Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2101598	06/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Total Healthcare	3504 Hwy 280, Alexander City, AL	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on reviews of proficiency testing (PT) records and an interview with the Technical Consultant, the surveyor determined the laboratory failed implement procedures to ensure proficiency testing failures were effectively investigated, with corrective actions documented and implemented to prevent recurrence. This was noted on two of four 2021-2022 Hematology surveys. The findings include: 1. A review of the 2021-2022 CAP (College of American Pathologists) Hematology PT records revealed the following scores: A) 2021 FH1-A: WBC (White Blood Cells) 80%, RBC (Red Blood Cells) 40%, Hemoglobin 60%, and Hematocrit 40% for an overall failing score of 63% for Hematology. B) 2022 FH1-A: WBC 60%, RBC 40%, Hemoglobin 40%, and Hematocrit 40% for an overall failing score of 57% for Hematology. 2. A review of the laboratory's corrective action revealed the following: A) 2021 FH1-A: "Repeated the unacceptable test results; all results within the expected ranges." B) 2022 FH1-A: "All samples passed after rerunning. Reviewed QC [Quality Control]... All maintenance up to date. Patients running normal." 3. During an interview on 6/2/2022 at 1:45 PM, the surveyor reviewed the QC, calibration and maintenance on the Hematology analyzer with the Technical Consultant who confirmed there was no issues with the instrument. 4. As the interview continued at approximately 2:00 PM on 6/2/2022, the surveyor asked the Technical Consultant if she had determined what the problem was so corrective actions could be implemented to prevent a third failure. The Technical Consultant then stated mixing issues could have caused the failures since there were new testing personnel. The Technical

	Consultant stated she had demonstrated how PT samples should be run after the 2022 FH1-A survey failures, and explained PT samples must be thoroughly mixed before testing. The surveyor then asked if she had documented the additional training; the Technical Consultant confirmed she had not. SURVEYOR ID #32558 Licensure and Certification Surveyor