Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1020567	10/23/2018
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the federal proficiency testing data, onsite proficiency testing data , and interview of the technical consultant (TC), the laboratory failed to successfully participate in the American Proficiency Institute proficiency testing program for hematology testing, in which the laboratory is certified under CLIA (Refer to D2131)
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two

	consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the federal proficiency testing data, onsite proficiency testing data , interview of the technical consultant (TC) and the testing person (TP), the laboratory failed to successfully participate in the American Proficiency Institute proficiency testing (PT) program for hematology testing, in which the laboratory is certified under CLIA. Findings: 1. The laboratory did not submit PT samples for the 2018 1st and 2nd event hematology. 2. The TC and the TP stated that the samples were not sent by the PT agency and therefore were not completed.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation of the chemistry analyzer around 12 Noon, interview with the technical consultant, and the testing person, the laboratory failed to ensure that the chemistry analyzer internal temperature was within the manufacturers optimal testing range for delivering accurate and reliable patient test results (Refer to D5413); And evaluations of the analyzer analytic quality and corrective action procedures were not perform to fix the chemistry analyzer prior to reporting patient test results. (Refer to D5791)
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 review of the written procedure manual, interview with the technical consultant (TC), and the testing person (TP), the laboratory did not have written procedures for all areas of laboratory testing. Findings: 1. The TP stated that Friday of every week frozen urine specimens are transported to one of the sister locations for testing. 2. The laboratory did not have written step by step instructions and procedures for the collection, labeling, storage, transportation, and receiving patient results once the test is completed at the sister location for the inhouse testing personnel to follow. 3. The TP and the TC confirmed that written procedures for frozen specimens were not available.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 observation of the chemistry analyzer around 12 Noon, interview with the technical consultant (TC), and the testing person (TP), the laboratory did not ensure that the chemistry analyzer internal temperature was within the manufacturers optimal testing range for delivering accurate and reliable patient test results. Findings: 1. The TP documented on the "action log" in July 2018 that the chemistry analyzer internal refrigerator was down. 2. The TP called technical support. The TP stated that the tech recommended while onsite that the internal carousel should be refrigerated until the unit is fixed and patient testing can continue. 3. On the day of the survey the analyzer internal temperature showed 12.0 Degrees Celsius. 4. The manufactures range states that the internal analyzer temperature should be between 1.0 and 6.5 Degrees Celsius. 5. The laboratory did not repeat the step of refrigerating the analyzer carousel throughout the day to maintain the temperature within the manufacturers specified range. 6. The TP would remove the analyzer carousel, refrigerated the carousel, take the carousel out of the refrigerator on days patient testing was performed and run specimens throughout the day 7. The laboratory did not record the analyzer internal temperature throughout the day when patient testing was performed to ensure that the analyzer was within the manufacturers test range. The analyzer temperature could be seen on the monitor and was shown to be out of range on the day of the survey. 8. The TP stated that she put the carousel in the laboratory refrigerator overnight and remove the carousel in the morning of patient testing. 9. The TP stated that the temperature has not been in range since she reported it to the TC and the laboratory director back in July 2018. 10. The TC and the TP confirmed that the analyzer temperature was not documented when out of range and the carousel was not refrigerated throughout the day of patient testing to maintain the manufacturers temperature range.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of chemistry calibration records, interview with the technical consultant (TC), and the testing person, the laboratory did not perform calibration verification procedures for all areas of the laboratory where patient testing is performed. Findings: 1. The laboratory did not perform calibration verification procedures at least every six months for chemistry testing. 2. The TC stated that they perform calibration verification procedures for the chemistry analyzer but was unable to find where the records are stored.
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 of the chemistry analyzer around 12 Noon, interview with the technical consultant (TC), and the testing person (TP), the laboratory did not ensure that the chemistry analyzer internal temperature was within the manufacturers optimal testing range for delivering accurate and reliable patient test results and did not document analytic systems quality assessment procedures. Findings: D5413 1. The TP documented on the "action log" in July 2018 that the chemistry analyzer internal refrigerator was down. 2. The TP called technical support. The TP stated on the "action log" that the tech recommended that the internal carousel should be refrigerated until the unit is fixed and patient testing can continue. 3. While onsite the technical representative did not leave a written report of the visit at the laboratory with steps and procedures that should be performed by laboratory personnel to ensure that accurate and reliable patient test results were reported. 4. On the day of the survey the

	analyzer internal temperature showed 12.0 Degrees Celsius while patient testing was being performed. The analyzer temperature could be seen on the monitor and was shown to be out of range on the day of the survey. 5. The manufactures range states that the internal analyzer temperature should be between 1.0 and 6.5 Degrees Celsius. 6. The laboratory did not take steps to correct and resolve the analyzer refrigerator problem once the TP identified the internal refrigerator was down and when the manufacturers tech support staff was onsite. 7. The laboratory did not document any further corrective action procedures after the initial write up performed by TP in July 2018 and did not document analytic systems quality assessment procedures while the analyzer internal temperature was not in range.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the patient final report, interview with the technical consultant, and the testing person (TP), the laboratory did not have the correct address printed on the final reports where the actual patient testing was performed. Findings: 1. Two patient final reports printed from the month of September 2018 and one report from the month of October 2018 did not have the 9715 Medical Center Drive, Rockville MD address printed on the final report to show where testing was performed. 2. The TP stated that the issue was reported to the information technology department a few months ago. And each time a patient report has to be printed she has to manually change the test location to the correct address.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the federal proficiency testing data, onsite proficiency testing data , and interview of the technical consultant, the laboratory director failed to ensure that the laboratory successfully participated in the American Proficiency Institute program for hematology testing, in which the laboratory is certified under CLIA. (Refer to D2131); failed to provide quality laboratory services for all aspects of patient testing (Refer to D6007); failed to ensure that an approved corrective action plan was followed when the laboratory failed to successfully participate in the American

	Proficiency Institute program for hematology testing(Refer to D6019); And failed to ensure that quality assessment procedures were maintained to ensure accurate and reliable patient testing (Refer to D6021)
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on observation of the chemistry analyzer around 12 Noon, interview with the technical consultant (TC), and the testing person (TP), the laboratory director (LD) failed to ensure that the chemistry analyzer internal temperature was within the manufacturers optimal testing range for delivering accurate and reliable patient test results and failed to provide quality laboratory services for all aspects of patient testing. Findings: Refer to D5413 and D5791 1. The TP documented on the "action log" in July 2018 that the chemistry analyzer internal refrigerator was down. 2. The TP called technical support. The TP stated that the tech recommended while onsite that the internal carousel should be refrigerated until the unit is fixed and patient testing can continue. 3. The LD failed to ensure that all corrective action procedures were performed and the chemistry analyzer was functioning properly before patient test results were reported. 4. The LD signed the "action log" report on August 3, 2018 after the TP reported the problem in July 2018.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the federal proficiency testing data, onsite proficiency testing data, interview of the technical consultant (TC), and the testing person (TP), the laboratory director failed to ensure that an approved corrective action plan was followed when the laboratory failed to successfully participate in the American Proficiency Institute PT program for hematology testing. Findings: Refer to D2131 1. The laboratory did not submit PT samples for the 2018 1st and 2nd event hematology. 2. The TC and the TP stated that the samples were not sent by the PT agency and therefore PT samples were not completed. 3. The laboratory director failed to perform corrective action procedures to ensure satisfactory completion of performing PT.

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 observation of the chemistry analyzer around 12 Noon, interview with the technical consultant (TC), and the testing person (TP), the laboratory director (LD) failed to ensure that the chemistry analyzer internal temperature was within the manufacturers optimal testing range for delivering accurate and reliable patient test results and failed to ensure that quality assessment (QA) procedures were maintained to ensure accurate and reliable patient testing. Findings: Refer to D5413 and D5791 1. The TP documented on the "action log" in July 2018 that the chemistry analyzer internal refrigerator was down. 2. The TP called technical support. The TP stated that the tech recommended while onsite that the internal carousel should be refrigerated until the unit is fixed and patient testing can continue. 3. The LD failed to ensure that all corrective action procedures, QA procedures were performed, and the chemistry analyzer was functioning properly before patient test results were reported. 4. The LD signed the "action log" report on August 3, 2018 after the TP reported the problem in July 2018.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY 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 chemistry calibration records, interview with the technical consultant (TC) and the testing person, the TC failed to ensure that calibration verification procedures were performed for all areas of the laboratory where patient testing is performed (Refer to D6040); failed to ensure that all technical problems involving the chemistry analyzer were resolved and documented when the analyzer did not meet the manufactures and laboratory criteria of acceptability. (Refer to D6043); And failed to ensure that all corrective action procedures were performed and the chemistry analyzer was functioning properly before patient test results were reported (Refer to D6044).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

	This STANDARD is not met as evidenced by: Based on review of chemistry calibration records, interview with the technical consultant (TC), and the testing person, the TC failed to ensure that calibration verification procedures were performed for all areas of the laboratory where patient testing is performed. Findings: Refer to D5439 1. The laboratory did not perform calibration verification procedures at least every six months for chemistry testing. 2. The TC stated that they perform calibration verification procedures for the chemistry analyzer but was unable to find where the records are stored.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on observation of the chemistry analyzer around 12 Noon, interview with the technical consultant (TC), and the testing person, the TC failed to ensure that the chemistry analyzer internal temperature was within the manufacturers optimal testing range for delivering accurate and reliable patient test results. Findings: D5413 and D5791 1. The TC failed to ensure that all technical problems involving the chemistry analyzer were resolved and documented when the analyzer did not meet the manufactures and laboratory criteria of acceptability.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on observation of the chemistry analyzer around 12 Noon, interview with the technical consultant (TC), and the testing person (TP), the TC failed to ensure that the chemistry analyzer internal temperature was within the manufacturers optimal testing range for delivering accurate and reliable patient test results. Findings: Refer D5413 and D5791 1. The TP documented on the "action log" in July 2018 that the chemistry analyzer internal refrigerator was down. 2. The TP called technical support. The TP stated that the tech recommended while onsite that the internal carousel should be refrigerated until the unit is fixed and patient testing can continue. 3. The TC failed to ensure that all corrective action procedures were performed and the chemistry analyzer was functioning properly before patient test results were reported. 4. The TC signed the "action log" report on August 3, 2018 after the TP reported the problem in July 2018.
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 written procedure, interview with the technical consultant, and the testing person, the testing person (TP) failed to follow the procedure when performing quality control (QC) testing. Findings: 1. The TP did not perform the new lot verification procedure on September 25, 2018 when the hematology QC lot number and expiration dates changed. 2. The written procedure states to perform the new lot verification each time controls are changed and run for five days to ensure that QC is acceptable. 3. The TP stated that she does perform the new lot verification procedure but she forgot to do it in September 2018.