| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 21D2091711 | 05/28/2019 |
| **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 |
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| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory failed to ensure that the laboratory director (LD) and testing persons signed PT attestation statements, attesting that PT specimens were run in the same way as patient samples. Findings: 1. A review of chemistry PT records from 2018 showed that the LD did not sign the attestation statements for 2 out of 4 remedial PT events; and 2. The individuals performing PT failed to sign the attestation statements for 4 out of 4 remedial PT events. 3. During an interview on 5/28/19 at 2: 45 PM, the TC confirmed that the attestation statements were not signed by the LD of testing persons. |
| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(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 |

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| | the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that a copy of all PT records were maintained for a minimum of two years from the date of the PT testing event. Findings: 1. A review of hematology PT records from 2018 to 2019 showed that the attestation form which documents that PT samples were tested in the same manner as patient specimens was not available for 3rd event, 2018. 3. During an interview on 5 /28/19 at 2:45 PM, the TC confirmed that PT documents for the events listed above were not maintained with the hematology PT records reviewed. |
| **D3039** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(5)<br><br>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality assurance (QA) record review and interview with the technical consultant (TC), the laboratory did not ensure that QA records were maintained for at least 2 years. Findings: 1. A review of QA records from January, 2018 to April, 2019 showed that copies of the Levey-Jennings reports from hematology quality control were missing for 8 out of 16 months. 2. During an interview on 5/29/19 at 2:45 PM, the TC confirmed that hematology QA records were not maintained for a minimum of 2 years. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Note: This is a repeat deficiency. The laboratory was cited during the initial survey on |

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| | 11/30/2017 for the laboratory's procedure manual not reflecting the actual practice of the laboratory. The plan of correction stated that this would be corrected. Based on standard operating procedure manual (SOPM) review and interview with the technical consultant (TC), the laboratory's written policies and procedures did not reflect the actual practice of the laboratory. Findings: 1. The procedure, "General Lab Operational Policies," "Reagents and Supplies" states that "all items used in the laboratory must be marked with the date opened, and if opening the item changes the expiration date, the opened expiration date must be written on it as well." On 5/28/19 at 9:15 AM it was observed that the opened and in use hematology controls in the laboratory refrigerator were not labeled with the expiration date. During an interview at that time, testing person #1 stated that the hematology controls expired 2 weeks after opening; and 2. The procedure "Reagents and Supplies" also states that "supplies received (including reagents and kits) must be logged in on the appropriate logs." Record review showed that the EasyRA chemistry analyzer stored records of the on-board reagents only, and that no other hematology or chemistry reagent or quality control logs were present at the time of the survey. 3. The SOPM for the EasyRA chemistry analyzer states that the "monthly cleaning tasks" are to "bleach the diluent bottle," "bleach the waste bottle," "clean the wash cup," and "clean the ISE sample cup." A review of monthly chemistry analyzer maintenance records from August, 2018 to May, 2019 showed that "bleach the diluent bottle" was performed 2 out of 10 months; "bleach the waste bottle" was performed 3 out of 10 months; "clean the wash cup" was performed 4 out of 10 months; and "clean the ISE sample cup" was performed 3 out of 10 months; and 4. The Sysmex hematology analyzer maintenance log lists "Clean SRV Tray" as weekly maintenance and "Clean RBC & WBC Transducer" and "Clean Waste Chamber" as monthly maintenance. A review of monthly hematology analyzer maintenance records from December, 2017 to April, 2019 showed that weekly maintenance was not documented 1 of 4 weeks in 6/2018; 2 of 4 weeks in 8/2018; 1 of 4 weeks in 12/2018; 1 of 4 weeks in 1/2019; 2 of 4 weeks in 3/2019; and 1 of 4 weeks in 4/2019; and 5. Monthly hematology analyzer maintenance, "Clean RBC & WBC Transducer" was not documented 4/2018, 6/2018, and 8/2018 and "Clean Waste Chamber" was not documented 4/2018, 5/2018, and 6 /2018. 6. The SOPM for the EasyRA chemistry analyzer states, "You must perform the Precision Test weekly to ensure performance" and that if the Precision Test fails to perform manufacturer specified "adjustments." It states, "after those adjustments have been made, repeat the test. If the test fails again, contact Service." A review of the EasyRA's "Precision Log" from 7/28/18 to 5/28/19 showed that 2 out of 49 weeks the laboratory did not run the weekly Precision Test; and 7. On 11 days the Precision Test failed. There was no documentation of troubleshooting performed or a record that service had been called for these days. 8. The procedure, "Proficiency Testing" states that "any failures or sub-optimal results should be investigated and the 'Proficiency Test Survey Exception Report' completed to document investigation." Two of 4 remedial chemistry PT events in 2018 received "sub-optimal results" but no "Proficiency Test Survey Exception Report" was completed for these events. 9. During an interview on 5/29/19 at 2:45 PM the TC confirmed that the laboratory SOPM's written procedures did not reflect the actual practice of the laboratory. |
| **D5409** | PROCEDURE MANUAL<br>CFR(s): 493.1251(e)<br><br>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). |

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| | This STANDARD is not met as evidenced by:<br>Based on standard operating procedure manual (SOPM) review and interview with laboratory staff, the laboratory did not document the date of discontinuance for written procedures that were no longer performed. Findings: 1. The procedure, "Immunochemistry Testing using the Tosoh A1A 900" lists the "Menu of Tests Performed" as B12, Ferritin, Folate, PSA, Vit D, CEA, CA27.29, BMG, and CA125. The SOPM also includes a procedure for running each of the above analytes. 2. During an interview with laboratory staff at 2:00 PM on the day of survey, the staff stated that the laboratory had discontinued testing for B12, Folate, Vit D, and BMG. The procedures for these tests were not identified as discontinued and were not dated to show when they were discontinued; and 3. The laboratory was also performing TSH, FT4, and FT3 testing on the Tosoh which was not accurately reflected in the SOPM. 4. This was confirmed during the interview with lab staff on the day of survey. |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>The laboratory did not ensure that hematology controls used on the Sysmex XP-300 were labeled with the expiration date once opened. Cross refer to D5403, #1. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This STANDARD is not met as evidenced by:<br>The laboratory failed to document lot numbers and expiration dates of chemistry and hematology reagents and quality control materials to ensure that they were not used after they exceeded their expiration date. Cross refer to D5403, #2. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by: |

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| | The laboratory did not ensure that weekly and monthly maintenance was performed on the EasyRA chemistry analyzer and Sysmex XP-300 hematology analyzer as recommended by the manufacturer. Cross refer to D5403, #3, #4, and #5. |
| **D5431** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(2)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>The laboratory did not ensure that the weekly function check was performed on the EasyRA chemistry analyzer as recommended by the manufacturer and that function tests were within manufacturer's established limits before patient testing was performed. Cross refer to D5403, #6 and #7 . |
| **D6015** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)<br><br>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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory director did not ensure that the laboratory was enrolled in an HHS approved PT program for the chemistry testing performed. Findings: 1. Routine chemistry PT was not performed for events 1, 2, and 3 of 2018 due to the laboratory's failure to enroll. 2. During an interview on 5/28/19 at 10:15 AM, the TC stated that they "did not know" that the lab had not performed chemistry PT until November, 2018 and ordered 2 remedial PT kits. The TC confirmed that chemistry PT was not performed in 2018 due to the laboratory's failure to enroll. |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<br><br>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;<br><br>This STANDARD is not met as evidenced by: |

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| | Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the Laboratory Director (LD) did not ensure that all PT reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. A review of chemistry PT records from 2018 showed that PT results were not reviewed and signed by the LD for 3 out of 4 remedial PT events in 2018; and 2. Hematology PT results from the 3rd event, 2018 were not reviewed and signed by the LD. 3. During an interview on 5/28/19 at 2:45 PM, the TC confirmed that PT results from the events listed above were not reviewed and signed by the LD. |
| **D6019** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iv)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on standard operating procedure manual (SOPM) and proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that a corrective action plan was followed when chemistry PT results were found to be unacceptable. Findings: 1. The laboratory procedure, "Proficiency Testing" states that "Failures must be thoroughly investigated and corrective actions documented. Follow the 'Proficiency Testing Survey Exception Report' protocol and complete the Proficiency Survey Report Form. Document all corrective actions, attaching additional information if needed." 2. The laboratory failed to enroll in PT for routine chemistry testing for 2018. A total of 4 remedial PT sample kits were purchased and tested. 3. For the American Proficiency Institute (API) kit, samples 62R-CH-01 through 62R-CH-05 the laboratory scored 40% for albumin, and 60% for sodium; for API kit, samples 63R-CH-01 through 63R-CH-05, the laboratory scored 60% for albumin; and for a kit from American Association of Bioanalysts, the laboratory scored 60% for sodium. 4. There was no "Proficiency Survey Report Form" completed, showing that an investigation had been performed into the reasons for the failed PT, for 3 of 3 remedial PT events listed above. 5. During an interview on 5/28/19 at 2:45 PM, the TC confirmed that a corrective action plan had not been performed for 3 of 3 failed remedial chemistry PT events for 2018. |
| **D6022** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on review of the quality assurance (QA) plan and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that the QA plan was maintained to identify failures and corrective actions taken when failures are identified. Findings: 1. Record review showed that proficiency testing (PT) attestation worksheets were not signed by the LD and testing persons (see D2009), PT records were incomplete (see D2015), QA records were not maintained (see D3039), the procedure manual did not accurately reflect the current practice of the laboratory (see D5403 and D5409), hematology controls were not labeled with the expiration date (D5415), lot numbers and expiration dates of reagents and controls were not documented (see D5417), instrument maintenance was not performed according to manufacturer specifications (see D5429), instrument function checks were not performed according to manufacturer specifications (see D5431), the laboratory failed to enroll in PT for routine chemistry testing (see D6015), PT results were not reviewed by the LD (see D6018), and corrective actions were not performed for failed PT (see D6019). 2. Procedure manual review showed that the procedure, "Quality Assessment," subsection, "QA Policies Review" states that "The QA Plan and all activities will be reviewed annually by the Lab Director and the Technical Consultant and assessed for effectiveness of policies." A review of the procedure manual, quality control records, maintenance logs, and PT worksheets showed that the QA reviews performed by the TC did not identify errors in quality. 3. During an interview on 5/28 /19 at 2:45 PM, the TC confirmed that the laboratory's QA plan was not maintained to identify failures in quality as they occur. |
| **D6041** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(3)<br><br>(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;<br><br>This STANDARD is not met as evidenced by:<br>The technical consultant failed to ensure that the laboratory was enrolled in proficiency testing for all tests performed in the laboratory. Cross refer to D6015. |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with the technical consultant (TC), the TC failed to perform and document the competency reviews on all testing personnel at least semiannually during the first year the testing person performed patient testing. Findings: 1. The laboratory currently has 2 testing personnel listed on the "Laboratory Personnel Report (CLIA) (CMS-209)." Training documents showed that the initial training for testing person #1 was performed 11/16/17. 2. A review of competency assessment documents from November, 2017 to present showed that a 6 month competency assessment was performed on testing person #1 but that there was no documentation of a competency assessment being performed after 12 months. 3. |

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| | During the survey on 5/28/19 at 2:45 PM the TC confirmed that there was no annual evaluation performed for 1 of 2 testing personnel performing patient testing in the laboratory. |