Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0988648	08/06/2021
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with testing personnel (TP) #1, the laboratory failed to provide the PT attestation statements signed by the analyst and the laboratory director from 2019 and 2020. Findings Include: 1. On the day of survey, 08/06/2021, the following API PT attestation statements were not signed by the analyst and the laboratory director in 2019 and 2020: a. Chemistry: - 2019 Event #3. - 2020 Event #1. b. Hematology: - 2019 Event #2. 2. TP#1 confirmed the findings above on 08/06/2021 around 08:30 am. *** REPEAT DEFICIENCY.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State

	Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on lack of documentation and interview with testing personnel (TP) #1, the laboratory failed to provide documentation of SARS-CO-V-2 antibody test results reported to the appropriate agencies as required for 1,588 of 1,588 patients tested from 08/17/2020 to 08/06/2021. Findings Include: 1. On the day of survey, 08/06/2021, TP#1 was unable to provide documentation of SARS-CoV-2 antibody tests performed on the Beckman Coulter Access 2 analyzer reported to the Pennsylvania National Electronic Disease Surveillance System (PA - NEDSS). 5. From 08/17/2020 to 08/06/2021 the following number of SARS-CoV-2 specimen were analyzed on the Beckman Coulter Access 2. - Total: 1588. - Positive: 471. - Negative: 1,117. 6. TP#1 confirmed via email on 08/09/2021 around 1:50 pm, that the laboratory did not report SARS-CoV-2 results to local/state agencies.
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 laboratory procedures and interview testing personnel (TP) #1, the laboratory failed to establish a competency assessment procedure to assess 2 of 2 testing personnel (TP) and 1 of 1 technical consultant (TC) for competency in 2019, 2020 and 2021. Findings include: 1. On the day of survey, 08/06/2021, the laboratory could not provide a competency assessment procedure to assess the competency for 2 of 2 TP who performed testing on the Alfa Wassermann Ace Axcel, Beckman coulter Access 2 and the Sysmex XN - 450 in 2019, 2020 and 2021. 2. The laboratory could not provide competency assessment records for 1 of 1 TC performed in 2019, 2020 and 2021. 3. TP#1 confirmed the findings above on 08/06/2021 around 08:00 am. *** 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 testing personnel (TP) #1, the Laboratory Director failed to ensure all PT reports received, were reviewed and corrective actions were taken for unsuccessful PT performed in 2020 and 2021. Findings include: 1. On the day of

	survey, 08/06/2021, review of the API PT records revealed, the laboratory did not document corrective actions for the following unsuccessful PT events in 2020 and 2021: a. 2020 Chemistry event #2: 80% for ALT. b. 2021 Chemistry event #2: 80% for ALT. 80% for Phosphorous. 2. TP#1 confirmed the findings above on 08/06/2021 around 08:15 am.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with testing personnel (TP) #1, the laboratory director failed to ensure at least twice annually, the laboratory verified the accuracy of the Bio Rad Tox/SEE drug screen tests performed from 6/18 /2020 to 3/30/2021. Findings Include: 1. On the day of survey, 08/06/2021, TP#1 could not provide twice annual verification of accuracy for the Bio Rad Tox/SEE drug screen tests performed from 6/18/2020 to 3/30/2021. 2. TP#1 confirmed the findings above on 08/06/2021 around 10:47 am.
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 review of the laboratory procedure manual and interview with the testing personnel (TP) #1, the laboratory failed to include a procedure for reporting positive and negative SARS-CoV-2 testing to the appropriate health agencies as required from August 2020 to the day of survey. Findings include: 1. On the day of survey, 08/06 /2021, the laboratory could not provide a procedure for reporting positive and negative SARS-CoV-2 testing to the appropriate health agencies as required from 08 /17/2020 to 08/06/2021. 2. From 08/17/2020 to 08/06/2021: 1,588 SARS-CoV-2 specimen were analyzed. 3. TP#1 confirmed the findings above on 08/06/2021 around 8:30 a.m.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)

	The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A. Based on review of laboratory policies and interview with testing personnel (TP) #1, the laboratory failed to establish polices for the SARS-CoV-2 antibody testing and for the Alfa Wassermann Ace Axcel analyzer policies from 08/06/2020 to the day of survey. Findings Include: 1. On the day of survey, 08/06/2021, the laboratory could not provide a policy for SARS-CoV-2 antibody tests perform on the Beckman Coulter Access 2 analyzer from 08/17/2020 to 08/06/2021. 2. The laboratory could not provide a testing policy for Alfa Wassermann Ace Axcel analyzer. 3. TP#1 confirmed the findings above on 08/06/2021 around 8:10 am. B. Based on review of laboratory policies and interview with testing personnel (TP) #1, the laboratory failed to establish procedure manuals for the Beckman Coulter Access 2 and Bio Rad Tox/See drug test that include: calibration verification procedures, quality control procedures, corrective action procedures, the laboratory's procedure for entering results, and reporting patient results from 08/06/2019 to the day of survey. Findings include: 1. On the day of survey, 08/06/2021, review of the laboratory procedure manuals revealed, the Beckman Coulter Access 2 and Bio Rad Tox/See drug test procedures did not include the following from 08/06/2019 to 08/06/2021: - Calibration and calibration verification procedures. - Quality control procedures. - Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. - Procedures for entering results in the patient records and reporting patient results. 2. TP#1 confirmed the findings above on 08/06/2021 around 8:10 am.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with testing personnel (TP) #1, the laboratory failed to include a positive and negative control each day of patient testing for the Bio Rad Tox/SEE Drug Screen test from 2020 to the day of survey. Findings include: 1. On the day of survey, 08/06/2021, the laboratory could not provide documentation of QC performed each day of patient testing for the Bio Rad Tox/SEE Drug Screen test performed from 6/18/2020 to 3/30/2021. 2. In 2020, 10 of 17 patient drug screens were performed with no QC. 3. In 2021, 01 of 02 patient drug screens were performed with no QC. 2. TP#1 confirmed the findings above on 08 /06/2021 around 10:45 am.

D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of laboratory records, and interview with testing personnel (TP) #1, the laboratory failed to provide overall management and direction of the laboratory in accordance with 493.1407 for a moderate complexity laboratory. Refer: D6018 and D6021. .
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the American proficiency institute (API) proficiency testing (PT) records and interview with testing personnel (TP) #1, the Laboratory Director failed to ensure all PT reports received, were reviewed and corrective actions were taken for unsatisfactory PT performed in 2019 and 2020. Findings include: 1. On the day of survey, 08/06/2021, review of the API PT records revealed, the laboratory did not documentation corrective actions taken for the following unsatisfactory PT events in 2019 and 2020: a. 2019 Chemistry event #3: 60% for Alanine transaminase (ALT). 0% for Albumin. 20% for Glucose. 40% for Blood urea nitrogen (BUN). b. 2019 Endocrinology event #3: 0% for Free TY. 2. TP#1 confirmed the findings above on 08 /06/2021 around 08:15 am.
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 testing personnel (TP) #1, the laboratory director (LD) failed to ensure QA programs were established and maintained to assure the quality of laboratory services provided from

	2019 to the day of survey. Findings Include: 1. On the date of survey, 08/06/2021, review of the QA policy revealed, the policy in use was not signed by the LD. 2. The laboratory could not provide QA activities performed from August 2019 to August 2021. 3. TP#1 confirmed the findings above on 08/06/2021 around 12:50 pm. *** REPEAT DEFICIENCY.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #1, the laboratory did not have the required records accessible during the course of the inspection on 08/06/2021. Findings Include: 1. On the day of survey, 08/06/2021, the laboratory could not provide the following records upon request: - Quality assessment records from 08/06/2019 to 08/06/2021. - Centrifuge Maintenance logs from August 2019 to January 2020. - Room temperature logs from August 2019 to November 2020. - Refrigerator and freezer temperature logs August 2019 to October 2020. - Alfa Wassermann Ace Axcel Maintenance Logs from August 2019 to March 2020. - Beckman coulter Access 2 Maintenance logs from August 2019 to June 2020. - Proficiency testing policy. - Alfa Wassermann Ace Axcel calibration verifcations performed before 5/21/2020. 2. TP#1 confirmed the findings above on 08/06/2021 around 11:30 a.m.