

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0648060	(X3) Date Survey Completed 10/12/2018
Name of Provider or Supplier Myrtue Medical Center Laboratory	Street Address, City, State 1213 Garfield Avenue, Harlan, 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 the Illumigene maintenance log and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 10/12/2018, the laboratory failed to perform and document daily maintenance on the Illumigene analyzer for 30 out of 30 days and monthly maintenance for one out of one month of patient testing (September 2018). The findings include: 1. The Illumigene maintenance log stated the laboratory must daily: *Perform the self check test *Record the heat block temperature *Clean the analyzer 2. The Illumigene maintenance log stated the laboratory must monthly verify the standards in block A and block B. 3. At the time of the survey, the laboratory did not have documentation of the daily and monthly maintenance being performed on the Illumigene analyzer from September 2018.</p>