

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0988648	(X3) Date Survey Completed 12/19/2018
Name of Provider or Supplier Hayman Salib Md Hematology Oncology	Street Address, City, State 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	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based upon a review of American Proficiency Institute (API) Proficiency Testing (PT) records and interview with Testing Personnel (TP) #1, the laboratory failed to maintain copies of 7 of 11 attestation statements and 4 of 11 attestation statements were not signed by the Laboratory Director (LD) in 2017 and 2018. Findings include: 1. On the day of survey, 12/19/2018, review of API PT records (2017 Event 1 - 2018 Event 2) revealed, the following missing attestation statements and attestation statements that were not signed by the LD: Missing attestation statements: - 2017 Chemistry Event #1 and #3 - 2017 Hematology Event #3 - 2018 Chemistry Event #1 and #3 - 2018 Hematology Event #1 and #2 Attestation statements not signed by the LD: - 2017 Chemistry and Hematology Event #2 - 2018 Chemistry Event #2 - 2018 Hematology Event #3 2. TP#1 confirmed the above findings on 12/19/2018 around 2:05 PM.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p>

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 competency assessment records and interview with Testing Personnel (TP) #1 and Laboratory Director (LD), the LD failed to assess the competency of 1 out of 1 TP who performs chemistry and hematology testing from 2017 to the date of survey. Findings include: 1. Review of the Laboratory Quality Assurance Plan procedure manual (IV), under Training and Continuing Education of Personnel states, "Employee competency will be reviewed annually". 2. On the day of survey, 12/19/2018, review of TP#1's records revealed, the LD never assessed the competency of TP#1 for performing chemistry and hematology tests in 2017 and 2018. 3. The laboratory performed 45, 000 patient testing in 2017. 4. The LD confirmed that TP was hired January 2017 but their competency was never assessed on 12/19/2018 around 2:30 PM.

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on the review of the Beckman Coulter Access 2 procedure manual and interview with Testing Personnel (TP) #1, the Laboratory Director (LD) failed to approve and sign the Beckman Coulter Access 2 procedure manual before use in 2018. Findings include: 1. On the day of survey, 12/19/2018, review of procedure manuals revealed, the Beckman Coulter Access 2 procedure manual was not approved and signed by LD. 2. In 2018: 15,000 patient tests were performed. 3. The LD and TP#1 confirmed the findings of the above on 12/19/2018 around 2:45 PM

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

A. Based on a review of BioRad Liquichek Immunoassay Plus Controls, Levels 1, 2 and 3 package insert, review of quality control records, interview with Testing Personnel (TP) #1, and observation of controls stored in a refrigerator, the laboratory failed to monitor and document the conditions of storage for 3 out of 3 vials of BioRad Plus Controls from 2017 to the date of survey. Findings include: 1. The

BioRad Liquichek Immunoassay Plus Control, Levels 1, 2 and 3 package insert under STORAGE AND STABILITY states, "This product will be stable until the expiration date when stored unopened at -20 to -70 C. Thawed Unopened: When thawed and stored unopened at 2 - 8 C, this product will be stable as follows: - All Analytes: 30 days Except: - Androstenedione: 25 days - Prolactin, PSA (Free) and PSA (Total): 14 days - Estradiol: 8 days - Folate: 4 days Date of thaw should be noted. Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8 C, this product will be stable as follows: - All analytes: 14 days Except: - Estradiol: 5 days - Folate: 4 days Once thawed, do not refreeze this product. Discard the remaining material. This product is shipped under frozen conditions." 2. On the day of survey, 12/19/2018, the laboratory could not provide documentation of monitoring the temperature of the refrigerator controls were stored in. 3. 3 out of 3 bottles of BioRad Liquichek Immunoassay Plus Controls, Levels 1, 2 and 3 were stored in refrigerator located in the laboratory. 4. TP#1 confirmed the findings above on 12/19/2018 around 04:30 PM. ** C = Celsius B. Based on a review of Refrigerator temperature records and interview with Testing Personnel (TP) #1, the laboratory failed specify and document the system control limits (reference range) for storage of chemistry and hematology Controls stored in the refrigerator in the laboratory from 2017 to the day of survey. Findings Include: 1. On the day of survey, 12/19/2018, the review of refrigerator temperature logs revealed: - 2017 (01/03/2017- 12/29/2017) 4 out of 11 logs did not include refrigerator temperature reference ranges. - 2018 (01/01/2018- 12/18/2018) 14 out of 14 logs did not include refrigerator temperature reference ranges. 3. In 2018: 45,000 patient tests were performed. 4. Interview with TP#1 confirmed the above findings on 12/19/2018 around 04:30 PM

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on review of BioRad Liquichek Immunoassay Plus Control, Levels 1, 2 and 3 package insert and observation of controls stored in a refrigerator, the laboratory failed to label expiration dates for 3 out of 3 bottles of controls indicating their stability from 2017 to the date of survey. Findings include: 1. The BioRad Liquichek Immunoassay Plus Control Levels 1, 2, and 3 package insert under STORAGE AND STABILITY states, "This product will be stable until the expiration date when stored unopened at -20 to -70 C. Thawed Unopened: When thawed and stored unopened at 2 - 8 C, this product will be stable as follows: - All Analytes: 30 days Except: - Androstenedione: 25 days - Prolactin, PSA (Free) and PSA (Total): 14 days - Estradiol: 8 days - Folate: 4 days Date of thaw should be noted. Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8 C, this product will be stable as follows: - All analytes: 14 days Except: - Estradiol: 5 days - Folate: 4 days Once thawed, do not refreeze this product. Discard the remaining material. This product is shipped under frozen conditions." 2. On the day of survey, 12/19/2018, the Surveyors observed that 3 out of 3 bottles of BioRad controls were in use, were not labeled

indicating the opened or stability expiration date on the controls to determine if they were used beyond the required manufacturer's stability dates. 3. Interview with TP #1 confirmed the findings above on 12/19/2018 around 4:30 PM ** C = Celsius

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 laboratory records, interview with Testing Personnel (TP) #1 and the Laboratory Director (LD), the LD failed to maintain the laboratory's quality assessment program to ensure the quality of services provided in the laboratory from 2017 to the date of survey. Findings include: 1. The Laboratories Quality Assurance plan states "To ensure high quality tests results that accurately reflect the status of the patient. To identify and correct issues through an ongoing review and education process." 2. On the day of survey, 12/19/2018, review of the following documents revealed the labortaory failed to follow their Quality Assurance plan: - The Beckman Coulter Access 2 Validation Data, revealed the LD did not review and sign before the instrument was put into use. - Proficiency attestation forms (See D2015). - Labeling controls (See D5415). - Conditions of storage (See D5413) 3. Review of temperature logs revealed the LD did not review and approve 25 out of 25 refrigerator temperature logs in 2017 and 2018. 4. The LD and TP#1 confirmed the findings above on 12/19 /2018 around 4:30 PM.