

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2046929	<b>(X3) Date Survey Completed</b>  08/26/2021
<b>Name of Provider or Supplier</b>  Fairview Pathology	<b>Street Address, City, State</b>  17000 Executive Plaza Suite 202, Dearborn, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> 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:</p> <p>. A. Based on observation, record review, and interview with the Laboratory Director (LD), the laboratory failed to perform and document timer calibrations for 3 (Serial number (S/N) 151974019, S/N 151834685, and S/N 160145791) of 4 timers before their expiration dates. Findings include: 1. During a tour of the laboratory on 8/26 /2021 at 11:10 am, the surveyor observed the use of 3 of 4 timers in use past their expiration dates as follows: a. S/N 151974019 - expired 12/29/2017 b. S/N 151834685 - expired 11/05/2017 c. S/N 160145791 - expired 1/22/2018 2. An interview on 8/26 /2021 at 11:10 am, the LD confirmed the laboratory failed to perform and document timer calibrations or replace the timer. B. Based on record review, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to perform and document the weekly and monthly quality control for the eyewash maintenance for 24 months ( September - December 2019, February - December 2020, and January - August 2021) of 24 months reviewed. Findings include: 1. A record review of the "Eyewash Maintenance Chart" states the following 3 steps to be completed: a. "Activated the eyewash station weekly to flush out stagnant water and to check that the eyewash station operating properly (let run for a minimum of 30 seconds)." b. "Once a month check the temperature of the water coming from the eyewash station; verify that it is within the acceptable temperature range. If out of range report to maintenance for repairs." c. "Record date and your initials when testing is complete." 2. A record review of the "Eyewash Maintenance Chart" revealed the laboratory did not perform and document the maintenance of the eyewash station weekly and monthly as instructed as follows: a. September - December 2019 - lack of</p>

weekly and monthly documentation b. February - December 2020 - lack of weekly and monthly documentation c. January - August 2021 - lack of monthly documentation d. No documentation of an acceptable temperature range for the water

3. An interview on 8/26/2021 at 10:20 am, the LD confirmed the eyewash quality control was not documented weekly and monthly as instructed.