

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1061078	(X3) Date Survey Completed 03/16/2021
Name of Provider or Supplier Northfield Hospital & Clinics-Northfield Clinic	Street Address, City, State 2000 North Avenue, Northfield, MN	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform quality control (QC) activities as established in the Bacteriology Individualized Quality Control Plan (IQCP) in 2 of 4 months reviewed . Findings are as follows: 1. The laboratory performed Bacteriology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:05 a. m. on 03/16/21. 2. A Meridian Bioscience Revogene molecular analyzer was observed as present and available for use during the tour. The laboratory began performing the Revogene Strep A assay in August 2020 as indicated by the TC and confirmed in laboratory records. 3. Revogene Strep A QC performance was required every 30 days as established in the Gene POC Strep A using Meridian Revogene procedure and in the laboratory's IQCP for the test, both found in the Clinic Laboratory Policy and Procedure Manual. 4. The laboratory exceeded the 30 day time interval for QC performance in 2 of 4 months reviewed, potentially affecting 4 patient (Pt)test results. See below. QC date Pt test date Days elapsed 10/26/20 11/30/20 35 12/01/20 01/05/21 36 01/06/21 37 01/07/21 38 5. In an interview at 2:30 p.m. on 03/16/21, the TC confirmed the above finding.</p>