Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0214558	05/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Crossroads Medical Laboratory Llc	4801 Dorsey Hall Drive Suite 200, Ellicott City, 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
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical supervisor (TS), the laboratory director failed to ensure that corrective actions were implemented to prevent recurring unacceptable results and that training of testing personnel (TP) on PT issues was documented. Findings: 1. The laboratory was enrolled in PT with Medical Laboratory Evaluation (MLE) which sent three PT events annually (M1-M3). 2. The PT records from 2022-2023 were reviewed for a total of four PT events. 3. The analyte ferritin failed three PT events in a row. a. Ferritin scored 0% in the 2022 MLE-M1 event. Both PT samples had results that fell below the acceptable range. b. Ferritin scored 0% in the 2022 MLE-M2 event. Both PT samples had results that fell below the acceptable range. c. Ferritin scored 50% in the 2022 MLE-M3 event. The unacceptable result fell below the acceptable range. 4. The PT records for the 2022 MLE-M1 event noted that the "controls appear good may have been running lower" and "will continue to monitor." 5. The PT records for the 2022 MLE-M2 event noted that the samples were rerun with higher results, the quality control (QC) was within 2 standard deviations, and that it was "noticed cups were not filled high enough." The summary stated "Possible operator error. Techs have been informed to make sure cups are fill with at least 500 mls [milliliters]." There was no documentation that TP were trained as part of correction actions for unsuccessful PT results. 6. The PT records for the 2022 MLE-M3 event stated that the QC was within range and the PT sample was rerun and was still below the acceptable ranges, though there was very little sample left for the repeat. 7. There was no documented investigation into the root cause of why the ferritin PT results were falling below the acceptable PT ranges or whether patient results were potentially affected. 8. The

	analytes sex hormone binding globulin (SHBG) and testosterone scored 0% in the 2023 MLE-M1 event. It was noted that the samples were reconstituted to 5 mls instead of 2 mls as required. There was no documentation that TP were trained as part of corrective actions for unsuccessful PT results. 9. During the survey on 05/11/2023 at 4:30 PM, the TS confirmed that there was no documented investigation into the root cause of the unsuccessful ferritin PT results and that training of TP for unsuccessful PT was not documented.
D6148	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(a)(4) The general supervisor is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained. This STANDARD is not met as evidenced by: Based on review of the reagent lot to lot worksheets for the Atellica chemistry analyzer and interview with the general supervisor (GS), the GS failed to ensure that the testing personnel were following the instructions for performing and recording the appropriate information when there was a change in the lot number(#) of the reagents being used. Findings: 1. The reagent lot to lot worksheets for verifying that there were no significant changes in the quality control (QC) results from July 2021 through May 2023 for triglycerides were reviewed. 2. On 10/07/21 the new lot# 211398 with an expiration (exp) date of 04/01/22 was tested against the old lot#. 3. On 11/26/21 the new lot# 211444 exp date of 02/01/22 was tested against the old lot# 211398 with an exp date of 04/01/22. 4. On 07/08/22 the new lot# 211480 with an exp date of 10/01 /23 was tested against the old lot# 211479 with an exp date of 09/01/22. 5. On 10/07 /22 the new lot# 221740 with an exp date of 06/01/23 was tested against the old lot# 2115886 with an exp date of 02/01/22. 6. On 03/17/23 the new lot# 120249 with an exp date of 12/18/23 was tested against the old lot# 170166 with an exp date of 10/13 /23. 7. The reagent lot to lot records show that the lab switched to new lots on 11/26 /21, 07/08/22, 10/07/22, and 03/17/23 but the previous lots listed on the worksheets had not been validated against another previous lot#. Lot# 211444, 211480, 221740, and 120249 had not been validated prior to being put into use and the gaps in between testing the new lots varied from 5 to 10 months. 8. The reagent lot to lot worksheets for verifying that there are no significant changes in the quality control results from July 2021 through May 2023 for calcium were reviewed. 9. On 08/02/21 the new lot# 211438 exp date of 06/01/22 was tested against the old lot# 201251 with an exp date of 08/01/22. 10. On 07/06/22 the new lot# 211438 exp date of 06/01/22 was tested against the old lot# 201251 with an exp date of 08/01/22. 11. On 10/03/22 the new lot# 221575 exp date of 01/01/23 was tested against the old lot# 21526 with an exp date of 10/01/22. 12. On 01/03/23 the new lot# 221629 exp date of 02/01/23 was tested against the old lot# 221575 with an exp date of 01/01/23. 13. On 02/02/23 the new lot# 22733 exp date of 06/01/23 was tested against the old lot# 221629 with an exp date of 02/01/23. 14. On 04/07/23 the new lot# 221951 exp date of 12/01/23 was tested against the old lot# 221733 with an exp date of 06/01/23. 15. The reagent lot to lot records show that the lab switched to new lots on 08/02/21, 07/06/22, 10/03/22, 01 /03/23, 02/02/12, and 04/07/23 but the previous lots listed on the worksheets had not been validated against another previous lot#. 16. Lot# 211438 and 211484 had not been validated prior to being put into use and the gaps in between testing the new lots varied from 1 to 11 months. Three lot#'s were recorded incorrectly on the worksheet (cross refer to #'s 12-14 listed above). 17. During the survey on 05/11/2023 at 4:30 PM, the GS confirmed that the laboratory staff were not using the reagent lot to lot

	worksheets to verify that there were no significant changes in the QC results prior to switching to the new lot.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high 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: Based on review of the reagent lot to lot worksheets for the Atellica chemistry analyzer and interview with the general supervisor, the testing person failed to follow the instructions for performing and recording the appropriate information when there was a change in the lot number of the reagents used in the laboratory. Cross refer to tag D6148 for findings.