

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0230966	(X3) Date Survey Completed 09/11/2018
Name of Provider or Supplier Emporia Medical Associates	Street Address, City, State 6 Doctors Drive, Emporia, VA	
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
D0000	An announced CLIA recertification survey was conducted at Emporia Medical Associates on September 11, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 a review of instrument maintenance logs, user manual instructions, laboratory tour, manufacturer's field service preventative maintenance (PM) records, and interviews, the laboratory failed to document chemistry instrument probe and pipette tip replacement maintenance for eighteen (18) of eighteen (18) months reviewed from December 2016 to April 2018. Findings include: 1. Review of the laboratory's Roche COBAS Integra 400 Plus chemistry analyzer's Daily Check List and Maintenance Logs revealed a required maintenance procedure for replacement of Probe B, Probe C, Plunger Tip Pipette B, and Plunger Tip Pipette C listed as perform on semi-annual and/or at 50,000 tests. Review of the probe replacement maintenance records from December 2016 to April 2018 revealed: Probe C replacement on 06/30 /17 No record of Probe B, Plunger Tip Pipette B, or Plunger Tip Pipette C replacement was documented for eighteen (18) of the eighteen (18) months reviewed. 2. Review of the Roche COBAS Integra 400 Plus Users Manual revealed the manufacturer's instructions "for continuous accuracy you must replace the probes (B and C) when due and as a troubleshooting measure to overcome poor pipetting accuracy". 3. During a laboratory tour at approximately 1:30 PM on 9/11/18, the inspector inquired how the laboratory documents performance of the COBAS Probe</p>

B, Probe C, Plunger Tip Pipette B, and Plunger Tip Pipette C replacement. The technical consultant (TC) stated: "we or our field service replaces the probes and pipette tips at least every six months and we initial and date our logs when it is performed". 4. Review of the Roche manufacturer's field service PM records revealed no documentation that Probe B, Plunger Tip Pipette B, or Plunger Tip Pipette C were replaced during routine scheduled or trouble shooting PM visits from December 2016 to April 2018. 5. In an interview with the TC at approximately 3:30 PM, it was confirmed that the laboratory failed to document the required Roche COBAS chemistry instrument probe and pipette tip replacement maintenance for eighteen (18) of eighteen (18) months reviewed as outlined above.