

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2173386	<b>(X3) Date Survey Completed</b>  03/10/2021
<b>Name of Provider or Supplier</b>  Urology Specialist Group Llc	<b>Street Address, City, State</b>  2140 W 68th St Suite 302, Hialeah, FL	
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>D0000</b>	A complaint survey for 2021001268 was conducted on 3/03/2021-3/10/2021 at Urology Specialist Group LLC. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to create a general quality assurance (QA) policy for the laboratory regarding Polymerase chain reaction (PCR) testing with Quant studio 3. Findings Included: Review of QuantStudio 3 instrument folder displayed the validation of the instrument was completed on 2/25/2021. Review of QuantStudio 3 manual revealed no documentation of a QA policy onsite. During an interview on 3/9/2021 at 3:11pm, the office manager confirmed there was no QA policy for the PCR testing with QuantStudio 3.</p>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have the current</p>

laboratory director (LD) sign the procedure manual to approve the use since their hire date on 1/15/2021. Findings Included: A review of CMS-116 revealed LD#B as the current LD. Review of Hiring Emails revealed LD#B started as LD on 1/15/2021. Review of Procedure Manual revealed no documentation of an approval signature by LD#B in the procedure manual. During an interview on 3/9/2021 at 3:11 pm , the office manager confirmed LD#B had not signed the procedure manual for use as of 1 /15/2021.