

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0978140	(X3) Date Survey Completed 01/24/2019
Name of Provider or Supplier Azizkhan Internal Medicine Associates	Street Address, City, State 888 Poplar Church Road, Camp Hill, PA	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory tour and interview with the sole Testing Personnel (TP), the laboratory failed to ensure that 2 of 2 Becton Dickinson (BD) Sodium Citrate vacutainer tubes were not used beyond their expiration date. Findings Include: 1. On the day of survey (01/24/2019). While on tour of the laboratory, 2 of 2 BD blue top Sodium Citrate tubes (Lot # 011842) were found that expired 10/31/2018. 2. The TP confirmed the above finding above on 01/24/2019 around 11:00 am.</p>
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on review of equipment calibration records, review of the Traceable Certificate of Calibration for Dual Thermometer w/ Bottle Probe, and interview with the sole Testing Personnel (TP), the laboratory failed to establish, perform and document the calibration of 3 of 3 Fisher Scientific Traceable Min - Max thermometers. Findings include: 1. The manufacturer's form titled, "Traceable Certificate of Calibration for</p>

Dual Thermometer w/ Bottle Probe", shows a calibration date of 01/30/2012 and a calibration due date of 01/30/2014. 2. On the day of survey, 01/24/2019, while on tour of the laboratory, observation of 3 of 3 Fisher Scientific Traceable Min - Max thermometers maintenance stickers, revealed there refrigerator and freezer thermometers were due to be calibrated on 01/30/2014 and the TP was unable to produce a maintenance procedure and calibration documentation for the thermometers. 3. The TP confirmed the findings above on 01/24/2019 around 10:45 am.