Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0211975	(X3) Date Survey Completed 08/24/2022
Name of Provider or Supplier Rcca Md Llc- Chop	Street Address, City, State 18111 Prince Phillips Drive, Suite 327, Olney, 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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the technical consultant (TC) and laboratory director (LD), the laboratory failed to be constructed, and arranged, to provide a safe environment to protect testing personnel from potential chemical hazards and biohazardous materials. Findings: 1. The laboratory is required to implement safety policies and procedures to ensure safety for the testing personnel. The Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) provide guidelines for laboratory safety. 2. There are three analyzers in the laboratory space. The Medica EasyRA chemistry analyzer (W/D/H: 40"(inches) x 26" x 15") and Medonic M5 hematology analyzer (width (W)/depth (D)/ height (H): 16.97" x 14.33" x 19.53") are benchtop analyzers and the Tosoh AIA-900 immunoassay analyzer (W/D/H: 35.04" x 26.18" x 49.09") that stands alone. The lab has a portable air conditioner on the floor that vents through the ceiling and a refrigerator that is approximately (W/D/H: 18" x 25" x 36"). 3. The chemistry analyzer is on a table against the left wall. The benchtop space was overcrowded with two computer keyboards and the patient specimens were in a rack on top of the analyzer. 4. The immunoassay analyzer was along the back wall. There is about 10" between the table that holds the chemistry analyzer and the immunoassay analyzer extends in front of the chemistry analyzer by 26". The space in between is cluttered with at least six xerox size paper boxes and a gallon jug container. The immunoassay analyzer was cluttered with chemistry reagents, sani-wipes, tissues, plastic bags, patient specimen racks, and a barcode scanner. 5. The wall on the right side of the lab had a counter that extended the length of the wall. At the far left end of the counter top was a printer; then a stack of gloves; a monitor and keyboard with a rocker for the

	hematology specimens behind the monitor; eyewash bottle; spill kit; hand sanitizer and lotion; container with scissors and pens; and the hematology analyzer. On top of the hematology analyzer were two half full urine specimen cups; two purple top tubes with blood; a barcode scanner; and other assorted stuff. 6. Adjacent to the counter on the right side of the lab was the refrigerator that extended 25" from the front wall. There was approximately 2" between the counter and the refrigerator. In order for the testing person to perform a test on the hematology analyzer they would have to lean over the refrigerator that had two accordion files; three lab binders and assorted clutter to reach the front of the analyzer to perform the test. 7. In front of the refrigerator was a rolling stool. Next to the refrigerator was a tall plastic container with at least two boxes on top with a hole punch device on top. In front of the plastic container was the portable air conditioner that vented through the ceiling 8. Laboratory benchtop space was overcrowded with instrumentation, reagent packs, and patients' specimens leaving limited space for testing personnel to adequately perform patient testing without the potential for biohazardous contamination. 9. During the survey on 08/24/2022 at 1:15 PM, the TC confirmed that the laboratory was crowded and the LD stated that the owner of the building would not allow them to reconfigure the walls of the laboratory. The laboratory failed to be constructed, and arranged, to provide a safe environment to protect testing personnel from potential chemical hazards and biohazardous materials.
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 standard operating procedure (SOP) and interview with the testing person (TP) and technical consultant (TC), the laboratory's procedure manual failed to include written instructions for storing serum to be tested on a weekly basis on the Tosoh AIA-900 immunology analyzer. Findings: 1. The TP explained that the specimens were tested on the Tosoh on a weekly basis due to a low test volume. The SOP did not include written instructions on how to label and store the specimen until it was time for testing. 2. During the survey on 08/24/2022 at 1:15 PM, the TC and TP confirmed that the laboratory's SOP did not include written instructions on how to label and store the specimen until it was time for testing.

D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) final report records and interview with the testing person (TP) and technical consultant (TC) , the laboratory's record system failed to include the identity of the personnel who performed the PT and patient testing on the hematology analyzer. Findings: 1. Review of the hematology PT attestation worksheet for the third event in 2021 listed three signatures for TP. The final test reports showed that the only initials listed were "RCH." The hematology PT records did not include any other final reports with the initials of the other two TP who signed the attestation worksheet. 2. The lead TP stated there were three TP qualified to perform testing on the hematology analyzer. The TP confirmed that one of the three TP no longer knew their sign-on identification for the hematology analyzer and uses the sign-on identification of a TP that stopped working at the lab a year ago. 3. During the survey on 08/24/2022 at 1:15 PM, the TP and TC confirmed that the final reports for hematology testing did not always include the initials of the person who performed the testing.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of the final test reports and interview with the technical consultant (TC) and laboratory director (LD), the final report failed to define reference intervals for normal and abnormal patient results for "estimated GFR (glomerular filtration rate) for African-Americans and Non-African Americans." Findings: 1. The final reports that were reviewed listed the result and units of measurement for estimated GFR for African-Americans and Non-African Americans, but did define the intervals for normal and abnormal patient results. 2. During the survey on 08/24/2022 at 1:15 PM, the TC and LD confirmed that the laboratory's final patient report failed to include the interpretative information of normal and abnormal patient results.