| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 03D1051928 | 10/31/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Honorhealth Cancer Care | 14674 W Mountain View Blvd, #105, Surprise, AZ | |

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 |
|---|---|
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing (PT) records from 2018 for testing performed in the specialty of Hematology and interview with the technical consultant, the laboratory director failed to sign the PT attestation statement. Findings include: 1. The laboratory performs patient testing in the specialty of Hematology, with an approximate annual test volume of 8,400. 2. The PT attestation statement presented for review for the second testing event of 2018 lacked the director's signature. 3. The technical consultant confirmed that the PT attestation statement indicated above was not signed by the laboratory director. |
| **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. |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>Based on lack of Proficiency Testing (PT) records for review from 2017 and interview with the technical consultant, the laboratory failed to maintain a copy of all PT records for a minimum of 2 years. Findings include: 1. The laboratory performs patient testing in the specialty of hematology, with an approximate annual test volume of 8,400. The laboratory participates in three PT events annually. 2. No documentation was presented for review for the 1st and 2nd event of 2017 to indicate the laboratory maintained copies of all the PT records, including a copy of the PT program report form used by the laboratory to record results, instrument printouts showing the samples were tested by the laboratory, and the attestation statement signed by the analyst and laboratory director. 3. The technical consultant confirmed that the PT records indicated above could not be located during the survey. |
| **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 lack of Quality Assessment (QA) policies for review and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated correct problems identified in the general laboratory systems, including but not limited to, proficiency testing performance and personnel competency. Findings include: 1. No QA documentation was presented for review during the survey to indicate the laboratory had established written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated correct problems identified in the general laboratory systems. 2. The facility personnel confirmed that the laboratory could not produce evidence of established QA policies specific to general laboratory systems during the survey. |
| **D5391** | PREANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Quality Assessment (QA) documentation and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the preanalytic systems. Findings include: 1. No written QA policies and procedures specific to the preanalytic systems were presented for review during the survey. 2. The facility personnel confirmed that the laboratory could not produce evidence of an established preanalytic QA policy at the time of the survey. |

| | |
|---|---|
| **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 the severity and number of deficiencies cited for quality control practices identified during the survey conducted on October 31, 2018, it was determined that the laboratory failed to monitor the overall quality of the analytic systems and correct problems as specified in 493.1289 for patient testing performed by the laboratory in the specialty of Hematology. See D5401, D5435, D5437 and D5445 for findings. |
| **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 lack of a written procedure for review and interview with the facility personnel, the laboratory failed to have a written procedure for testing performed under the specialty of hematology. Findings include: 1. The laboratory performs patient testing on the Horiba Micros 60 hematology analyzer, with an approximate annual test volume of 8,400. 2. No evidence of an approved procedure manual was presented for review during the survey conducted on October 31, 2018. 3. The facility personnel confirmed that the laboratory did not have an approved written procedure for testing that occurs on the Horiba Micros 60 hematology analyzer. |
| **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 lack of established policies for review, lack of records for review and interview with the technical consultant, the laboratory failed to perform and document |

| | |
|---|---|
| | background counts on the Horiba Micros 60 hematology analyzer prior to patient testing. Findings include: 1. The laboratory performs patient testing on the Horiba Micros 60 hematology analyzer, with an approximate annual test volume of 8,400. 2. No policy and/or procedure was presented for review during the survey to indicate the laboratory defined a function check protocol for performing background counts each day prior to patient testing on the Horiba Micros 60 hematology analyzer, to ensure that the instrument is functioning correctly and calibrated properly. 3. No documentation was presented for review during the survey to indicate the laboratory performed background counts on the Horiba Micros 60 hematology analyzer prior to patient testing from July 13, 2017 through July 27, 2017. 4. The technical consultant confirmed that the laboratory failed to produce documentation of an established protocol for performing background counts, and failed to produce evidence of background counts performed during the time frame indicated above. |
| **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 calibration records for the Horiba Mircros 60 hematology analyzer and interview with the facility personnel, the laboratory failed to perform and document calibration procedures as required. Findings include: 1. The laboratory utilizes the Horiba Micros 60 hematology analyzer to perform patient testing, with an approximate annual test volume of 8,400. 2. No documentation was presented for review during the survey conducted on October 31, 2018 to indicate the laboratory performed and documented calibration procedures every 6 months as required by the manufacturer for the analyzer indicated above. Calibration records reviewed from January 2017 through the date of the survey indicated the analyzer was only calibrated in July 2017, February 2018 and May 2018. 3. The facility personnel confirmed that the laboratory only performed a calibration once during 2017. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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. |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>Based on lack of Quality Control (QC) records, review of patient test reports and interview with the facility personnel, the laboratory failed to perform control procedures using the frequency established by the laboratory. Findings include: 1. The laboratory performs Complete Blood Count (CBC) testing in the specialty of Hematology on the Horiba Micros 60 analyzer with an approximate annual test volume of 8,400. 2. The facility personnel confirmed that it is the practice of the laboratory to successfully perform 3 levels of control material (Low, Normal, High) prior to patient testing each day, however the laboratory could not produce evidence of a written quality control policy during the survey. 3. No documentation of QC testing (Low, Normal or High) was presented for review during the survey for patient testing that was performed by the laboratory from July 13, 2017 through July 27, 2017. 4. The number of patients tested during that time period could not be determined at the time of the survey. 5. The facility personnel confirmed that the laboratory did not perform control procedures as required for CBC testing on the dates indicated above. |
| **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 lack of Quality Assessment (QA) documentation and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the analytic systems. Findings include: 1. No written QA policies and procedures specific to the analytic systems were presented for review during the survey. 2. No QA documentation was presented for review during the survey to indicate the laboratory had a system in place to track the frequency of performance of QC for the Horiba analyzer, specifically to ensure that QC was successfully performed each day prior to patient testing. See D5445 for findings. 3. The facility personnel confirmed that the laboratory could not produce evidence of an established analytic QA policy at the time of the survey. |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Quality Assessment (QA) documentation and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems |

| | |
|---|---|
| | identified in the postanalytic systems. Findings include: 1. No written QA policies and procedures specific to the postanalytic system were presented for review during the survey. 2. The facility personnel confirmed that the laboratory could not produce evidence of an established postanalytic QA policy at the time of the survey. |
| **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>Based on lack of Quality Control (QC) procedure and QC documentation for review, the laboratory director failed to ensure that a quality control program is established and maintained to assure the quality of laboratory services provided. See D5445 for findings. |
| **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 a lack of quality assessment documentation for review, the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. See D5291, D5391, D5791 and D5891 for findings. |
| **D6033** | TECHNICAL CONSULTANT-MODERATE COMPEXITY<br>CFR(s): 493.1409<br><br>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>The Condition of Technical Consultant was found to be not met based on the failure of the laboratory to have a Technical Consultant who provides technical oversight as evidenced by: D6042 - failure to ensure that a Quality Control program is maintained and failure to ensure that acceptable levels of analytic performance were maintained throughout the entire testing process; and D6053 - failure to evaluate and document |

| | |
|---|---|
| | the performance of individuals responsible for moderate complexity testing at least annually. |
| **D6042** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(4)<br><br>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of quality control records for testing performed in the specialty of Hematology and lack of quality control policies and procedures for review during the survey, the technical consultant failed to ensure that the parameters for acceptable levels of analytic performance are maintained throughout the entire testing process. See D5445 for findings. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of competency evaluation documentation for review and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually. Findings include: 1. During the survey conducted on October 31, 2018, no 2016 annual competency evaluation documentation was presented for review for one testing personnel. 2. No 2017 annual competency evaluation documentation was presented for review for four out of four testing personnel. 3. The facility personnel confirmed that the laboratory failed to provide documentation of an annual competency evaluation from 2016 and 2017 for the testing personnel indicated above. |