

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D2178342	<b>(X3) Date Survey Completed</b>  10/28/2020
<b>Name of Provider or Supplier</b>  A & M Medical & Diagnostic	<b>Street Address, City, State</b>  304 Teaco Road Suite A, Kennett, MO	
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>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of Beckman AU480 chemistry analyzer performance specifications and interview with the technical consultant, the laboratory failed to verify reportable range of test results for the test system and failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patient test results. Findings: 1. Review of the Beckman Au480 chemistry analyzer showed the analytes Amphetamine, Barbiturate, Oxycodone, Benzodiazepine, EDDP, PCP, Buprenorphine, Fentanyl, THC, Cocaine, Opiates and Tramado lacked documentation of reportable range and reference intervals (normal values). 2. Interview with the technical consultant on October 28, 2020 at 9:00 AM confirmed the laboratory failed to verify reportable range of test results for the test system and failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patient test results.</p>