

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0121725	(X3) Date Survey Completed 08/01/2019
Name of Provider or Supplier Princeton Medical Group - Princeton	Street Address, City, State 419 N Harrison St, Princeton, NJ	
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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) Work Records (WR) and interview with the Testing Personnel (TP), the laboratory failed to document Corrective Action (CA) when the Quality Controls were out of range for analytes run on the Beckman Coulter AU480 in the calendar year 2019. The findings include: 1. On 7/22/19 Total bilirubin QC level 3 was run three times with no CA documented. 2. On 7/23/19 Total bilirubin QC level 3 was run two times with no CA documented. 3. On 7/24/19 high-density lipoprotein QC levels 1,2 and 3 were run three times with no CA documented. 4. On 7/25/19 blood urea nitrogen QC levels 1,2 3 were run two times with no CA documented 5. On 7/29/19 blood urea nitrogen QC levels 2 was run two times with no CA documented 6. The TP confirmed on 8/1/19 at 10:45 am the laboratory did not document CA.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an</p>

ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Final Report (FR) and interview with the General Supervisor (GS), the laboratory failed to correct problems in the postanalytic system when reporting Manual Differential (MD) tests from March 2019 to the date of the survey. The findings include: 1. The laboratory reported both the Automated Differential (AD) and the MD results on five out of five patients reviewed that had a MD test performed. 2. The laboratory reported the absolute cell count resulted from a MD under the AD on Accession 229598 and 1115865. 3. The laboratory reported % Neutrophil (Neu) as 79 % from the AD but the instrument printout revealed Neu to be 45.6 % and a MD 73% on Accession 1115865. 4. Accession 249333 had a platelet count of below the reference range but the laboratory reported is as adequate. 5. The FR on Accession 249333 had comments stating "Slide to be reviewed for confirmation and A manual review of the peripheral smear will be performed" but the slide had been reviewed and the platelet count was confirmed. 6. The GS confirmed on 8/1/19 at 1:30 pm that the laboratory did not have a follow their policy to monitor and correct problems in the post analytic system.