Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2151576	07/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Collaborative Laboratory Services	31 Sycamore St, Ste 202, Glastonbury, CT	

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 record review and staff interview the laboratory failed to self evaluate the Proficiency Testing (PT) scores graded as educational challenge as required by the College of American Pathologist (CAP) in the specialty of Hematology. Findings include: 1. Record review on 7/24/2024 of the CAP's PT summary report for FH13-B 2023 Hematology Auto Differentials, FH13 revealed the following: a. "Actions laboratories should take when a PT result is not graded. Your laboratory must identify all of the analytes with all Exception Reason Code and investigate the acceptability of performance." b. " Code 26: Educational challenge: Action Required: Response to CAP not required. Laboratory should document its review." 2. Record review on 7/24 /2024 of three PT "Original Evaluation" reports from CAP revealed the lack of documentation of investigation and review for exception reason code [26] for the following PT surveys: a. BCP-A 2024 Blood Cell ID, Photographs. b. FH13-B 2023 Hematology Auto Differentials, FH13. c. FH13-C 2023 Hematology Auto Differentials, FH13. 3. Staff interview with the Laboratory Administrative Director (LAD) on 7/24/2024 at 10:30 AM confirmed that PT evaluations with exception reason codes [26] were not investigated and documented by the Medical Laboratory Director or the designee. 4. The laboratory performs 23,766 tests annually in the specialty of Hematology.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the

	effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish and follow policies and procedures to evaluate corrective actions and efforts taken to prevent recurrence for Proficiency Testing (PT) scores with grade "Unacceptable" in the specialty of Hematology. Findings include: 1. Record review on 7/24/2024 of the laboratory's "Proficiency Testing, Reporting and Review" policy revealed lack of policy in place to review PT results in a timely fashion, investigate, establish and follow a corrective action plan when PT scores are graded with "Unacceptable" score. 2. Record review on 7/24/2024 of the College of American Pathologist (CAP) PT evaluation reports for FH13-C 2023 and FH13-A 2024 surveys revealed unacceptable score for "Cell ID or WBC Diff". 3. Record review on 7/24/2024 of the laboratory's "PT Exception Investigation Worksheet" for PT events FH13-C 2023 and FH13-A 2024 revealed the same investigation report documentation stating, " I believe it may be as simple as this sample not being mixed adequately before testing, especially being the last sample tested in this set. Since it resolved itself upon rerun, I am confident there are no underlying problems with this analyte and no further investigation is necessary, however, we will continue to monitor". 4. Record review on 7/24/2024 of the documentation for the unacceptable PT scores investigations revealed lack of effectiveness of the corrective action to prevent recurrence that resulted in obtaining another "Unacceptable" score for the FH13-A 2024 PT event. NOTE: The above documents listed in 3 revealed the lack of the Laboratory Director's and or general supervisor's review date and signature or documentation supporting staff reeducation to prevent reoccurrence 5. Staff interview with the Laboratory Administrative Director on 7/24/2024 at 10:30 AM confirmed the above findings. 6. The laboratory performs 23,766 tests annually in the specialty of Hematology.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview laboratory failed to follow its established written policies and procedures to evaluate and investigate Proficiency Testing (PT) failures within 3 weeks of receipt of original evaluations from the College of American Pathologist (CAP) in the specialty of Hematology. Findings include: 1. Record review on 7/24/2024 of the laboratory's "Proficiency Testing, Reporting and Review" procedure revealed the following: a. "Section 4. Reviewing Results: 4.1.2 If proficiency testing was not graded (such as educational challenge, lack of consensus) perform a self-evaluation with appropriate investigation as to the acceptability of results using the data presented in the Participant Summary. Refer to CAP performing a Self-Evaluation When Proficiency Testing is Not Graded document to choose a self evaluation method and Exception code chart included in the Participant Summary for

	action required for specific exception reason codes." b. " Section 4.2 Documentation of Evaluation: 4.2.1 Response to all investigations must be complete within 3 weeks of receipt. Department Supervisor or Lead Technologist, Laboratory Manager and Quality Manager review documentation of all proficiency testing. Medical Director is only required to review PT failures and investigation." 2. Record review on 7/24/2024 of the laboratory's evaluations from CAP revealed the following: a. FH13-C 2023 Hematology Auto Differentials, original evaluation was received on 11/1/2023 with an "Unacceptable Score" for specimen FH13-15. An investigation was done on 5/10 /2024 and reviewed by the Laboratory Administrative Director(LAD) on 7/24/2024. b. FH13-A 2024 Hematology Auto Differentials, original evaluation was received on 3/6 /2024 with an "Unacceptable Score" for specimen FH13-05. An investigation was done on 4/18/2024 and reviewed by the LAD on 7/24/2024. Note: Lack of documentation of Laboratory Director's review for investigations listed in 2a and 2b above. 3. Record review on 7/24/2024 of the laboratory's PT evaluations and investigation document for PT with "Unacceptable" score revealed the laboratory failed to follow the established procedure to investigate and take corrective actions within 3 weeks of receipt. 4. Staff interview with the LAD on 7/24/2024 at 10:05 AM confirmed the findings above. He/she further agreed on the evaluations were not being performed in a timely manner. 5. This laboratory performs 23,766 tests annually in the specialty of Hematology.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on record review and staff interview, the General Supervisor (GS) failed to assess the annual competency of testing personnel (TP) in a timely manner for their knowledge and skills necessary to perform high complexity laboratory testing in specialty of Hematology. Findings include: 1. Record review on 7/24/2024 of the laboratory's personnel competency assesment records for 4 of 4 TP's in the specialty of Hematology revealed the following: a. TP# 1: Start date 3/6/2023, Lack of documentation of competency assessment twice during the first year of employment. b. TP #2: Annual competency for 2022 signed by GS on 7/9/2024, Annual competency for 2023 signed by GS on 7/15/2024. c. TP #3: Annual competency for 2022 signed by GS on 7/9/2024, Annual competency for 2023 signed by GS on 7/9 /2024. d. TP #4: Annual competency for 2022 signed by GS on 7/9/2024, Annual competency for 2023 signed by GS on 7/9/2024. Note: Findings in 1 above revealed the GS failed to assess TP#1 twice annually during the first year of employment and review the 3 of 3 TP's annual competencies for 2022 and 2023 in a timely manner. 2. Staff Interview with the Laboratory Administrative Director on 07/24/2024 at 11:05 AM, confirmed the GS failed to assess the annual competency evaluations in a timely manner for 3 of 3 TP in 2022 and 2023 and failed to assess TP#1 twice annually during the first year of employment. 3. This laboratory performs 23,766 tests annually in the specialty of Hematology.