| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 49D0702896 | 01/28/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Hematology Oncology Assoc Of Fredericksburg | 4501 Empire Court, Fredericksburg, VA | |

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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| **D0000** | An announced CLIA recertification survey was conducted at Hematology Oncology Associates of Fredericksburg on January 27 and 28, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows: |
| **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 the PT event.<br><br>This STANDARD is not met as evidenced by:<br>**REPEAT DEFICIENCY** Based on a review of the laboratory's policies and procedures, proficiency testing (PT) documentation, and an interview, the laboratory failed to follow their established policy and retain attestation statements signed by the laboratory director (LD) for one (1) of sixteen (16) events reviewed for calendar years 2018 and 2019. Findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Proficiency Testing", which stated "7. Upon completion of the testing, the Laboratory Director or his designee must review and sign the result reporting form. The Lab Director and all testing personnel must sign the Attestation Statement." 2. Review of the laboratory's American Proficiency Institute (API) 2018 and 2019 Core Chemistry Events 1,2 3; 2018 and 2019 |

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| | Miscellaneous Chemistry Events 1, 2, 3; and 2018 and 2019 Hematology/Coagulation Events 1, 2, 3 PT documentation, a total of 16 events, revealed no attestation statement signed by the LD for the 2019 API Miscellaneous Chemistry Event 2. The surveyor requested to review the signed attestation for the 2019 API Miscellaneous Chemistry Event 2. The laboratory provided no documentation to review. 3. In an interview with the Technical Supervisor on January 27, 2020 at approximately 2:00 PM, the above findings were confirmed. |
| **D2094** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(e)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's policies and procedures, proficiency testing (PT) records, and interview, the laboratory failed to follow their established policy and document remedial action taken for one (1) unsatisfactory scored Vitamin B12 analyte event out of six (6) events reviewed for calendar years 2018 and 2019. Findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Proficiency Testing", which stated, "12. c. 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. Review of the laboratory's 2018 and 2019 American Proficiency Institute (API) PT results, a total of 6 events, revealed a lack of documentation of the corrective or remedial action taken for the 2018 API Miscellaneous Chemistry Event 1 with a B12 analyte score of 67%. The surveyor requested documentation of remedial action taken for 2018 API Miscellaneous Chemistry Event 1-B12. The laboratory provided no documentation to review. 3. In an interview with the Technical Supervisor on January 27, 2020 at approximately 2:00 PM, the above findings were confirmed |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of policies and procedures, verification of accuracy records, and an interview, the laboratory failed to perform one (1) of two (2) verification of accuracy evaluations for flow cytometry testing in calendar year 2019. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a lack of a twice annual accuracy verification policy for flow cytometry testing. 2. Review of the laboratory's twice annual verification of accuracy documentation for calendar year 2019 revealed one flow cytometry verification of accuracy was performed and |

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| | evaluated in calendar year 2019 (recorded on 2/22/19). The surveyor requested documentation of additional verification of accuracy documentation for 2019. The laboratory provided no additional documentation for review. 3. In an exit interview with the technical supervisors, laboratory manager and general supervisor on January 28, 2020 at approximately 2:30 PM, the above findings were confirmed. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on a laboratory tour, review of the laboratory's policy and procedure manual, instrument package inserts, manufacturer's operators guide, temperature guides, validation/verification records, calibration verification records, instrument comparison records, quality assessment documents and interviews, the laboratory failed to: 1. document written procedures for manual White Blood Cell (WBC) differentials and automated slide staining performed on the Hematek slide stainer (Cross Reference D5401 A and B); 2. document temperatures and humidity for the TOSOH laboratory (Cross Reference D5413); 3. perform validation of performance characteristics of manual White Blood Cell (WBC) differentials prior to patient testing and validation of the TOSOH A1A 900 after the instrument was moved to another room (Cross Reference D5421 A & B); 4. follow manufacturer's protocols for function checks for the laboratory's SSP-Series Portable Balance (Cross Reference (Cross Reference D5433); 5. follow their established policy for the calibration verification every 6 months for those analytes tested on the TOSOH A1A 900 with fewer than three calibrators (Cross Reference D5439) - REPEAT DEFICIENCY; 6. establish and follow a policy for the comparison of the two Medica EasyRA Chemistry analyzer (Cross Reference D5775) - REPEAT DEFICIENCY. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on a tour of the laboratory, review of the laboratory's policy and procedure manual, lack of documentation and interviews, the laboratory failed to have documentation of a written policy for the performance of manual White Blood Cell (WBC) differentials at the time of the survey on January 27, 2020. Findings include: 1. During a tour of the laboratory on January 27, 2020 at approximately 1:15 PM, the surveyor noted a microscope, manual differential counter and Hematek slide stainer. The surveyor asked Technical Supervisor 2 how long they have been performing |

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| | manual differentials. The Technical Supervisor 2 responded that they recently began performing manual differentials. Testing Personnel A (TP A)commented that they began performing manual differentials not long before she was hired at the end of June 2019 and that they only perform manual differentials when ordered by the provider. 2. Review of the laboratory's policy and procedure manual revealed the laboratory lacked documentation of a written procedure for the performance of manual WBC differentials. The surveyor requested to review a written manual WBC differential procedure. The laboratory provided no procedure for review. 3. In an exit interview with the technical supervisors, laboratory manager and general supervisor on January 28, 2020 at approximately 2:30 PM, the above findings were confirmed. B. Based on a tour of the laboratory, review of the laboratory's policy and procedure manual, lack of documentation and interviews, the laboratory failed to have documentation of a written procedure for the performance of automated staining of slides on the Hematek slide stainer at the time of the survey on January 27, 2020. Findings include: 1. During a tour of the laboratory on January 27, 2020 at approximately 1:15 PM, the surveyor noted a microscope, manual differential counter and Hematek slide stainer. The surveyor asked Technical Supervisor 2 how long they have been performing manual differentials. The Technical Supervisor 2 responded that they recently began performing manual differentials. Testing Personnel A (TP A) commented that they began performing manual differentials not long before she was hired at the end of June 2019 and that they only perform manual differentials when ordered by the provider. 2. Review of the laboratory's policy and procedure manual revealed the laboratory lacked documentation of a written procedure for the performance of automated staining of slides on the Hematek slide stainer. The surveyor requested to review a written procedure for the Hematek slide stainer. The laboratory provided no procedure for review. 3. In an exit interview with the technical supervisors, laboratory manager and general supervisor on January 28, 2020 at approximately 2:30 PM, the above findings were confirmed. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's policies and procedures, temperature logs, lack of documentation and an interview, the laboratory failed to follow their established policy for the documentation of the daily temperature and humidity of the TOSOH Chemistry laboratory for four (4) months (April 2018, May 2018, June 2018, and August 2018) out of seven (7) months reviewed. Findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Temperature, Humidity, and Eyewash Checks", which stated "2. Temperature and humidly levels will be recorded in the appropriate columns on the "Temperature and Humidity Log" and initialed by the person who checked them." 2. Review of the March 2018 to September 2018 temperature charts for the "TOSOH" room (instrument was moved to a different room on August 28, 2018) revealed a lack of documentation of the room temperature and |

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| | humidity for April 2018, May 2018, June 2018 and August 2018. The surveyor requested documentation of the daily room temperature and humidity of the "TOSOH' room. The laboratory provided no documentation to review. 3. In an exit interview with the technical supervisors, laboratory manager and general supervisor on January 28, 2020 at approximately 2:30 PM, the above findings were confirmed. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on a tour of the laboratory, review of the laboratory's validation records, patient test logs, and interviews, the laboratory failed to perform and evaluate accuracy, precision, and verification of reference ranges for manual White Blood cell (WBC) differentials prior to performing patient testing from April 2019 until the date of the survey on January 27, 2020. The findings include: 1. During a tour of the laboratory on January 27, 2020 at approximately 1:15 PM, the surveyor noted a microscope, manual differential counter and Hematek slide stainer. The surveyor asked Technical Supervisor 2 how long they have been performing manual differentials. The Technical Supervisor 2 responded they recently began performing manual differentials. Testing Personnel A (TP A) commented that they began performing manual differentials not long before she was hired at the end of June 2019 and that they only perform manual differentials when ordered by the provider. 2. Review of the laboratory's validation records revealed a lack of documentation of the accuracy, precision, and reference range verification for manual WBC differentials. The surveyor requested the documentation of the validation records for manual WBC differentials. At approximately 1:15 PM on January 28, 2020, the Technical Supervisor 2 stated they had not performed validation of the manual WBC differentials. 3. Review of the laboratory's Laboratory Information System (LIS), Medlinks, revealed one-hundred fifty-one manual WBC differentials were performed from April 26, 2019 until the date of the survey on January 27, 2020. 4. In an exit interview with the technical supervisors, laboratory manager and general supervisor on January 28, 2020 at approximately 2:30 PM, the above findings were confirmed.<br>B. Based on a review of the laboratory's performance validation records, and interviews, the laboratory failed to evaluate and verify the accuracy, precision and reportable range for Beta 2 microglobulin, CA 125, CA 27.29, Carcin-embryonic Antigen (CEA), Ferritin, Prostatic Specific Antigen (PSA), Vitamin B12 and Vitamin D testing after moving the TOSOH A1A 900 analyzer to a different location on August 28, 2018. Findings include: 1. Review of the TOSOH A1A 900 analyzer performance verification documentation revealed a lack of documentation of the verification of accuracy, precision and reportable range for Beta 2 microglobulin, CA 125, CA 27.29, CEA, Ferritin, PSA, Vitamin B12 and Vitamin D testing after moving the TOSOH A1A 900 analyzer to a different location on August 28, 2018. The surveyor requested the documentation of the validation records for the TOSOH A1A 900. At approximately 10:20 AM on January 28, 2020, the Technical Supervisor |

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| | stated that they had not performed a validation of the TOSOH A1A 900 after it was moved to a different room. 2. In an exit interview with the technical supervisors, laboratory manager and general supervisor on January 28, 2020 at approximately 2:30 PM, the above findings were confirmed. |
| **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>Based on a review of the laboratory's policies and procedures, SSP-Series Portable Balances Operation's Manual, instrument maintenance records, and interviews, the laboratory failed to follow manufacturer's maintenance protocols for function checks for the laboratory's SSP-Series Portable Balance (Serial number 07252016131) from March 2019 until date of the survey on January 27, 2020. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, "Antibody Cocktail Preparation and QC', which stated "EQUIPMENT AND MATERIALS-1. Analytical balance capable of weighing from 0.01 grams to 200 grams." 2. In an interview with Technical Supervisor (TS) 2 at 9:00 AM on January 28, 2020, the surveyor asked TS 2 if the laboratory had a balance, where the laboratory's balance was stored and if the balance was being calibrated each week and when moved. TS 2 stated that, when needed, the balance is pulled out of the cabinet to use. TS 2 stated "They didn't know calibration was needed at least once a week and when moved." 3. Review of the SSP-Series Portable Balances Operation's Manual revealed a section, "INSTALLATION & SET-UP", which stated "Calibrate. All SSP-Series are calibrated at the factory prior to shipment. Transportation of the instrument plus the differences in barometric pressure, humidity and ambient temperate conditions require calibration at the point of use. Calibrate regularly, at least once a week, to ensure accurate weighing results." and "CALIBRATION-Calibration is required at installation (see Installation & Set-up) and at regular intervals thereafter. Calibrate if the balance is moved to a new location." The surveyor asked TS 2 for documentation of the balance's calibration for the dates when the balanced was used from March 2019 until the date of the survey on January 27, 2020. The laboratory provided no documentation for review. 4. In an exit interview with the technical supervisors, laboratory manager and general supervisor on January 28, 2020 at approximately 2:30 PM, the above findings were confirmed. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following |

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| | occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>**REPEAT DEFICIENCY** Based on a review of the laboratory's policy and procedure manual, manufacturer's package inserts, TOSOH A1A 900 calibration verification records, and interviews, the laboratory failed to follow their established policy and perform calibration verification studies every 6 months for those analytes tested on the TOSOH A1A 900 which use fewer than three (3) calibrators from April 2018 until the date of the survey on January 27, 2020. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a procedure, "Immunochemistry Testing using the TOSOH A1A 900", which stated "Calibration verification is required every 6 months for those analytes which use fewer than 3 calibrators Refer to calibration verification materials package inserts for specific instructions in calibration verification." 2. Review of manufacturer's package inserts for the analytes performed on the TOSOH A1A 900 revealed the following analytes with fewer than 3 calibrators: Carcino-embryonic Antigen (CEA), Prostatic Specific Antigen (PSA), and Ferritin. 3. Review of the laboratory's TOSOH A1A 900 analyzer verification records from April 2018 to date of the survey on January 27, 2020 revealed the verification studies were performed as listed below: CEA - 9/24/18, 6/10 /19, 12/6/19: Ferritin - 9/24/18, 6/5/19, 12/6/19; PSA - 9/24/18, and 8/14/19. The surveyor requested documentation of calibration verifications for March 2019 for CEA, PSA and Ferritin. The laboratory provided no documentation for review. At approximately 10:25 AM on January 28, 2020, Technical Supervisor 2, stated that they did not perform calibration verification on the TOSOH A1A 900 for CEA, and Ferritin until June 2019 and PSA until August 2019. 4. Review of the laboratory's Laboratory Information System (LIS), Medlinks, revealed the following number of patient samples were analyzed on the TOSOH A1A 900 for : CEA-131 patient samples from 3/25/29 to 6/10/19; Ferritin- 52 patient samples from 3/25/19 to 6/10 /19; and PSA- 197 patient samples from 3/25/19 to 8/14/19. 5. In an exit interview with the technical supervisors, laboratory manager and general supervisor on January 28, 2020 at approximately 2:30 PM, the above findings were confirmed. |
| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.<br><br>This STANDARD is not met as evidenced by: |

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| | **REPEAT DEFICIENCY** A. Based on a tour of the laboratory, review of policies and procedures, chemistry records, and interviews, the laboratory failed to establish and follow a policy for the comparison of Chemistry test results performed on the two (2) Medica EasyRA instruments from April 2018 to the date of the survey on January 27, 2020. Findings include: 1. A tour of the laboratory at approximately 1:15 PM on January 27, 2020 revealed that the laboratory has 2 Medica EasyRA Chemistry analyzers. The instruments were identified as "Slow" (Serial Number 01445112) and "Fast" (Serial Number 20917002816). 2. Review of the policies and procedures revealed no documentation of a policy or procedure to evaluate a comparison of Albumin, Alkaline Phosphotase, Alanine Aminotranferase, Aspatate Aminotransferase, Blood Urea Nitrogen, Calcium, Chloride, Carbon Dioxide, Creatinine, Glucose, Lactate Dehydrogenase, Magnesium, Phosphorus, Potassium, Sodium, Total Bilirubin, and Total Protein results assayed on the 2 Medica EasyRA analyzers. 3. Review of the chemistry records, from April 2018 and up to the date of survey on January 27, 2019 revealed a lack of documentation or evaluation of the Albumin, Alkaline Phosphotase, Alanine Aminotranferase, Aspatate Aminotransferase, Blood Urea Nitrogen, Calcium, Chloride, Carbon Dioxide, Creatinine, Glucose, Lactate Dehydrogenase, Magnesium, Phosphorus, Potassium, Sodium, Total Bilirubin, and Total Protein result comparison records for the 2 Chemistry analyzers listed above. The surveyor requested documentation of the 2 Medica EasyRA result comparisons. Technical Supervisor 2 (TS 2) stated "They perform instrument comparison for the 2 Hematology analyzers but forgot about the 2 Chemistry analyzers." The laboratory provided no documentation to review. 4. In an exit interview with the technical supervisors, laboratory manager and general supervisor on January 28, 2020 at approximately 2:30 PM, the above findings were confirmed. B. Based on a tour of the laboratory, review of policies and procedures, Hematology records, and interviews, the laboratory failed to establish and follow a policy for the comparison of Automated White Blood Cell (WBC) differentials performed on the Sysmex XNL 430 Hematology analyzers and manual WBC differentials from April 2019 to the date of the survey on January 27, 2020. The findings include: 1. During a tour of the laboratory on January 27, 2020 at approximately 1:15 PM, the surveyor noted a microscope, manual differential counter and Hematek slide stainer. The surveyor asked Technical Supervisor 2 how long they have been performing manual differentials. The Technical Supervisor 2 responded they recently began performing manual differentials. Testing Personnel A (TP A) commented that they began performing manual differentials not long before she was hired at the end of June 2019 and that they only perform manual differentials when ordered by the provider. 2. Review of the policies and procedures revealed no documentation of a policy or procedure to evaluate a comparison of Automated White Blood Cell (WBC) differentials performed on the Sysmex XNL 430 Hematology analyzers and manual WBC differentials. 3. Review of the Hematology records, from April 2019 and up to the date of survey on January 27, 2019 revealed a lack of documentation or evaluation of the comparison of the Automated White Blood Cell (WBC) differentials performed on the Sysmex XNL 430 Hematology analyzers and manual WBC differentials. The surveyor requested the documentation of the comparison of the automated and manual WBC differentials. At approximately 1:15 PM on January 28, 2020, the Technical Supervisor 2 stated they had not performed a comparison of the automated and manual WBC differentials. 4. Review of the laboratory's Laboratory Information System (LIS), Medlinks, revealed one-hundred fifty-one manual WBC differentials were performed from April 26, 2019 until the date of the survey on January 27, 2020. 5. In an exit interview with the technical supervisors, laboratory manager and general supervisor on January 28, 2020 at approximately 2:30 PM, the above findings were confirmed. |

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| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the Quality Assurance (QA) plan, QA Quality Assessment audits, laboratory's policies and procedures, manufacturer's operating guide, package inserts, instrument and method validation records, calibration verification records, and interviews, the laboratory's established QA plan failed to identify and address analytic issues in the specialties of Diagnostic Immunology, Chemistry, and Hematology (Cross Reference D5401, D5413, D5421, D5431, D5439, and D5775). Findings include: 1. Review of the laboratory's policies and procedures, manufacturer's operating guide, temperature logs, package inserts, instrument and method validation records, calibration verification records, and interviews revealed: - A lack of a written procedure for the performance of manual White Blood Cell (WBC) differentials at the time of the survey on January 27, 2020 (Cross Reference D5401). - A lack of a written procedure for the performance of automated staining of slides on the Hematek slide stainer at the time of survey on January 27, 2020 (Cross Reference D5401). - A lack of monitoring or documentation of the daily temperature and humidity of the TOSOH Chemistry laboratory for April 2018, May 2018, June 2018 and August 2018 (Cross Reference D5413). - A lack of documentation of the performance of accuracy, precision, and verification of normal ranges of manual WBC differentials prior to patient testing in April 2019 (Cross Reference D5421 A.). - A lack of documentation of the performance of the verification of accuracy, precision and reportable range for the TOSOH A1A 900 when the instrument was moved to another room on August 28, 2019 (Cross Reference D5421 B.). - A failure of the laboratory to follow the manufacturer's maintenance protocols for function checks of the laboratory's SSP-Series Portable Balance from March 2019 until the date of the survey on January 27, 2020 (Cross Reference D5431). - A failure of the laboratory to perform calibration verification studies every six months for Carcinoembryonic Antigen (CEA), Prostatic Specific Antigen (PSA) and Ferritin from April 2018 until the date of the survey on January 27, 2020 (Cross Reference D5439). -A failure of the laboratory to establish and follow a policy for the comparison of the Chemistry test results performed on the two (2) Medica EasyRA instruments from April 2018 to the date of the survey on January 27, 2020 (Cross Reference D5775 A.). -A failure of the laboratory to establish and follow a policy for the comparison of Automated White Blood Cell (WBC) differentials performed on the Sysmex XNL 430 Hematology analyzers and manual WBC differentials from April 2019 to the date of the survey on January 27, 2020 (Cross Reference D5775 B.). 2. Review of the QA plan revealed a "Quality Assessment Plan", which stated, "The lab service is under the jurisdiction of the Lab Director. It is the responsibility of the Technical Consultant to implement the plan. The Laboratory Director and Technical Consultant will be responsible either directly or by delegation for the following: 1. Ensuring the QA Plan meets all standards and is consistent with the philosophy of the entire organization. 2. Periodic review of any action, maintenance, quality control or problem logs which are kept by testing personnel, and resolution of any problem not immediately addressed by personnel. 3. Implementing actions to improve service. 4. Follow-up reviews to show proof of improved service. 5. Implementation of policies and procedures and evaluation of |

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| | their effectiveness. 6. Assuring the prompt, accurate, and reliable reporting of test results. 7. Assuring the adequacy and competency of staff. 8. Maintaining required enrollment in Proficiency testing programs, with appropriate review and actions. 9. Overseeing the quality control program." 3. Review of the laboratory's quarterly audits reports for 2018 and 2019 revealed a schedule/checklist used by the laboratory for quality assessment monitoring. The schedule/checklist listed the following monitors: "1st quarter-QC review, maintenance/action log reviews. Safety QA audit, Chart QA Process Audit, Kit Testing Audit; 2nd quarter-QC review, maintenance /action log reviews, PT review, Personnel QA, Procedure Manual reviews, RPM checks; 3rd quarter-QC review, maintenance/action logs, Procedure Manual reviews reviews, expired reagent audit, LIS QA audit; and 4th quarter-QC review, maintenance /action log reviews, Consultant competency, PT review and QA audit." Review of the quarterly audit checklists reviewed and signed by the Technical Supervisor from April 2018 until the date of the survey on January 27, 2020 revealed a lack of mention of the above missing documents and corrective actions taken for the lack of documents. 4. In an exit interview with the technical supervisors, laboratory manager and general supervisor on January 28, 2020 at approximately 2:30 PM, the above findings were confirmed. |
| **D5807** | TEST REPORT<br>CFR(s): 493.1291(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of patient test reports, lack of documentation, and interview, the laboratory's Onco Electronic Medical Record (EMR) final patient report failed to contain lymphocyte reference intervals or normal values for two (2) manual White Blood Cell (WBC) differential counts reviewed at the date of survey on January 28, 2020. Findings include: 1. Review of 2 patient test reports generated from the Onco EMR revealed lack of documentation of lymphocyte reference intervals or normal values for 2 manual WBC differential counts reviewed. 2. In an exit interview with the technical supervisors, laboratory manager and general supervisor on January 28, 2020 at approximately 2:30 PM, the above findings were confirmed. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on a tour of the laboratory, review of the laboratory's policies and procedures, instrument and method validation records, manufacturer's operator's guide, package inserts, patient test logs, calibration verification records, temperature logs, the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, laboratory personnel files, proficiency testing (PT) records, and interviews, the laboratory director failed to: 1. ensure the established quality assessment plan identified and |

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| | addressed issues in the analytic systems of Diagnostic Immunology, Chemistry, and Hematology (Cross Reference D6094); 2. ensure the evaluation and verification of the accuracy, precision, and reference ranges for manual White Blood Cell (WBC) differentials prior to patient testing (Cross Reference D5421 A.); 3. ensure the evaluation and verification of the accuracy, precision and reportable range for Beta 2 microglobulin, CA 125, CA27.29, Carcino-embryonic Antigen (CEA), Ferritin, Prostatic Specific Antigen (PSA), Vitamin B12 and Vitamin D testing after moving the TOSOH A1A analyzer to a different location (Cross Reference D5421 B.); 4. document initial training and competency assessments for two of two testing personnel (Cross Reference D6102); and 5. outline in writing the testing duties /procedures for five of five Testing Personnel (Cross Reference D6107). |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of Quality Assurance (QA) plan, laboratory's policies and procedures, manufacturer's operating guide, package inserts, instrument and method validation records, calibration verification records, temperature logs and interviews, the laboratory director failed to ensure the established quality assurance plan identified and addressed issues in the analytic systems of Diagnostic Immunology, Chemistry and Hematology. (Cross Reference D5791) |
| **D6095** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(6)<br><br>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on a tour of the laboratory, review of the laboratory's validation records, patient test logs, and interviews, the Laboratory Director (LD) failed to ensure the verification of the accuracy, precision, method comparison and reference range for manual White Blood cell (WBC) differentials prior to performing patient testing. (Cross Reference D5421 A.). B. Based on a review of the laboratory's performance validation records, and interviews, the Laboratory Director (LD) failed to ensure evaluation and verification of the accuracy, precision and reportable range for Beta 2 microglobulin, CA 125, CA 27.29, CEA, Ferritin, Prostatic Specific Antigen (PSA), Vitamin B12 and Vitamin D testing after moving the TOSOH A1A 900 analyzer to a different location on August 28, 2018. (Cross Reference D5421 B.) |
| **D6102** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(12)<br><br>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated |

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| | that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, laboratory's policies and procedures, lack of documentation, Quality Control documents, patient test reports and interviews, the Laboratory Director (LD) failed to document initial training and competency assessments for two (2) of two (2) testing personnel who perform high complexity testing. Findings include: 1. Review of the CMS 209 Laboratory Personnel Report revealed two (2) testing personnel who perform high complexity testing. (See attached Personnel Code Sheet.) 2. Review of the laboratory personnel files revealed: A lack of documentation of initial manual White Blood Cell (WBC) differential training or competency assessment for Testing Personnel (TP) A. A lack of documentation of initial manual WBC differential and Flow Cytometry training or competency assessment, and semi-annual competency assessment for Testing Personnel B. The surveyor requested to review the documentation. The laboratory provided no documentation of the initial manual White Blood Cell (WBC) differential training or competency assessment records for Testing Personnel A and the initial WBC differential and Flow Cytometry training or competency assessment, and semi-annual competency assessment for Testing Personnel B. 3. Review of the laboratory's policies and procedures revealed a policy, "Personnel Training & Competency Assessment", which states "1. All employees performing laboratory testing will have training in every test/procedure performed in the lab, and this training will be documented and maintained in the employee's personnel file. a. Training will be documented in writing within 90 days of employment, or of completion of training. (initial training) b. Documentation will be maintained for the duration of employment plus 2 years. 2. All employees performing laboratory testing will demonstrate competency in every test/procedure performed. This competency will be assessed by the Technical Consultant or the Lab Director...." 4. Review of the laboratory's Quality Control documents and patient test reports revealed TP A was performing high complexity manual WBC differentials from date of hire in June 2019 until the date of survey on January 27, 2020. Review of the laboratory's Quality Control documents and patient test reports revealed that TP B was performing high complexity Flow Cytometry testing from March 2019 until the date of the survey on January 27, 2020 and manual WBC differentials since April 2019 until the date of the survey. 5. In an exit interview with the technical supervisors, laboratory manager and general supervisor on January 28, 2020 at approximately 2:30 PM, the above findings were confirmed. |
| **D6107** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(15)<br><br>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), a laboratory tour, review of testing personnel (TP) records, and interview, the laboratory director (LD) failed to outline, in writing, the TOSOH A1A 900 Chemistry analyzer, Medica EasyRA Chemistry analyzer, Sysmex XN 430 Hematology analyzer, manual White Blood Cell (WBC) differentials, and Beckman Navios EX Flow Cytometer testing duties/procedures for five (5) of five (5) Testing Personnel on the date of the survey on January 27, 2020. Findings include: 1. Review of the CMS 209 personnel form revealed 5 testing personnel. (See Personnel Code Sheet.) 2. During a tour of the laboratory on January 27, 2020 at approximate 1: 15 PM, the surveyor noted the following analyzers and test methods in use for non-waived patient testing: TOSOH A1A 900 Chemistry analyzer, Medica EasyRA Chemistry analyzer, Sysmex XN 430 Hematology analyzer, manual White Blood Cell (WBC) differentials procedure, and Beckman Navios EX Flow Cytometer 3. Review of the available personnel records revealed a lack of documentation of the TOSOH A1A 900 Chemistry analyzer, Medica EasyRA Chemistry analyzer, Sysmex XN 430 Hematology analyzer, manual White Blood Cell (WBC) differentials, and Beckman Navios EX Flow Cytometer job designations or performance descriptions for five (5) Testing Personnel: TP A, B, C, D and E. The surveyor requested the job designations or performance descriptions for TP A, B, C, D and E. No written designation was available for review. 4. In an exit interview with the technical supervisors, laboratory manager and general supervisor on January 28, 2020 at approximately 2:30 PM, the above findings were confirmed. |