Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2091711	10/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Chesapeake Oncology Hematology Assoc	305 Hospital Drive, 2nd Floor, Glen Burnie, MD	

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
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to document the investigation into the root cause of and the remedial actions taken for unacceptable results for chemistry PT. Findings: 1. The laboratory's "Proficiency Testing" procedure stated "A FAILURE is any grade less than 80%. All Failures must be thoroughly investigated to determine cause and corrective actions must be initiated." 2. During the survey on 10/27/2023, the TC provided the surveyor with a document titled "Corrective Actions Checklist for Proficiency Testing Failures" (CA checklist) which was a template to aid in the investigation of the root cause of the PT failures. 3. The laboratory received a 40% for total bilirubin in the 2022 2nd chemistry event. The evaluation form included a statement that the PT samples were retested and "7 out of linearity", but did not include a documented investigation into the root cause of the failure, what remedial actions were taken, and whether patient results were affected. 4. The laboratory received a 40% for sodium and a 0% for CA 125 in the 2023 1st chemistry event. The evaluation form included statements that the 2 CA 125 PT samples were retested and 1 of the 2 samples still had out of range (OOR) results and that the 3 OOR sodium PT samples were retested and 2 of the 3 samples still had OOR results. There was no documented investigation into the root cause of the failures. 5. The laboratory

	received a 60% for albumin, a 60% for total protein, a 60% for urea nitrogen, and a 0% for CA 125 in the 2023 3rd chemistry event. The evaluation form included a statement that the PT samples were repeated. There was no documentation of an investigation into the root cause of the failures, what remedial actions were taken, and whether patient results were affected. This was the 2nd failure for CA 125 within 3 PT events. 6. The CA checklist was not completed for any of the failed results listed above. 7. During the survey on 10/27/2023 at 5:30 PM, the TC confirmed that there was no documentation of the investigation into the root cause of the PT failures and remedial actions taken.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of the manufacturer's product insert (PI), review of test requisitions, and interview with the testing person (TP), the laboratory failed to ensure that the test requisitions contained the time of specimen collection to ensure that specimens were analyzed within the manufacturer's defined stability limits for chemistry testing. Findings: 1. The laboratory used a Medica EasyRA chemistry analyzer. 2. The PI for total bilirubin stated "This assay should be done within 2 hours from collection, as bilirubin is unstable in the sample. If the samples cannot be assayed within this time, store samples for 3 days at 2-8C. " 3. The laboratory tested patient specimens that were collected onsite and hand delivered to the laboratory and from two remote sites that were delivered to the laboratory in the afternoon via a courier. 4. The TP stated that the specimens from the remote sites were stored at room temperature until the courier picked them up and transported the specimens to the laboratory in a cooler containing ice packs. 5. The specimens collected onsite were collected from a different group that entered the requisitions directly into a laboratory information system (LIS). The TP stated they did not have access to other group's electronic requisitions in the LIS, but was able to view the orders in a separate database. The TP stated that the orders from the separate database did not capture accurate collection times, only the time the order was placed in the database. 6. The specimens received from the remote sites included paper requisitions which included the collection date, but not the collection time. 7. During the survey on 10/27/2023 at 4:30 PM, the TP confirmed that the electronic database and the paper requisitions did not contain specimen collection times to ensure that patients were tested within the manufacturer's defined stability limits and that they did not have access to the electronic requisitions for the specimens collected onsite.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient results in the laboratory information system (LIS) and interview with the testing person (TP), the laboratory failed to ensure that the LIS indicated the laboratory where patient testing occurred. Findings: 1. The laboratory performed chemistry, endocrinology, and hematology testing. Patient specimens were sent to a reference laboratory for testing not performed at the laboratory or when an instrument was not in use. 2. During the survey on 10/27/2023 at 4:55 PM, the TP confirmed that the LIS did not specify which laboratory performed the testing for the patient results listed in the LIS.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of the procedure, review of patient test reports, and interview with the technical consultant (TC), the laboratory failed to ensure that the test reports contained accurate reference ranges for hemoglobin, hematocrit, and total protein. Findings: 1. The laboratory's procedure included a table listing the following reference ranges: a. Hemoglobin: females 9.9-13.6 g/dL, males 11.3-15.7 g/dL b. Hematocrit: females 30.2-42.3 %, males 32.6-47.5 % c. Total protein: 6.0-8.3 g/dL 2. The final report for a randomly selected female patient listed the normal range for hemoglobin as 11.0-15.0 g/dL, hematocrit as 32.6-47.5 % (which is the reference range for males), and total protein as 3.0-9.0 g/dL. 3. During the survey on 10/27 /2023 at 5:30 PM, the TC confirmed that the reference ranges listed on the test report did not match those listed in the procedure.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: The laboratory director failed to ensure that a corrective action plan was implemented and followed when the laboratory received scores of 0% in two out of three proficiency testing events for CA 125. Cross-refer to tag D2094 for details.