| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 31D2133984 | 04/03/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Advanced Care Oncology & | 741 Northfield Ave, West Orange, NJ | |

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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| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to enroll in an approved PT program for Complete Blood Count test from July 2017 to the date of survey. The TP # 1 listed on CMS form 209 confirmed on 4/3/18 at 10:45 am the laboratory was not enrolled in PT testing. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>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 general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Procedure Manual and interview with the Testing |

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| | Personnel ( TP), the laboratory failed to establish a written procedure for enrollment, performance and evaluation of Proficiency Testing (PT) from July 2017 to the date of survey. The TP # 1 listed on CMS form 209 confirmed on 4/3/18 at 11:00 am that a PT procedure was not established. |
| **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>Based on surveyor review of the Procedure Manual (PM) and interview with the Tesing Personnel (TP), the laboratory failed to follow "Reagent Verification" procedure from July 2017 to the date of survey. The finding includes: 1. The PM stated that new lot of Cellpack and Stromatolyse-WH must be verified against old reagent lot but there was no documented evidence that it was performed. 2. The TP # 1 listed on CMS form 209 confirmed on 4/3/18 at 10:45 am that PM was not followed. |
| **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>Based on lack of Performance Specifications (PS) records and interview with the Testing Personnel (TP), the laboratory failed to verify PS for Complete Blood Count tests performed on the Sysmex XS 1000i analyzer from July 2017 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 4/3/18 at 11:15 am that the PS were not performed. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on surveyor review of the Laboratory Records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to provide overall management |

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| | and direction to the laboratory. The findings include: 1. The LD failed to ensure that competency assessmet was performed accurately. Cross refer to D 6004. 2. The LD failed to eusure that the laboratory enrolled for proficiency testing correctly. Cross refer to D 6015. 3. The LD failed to eusure that Quality Control programs were maintained. Cross refer to D 6020. 4. The LD failed to establish that Quality Assessment programs were established and maintained. Cross refer to D 6021. 5. The LD failed to ensure that prior to testing patients' samples all testing personnel had the appropriate training. Cross refer to D 6029. |
| **D6004** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, 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 surveyor review of the Personnel Records (PR) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure the competency of Testing Personnel (TP) in the performance of Complete Blood Count analysis was performed and documented correctly in 2017. The findings include: 1. Review of PR indicated that the evaluation for Competency Assessment (CA) of two out of three TP did not include all six criteria as stated at 493.1413 (b) (8) (i) (ii) (iii) (iv) (v) (vi). 2. The designated TP # 1 listed on CMS form 209 confirmed the lack of all required criteria in evaluating the CA for TP. 3. The LD did not ensure that the evaluation of CA performed by the assigned TP # 1was not qualified to perform CA. 4. The TP # 1 confirmed on 4/3/18 at 11:30 am that LD did not ensure the competency was performed and documented accurately. |
| **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 surveyor review of Proficiency Testing (PT) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure the laboratory was enrolled in an appropriate module with approved PT program from July 2017 to the date of the survey. The findings include: 1. The LD did not ensure that the laboratory had enrolled in a correct module with American Proficiency Institute. 2. PT must be |

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| | enrolled for each CLIA number. 3. The TP # 1 listed on CMS form 209 confirmed on 4/3/18 at 10:00 am the laboratory was not enrolled in correct module. |
| **D6020** | 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 program is established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>a) Based on surveyor review of the Quality Control records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to maintain a Quality Control Program (QCP) that verified the Quality Control (QC) materials performance prior to initial use for the Complete Blood Count analysis in the Sysmex XS 1000i analyzer from July 2017 to the date of survey. The findings include: 1. The laboratory had no QC lots verification records of five out of five lots used so far. 2. The TP # 1 listed on CMS form 209 confirmed on 4/3/18 at 11:00 am that QC material was no not verified. b) Based on surveyor review of the QC records, Manufacture Package Insert (MPI), QC material, and interview with the Testing Personnel (TP), the LD failed to ensure that laboratory was following QCP for Complete Blood Count tests performed on the Sysmex XS 1000i analyzer in Octber 2017 and February 2018. The findings include: 1. The laboratory used expired QC material for Complete Blood Count tests performed on the Sysmex XS 1000i analyzer in Octber 2017 and February 2018. 2. The laboratory used expired QC lot # 72130804, 805 and 806 on 10/24/17, 10/25/17 and 10/26/17 when QC expired on 10/22/17. 3. The laboratory used expired QC lot # 73250804, 805 and 806 on 2/13/18 when QC expired on 2/10/18. 4. Approximately 60 patient specimens were run on each day. 5. The TP #1 listed on CMS form 209 confirmed on 4/3/18 at 11:45 am that the laboratory used expired QC material. c) Based on the surveyor review of the QC records and interview with the TP, the LD failed to ensure that the laboratory rotated control material testing among all TP who perform Complete Blood Count test from July 2017 to the date of survey. The finding includes: 1. The QC was performed by one out of three TP on each day of patient testing. 2. The TP #1 listed on the CMS form 209 confirmed on 8/18/15 at 10:35 AM that only one out of three TP performed QC testing. |
| **D6021** | 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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Procedure Manual (PM), the Manufacturer Package Inserts |

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| | (MPI) and interview with the Testing Personnel (TP) , the Laboratory Director (LD) failed to ensure that the establishment and maintenance of Quality Assessment programs(QAP) in all phases ( pre-analytical, analytical, post-analytical) of Complete Blood Count testing in the Sysmex XS 1000i analyzer from July 2017 to the date of survey. The findings include: 1. Review of laboratory records revealed that the laboratory had no written Quality Assessment program. 2. Although the MPI instruction stated that quality control material must be stored in the refrigerator at 2-8 degress Centigrade (C), the laboratory stored at 10 degrees C on the day of survey. The same temperature was observed at 9:30 and 11:30 am. 3. The laboratory did not monitor and document refrigerator temperature where quality control material were stored from July 2017. 4. There was no established procedure to evaluate, periodically, the reliability and accuracy of electronic data transmission from Sysmex XS 1000i analyzer to the electronic medical records. 5. The LD failed to establish a procedure for verifying new QC material used on Sysmex XS 1000i analyzer from July 2017. 6. The TP # 1 listed on CMS form 209 confirmed on 4/3/18 at 11:45 am that the QAP was not establised and maintained. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<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)(11) 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 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>a) Based on review of Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that the training records were documented for three of three TP for Complete Blood Count tests from July 2017 to the date of survey. The TP # 1 listed on the CMS form 209 confirmed on 4/3/18 that LD did not ensure that training records were in PF. b) Based on review of PF and interview with the TP, the LD failed to ensure that the TP # 1 was not qualified to perform the competency assessment of testing personnel. The finding includes: 1. Personnel records indicated the TP # 1 had a high school diploma and she confirmed it. c) Based on review of PF and interview with the TP, the LD failed to ensure that all TP had their job duties and responsibilities doumented. The TP # 1 confirmed on 4/3 /18 at 11:45 am that the LD did not establish job duties and responsibilities for TP. |