Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2258662	09/22/2026
Name of Provider or Supplier	**Street Address, City, State**	
Honorhealth Complete Care	16575 W Waddell Rd, 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
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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. This STANDARD is not met as evidenced by: Based on review of hematology test records, review of quality control assay sheets for hematology testing and interview with the technical consultant (TC-2) on 9/22/26 at 12:54 PM, the laboratory failed to verify that results of quality control testing correlated with the established limits of the manufacturer's quality control (QC) materials for 9 out of 9 control lots used on the Sysmex XN-L 550 hematology analyzer from 1/12/25 through 9/22/26. Findings include: 1. The laboratory performs Complete Blood Count (CBC) testing on the Sysmex XN-L 550 analyzer, with a reported annual test volume of 71,952. 2. The laboratory utilizes the XN-L Check controls (manufactured by Streck), which have control ranges established by the manufacturer. Each lot contains control materials for 3 levels of QC including Low, Normal and High. 3. No documentation was presented for review to indicate the laboratory verified that control results correlate with the manufacturer's established limits of each lot of XN-L control material for 9 out of 9 lots used on the analyzer from 1/12/25 through 9/22/26. 4. TC-2 interviewed on 9/22/26 at 12:54 PM confirmed the laboratory failed to verify each of the 9 lots of quality control material used on the hematology analyzer from 1/12/25 through 9/22/26.