

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0301189	<b>(X3) Date Survey Completed</b>  10/21/2020
<b>Name of Provider or Supplier</b>  Urology Centers Of Alabama, Pc	<b>Street Address, City, State</b>  3485 Independence Drive, Birmingham, 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>D6086</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the validation records for two Thermocyclers for PCR (Polymerase Chain Reaction) molecular testing for wound/urinary tract and respiratory infections, and an interview with the Laboratory Manager (also the General Supervisor), the surveyor determined the Laboratory Director (LD) failed to ensure the acceptability of the study, prior to patient testing. The LD further failed to ensure the validation procedure of the newly installed Ace Alera, Chemistry analyzer, was reviewed and approved for use in the laboratory. This affected two of five newly installed instruments/methodologies, implemented in the laboratory, since the previous survey on 2/21/2018. The findings include: 1. A review of validation records (no date) for two Thermocyclers for PCR molecular testing revealed the LD had not signed, indicating review and approval of the equipment for use in the laboratory. 2. During an interview on 10/21/2020 at 10:51 AM, the surveyor inquired about the installation of the equipment and the date of validation. The Laboratory Manager (LM) stated the documents were sent to her electronically by technical personnel, listed on the CMS form #209 (she identified as a technical supervisor, not employed by the laboratory). The LM confirmed the documents did not have the LD's signature, nor the signature of a qualified Technical Supervisor, and had not been reviewed by the LD. The documents, sent electronically, failed to include a date for the validation study, however the LM stated the validation study was performed on July 6, 2020. The LM further stated patient testing on the equipment began August 18, 2020. 3. In an interview at 4:10 PM on 10/21/2020, the LD confirmed she had not reviewed and signed the validation of the PCR testing. 4. A review of the validation records for the</p>

Ace Alera, Chemistry analyzer, revealed the validation procedures (accuracy, reportable range study, precision and method correlations) were done on May 27, 2020. The LM signed the validation studies, however the LD had not reviewed and approved the validation, which may have been indicated by her signature and effective date. Laboratory staff were currently testing patient specimens on the analyzer, which had not been approved for use by the LD. 5. In an interview on 10/21/2020 at 4:46 PM, the LD reviewed the validation of the Ace Alera and stated she could not see on the documents anywhere she had signed. 6. On 10/21/2020 at 4:46 PM, the surveyor discussed with the LD director the responsibility for ensuring validations were acceptable, prior to use in the laboratory; the importance of her signature and the effective dates for validations and policies/procedures; and letters of delegation.