Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2026177	05/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Honorhealth Cancer Care	20745 N Scottsdale Rd, Ste 115, Scottsdale, 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
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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. This STANDARD is not met as evidenced by: Based on review of laboratory policy, lack of instrument function check records for review and interview with the technical consultant, the laboratory failed to perform and document background counts on the Sysmex XN-450 hematology analyzer each day prior to patient testing. Findings include: 1. The laboratory began patient testing on the Sysmex XN-450 hematology analyzer on June 19, 2018, with an approximate annual test volume of 16,900. The laboratory tests patient specimens on approximately 20 days a month. 2. The laboratory's policy, "Operating Procedure" includes 5 steps involved in the Start-Up Procedure: Visual Inspection of the analyzer /system/reagents, Turning ON the entire system, Log on to the XN-450, Analyzer Self-Checks and Analyze Quality Control Material. The Analyzer Self-Checks include initialization of the mechanical parts; Rinse; Temperature Stabilization; Background Check (up to 3 times). The background check must be within acceptable limits as defined in the the procedure. 3. The Background Log reviewed during the survey indicated the laboratory failed to perform the background check each day of patient testing. The background log listed a passing background check for only 8 days in July 2018, 7 days in August 2018, 5 days in September 2018, and 9 days in October 2018. 4. The technical consultant confirmed that the laboratory failed to produce evidence of

	background counts performed each day of patient testing during the time frames indicated above.
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 the laboratory's test reports and interview with the facility personnel, the laboratory failed to indicate the correct facility name on the test report. Findings include: 1. The laboratory performs Complete Blood Count (CBC) testing on patient specimens in the specialty of Hematology, with an approximate annual test volume of 16,900. On the date of the survey conducted on May 22, 2019, the laboratory name listed is the CMS Database for CLIA# 03D2026177 was Virginia G Piper Cancer Center Network North Scottsdale. 2. Three out of three patient test reports reviewed during the survey (#1010469447, 1011967312 and 1013667059) were missing the name of the laboratory where the CBC testing was performed. Each patient test report listed the name of the laboratory as Honor Health Scottsdale Oncology. 3. The facility personnel confirmed that the correct laboratory name was missing from the test reports indicated above.