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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>23D2046929              | <b>(X3) Date Survey Completed</b><br><br>03/16/2023 |
| <b>Name of Provider or Supplier</b><br><br>Fairview Pathology  | <b>Street Address, City, State</b><br><br>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>   |
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| <b>D5429</b>              | <p><b>MAINTENANCE AND FUNCTION CHECKS</b><br/>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:<br/>                     . Based on observation, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to perform and document the timer calibration checks as required by the manufacturer before the expiration for 1 (Traceable timer) of 1 timer in use. Findings include: 1. During a tour of the laboratory on 3/16/2023 at 9:07 am, the surveyor observed a timer in the histopathology processing laboratory in use past the expiration date of 11/25/2021. 2. A record review of the procedure manual revealed no maintenance procedure for the frequency of timer calibrations and /or replacement prior to expiration date noted on the timer. 3. A record reviewed revealed a lack of documentation for the calibration of the timer and/or replacement by the expiration date noted on the timer. 4. A interview on 3/16/2023 at 12:15 pm, the LD confirmed the timer was not calibrated and/or replaced before their expiration.<br/>                     ***Repeat Deficiency from the 8/26/2021 survey***</p> |