

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0669852	(X3) Date Survey Completed 06/19/2018
Name of Provider or Supplier Mercy Health Family Physicians	Street Address, City, State 247 S Burnett Road, Suite 210, Springfield, OH	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on record review, and an interview with the Laboratory Coordinator, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems. All patients tested at this laboratory have the potential to be affected by this deficient practice. Findings include: 1. Review of the quality assessment policy and procedure found the following: "To ensure Quality Assessment is monitored in the laboratory, the following procedure will be performed on a quarterly basis..." 2. Review of documentation found that quality assessment was performed once in 2016, and not at all in 2017 or 2018. 3. An interview with the Laboratory Coordinator, on 6/19/18 at 10:42 am, confirmed that quality assessment was not performed at the intervals stated in their policy and procedure.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities</p>

specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on record review, and an interview with the Laboratory Coordinator, the laboratory failed to follow a maintenance protocol that ensured microscope, centrifuge and timer performance, which was necessary for accurate and reliable microscopic urinalysis test results and test reporting. All patients tested at this laboratory have the potential to be affected by this deficient practice. Findings Include: 1. Review of the instrument maintenance policy and procedure found the following: "The microscope used for microscopic examination of urines will be professionally cleaned once per year. The centrifuge used to spin urines will have the RPMs and timer checked four times per year as per manufacturer's recommendations." 2. Review of documentation found that instrument maintenance was not performed in 2017 or 2018. 3. An interview with the Laboratory Coordinator, on 6/19/18 at 9:55 am, confirmed that instrument maintenance was not performed at the intervals stated in their policy and procedure.