Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	03D2026564	03/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Honorhealth Cancer Care	10320 W Mcdowell Rd, Bldg H, Ste 8025, Avondale, 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 CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2017 for testing performed in the specialty of Hematology and interview with the technical consultant, the laboratory director failed to sign the PT attestation statements. Findings include: 1. The laboratory performs patient testing in the specialty of Hematology, with an approximate annual test volume of 32,400. 2. The PT attestation statements presented for review for the first testing event of 2017, second testing event of 2017 and third testing event of 2017 lacked the director's signature. 3. The technical consultant confirmed that the PT attestation statements indicated above were not signed by the laboratory director.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-

	approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of Proficiency Testing (PT) reports for 2017 sent to the State Agency by the PT provider, the laboratory failed to successfully participate in a PT program for the regulated analyte, WBC Differential, under the specialty of Hematology. Findings include: 1. The laboratory's PT performance was unsatisfactory for the 1st event of 2017 for the regulated analyte, WBC Differential, with a score of 67%. 2. The laboratory's PT performance was unsatisfactory for the 3rd event of 2017 for the regulated analyte, WBC Differential, with a score of 0%.
D2128	HEMATOLOGY CFR(s): 493.851(e) (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. This STANDARD is not met as evidenced by: Based on review of corrective action documentation during the survey conducted on March 7, 2018 and interview with the facility personnel, the laboratory failed to document training and technical assistance and if remedial action was taken to correct the PT failure for the analyte, WBC Differential, for the 1st and 3rd events of 2017. See D2016 for findings.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on information furnished to the State Agency by the Proficiency Testing (PT) provider, the laboratory failed to achieve satisfactory performance for the regulated analyte, WBC Differential, for the 1st and 3rd event of 2017 resulting in unsuccessful PT performance. See D2016 for findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's established Quality Assessment (QA) policies, laboratory personnel records, Proficiency Testing (PT) records and interview with the facility personnel, the laboratory failed to follow 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, (A) employee competency and (B) proficiency testing performance. Findings include: A1. The laboratory's established Quality Assurance Plan states, "New employees will be thoroughly oriented to our systems, processes, and procedures. A checklist that documents this training is retained in the employee's personnel file....A formal performance evaluation is conducted at the end of the first six months of employment and each year of employment thereafter". The Quality Assurance Plan indicates that there are four Supervisory Monthly Checklists including Patient Test Management, Proficiency Testing, Maintenance/Calibration/Quality Control, and Communications /Complaints/Problems/Personnel that are used throughout the year and serve to facilitate an individual annual QA review. A2. No QA documentation was presented for review during the survey to indicate the laboratory followed written policies and procedures by performing and documenting QA checklists and reviews to identify problems associated with employee training and competency. See D6029, D6053 and D6054 for specific findings. B1. The laboratory's established Quality Assurance Plan for Proficiency Testing (PT) states, "Each PT event will be evaluated as the results are received. Appropriate corrective action will be taken at that time to prevent future failures and improve the quality of patient test results". B2. No documentation was presented for review during the survey conducted on March 7, 2018 to indicate the laboratory performed and documented the monthly QA checklists as indicated above during 2017, to address unsatisfactory PT results. The laboratory presented a corrective action document related to the PT failure for the 3rd event of 2017 that was signed and dated by the technical consultant on 03/07/18. 3. The last documented QA review was a "Monthly Checklist-Analytic" for the month of January 2017 that was completed and signed by the Technical Consultant on 02/16/17. 4. The facility personnel confirmed that the laboratory had not performed or documented QA activities as stated in their policy since February 2017.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient test reports, review of quality control (QC) policies and records for CBC testing performed on the Horiba Micros 60 analyzer and interview

	with the facility personnel, the laboratory failed to perform two control materials of different concentrations each day patient testing occured. Findings include: 1. The laboratory performs patient CBC testing in the specialty of Hematology, with an approximate annual test volume of 32,400. 2. The laboratory's policy titled, "Quality Control" states, "No patient test should be reported unless the QC for that test is complete and correct. For three level controls, patient results may be accepted if two of the three controls are in range....Two valid levels of quality control results must be obtained by running two of three control vials of the Mintrol 16 Low, Normal and High Control material at the beginning of each day of operation, prior to running patient samples, and after any daily maintenance has been performed". 3. The QC documentation presented for review for the testing date of May 30, 2017 indicated that the QC for the calculated result, MCV, was out of the laboratory's acceptable range for the Normal control (Lot#MX405) with a result of 85 and for the High control (Lot# MX405) with a result of 94. 4. The QC documentation presented for review for the testing date of May 31, 2017 indicated that the QC for the anlayte, RBC, was out of the laboratory's acceptable range for the Normal control (Lot#MX405) with a result of 4.58 and for the High control (Lot# MX405) with a result of 5.54. 5. No other documentation was presented for review to indicate the laboratory successfully repeated the two levels of QC testing for the MCV and RBC on the dates indicated above. 6. The facility personnel confirmed that the laboratory failed to successfully perform 2 levels of quality control for the MCV and RBC, as indicated above, prior to reporting patients' test results on each date. 7. The number of patients tested on the dates indicated above could not be determined at the time of the survey.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) policy, lack of QC lot change documentation and interview with the facility personnel, the laboratory failed to verify the criteria for acceptability of quality control materials. Findings include: 1. The laboratory performs Complete Blood Count (CBC) testing on patient specimens using the Horiba Micros 60 hematology analyzer. It is the practice of the laboratory to perform 3 levels of QC material each day prior to patient testing. 2. Testing personnel interviewed during the survey stated that the laboratory implements a new lot of QC material on the first of each month. 3. The laboratory's policy titled, "Quality Control" states, "Each new lot number of quality control must be validated by testing two to fives times prior to the expiration of the current lot number. Verify that the values

	reported are within the manufacturer's recommended range". 4. No documentation was presented for review during the survey conducted on March 7, 2018 to indicate the laboratory verified the criteria for acceptability of each lot of control materials used on the Horiba analyzer from January 2016 through the date of the survey. 5. The facility personnel confirmed that the laboratory had not verified the criteria for acceptability of control lots that were perfomed on the analyzer stated above.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control (QC) results and interview with the facility personnel, the laboratory failed to ensure QC results were acceptable prior to reporting patient test results. Findings include: 1. The laboratory performs patient CBC testing in the specialty of Hematology, with an approximate annual test volume of 32,400. 2. Review of the MCV QC records from 05/30/17 and the RBC QC records from 05/31/17 indicated the QC results did not meet the laboratory's and manufacturer's test system criteria for acceptability before reporting patient test results. See D5447 for findings. 3. The facility personnel confirmed that the analyzer was still used for patient testing after QC was performed and did not meet the laboratory's and/or the manufacturer's criteria for acceptability. 4. The number of patients tested on the dates indicated above could not be determined at the time of the survey.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the facility personnel, it was determined that the laboratory failed to document corrective action for QC results that failed to meet acceptability. Findings include: 1. Review of the laboratory's QC records from May 2017 for testing performed on the Horiba Micros 60 hematology analyzer indicated a hand-written statement stating, "Reviewed 6/28 /17, QC out end of May multiple levels/analytes, nothing done. Request Cal ASAP prior to next PT sample shipment 7/10 or 7/11." 2. No other documentation was presented for review during the survey to indicate the laboratory performed and documented corrective actions to resolve QC failures and address patient outcome related to the QC failures once the problem was identified. See D5481 for findings. 3. The facility personnel confirmed that the laboratory did not effectively document

	corrective action and address patient outcome for the QC failures identified during the survey.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) policies, and interview with the facility personnel, the laboratory failed to follow written policies and procedures to perform and document QA activities related to the analytic systems. Findings include: 1. The laboatory's established policy titled, "Quality Assurance Plan" indicates that a monthly checklist or tracking sheet is used to monitor Maintenance, Calibration and Quality Control. 2. No monthly QA checklist was presented for review during the survey conducted on March 7, 2018 to indicate the laboratory monitored, assessed and corrected problems identified in the analytic systems since January 2017. The last documented monthly analytic QA review was completed in February 2017 for testing that was performed in January 2017. 3. The facility personnel confirmed that the laboratory failed to perform and document QA activities as outlined in laboratory policy since February 2017.
D5805	TEST REPORT CFR(s): 493.1291(c) 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. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, the laboratory failed to include on the test report the laboratory name and address where the testing was performed. Findings include: 1. The laboratory performs patient testing in the specialty of Hematology, with an approximate annual test volume of 32,400. 2. Four out of four test reports reviewed during the survey, patient #3464283, 637083, 673048516 and 673077063, were missing the laboratory name and address where the testing was performed. 3. The facility personnel confirmed that the laboratory name and address where the testing was performed was not indicated on the test reports referenced above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	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. This CONDITION is not met as evidenced by: Due to the number and severity of deficient practices identified during the survey, the Condition of Laboratory Director was found to be not met as evidenced by: D6016 - failure to ensure that Proficiency Testing samples are tested as required under Subpart H; D6020 -failure to ensure that the quality control program was maintained to assure the quality of patient testing performed on the Horiba Micors 60 analyzer; D6021 - failure to ensure that quality assessment programs are maintained to assure the quality of laboratory services provided; and D6029 - failure to ensure that all laboratory personnel have the appropriate training prior to testing patients' specimens.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on information furnished to the State Agency by the Proficiency Testing (PT) provider and review of PT records during the survey, it was determined that the laboratory director failed to ensure that PT samples are tested in a manner that results in successful participation in a proficiency testing program for the regulated analyte, WBC Differential. See D2016 and D6000 for findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control (QC) records and policies and interview with the facility personnel, the laboratory director failed to ensure that the quality control program was maintained to assure the quality of patient testing performed on the Horiba Micors 60 analyzer. See D5447, D5469 and D5481 for findings.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	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. This STANDARD is not met as evidenced by: Based on lack of quality assessment documentation, the laboratory director failed to ensure that quality assessment programs are maintained to assure the quality of laboratory services provided. See D5291 and D5791 for findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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. This STANDARD is not met as evidenced by: Based on lack of training documentation and interview with the facility personnel, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate training for the type and complexity of services offered. Findings include: 1. The laboratory performs patient testing on the Horiba Micros 60 hematology analyzer, with an approximate annual test volume of 32,400. 2. No documentation of initial training was presented for review for six out of six testing personnel who perform patient testing on the hematology analyzer indicated above. 3. The technical consultant confirmed that the testing personnel indicated above did not have documentation of initial training.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of eight out of eleven testing personnel, at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for eight out of eleven testing personnel. 2. The facility personnel confirmed that the laboratory did

	not have documentation of a semiannual competency evaluation for the eight testing personnel indicated above.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) 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. This STANDARD is not met as evidenced by: 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. No 2017 annual competency evaluation documentation was presented for review for eleven out of eleven testing personnel. 2. The facility personnel confirmed that the laboratory failed to provide documentation of an annual competency evaluation from 2017 for the testing personnel indicated above.