert must be saved for a minimum of 2 years." 2. The "Quality Control Protocol" stated that "Acceptable ranges are specified in package inserts which are kept with quality control records." 3. The QC records did not contain the package inserts from the manufacturer's assayed QC material. 4. The "Quality Control" procedure stated that "QC results obtained from every run must be documented and saved for a minimum of two years." 5. Every month the QC results were printed out, reviewed by the TC, and retained with the QC records. 6. Review of QC records from 11/08/2021-03/31/2023 showed that QC results from 02/01/2022-02 /08/2022 and 05/02/2022-06/14/2022 were missing. 7. During the survey on 04/28 /2023 at 1:15 PM, the TC confirmed that the hematology QC package inserts were not retained and the QC results for 02/01/2022-02/08/2022 and 05/02/2022-06/14/2022 were missing from the records.
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 review of the procedure, review of the product insert, observation, and interview with the technical consultant (TC), the laboratory failed to label the vial of opened hematology quality control (QC) material with the updated expiration date. Findings: 1. The "General Laboratory Operational Policies" stated that "All items used in the laboratory must be marked with Date Opened/In Use. If the expiration date is changed due to Open Date - the 'new' expiration date must be indicated as well." 2. The product insert for the hematology QC stated an open vial stability of 14 days and the "Quality Control" procedure stated "QC material must not be tested beyond the expiration date on the package. Opened vials must not be tested beyond the opened expiration date of 14 days." 3. The opened and in use QC material located in the fridge was labeled with an opened date of 04/17/2023. The updated open vial expiration date of 05/01/2023 was not documented on the QC vial. 4. During the survey on 04/28/2023 at 1:15 PM, the TC confirmed that the opened QC vial was not labeled with the updated expiration date.
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 review of manufacturer's user's manual, review of maintenance records, and interview with the technical consultant (TC), the laboratory failed to perform and document all monthly maintenance activities for the hematology analyzer. Findings: 1. The laboratory used a Medonic M-series analyzer for hematology testing. 2. The manufacturer's user's manual listed "Clot Prevention" as one of the monthly maintenance activities and stated "This process will decrease the risk of debris material building up in the instrument system. This should be performed at least once a month or every 1000 samples." 3. The TC stated that the laboratory tested an estimated 3,000 samples annually. 4. The Medonic monthly maintenance checklists were reviewed from 01/2022-04/2023 and the performance of "Clot Prevention (Enzymatic)" activity was not documented as performed for 16 of 16 months reviewed. 5. During the survey on 04/28/2023 at 1:15 PM, the TC confirmed that the clot prevention maintenance activity was not documented as performed from 01/2022-04/2023.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the procedure manual, review of quality control (QC) records, and interview with the technical consultant (TC), the laboratory failed to consistently perform parallel testing of new hematology QC lots to verify performance as stated in the procedure. Findings: 1. The "Quality Control Protocol" stated that "Parallel testing of new lot numbers of QC should be performed at least once, but preferably several days by different operators, to confirm validity of new controls before being put into use. This should be documented accordingly." 2. The "Quality Control" procedure stated that "New Lot Numbers of QC materials should be overlapped with existing lot numbers at least once to ensure proper reactivity." 3. The QC records from 11/08 /2021-03/31/2023 were reviewed and contained results for a total of 11 lot numbers. 4. Records showed that 8 of 11 hematology QC lots were not parallel tested prior to

	being put into use. 5. During the survey on 04/28/2023 at 1:15 PM, the TC confirmed that all new hematology QC lots were not consistently being parallel tested prior to being put into use.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the procedure manual and critical value logs and interview with the technical consultant (TC), the laboratory failed to document the date and time providers were notified when patient test results were critical values. Findings: 1. The "Panic Logs" procedure stated "Prior to releasing result, the critical value is reported in person or via telephone to ordering provider or authorized designee. Document date, time and name of individual notified and initials of technician responsible for reporting." 2. The critical value log had a section to record the "Date/Time" that the providers were notified of critical values. 3. Review of critical value reporting logs showed that the testing personnel were not documenting the date and time the providers or authorized designees were notified of critical values. 4. During the survey on 04/28/2023 at 1:15 PM, the TC confirmed that the testing personnel were not documenting the date and time when providers were notified of critical values.
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 review of monthly quality assessment (QA) reviews and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that the QA program monitored the overall quality of laboratory services provided. Findings: 1. "Quality Assessment Review" forms (QA review) were completed about every month. The forms included a section to enter the "Period of Review" and the signature and date of review for the TC and LD. There was a QA review form for "Quality Control" and "Quality Assurance Log Reviews" each listing activities to be reviewed each month. After each activity there was a space to document a check mark for "YES," "NO," or "N/A." There was a section at the bottom of both forms to document comments. 2. One of the items on the list of the "Quality Assurance Log Reviews" QA review form was "Panic Value Reporting." None of the QA reviews made a note that the testing personnel were not documenting the date and time the providers were notified of the critical values (refer to tag D5813 for details). 3. One of the items on the list of the "Quality Control" QA review form was "Lot # documented, expiration date checked, ranges verified." The lot numbers, expiration dates, and ranges would

	have been verified against the package inserts from the hematology QC material. All QA reviews documented a check mark for "YES" for this QA activity. The QA review did not ensure that the QC package inserts used for verification were maintained for at least two years (refer to tag D3031 for details). 4. The "Quality Assurance Log Reviews" QA review for the period of 01/21/2023-02/17/2023 documented a check mark under "YES" for the questions "Were any Panic Values obtained in testing?" and "Were values reported and repeated back for verification?" During this period of time, no critical values were reported to providers. The QA review was signed by the TC and LD on 02/17/2023. 5. The "Quality Control" QA review for the period of 01/21/2023-02/17/2023 contained a written note that QC lot 222123 was parallel tested prior to use. The QC printouts showed that QC lot 222123 was first tested on 02/02/2022 and the previous lot, lot 222093, was last tested on 01 /31/2023. There were no records showing that lot 221123 was parallel tested with lot 22093 prior to being put into use (refer to tag D5469 for details). The QA log was signed by the TC and LD on 02/17/2023. 6. The QC records, including the results and Levy-Jennings graphs, were missing from 05/02/2022-06/14/2022 (refer to tag D3031 for details). The "Quality Control" QA review for the period of 05/07/2022-06/03 /2022 documented a check mark under "YES" for the statement "Levy Jennings graphs printed for evaluation." The QA review was signed by the TC and LD on 06/03 /2022. 7. During the survey on 04/28/2023 at 12:45 PM, the TC confirmed that the activities listed on the QA review forms were sometimes check marked without close review or documentation of issues found with the performance of each activity.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: The technical consultant failed to ensure that the testing personnel were retaining quality control (QC) package inserts, were performing all preventive maintenance activities required for the hematology analyzer, and were performing parallel testing on all new hematology QC lots. Refer to tags D3031, D5429, and D5469, respectively, for details.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: The testing personnel failed to document the date and time providers or authorized designees were notified of critical values according to the procedure. Cross refer to tag D5813 for details.
D6071	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(2)

	Each individual performing moderate complexity testing must maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples. This STANDARD is not met as evidenced by: The testing personnel failed to ensure the proficiency testing (PT) attestation statement was maintained with the PT records. Cross refer to tag D2015 for details.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of the procedure manual, quality control (QC) records, and instrument preventive maintenance records and interview with the technical supervisor (TS), the testing personnel (TP) failed to follow the procedure manual for QC and instrument maintenance activities. Findings: 1. The TP failed to retain QC package inserts. Cross refer to tag D3031 for details. 2. The TP failed to label the opened QC vials with the updated expiration date. Cross refer to tag D5415 for details. 3. The TP failed to document the performance of the clot prevention monthly routine maintenance activity. Cross refer to tag D5429 for details. 4. The TP failed to consistently perform parallel testing to validate new lots of QC material. Cross refer to tag D5469 for details. 5. During the survey on 04/28/2023 at 1:15 PM, the TC confirmed that the TP were not following the laboratory's procedure manual.