

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2170216	(X3) Date Survey Completed 09/30/2020
Name of Provider or Supplier Your Kids Urgent Care	Street Address, City, State 790 Montgomery Hwy Suite 112, Vestavia Hills, AL	
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 initial laboratory tour observations, a review of the qualitative quality control (QC) records and patient logs, and interviews with the Owner/Administrator and the Laboratory Manager (also Testing Personnel #1), the surveyor determined the laboratory failed to perform QC on ten out of thirteen days of patient testing for Mycoplasma and Infectious Mononucleosis (Mono) in 2019 and 2020 The findings include: 1. During the initial tour of the laboratory on 9/30/2020 at approximately 2:15 PM, Mycoplasma testing (currently using the Immuno Card kit for the detection of IgM to Mycoplasma pneumonia, a moderate complexity qualitative test) was included on the test menu. The Laboratory Manager also stated he performed patient testing for Mono using a serum sample. The surveyor explained using serum or plasma for Mono makes the test moderate complexity. 2. During an interview with the Laboratory Manager on 9/30/2020 at 6:25 PM, the surveyor asked how often the laboratory ran QC for Mycoplasma and Mono; the Manager stated positive and negative QC was performed on each new kit lot number, as per manufacturer's instructions. The surveyor explained CLIA required two levels of quality control each day of moderate complexity patient testing. However, if the manufacturer only required QC on each new lot number, the laboratory had the option of implementing an IQCP (Individualized Quality Control Plan). The laboratory procedure manual did not include an IQCP, and the Laboratory Manager could not provide an IQCP for the surveyor's review. 3. A review of the Mycoplasma QC log revealed positive and</p>

negative QC was performed on 11/23, 12/7 and 12/8/2019, along with the patient testing. However, patients were also tested on five days when no QC was run (12/12/19, 12/21/19, 1/1/20, 2/3/20 and 3/10/20). 4. A review of the Mono QC log revealed positive and negative QC was performed on 11/14/19 and 1/27/20 (on new kits). However, patient testing (using serum, per the Laboratory Manager) was performed on five days when no QC was run (12/15/19, 1/8/20, 1/27/20, 2/5/20 and 2/16/20). 5. During the exit interview on 9/30/2020 at 6:40 PM, the above noted deficiencies were reviewed and confirmed with the Owner/Administrator. SURVEYOR ID #32558
Licensure and Certification Surveyor