

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0384932	(X3) Date Survey Completed 08/25/2021
Name of Provider or Supplier Labcorp Waterloo	Street Address, City, State 905 Franklin Street, Waterloo, IA	
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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 08/25/2021, the laboratory failed to perform a negative and positive control at least each day of patient testing for respiratory syncytial virus (RSV) testing for one out of six days of patient testing (08/17/2021) in August 2021. The findings include: 1. The laboratory's RSV testing policy stated that the laboratory would perform a negative and positive control each day of patient testing. 2. Patient A had RSV testing performed on 08/17/2021. 3. Review of the laboratory's RSV testing log indicated that the laboratory did not document a positive and negative control on 08/17/2021. 4. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have RSV QC records for testing performed on 08/17/2021.</p>