

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2151576	(X3) Date Survey Completed 07/15/2026
Name of Provider or Supplier Collaborative Laboratory Services	Street Address, City, State 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
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on record review and staff interview the general supervisor failed to follow the laboratory's established policy and procedure to review quality control results, identify, investigate and document quality control problems within the testing system in the specialty of Hematology. Findings include: 1. Record review on 07/15/2026 of the laboratory's established "Quality Control Review Procedure" revealed the following: a. "It is the responsibility of the quality control review technologist to review quality control results, to identify, investigate and assist in correcting quality control problems that occur within the testing system." b. "Monthly: On the first day of each month, print Levey-Jennings charts for the previous month. Review charts for acceptable performance of all testing systems. Add comments as needed. Charts are reviewed by QA Manager or department supervisor." 2. Record review on 07/15/2026 of the laboratory's " February 26- weekly Heme Review, March 5 Glastonbury CC" revealed quality control values were reviewed by a personnel not listed on CMS-209 as follows: a. "Signed : Non-Testing Personnel (NTP)"- not on CMS-209". b. "Resulting Instant: "From 2/22/2026 0000 to 03/31/2026 2359." c. "Signed: "03/05 /2026 NTP." d. Lack of documentation of the laboratory's General Supervisor(GS) reviewing the quality control Levey Jennings charts as indicated in the procedure maual as mentioned in line item 1 above. 3. Staff interview 07/15/2026 at 09:56 AM with the Testing Personnel #1(TP#1) confirmed that all the quality control charts including the monthly Levey Jenning charts were reviewed by a testing personnel not working in this laboratory instead of the GS. 4. Staff interview 07/15/2026 at 09:57 AM with the GS confirmed that he/she does not review the Levey Jennings charts.

The GS further confirmed that quality control (QC) reports are reviewed by personnel who do not work at this laboratory. Instead, the QC reports are reviewed by personnel at the main laboratory, which is located at a different address.

D6088

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)

(e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that--

This STANDARD is not met as evidenced by:

Based on record review of the Centers for Medicare and Medicaid Services (CMS) Proficiency Testing (PT), Certification and Survey Provider Enhanced Reporting System (CASPER Report 0155D) report and staff interview the laboratory director failed to ensure that the laboratory was enrolled in a U.S. Department of Health and Human Services (HHS) approved PT program for the first event of 2026 in the specialty of Hematology while continuing to test patient samples. Findings include: 1. Record review on 07/15/2026 of the laboratory's established "Proficiency Testing, Reporting and Review" policy revealed the laboratory is enrolled in College of American Pathologists (CAP) PT program. 2. Record review on 07/15/2026 of the "CASPER Report 0155D" revealed lack of PT scores for the Event 1, 2026 for the "Analytes: # 0760- Hematology, 0765# Cell ID, #0770- WBC Differential, #0775- RBC, #0785- HCT (NON-WAIVED), #0795- HGB (NON-WAIVED), #0805- WBC COUNT, #0815- PLATELETS." 3. Record review on 07/15/2026 of the laboratory's "CAP PT Shipping Calendar, Year: 2026" revealed the following: a. "CAP # 8396869-01". b. LAB Name: Saint Francis Hospital Collaborative Laboratory Services-Glastonbury Campus". c. Ship Date: 04/27/2026- BCP-B 2026 & FH13-B 2026, 09/14/2026- BCP-C 2026 & FH13-C 2026." d. Lack of documentation of a shipment date for BCP-A 2026 & FH13-A 2026 PT survey samples. 4. Record review on 07/15/2026 of the laboratory's CAP binder revealed the laboratory had performed "Alternate Proficiency Assessment" for the "Hematology Automated Diff Survey (FH13-A)" on 02/09/2026 as follows: a. "Test Name: Hematology Automated Diff Survey (FH13-A)". b. "Department: Glast. Hemonc Lab (HONCG)". c. "Sample Identification: FH13-A, 13-01, 13-02, 13-03, 13-04, 13-05". d. "See attached. Run FH13-A (2026) Survey that was borrowed from the main lab." 5. Record review on 07/15/2026 of the laboratory's CAP binder revealed the laboratory had performed "Alternate Proficiency Assessment" for the "Blood Cell Identification (BCP)- BCP-A 2026" on 02/09/2026 as follows: a. "Test Name: Blood Cell Identification" b. "Department: Glast. Hemonc Lab (HONCG)". c. "Sample Identification: BCP-01, 02, 03, 04, 05 (Graded) and 06,07,08,09,10 (ungraded)". d. "See attached. Blood Cell ID from current BCP-A survey pics borrowed from main lab, see attached paperwork." 6. Record review on 07/15/2026 of the email communications between the General Supervisor (GS) and the Testing Personnel (TP#1) revealed the following: a. Email from TP#1 to GS dated January 27, 2026 at 08:02 AM revealed: " when I look for both Hartford and Glastonbury Cancer Centers, there are no shipped CAP surveys for either location." b. Email from TP#1 to GS dated January 27, 2026 at 08:59 AM revealed: " I just called the customer service line at CAP and they said that no surveys have been ordered for both the locations for 2026." 7. Staff interview on 07/15/2026 at 09:33 AM with the GS confirmed the above findings and that the laboratory did not receive the PT samples for Event 1 of 2026. The GS further stated that the survey materials were ordered along with the main hospital laboratory and does not know how the two cancer center laboratories did not get enrolled for the Event 1 of 2026 PT

survey. 8. Staff interview on 07/15/2026 at 10:05 AM with the TP#1 confirmed the findings in line item 3, 4 and 5 listed above.