

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0327580	(X3) Date Survey Completed 10/29/2018
Name of Provider or Supplier Medical And Surgical Associates	Street Address, City, State 1930 Tamarack Rd, Newark, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on policy and procedure review, record review, and an interview with the Technical Consultant (TC), the laboratory failed to follow their written calibration verification procedures. Findings Include: 1. Review of the policy and procedure manual titled "MedSol General Laboratory Policy and Procedure Manual, Medical and Surgical Associates, 1930 Tamarack Rd, Newark Ohio 43055" signed and dated by the lab director on 10/18/2018 found the following statement: " Calibration Verification is performed every six months, as stated in current CLIA and state regulations." 2. Review of calibration verification records revealed calibration verification was performed only one time during 2017 for the AW Axcel. Further review of calibration verification records revealed calibration verification was not performed during 2016 and 2017 for the TOSOH 900. 3. The TC confirmed calibration verification was performed only once in 2017 for the AW Axcel and was not performed in 2016 and 2017 for the TOSOH 900. The interview occurred on 10/29 /2018 at 11:35 AM.</p>