

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D1083536	(X3) Date Survey Completed 02/26/2019
Name of Provider or Supplier Mercy Clinic Ent Allergy Joplin	Street Address, City, State 100 Mercy Way Suite 560, Joplin, MO	
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
D5479	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of Hycor package insert for controls, observation of controls and interview with the technical consultant the laboratory failed to follow manufacturer's specifications for controls. Findings: 1. Review of the Hycor package insert for Specific & Total IgE controls states "When stored tightly stoppered at 2-8 degrees Celsius, the controls are stable until the expiration date printed on the vial label." 2. Observation of Hycor controls in refrigerator showed controls had been poured into a stoppered vial that is put on instrument each day of patient testing. Stopper is removed from control vial and put on Hytec 288, control vial is removed approximately 24 hours later, stoppered and placed back in refrigerator until next day of patient testing. Laboratory could not provide internal temperature of Hytec 288. 3. Interview with the technical consultant on February 26, 2019 at 12:30 PM confirmed the laboratory failed to follow manufacturer's instructions for Hycor controls.</p>