Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2145146	02/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Honorhealth Cancer Care	19646 N 27th Ave Ste 301, Phoenix, 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 2018 and interview with the technical consultant, (A) the testing personnel failed to sign the PT attestation statement for the first event of 2018 and (B) the laboratory director failed to sign the PT attestation statements for the first and second testing events of 2018 in a timely manner. Findings include: 1. The laboratory began patient testing in the specialty of Hematology in March 2018, with an approximate annual test volume of 3,500. The laboratory participated in three Proficiency Testing events during 2018. A2. The PT attestation statement presented for review for the first event of 2018 lacked the testing personnel's signature. A3. The technical consultant confirmed that the attestation statement indicated above was not signed by the testing personnel. B2. The PT attestation statements presented for review during the survey for the first and second events of 2018 were not signed by the laboratory director's designee until February 11, 2019. B3. The laboratory submitted the PT records for the first event of 2018 to the PT Agency on March 21, 2018. B4. The laboratory submitted the PT records for the second event of 2018 to the PT Agency on July 27, 2018. B5. The technical consultant confirmed that the PT attestation statements indicated above were not signed by the laboratory director's designee until February 2019.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on lack of temperature documentation for review and interview with the technical consultant, the laboratory failed to document the (A) humidity and (B) room temperature of the laboratory where patient testing is performed and the analyzer reagents are utilized and stored. Findings include: 1. The laboratory began Complete Blood Count (CBC) testing in March 2018 under the specialty of Hematology, with an approximate annual test volume of 3,500. 2. The laboratory performs patient testing on the Sysmex XN450 analyzer which has a humidity requirement of 30% - 85%, as stated in the manufacturer's operating manual. A3. No documentation was presented for review during the survey conducted on February 22, 2019 to indicate the laboratory monitored and documented the humidity of the laboratory where patient testing was performed from March 2018 through the date of the survey. A4. The technical consultant confirmed that the laboratory failed to monitor and document the humidity of the room where patient testing is performed. B3. No documentation was presented for review during the survey conducted on February 22, 2019 to indicate the laboratory monitored and documented the room temperature of the laboratory where patient testing is performed and analyzer reagents are utilized and stored from March 2018 through the date of the survey. B4. The manufacturer's acceptable temperature range listed on the Sysmex reagents used for the analyzer is 2 - 30 degrees Celsius. B5. The technical consultant confirmed that the laboratory failed to monitor and document the room temperature where patient testing is performed and the analyzer reagents are utilized and stored.
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 Quality Assessment (QA) documentation, laboratory policies and procedures and interview with the technical consultant, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the repeat performance of Complete Blood Count (CBC) testing performed on the Sysmex XN450 analyzer. Findings include: 1. Review of patient test records (sample #1010661400) for CBC testing performed on 10/10/2018 indicated the specimen was tested on the Sysmex XN450 analyzer five different times between 8:27am and 8:39am. Each run resulted in the following instrument results/flag codes: 08:27am, Thrombocytopenia; 08:29am, no results measured; 08:31am, Thrombocytopenia; 08:36am, Thrombocytopenia, PLT Clumps?; 08:39am, Thrombocytopenia. 2. During the survey conducted on February 22, 2019, the surveyor and the technical consultant directly observed the "Action

	Codes" found on the analyzer for Thrombocytopenia which stated, "Follow Protocol". 3. No established protocol or policy was presented for review to indicate the laboratory had established a process for testing personnel to follow in the event that the analyzer generates a flag code or other error message during the testing process, including but not limited to, the number of times the sample is repeated and steps to take to determine which test results are released. 4. The technical consultant confirmed the laboratory did not have an established policy and procedure in place at the time of the survey with regard to flagged and/or repeated specimens.