Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0988648	06/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hayman Salib Md Hematology Oncology	3465 Nazareth Rd, Easton, PA	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) and College of American Pathologists (CAP) proficiency testing (PT) records and interview with the testing personnel #1 (TP), the laboratory failed to test API and CAP PT samples for routine chemistry, endocrinology, general immunology, and hematology in the same manner as patient specimens from 2021 to the date of survey. Findings include: 1. On the date of survey, 06/29/2023 at 10:40 am, during an interview, TP#1 stated that "PT samples were run twice on two separate days, then they select which result to report." 2. On the day of survey, 06/29/2023 at 11:09 am, the laboratory could not provide a written proficiency testing policy. 3. TP #1 confirmed the findings above on 06/29/2023 around 03:10 pm.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on review of the competency assessment records and interview with the testing personnel #1 (TP), the laboratory failed to establish written policies and procedures to assess the competency 1 of 1 technical consultant (TC) for the supervisory responsibilities from 08/06/2021 to the day of survey. Findings include: 1. On the date of survey, 06/29/2023 at 11:48 am, the laboratory could not provide a competency assessment procedure to assess 1 of 1 TC for their supervisory responsibilities from 08 /06/2021 to 06/29/2023. 2. The laboratory could not provide competency assessment records for 1 of 1 TC for the supervisory responsibilities in 2021, 2022 and 2023. 3. The laboratory could not provide documentation for responsibilities and duties for TC. 4. TP#1 confirmed the findings above on 06/29/2023 around 03:00 pm. *Repeat deficiency.
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 American proficiency institute (API) proficiency testing (PT) records and interview with the testing personnel #1 (TP), the Laboratory Director failed to ensure 2 of 2 chemistry PT results were reviewed and corrective actions were taken for unsatisfactory PT in 2022. Findings include: 1. On the day of survey, 06/29 /2023 at 9:45 am, review of the API PT records revealed that the laboratory did not document corrective actions for the following 2 of 2 unsatisfactory PT results for chemistry in 2022: 2022 Chemistry-Core 2nd Event: 80% for triiodothyronine (T3). 80% for free triiodothyronine (FT3). 2. TP#1 confirmed the findings above on 06/29 /2023 around 03:10 pm.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the College of American Pathologist (CAP) proficiency testing (PT) records and interview with the testing personnel #1 (TP), the laboratory failed to verify the accuracy for 2 of 2 analytes for CAP PT tests in 2022 and 2023. Findings include: 1. On the day of survey, 06/29/2023 at 12:09 am, review of CAP PT records revealed that the laboratory did not verify the accuracy for the following 2 of 2 non graded analytes: - Soluble transferrin receptor (STFR) - CAP 2022, 2nd event and CAP 2023, 1st event - Bone specific alkaline phosphatase (BMV2) - CAP 2022, 2nd event 2. TP #1 confirmed the findings above on 06/29/2023 around 03:10 pm.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the testing personnel #1 (TP), the laboratory failed to perform and document maintenance on 2 of 3 thermometers used for monitoring temperatures for the freezer and refrigerator #2 from 08/06/2021 to 06/29/2023. Findings include: 1. On the day of survey, 06/29 /2023 at 02:50 pm, the laboratory could not provide maintenance/function check records for the following 2 of 3 thermometers used from August 2021 to June 2023: -Fisher thermometer S/N: 200404566 Due: 09Jul2022 -Thomas Scientific Thermometer S/N: 160765710 Due: 16Sep2018 2. TP #1 confirmed the findings above on 06/29/2023 around 03:10 pm.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the quality assurance (QA) policy and interview with the testing personnel #1 (TP), the laboratory director (LD) failed to ensure QA programs were maintained to assure the quality of laboratory services provided from 08/06/2021 to the day of survey. Findings include: 1. On the date of survey, 06/29/2023 at 12:31 pm, the laboratory could not provide documentation of the QA activities performed from 08/06/2021 to 06/29/2023. 2. TP#1 confirmed the findings above on 06/29/2023 around 03:00 pm. *Repeat deficiency.