

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0305512	<b>(X3) Date Survey Completed</b>  03/06/2018
<b>Name of Provider or Supplier</b>  Urology Associates	<b>Street Address, City, State</b>  168 Mobile Infirmiry Blvd, Mobile, 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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on information obtained during the entrance tour, a review of the Procedure Manual and "Independent Case Review" documentation (used for accuracy verification of Histopathology testing), and an interview with the Technical Consultant, the surveyor determined the Laboratory Director failed to document his assessment and comparison of the peer groups' results with the laboratory's results. This was noted on four out of four accuracy verification activities reviewed. The findings include: 1. During the entrance interview and tour of the laboratory at approximately 11:30 AM on 3/6/2018, the Technical Consultant stated the new Laboratory Director had added the specialty of Histopathology to the menu in late 2016. The Director performed on-site reading of slides from his patients' prostate biopsies which are processed and stained at another laboratory. 2. A review of the procedure manual revealed the new policy, "Independent Case Review", which stated the laboratory would send out slides from two cases semi-annually for independent review. 3. A review of the "Independent Case Review" documentation revealed the laboratory had sent out slides from two cases in March 2017 and two cases in October 2017. The in-house results reports were attached to each of the corresponding peer group reports. The surveyor observed the Laboratory Director's signature on each of the peer group reports, however there was no indication of whether the results were comparable with the in-house laboratory results. There was no record of a comparison indicating there were no discrepancies, minor discrepancies with no effect on patient care, or major discrepancies which would require documentation of corrective action and resolution. On two of the cases the surveyor observed discrepancies in the Gleason scores, however there was documentation of whether this was significant,</p>

and whether corrective actions were required. 4. During an interview on 3/6/2018 at 2:05 PM, the above noted findings were reviewed and confirmed with the Technical Consultant. .

**D5473**

**CONTROL PROCEDURES**

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a lack of documentation for the daily slide control quality, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to assess and document the slide stain quality each day of patient testing from October 2016 till the day of the survey. The findings include: 1. During the entrance interview and tour of the laboratory at approximately 11:30 AM on 3/6/2018, the Technical Consultant stated the new Laboratory Director had added the specialty of Histopathology to the menu in 2016. The Director performed on-site reading of slides from his patients' prostate biopsies which are processed and stained at another laboratory. 2. A review of the Histology records revealed no documentation of the daily slide stain quality. During an interview on 3/6/2018 at 2:05 PM, the Technical Consultant was asked about the slide quality control (QC). The Technical Consultant then asked the Laboratory Director (via text message) if he performed this QC. The Director texted back the slide QC was performed at the processing laboratory. 3. As the interview continued on 3/6/2018 at approximately 2:05 PM, the surveyor explained, it is the responsibility of the testing personnel (i.e. the Director performing the reading) to assess and document the slide QC. The Technical Consultant then stated they had not known this was a CLIA requirement. Thus the above noted findings were confirmed. SURVEYOR:Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor