Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	21D0211975	02/22/2018
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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records, review of the written procedure manual, interview with the testing person, and the technical consultant, the laboratory did not ensure that PT results were reviewed and evaluated by the technical consultant or the laboratory director. Findings: 1. The laboratory did not have available on the day of the survey the American Proficiency Institute 2017 chemistry core performance evaluation for the first, second, nor the third event, that was reviewed by technical consultant or the laboratory director. 2. The "Procedure For Proficiency Testing" states that the PT performance review should be performed with in fourteen days by the technical consultant or the laboratory director.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by:

Based on review of quality control (QC) results, review of the written procedure manual, interview with the testing person, and the technical consultant, the laboratory did not perform corrective action procedures when chemistry QC did not meet the laboratory's criteria of acceptability. Findings: 1. The laboratory "quality control" procedure states that two levels of external controls must be ran and within acceptable range prior to running patient samples and corrective action procedures performed when there are problems with the controls. 2. The laboratory "quality assurance statement regarding action logs" procedure states that the "action log" is used to document all laboratory problems, QC failures, and the action log is placed with the analyzer. 3. On 4/28/17 the level one Vitamin D control was 14.5 ng/ml. The analyzer flagged the value as (L) with the comment, failed (accepted). Corrective action procedures were not performed and the control was not repeated. 4. On 5/26/17 the level one Vitamin D control was 13.3 ng/ml. The analyzer flagged the value as (L) with the comment, failed (accepted). Corrective action procedures were not performed and the control was not repeated. 5. On 8/1/17 the level one CA27.29 control was 29.4 U/ml and the level three control was 156.2 U/ml. The analyzer flagged the values as (H) with the comment, failed (accepted). Corrective action procedures were not performed and the control was not repeated. 6. . On 1/6/17 the level one Vitamin B 12 control was 696 pg/ml, the level two control was 933 pg/ml, and the level three control was 1745 pg/ml. The analyzer flagged the values as (H) with the comment, failed (accepted). Corrective action procedures were not performed and the controls were not repeated. 7. . On 3/24/17 the level one CEA control was 5.9 ng/ml, the level one CEA control was repeated, the repeated value was 5.8 ng/ml. The analyzer flagged both values as (H) with the comment, failed (accepted). Corrective action procedures were not performed. 8. On 3/24/17 the level two CEA control was 35.5 ng /ml, the level two CEA control was repeated, the repeated value was 37.0 ng/ml. The analyzer flagged both values as (H) with the comment, failed (accepted). Corrective action procedures were not performed. 9. On 3/24/17 the level three CEA control was 78.0 ng/ml, the level three CEA control was repeated, the was repeated value was 76.6 ng/ml. The analyzer flagged both values as (H) with the comment, failed (accepted). Corrective action procedures were not performed. 10. On 3/28/17 the level one CEA control was 5.5 ng/ml, the level two control was 37.8 ng/ml, and the level three control was 76.4 ng/ml. The analyzer flagged the values as (H) with the comment, failed (accepted). Corrective action procedures were not performed and the controls were not repeated. 11. On 1/10/17 the level one Folate control was 2.9 ng/ml, the level two control was 5.9 ng/ml, and the level three control was 10.6 ng/ml. The analyzer flagged the values as (L) with the comment, failed (accepted). Corrective action procedures were not performed and the controls were not repeated. 12. On 3/24/17 the level one Folate control was 3.0 ng/ml and the level two control was 6.2 ng/ml,. The analyzer flagged the values as (L) with the comment, failed (accepted). Corrective action procedures were not performed and the controls were not repeated. 13. On 3/28 /17 the level one Folate control was 3.0 ng/ml and the level two control was 6.1 ng /ml. The analyzer flagged the values as (L) with the comment, failed (accepted). Corrective action procedures were not performed and the controls were not repeated. 14. On 4/21/17 the level two Folate control was 6.4 ng/ml and the level three control was 10.7 ng/ml. The analyzer flagged the values as (L) with the comment, failed (accepted). Corrective action procedures were not performed and the controls were not repeated. 15. On 4/4/17 the level two Folate control was 6.4 ng/ml and the level three control was 10.7 ng/ml. The analyzer flagged the values as (L) with the comment, failed (accepted). Corrective action procedures were not performed and the controls were not repeated. 16. The last entry into the laboratory "Action Log " was on 3/13/15. 17. The technical consultant confirmed that corrective action procedures were not performed when QC did not meet the laboratory's criteria of acceptability.

	The testing person stated that patient testing was performed and review of final reports on the dates QC was not within range showed reported results for chemistry testing.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records, review of the written procedure manual, interview with the testing person, and the technical consultant, the laboratory director did not ensure that PT results were reviewed and evaluated to meet the laboratory's criteria of acceptability. Findings: Refer to D5211
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 proficiency testing (PT) records, review of the written procedure manual, interview with the testing person, and the technical consultant, the laboratory director did not ensure that corrective action procedures were performed when the laboratory failed PT. Findings: 1. The laboratory director did not perform corrective procedures and investigate the reason for failed "Vitamin D" 2. The laboratory received a failing score on the American Proficiency Institute 2017 1st event Vitamin D 33%. 3. The testing person stated that she repeated the "Vitamin D" but an investigation was not performed. 4. The "Procedure For Proficiency Testing" states that any unacceptable PT result should have an investigation and corrective action procedures performed. 5. The testing person confirmed that corrective action procedures were not performed for failed PT.
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 quality control (QC) results, review of the written procedure manual, interview with the testing person, and the technical consultant (TC), the TC failed to ensure that corrective action procedures were performed when the chemistry QC did not meet the laboratory's criteria of acceptability and failed to ensure that patient test results were not reported until all corrective procedures were performed (Refer to D5783)
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 review of quality control (QC) results, review of the written procedure manual, interview with the testing person, and the technical consultant (TC), the TC did not ensure that corrective action procedures were performed when the chemistry QC did not meet the laboratory's criteria of acceptability. Findings: Refer to D5783 1. The "Quality Assessment Log Review Policy" states that all logs will be evaluated and maintained to ensure the quality of laboratory services. 2. The "Quality Control" procedure states that the TC will review the quality control logs on a regular basis to ensure that controls are ran properly and verify remedial actions are taken when QC is not within range. 3. The TC did not document in the "QC Review Report" nor the "Quality Assessment Review" checklist the chemistry QC failures.
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 review of quality control (QC) results, review of the written procedure manual, interview with the testing person, and the technical consultant (TC), the TC did not ensure that corrective action procedures were performed when the chemistry QC did not meet the laboratory's criteria of acceptability and did not ensure that patient test results were not reported until all corrective procedures were performed. Findings: Refer to D5783