| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 44D0312039 | 11/18/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Scott County Community Hospital, Inc | 18797 Alberta St, Oneida, TN | |

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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| **D3007** | FACILITIES<br>CFR(s): 493.1101(b)<br><br>The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on the Laboratory's test menu on 11/15/19 and upon review of reagents for Magnesium, Digoxin, Phenobarbitol, Vancomycin and BNP (Brain Natriuretic Peptide) analytes and upon interview with the Medical Laboratory Technician (MLT) and the Laboratory Supervisor, it was determined the laboratory failed to have sufficient reagents to perform these tests that are within the laboratory's stated test performance menu. The findings include: 1. Based on the Laboratory's test menu as stated on 11/15/19 and review of reagents for Magnesium, Digoxin, Phenobarbitol, Vancomycin and BNP, the laboratory failed to have sufficient reagents to perform these tests that are within the laboratory's stated test performance menu. 2. An interview at approximately 4:00 p.m. on November 15, 2019 with the MLT and Laboratory Supervisor confirmed the laboratory was unable to perform tests Magnesium, Digoxin, Phenobarbitol, Vancomycin and BNP due to lack of sufficient reagents. ========== |
| **D3041** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(6)<br><br>Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. |

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| | This STANDARD is not met as evidenced by:<br>========== Based on a review of the send out log for 15 Complete Blood Count (CBC) reports for 10/15/19 and 10/16/19, lack of original reports from the testing laboratory, lack of testing laboratory's name, address and correct normal ranges on final report (which was manually entered into primary laboratory's computer system) and upon interview with the Medical Laboratory Technician (MLT), it was determined the CBC final reports did not contain the testing laboratory's name, address, correct normal ranges and the original reports had not been saved. The findings include: 1. A review of the send out log revealed 15 CBC's for 10/15/19 and 10/16/19 had been sent out for testing. 2. The laboratory failed to save the original CBC reports from the testing laboratory. 3. The laboratory failed to include the name and address of testing laboratory on final patient reports upon manual entry into laboratory/hospital computer system. 4. The laboratory failed to include the correct normal ranges from the testing laboratory upon manual entry into the laboratory/hospital computer system. 5. An interview at approximately 4:00 p.m. on November 14, 2019 with the MLT confirmed the 15 CBC final reports reviewed were sent to another laboratory for testing on 10/15/19 and 10/16/19 and did not contain testing laboratory's name and address, correct normal ranges from testing laboratory and that original report from testing laboratory had not been saved.<br>========== |
| **D5221** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(d)<br><br>All proficiency testing evaluation and verification activities must be documented.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on lack of Laboratory Director review of the Proficiency Testing (PT) records for 2018 and 2019 and interview with the Laboratory Supervisor, determined the Laboratory Director failed to ensure that PT evaluations and verification activities were reviewed and evaluated consistently for the two year period. The findings include: 1. There was no documentation of Laboratory Director review for Proficiency Testing evaluations for 2nd Event Chemistry in 2018 and 1st Event Chemistry in 2019. 2. There was no documentation of Laboratory Director review of Proficiency Testing attestation pages for 1st Event Chemistry and 3rd Event Blood Bank in 2018 and 1st and 2nd Event Chemistry, 1st Event Miscellaneous Chemistry, and 2nd Event Microbiology in 2019. 3. An interview with the Laboratory Supervisor at approximately 4:00 p.m. November 15, 2019 confirmed there was not consistent documentation of Laboratory Director review of PT evaluations and verification activities for 2018 and 2019.<br>========== |
| **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 |

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| | 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>========== Based on the lack of a Urine Microscopic procedure and upon interview with the Laboratory Supervisor, it was determined the laboratory failed to have a defined procedure for processing, reading and reporting Urine Microscopics upon review on November 14, 2019. The findings include: 1. There was no defined procedure for processing, reading and reporting Urine Microscopics on review date of November 14, 2019. 2. An interview at approximately 4:00 p.m. November 15, 2019 with the Laboratory Supervisor confirmed there was no defined procedure for processing, reading and reporting Urine Microscopics on review date of November 14, 2019.<br>========== |
| **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>========== 1. Based on observation of Laboratory and Blood Bank thermometers, review of thermometer verification protocol and upon interview with the Medical Laboratory Technician (MLT), it was determined the laboratory failed to ensure accuracy of thermometers for 2019. 2. Based on review of manufacturer's storage requirements, the 2019 storage temperature chart for Ddimer Controls (for use on the Alere Triage meter) and upon interview with the MLT, it was determined the laboratory failed to ensure proper storage of Ddimer controls for 2019. Based on Statement #1: The findings include: 1. Observation at approximately 10:00 a.m. on November 14, 2019, of Laboratory and Blood Bank thermometers, revealed expired accuracy verification for the following 8 thermometers: a. 1 Laboratory room temperature thermometer-expiration date of 4/28 /19 b. 4 Refrigerator Thermometers to include Blood Storage thermometers-expiration dates of 4/28/19 c. 1 Blood Bank Gel System Heatblock Thermometer-expiration date of 5/26/19 d. 1 Regular Blood Bank Heatblock Thermometer-expiration date of 5/26 /19 e. 1 Blood Bank Room Temperature Thermometer-expiration date of 6/14/19. 2. A review of the thermometer verification protocol states that Thermometers are to be |

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| | verified annually. 3. An interview at approximately 10:00 a.m. on November 14, 2019 with the MLT confirmed that thermometer accuracy verifications for 8 thermometers had not been performed for 2019. Based on Statement #2: The findings include: 1. A review of the manufacturer's storage requirements for Ddimer controls states to store at (minus 20 degrees Celsius or colder). 2. A review of documented storage temperatures for Ddimer Controls from February 1, 2019 to November 14, 2019 revealed 181 days that temperatures were not within acceptable storage requirements. 3. An interview at approximately 10:00 a.m. on November 14, 2019 with the MLT confirmed the storage temperatures for Ddimer controls for 2019 were not acceptable for 181 days from February 1, 2019 to November 14, 2019. ========== |
| **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:<br>========== Based on review of the Maintenance requirements for the Blood Bank Ortho Gel System, lack of maintenance documentation for the Gel System Micro Typing System Dispenser and for the Gel System Centrifuge and upon interview with the Laboratory Supervisor, it was determined the laboratory failed to perform and document maintenance per manufacturer's requirements for 2018 and 2019. The findings include: 1. A review of the maintenance requirements for the Blood Bank Ortho Gel System states that Calibration for the Micro Typing System Dispenser is to be performed periodically (annually), which had not been performed for 2018 and 2019. 2. A review of the maintenance requirements for the Gel System Centrifuge states RPM and timer display checks are to be documented daily with no documentation for 2018 and 2019. 3. An interview at approximately 11:00 a.m. on November 15, 2019 with the Laboratory Supervisor confirmed the laboratory failed to perform and document maintenance checks for the Ortho Gel System as required by the manufacturer for 2018 or 2019. ========== |
| **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 observation at approximately 10:00 a.m. on November 14, 2019 of two Blood Bank Pipettors used for making red cell dilutions, lack of procedure for performing pipettor accuracy verifications and upon interview with the Laboratory Supervisor, determined the laboratory failed to establish and follow procedure for ensuring accuracy of Blood Bank pipettors for 2018 and 2019. The findings include: 1. An observation at |

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| | approximately 10:00 a.m. on November 14, 2019 of two Blood Bank pipettors used for making red cell dilutions for Ortho Gel System. 2. Lack of procedure for performing pipettor accuracy verifications for 2018 and 2019. 3. An interview at approximately 4:00 p.m. on October 15, 2019 with the Laboratory Supervisor confirmed the laboratory failed to establish and follow procedure for Blood Bank Pipettor accuracy verification for the two year period.<br>========== |
| **D5435** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(2)<br><br>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on observation at approximately 9:00 a.m. on November 14, 2019 of large laboratory timer used for timing Erythrocyte Sedimentation Rates (ESR's) and an interview with the Laboratory Supervisor, determined the laboratory failed to establish and follow procedures for ensuring accuracy of timer for 2018 and 2019. The findings include: 1. An observation at approximately 9:00 a.m. on November 14, 2019 of timer used for ESR testing. 2. Lack of procedure and documentation for performing timer accuracy verification for 2018 and 2019. 3. An interview at approximately 4:00 p.m. on October 15, 2019 with the Laboratory Supervisor confirmed the ESR timer failed to have accuracy verification for the two year period.<br>========== |
| **D5437** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(a)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on lack of documentation for Linearity testing for Chemistry and Toxicology analytes performed on the Siemens E-XL Analyzer and upon interview with the MLT (Medical Laboratory Technician) and |

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| | Laboratory Supervisor, it was determined the laboratory failed to perform linearity testing every 6 months for 2018 and 2019 to ensure reportable range of testing. The findings include: 1. Lack of documentation for Linearity testing for Chemistry and Toxicology analytes performed on the Siemens E-XL Analyzer for 2018 and 2019. 2. An interview at approximately 4:00 p.m. on November 15, 2019 with the MLT and Laboratory Supervisor confirmed that Linearity testing had not been performed for 2018 and 2019 for Chemistry and Toxicology analytes performed on the Siemens E-XL Analyzer to ensure reportable range of testing.<br>========== |
| **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 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>========== Based on lack of calibration verifications for the Hematology analyzer for 2018 and 2019 and for the Arterial Blood Gas Analyzer at least every 6 months in 2018 and upon interview with the Laboratory Supervisor and Blood Gas Laboratory Supervisor, it was determined that calibration verifications were not performed at least once every 6 months for the two year period. The findings include: 1. There were no calibration verifications for review for the Hematology analyzer for 2018 and 2019. 2. Lack of calibration verification at least every 6 months in 2018 for the Blood Gas Analyzer. 3. An interview with the Laboratory Supervisor at approximately 4:00 p.m. on November 15, 2019 confirmed that calibration verifications for the Hematology analyzer had not been performed in 2018 or 2019. 4. An interview with the Blood Gas Laboratory Supervisor at approximately 1:00 p.m. on November 18, 2019 confirmed the Blood Gas Laboratory failed to perform Calibration Verification at least every 6 months on the Blood Gas Analyzer in 2018. ========== |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g) |

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| | 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on a review of the Laboratory's IQCP (Individualized Quality Control Plan) Quality Assessment (QA) Plan, review of monthly QA documentation for all tests under IQCP and upon interview with the Laboratory Supervisor, it was determined the laboratory failed to perform and document monthly reviews as stated per plan since 2018. The findings include: 1. A review of the IQCP Quality Assessment Plans states to perform QA reviews monthly for IQCP tests that include: Serum HCG (Human Chorionic Gonadotropin), Helicobacter Pylori, Mononeucleosis, HIV 1/2 (Human Immunodeficiency Virus 1&2), and Ddimer testing on the Triage Meter. 2. A review of the monthly QA documentation for all respective tests listed revealed no QA reviews documented since January 2018. 3. An interview at approximately 4:00 p.m. on November 15, 2019 with the Laboratory Supervisor confirmed the monthly QA reviews for the IQCP tests had not been documented since January of 2018.<br>========== |
| **D5555** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(c)(f)<br><br>(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on the Blood Bank procedure for Blood Storage Alarm Checks, lack of documented alarm checks for 2018 and 2019 and upon interview with the Laboratory Supervisor, determined the laboratory failed to monitor Blood Bank refrigerator alarm checks for the two year period. The findings include: 1. The Blood Bank procedure requires quarterly Blood Storage Alarm Checks. 2. Lack of documented alarm checks for the Blood Storage refrigerator for 2018 and 2019. 3. An interview at approximately 4:00 p.m. on November 15, 2019 with the Laboratory Supervisor confirmed the laboratory failed to monitor Blood Bank refrigerator alarm checks quarterly for the two year period.<br>========== |
| **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 |

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| | 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:<br>========== Based on observation 11/14/19 at approximately 9:00 a.m. of two Triage Meters in use for performing Ddimer's, lack of twice a year comparison evaluation for 2018 and 2019 and upon interview with the Laboratory Supervisor, it was determined the laboratory failed to perform and document twice a year evaluation between the two Triage Meters for performance of Ddimer's. The findings include: 1. Observed in use on 11/14/19 at approximately 9:00 a.m., during laboratory survey, of two Triage Meters used for Ddimer testing. 2. Lack of documentation for twice a year comparison evaluations between the two instruments for 2018 and 2019. 3. An interview at approximately 4:00 p.m. November 15, 2019 with the Laboratory Supervisor confirmed that twice a year comparisons for Ddimers performed on the Triage Meter were not performed for the 2 year period.<br>========== |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on review of 15 Complete Blood Count (CBC) reports for 10/15/19 and 10/16/19 and upon interviews with the Laboratory Assistant (LA), Medical Laboratory Technician (MLT) and Laboratory Supervisor, it was determined the 15 CBC's were sent to another laboratory for testing, the final results were manually entered into referring laboratory's computer system, there was no identification of the name and address of the testing laboratory on the final test reports, the normal ranges from the testing laboratory did not match the normal ranges on the patients' final reports and the laboratory stated the final reports from testing facility were not saved. The findings include: 1. A review of 15 CBC reports for 10/15/19 and 10/16/19 were sent to a another laboratory for testing. 2. The final CBC results were manually entered into the referring laboratory's computer system. 3. There was no identification of the testing laboratory's name and address on the final reports. 4. The normal ranges from the testing laboratory's reports did not match the final patient CBC reports as entered into the laboratory/hospital computer system. 5. The referring laboratory stated they did not save the reports from the testing laboratory. 6. Upon interviews at approximately 4:00 p.m. on November 15, 2019 with the LA, MLT and Laboratory Supervisor, it was confirmed the 15 CBC reports for 10/15/19 and 10/16/19 were tested at another laboratory, the final reports in the referring laboratory/hospital computer did not reflect where testing was |

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| | performed, did not reflect that results were manually entered, did not reflect the testing laboratory's normal ranges and that copies of the testing laboratory's final reports were not retained for more than a week after receipt.<br>========== |
| **D5817** | TEST REPORT<br>CFR(s): 493.1291(i)<br><br>If a laboratory refers patient specimens for testing-- (i)(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory; (i)(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and (i)(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on review of 15 Complete Blood Counts (CBC's) sent to another laboratory for testing on 10/15/19 and 10/16/19, review of patient results as manually entered into referring laboratory's computer system, testing laboratory's results and upon interview with the Medical Laboratory Technician (MLT), it was determined the referring laboratory failed to enter testing laboratory's normal reference ranges, the name and address of testing laboratory and failed to retain original copies from testing laboratory for a two year period. The findings include: 1. Upon review of 15 CBC's sent to another laboratory for testing on 10/15/19 and 10/16/19, it was revealed the referring laboratory failed to enter testing laboratory's normal reference ranges, the name and address of testing laboratory and failed to retain original copies of test reports for two years from testing laboratory. 2. An interview at approximately 4:00 p.m. on November 15, 2019 with the MLT confirmed the referring laboratory failed to enter testing laboratory's reference ranges, the name and address of testing laboratory and stated that original test reports were saved for a week, then discarded, for 15 CBC's sent out on 10/15/19 and 10/16/19.<br>========== |
| **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 documentation of laboratory deficiencies, the laboratory director failed to fulfill his/her duty to provide overall management and direction for the laboratory in accordance with $493.1445: failed to be responsible for the overall operation and administration of the laboratory (Refer to D6079); failed to ensure verification procedures were adequate to determine accuracy and precision of method (Refer to D6086); failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory (Refer to D6092); failed to ensure that quality control |

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| | programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur (Refer to D6093); failed to ensure reports of test results included perinent information required for interpretation (Refer to D6098); failed to ensure general supervisor provides on-site supervision of high complexity test performance (Refer to D6100).<br>========== |
| **D6079** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(a)(b)<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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on deficiencies found in the facility administration (Refer to D3007); retention requirements (Refer to D3041); general laboratory systems (Refer to D5221); analytic systems (Refer to D5403, D5413, D5429, D5431, D5435, D5437, D5439, D5445, D5555, D5775); postanalytic sytems (Refer to D5805 and D5817) and upon interview with the Laboratory Supervisor, it was determined the Laboratory Director has not demonstrated effective direction over the operation of the laboratory for 2018 and 2019. The findings include: 1. The deficiencies found in the facility administration, retention requirements, general laboratory systems, analytic systems and postanalytic systems revealed the Laboratory Director has not demonstrated effective direction over the operation of the laboratory for 2018 and 2019 (Refer to respective D-tags). 2. An interview at approximately 4:00 p.m. on November 15, 2019 confirmed the Laboratory Director has not demonstrated effective direction over the operation of the laboratory for the past 2 years. ========== |
| **D6086** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(ii)<br><br>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on lack of documentation for Linearity testing for Chemistry and Toxicology analytes performed on the Siemen's E-XL Analyzer, lack of documentation for Calibration Verifications for the Advia 2120 Hematology Analyzer and upon interview with the Laboratory Supervisor, it was determined the laboratory director failed to ensure verification procedures were performed for 2018 and 2019. The findings include: 1. There was no documentation |

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| | of Linearity testing performed for Chemistry and Toxicology analytes for 2018 and 2019. 2. There was no documentation of Calibration Verifications performed for the Hematology Analyzer for 2018 and 2019. 3. An interview at approximately 4:00 p.m. on November 15, 2019 with the Laboratory Supervisor confirmed the Laboratory Director failed to ensure verification procedures were performed for Chemistry, Toxicology and Hematology for the two year period.<br>========== |
| **D6092** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(iv)<br><br>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on lack of corrective action for unacceptable Proficiency Testing (PT) results for 2018 and 2019 and interview with Laboratory Supervisor, determined the Laboratory Director failed to ensure a corrective action plan was in place and followed for unacceptable PT results. The findings include: 1. There was no documentation of corrective action for the following unacceptable PT results: 3rd Event Hematology and 2nd Event Immunohematology in 2018; 1st and 2nd Events Chemistry, 1st Event Miscellaneous Chemistry and 1st Event Hematology/Urinalysis in 2019. 2. An interview at approximately 4:00 p.m. November 15, 2019 with the Laboratory Supervisor confirmed there was no corrective action for unacceptable PT results for 2018 and 2019.<br>========== |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control 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 review of laboratory procedure stating the Laboratory Supervisor is to review Quality Controls (QC) monthly, lack of readily availability of QC records for patient tracers for 2018 and 2019, lack of Supervisor reviews for Hematology, Coagulation, Chemistry, Endocrinology and Toxicology Quality Controls and upon interview with the MLT (Medical Laboratory Technician) and Laboratory Supervisor, it was determined the Laboratory Director failed to ensure that a Quality Control program was maintained to assure the quality of the laboratory services for 2018 and 2019. The findings include: 1. Review of laboratory procedure stated the Laboratory Supervisor will review all Quality Controls on a monthly basis. 2. For patient tracer reviews for 2018 and 2019, the QC records were not readily available and when found had no documentation of Supervisor reviews for Hematology, Coagulation, Chemistry, Endocrinology and Toxicology Quality Controls. 3. An interview at approximately 4:00 p.m. on November 15, 2019 with the MLT stated that QC records were discarded after a week. 4. An interview at approximately 4:00 p.m. on November 15, 2019 with the Laboratory Supervisor confirmed that daily QC records were discarded and that he |

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| | had not been reviewing QC on a monthly basis for 2018 and 2019.<br>========== |
| **D6098** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(8)<br><br>The laboratory director must ensure that reports of test results include pertinent information required for interpretation.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on a review of 15 CBC (Complete Blood Count) reports for 10/15/19 and 10/16/19 sent to another laboratory for testing, failure of CBC reports to include testing laboratory's name, address and correct normal ranges on final reports upon manual entry into referring laboratory's computer system, lack of original test reports from the testing laboratory and upon interviews with the Laboratory Assistant and MLT (Medical Laboratory Technician), it was determined the laboratory director failed to ensure the CBC reports included pertinent information required for interpretation. The findings include: 1. A review of 15 CBC reports for 10/15/19 and 10/16/19, sent to another laboratory for testing, failed to include the testing laboratory's name, address and normal ranges on the final reports upon manual entry into the referring laboratory's computer system. 2. A review of the 15 CBC reports for 10/15/19 and 10/16/19, sent to another laboratory for testing, revealed the original test reports had not been saved. The Laboratory Assistant (Phlebotomist) had to call the testing laboratory and request copies of the original reports. 3. An interview at approximately 1:00 p.m. on November 14, 2019 with the Laboratory Assistant (Phlebotomist) confirmed the original reports for the 15 CBC's sent out for testing to another laboratory on 10/15/19 and 10/16/19 had not been retained. 4. An interview at approximately 1:00 p.m. on November 14, 2019 with the MLT, confirmed the 15 CBC reports sent to another laboratory for testing failed to contain the testing laboratory's name, address and normal ranges on the final report upon manual entry and the original test reports had not been saved.<br>========== |
| **D6100** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(10)<br><br>The laboratory director must ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(4).<br><br>This STANDARD is not met as evidenced by:<br>========== Based on deficiencies found in the facility administration (Refer to D3007); retention requirements (Refer to D3041); general laboratory systems (Refer to D5221); analytic systems (Refer to D5403, D5413, D5429, D5431, D5435, D5437, D5439, D5445, D5555, D5775); postanalytic sytems (Refer to D5805 and D5817) and upon interview with the Laboratory Supervisor, it was determined the Laboratory Director had not ensured a general supervisor has provided supervision of high complexity test performance for the laboratory for 2018 and 2019. The findings include: 1. Deficiencies found in the facility administration, retention requirements, general laboratory systems, analytic systems and postanalytic systems, revealed the Laboratory Director failed to ensure |

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| | the general supervisor had provided supervision of high compexity test performance for the laboratory for 2018 and 2019 (Refer to respective D-tags). 2. An interview at approximately 4:00 p.m. on November 15, 2019 with the Laboratory Supervisor confirmed the Laboratory Director failed to ensure supervision of the laboratory for the past 2 years. ========== |
| **D6120** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(7)(8)<br><br>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on Testing Personnel (TP) listed on the CMS Form 209, competency documentation and interview with the Laboratory Supervisor, it was determined the Supervisor failed to document competencies for 2018 and 2019. The findings include: 1. Two of six Testing Personnel (#1 and #2) listed on the CMS Form 209, hired 8/1/17, lacked annual competency documentation for 2018. 2. One of six Testing Personnel (#6) listed on the CMS Form 209, hired 5/29/19, lacked training and competency documentation upon hire date. 3. One of six Testing Personnel (#3) listed on the CMS Form 209 hired 7/31/17 lacked documentation of all 6 required criteria for assessing competency as noted on 2018 and 2019 competency reviews. 4. An interview at approximately 4: 00 p.m. on November 15, 2019 with the Laboratory Supervisor confirmed that 2 of 6 TP lacked annual competency documentation for 2018, 1 of 6 TP lacked training and competency upon hire date of 5/29/19 and 1 of 6 TP lacked documentation of all 6 criteria required for competency assessment for 2018 and 2019.<br>========== |
| **D6142** | GENERAL SUPERVISOR QUALIFICATIONS<br>CFR(s): 493.1461<br><br>The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on review of the Laboratory Policy stating the Laboratory Supervisor is to review Quality Control (QC) monthly, lack of QC review for 2018 and 2019 and upon interview with the Laboratory Supervisor, it was determined the Laboratory Supervisor failed to review laboratory quality controls monthly for all specialties to include Chemistry, Hematology, General Immunology, Urinalysis, Endocrinology, Toxicology and Immunohematology (Blood Bank) for the two year period. The findings include: 1. A review of the Laboratory Policy stated the Laboratory Supervisor is to review QC on a monthly basis. 2. A |

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| | review of the QC available for 2018 and 2019 revealed there was no documentation of review. 3. An interview at approximately 4:00 p.m. on November 15, 2019 with the Laboratory Supervisor confirmed that Quality Control for all specialties listed had not had monthly reviews for 2018 and 2019.<br>========== |