

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0310064	(X3) Date Survey Completed 05/06/2019
Name of Provider or Supplier Indravadan K Shah Md	Street Address, City, State 2341 McCallie Ave Suite 201, Chattanooga, TN	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of patient uric acid test records for 2017, lack of calibration records and an interview with the laboratory supervisor, the laboratory failed to retain chemistry calibration printouts for two (2) years. Findings include: 1. Review of one (1) of one patient chemistry uric acid test record disclosed that calibration printouts were not retained from September 19, 2017. 2. In an interview, on May 6, 2019, at 11:45am, the laboratory supervisor confirmed that chemistry uric acid calibration printouts were not retained for 2 years as required.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Quality Assurance (QA) Plan, testing personnel records, and an interview with the Laboratory Supervisor, determined the laboratory failed to follow written policies to assess testing personnel competency annually for Complete Blood Counts (CBC's) and Routine Chemistry for 2017-19. The findings include: 1. A review of the QA Plan revealed that testing personnel competencies would be</p>

assessed annually by the Laboratory Director. 2. A review of the personnel records revealed that testing personnel number 1-3 had competencies without the 6 minimum required areas documented for CBC testing and the wrong Chemistry analyzer (EON 300 vs the new Envoy 500+) for 2017-19. 3. An interview with the Laboratory Supervisor at approximately 10:15a.m. May 6, 2019 confirmed the laboratory failed to follow QA Plan for assessing annual competency for testing personnel number one through three for CBC and chemistry testing for the two year period.