

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0700883	(X3) Date Survey Completed 10/12/2023
Name of Provider or Supplier Cooper Voorhees Campus	Street Address, City, State 900 Centennial Blvd, Voorhees, NJ	
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	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Hematology Manager (HM), the laboratory failed to provide documentation for the establishment of the Sysmex e-Check (xs) quality control (QC) acceptable ranges on the Sysmex xs-1000i with each new lot from 4/27/21 to the date of the survey. The finding includes: 1. There was no documented evidence that QC acceptable ranges were established with each new lot. 2. The HM confirmed on 10/12/23 at 3:00 pm that new lots of QC had their acceptable ranges established but that they could not provide documentation due to limitations of the instrument software.</p>