Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0211975	07/31/2024
Name of Provider or Supplier	**Street Address, City, State**	
Rcca Md Llc- Chop	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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not complete documentation for investigations and corrective actions for proficiency test (PT) failures on the "Corrective Actions Checklist for Proficiency Test Failures" form (PT form). Findings: 1. The laboratory completed a PT form identified as the core 3 2023 PT form for two chemistry analytes that failed proficiency testing. The B12 test scored 50%, and the Vit D test scored 0%. 2. The comment entered on the core 3 2023 PT form for the vitamin D failure stated "vit D 'switched' samples # 2 still [illegible]. Reran acceptable". The comment indicates that the problem was that the samples were switched, but one sample was still unacceptable. The laboratory did not state how the failure was resolved, also the corrective action did not include a look back of patient results around the same time as the proficiency test failure to identify patient samples that may have also been switched, and what the laboratory would do to prevent switching samples or correct other problems identified during the investigation. 3. The laboratory did not provide an investigation, findings and corrective action (if needed) for the B12 test failure also identified on the core 3 2023 PT form. 4. The vitamin D test failure reported on the core 3 2023 form was the second proficiency test failure for the vitamin D test in 2023, as the laboratory also failed the first event in 2023. There was no mention of the previous PT failure and the investigation for the core 3 2023 PT event did not take the previous failure into account when it investigated the core 3 2023 vitamin D PT failure. The laboratory also did not describe the corrective action(s) it would take to ensure that the test was accurate or if patient testing was affected due to the two PT failures occurring during 2023. The laboratory did not identify an individual responsible for monitoring the vitamin D test corrective action (s) to ensure accurate and reliable patient testing. 5. The laboratory completed a PT

	form identified as the Chem 1- 2023 PT form for proficiency test failures for vitamin D, TIBC and potassium. The laboratory scored 50% for vitamin D and 80 % for both TIBC and potassium. The comment on the PT form stated: Vit D * K repeat acceptable. TIBC still [illegible] Review of patient results by provider determined no detrimental impact on pt results. 6. The investigation for the proficiency test failures identified on the Chem I - 2023 form did not state what possibly caused the PT failures, also there was no description of what may still affect the TIBC test. 7. The laboratory completed a PT form identified as the Chem 2-2023 PT form for two chemistry analytes, that failed proficiency testing, BMG (that received a score of 50%) and TP (that received a score of 0%). The comment on the PT form stated "Determined no significant impact on patient testing". The laboratory did not document the investigation, the findings of the investigation, how it arrived at the conclusion that patient testing was not affected by the PT failures and if corrective action was needed along with monitoring of corrective actions to ensure that the testing is performed in an accurate and reliable manner. 8. These findings were confirmed with the technical supervisor during interview at 12:00 pm on 7/31/24.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview, calibration documentation was missing from the chemistry testing records. Findings: 1. The October 2023 calibration chart for the test Vitamin B12 performed on the TOSOH analyzer was not in the test records even though the analyzer is calibrated monthly for Vitamin B12. 2. The April 2024 calibration chart for the folate test performed on the TOSOH analyzer was not in the test records even though the analyzer is calibrated monthly for folate. 3. This was confirmed during interview with the technical consultant on July 31, 2024 at 12:00 pm.