

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0665573	<b>(X3) Date Survey Completed</b>  01/19/2018
<b>Name of Provider or Supplier</b>  Temple Medical Clinic Pc	<b>Street Address, City, State</b>  859 Airport Drive, Alexander City, AL	
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>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2016 API (American Proficiency Institute) Proficiency Testing records and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to document corrective action for two of six surveys with results less than 100 % (percent). The findings include: 1. A review of the API Proficiency Testing records revealed the following: A) 2016-Chemistry Event #1: Uric Acid with a score of 80%, and B) 2016-Chemistry Event #3: Sodium with a score of 80%. There was no documentation of investigation or corrective actions for these scores of less than 100%. 2. In an interview on 1/19/2018 at 3:25 PM, the Testing Personnel #1 reviewed and confirmed the above noted findings, stating she had documented her investigation and corrective action for problems resulting in scores of 60%, but had failed to investigate the above scores of 80% each. Thus the above findings were confirmed. .</p>
<b>D5791</b>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the room temperature and humidity records, and an interview</p>

with Testing Personnel #1, the surveyor determined the laboratory failed to implement effective quality assessment reviews of the environmental logs to identify and correct problems. The findings include: 1. A review of quality assurance documentation revealed the laboratory performed quality assurance activities, however reviews of the environmental logs were inadequate to ensure the thermometer/hygrometer device was working correctly. For a period of more than two years (January 2016 until the date of the survey on 1/19/2018), staff had recorded the room temperature as 31 degrees C (Celsius) with no variation. Room humidity was recorded as 60% from 7/30/2016 until 1/19/2018 with no variation. Each month the Laboratory Director had signed the charts without comment or a suggestion to check the monitoring device for accuracy. 2. During an interview and examination of the thermometer/hygrometer device in the laboratory on 1/19/2018 at 3:15 PM, the surveyor asked if anyone had observed the temperature displayed had not changed from 31 degrees C in more than two year, and the humidity had been at 60% for a year and a half. Testing Personnel (TP) #1 stated she did not think anyone had noticed. When asked if the batteries had been checked recently, TP #1 put new batteries in the device, at which time the temperature displayed 27 degrees C, and the humidity was low ("LL"). When asked why correct monitoring of the temperature and humidity was important, TP #1 answered to ensure the correct environment for the Chemistry, Endocrinology and Hematology analyzers. Thus the above findings were confirmed. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor