

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0386503	(X3) Date Survey Completed 08/27/2019
Name of Provider or Supplier Mercy Towncrest Internal Medicine	Street Address, City, State 2460 Towncrest Drive, Iowa City, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of maintenance records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 10:15 am on 08/27/19, the laboratory failed to perform and document daily and weekly maintenance as defined by the manufacturer of the Polymedco OC-Auto Micro 80 instrument for 24 out of 30 days and 28 out of 30 weeks of patient testing from January-August 2019. The findings include: 1. The laboratory used the Polymedco OC-Auto Micro 80 instrument to detect fecal occult blood. 2. The instrument operation and maintenance schedule log defined the following to be performed and documented each day of testing: *Place latex bottle on analyzer and record reagent lot number; *Turn power on; *Calibrate if applicable and record calibrator lot number; *Record negative and positive control lot numbers; *Record negative and positive control results; and *End of day - choose option #6-flush; turn power off; remove latex reagent bottle, cap and place in refrigerator; and clean outside of analyzer and reagent bottle cradle evaporation cover. 3. The laboratory tested patient specimens once per week. The laboratory only documented the day of testing maintenance each week in April and August. 4. The instrument operation and maintenance schedule log defined the following to be performed and documented each week of testing: *Clean sample probe; *Clean reagent probe; *Clean dispo-cell cradle; and *Clean sample rack cradle. 5. The laboratory tested patients specimens once per week. The laboratory only documented the weekly maintenance in August. 6. The laboratory personnel confirmed that the laboratory did not perform and document instrument maintenance for Polymedco OC-Auto Micro 80 as defined by the manufacturer.</p>