Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1091566	11/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Urology Group Of Florida Llc	3399 Pga Blvd, Ste 230, Palm Beach Gardens, FL	

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
D0000	A recertification survey conducted from 11/08/2022 to 11/17/2022 found the UROLOGY GROUP OF FLORIDA, LLC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on lack of records and laboratory director (LD) interview, the laboratory failed to verify the accuracy of testing method at least twice annually for SARS-2 CoV immunoglobulin G (IgG) antibodies since 2021. Findings include: -Review of Clinical Laboratory Improvement Amendments (CLIA) Application For Certification CMS-116 form, revealed that the laboratory use the ACCESS SARS-CoV IgG test from Beckman Coulter for the detection of SARS-2 CoV IgG antibodies and the total estimated annual test volume of 848 tests. Records review revealed that the laboratory started testing since 02/01/2021. -The laboratory had no records of twice a year accuracy verification for the test of reference since they started testing. During an interview on 11/08/2022 at 2:10 PM with LD, he confirmed that the laboratory failed to perform at least twice a year accuracy verification for the SARS-2 CoV IgG test.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if

	applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on user manual review and interview with testing personnel (TP) A, the laboratory failed to document room humidity requirement to assure optimal operation of the Access 2 immunoassay system analyzer for 2 out 2 years reviewed. Findings include: Review of Beckman Coulter Access 2 user manual revealed an operating environment requirement of humidity of 20 to 85 %. No documentation of the room humidity found for 2021 and 2022. During an interview on 11/08/2022 at 11:30 AM, TP A confirmed that there was no record of room humidity control check for the room where the instrument was located.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to label Biorad Liquichek Immunoassay Plus Control level 1 and 3 in use with open date and the new expiration date at the time of the survey. Findings include: - During the laboratory tour on 11/08/2022 at 10:30 AM, the surveyor observed that the laboratory had in use 2 Liquichek Immunoassay Plus Control vials: one for level 1 and one for level 3 with Lot # 85300. The controls in use failed to have the opening date and the new expiration date. -Review of the Biorad insert, revealed that in Section "STORAGE AND STABILITY" stated on "Thawed Opened: Once thawed, opened and stored tightly capped at 2 to 8 C, this product will be stable as follows: -All analytes: 14 days." During an interview on 11/08/2022 at 11:35 AM, the Testing Personnel # A, confirmed that controls in use were not labeled as described above.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow manufacturer's instructions to perform calibration to the Access SARS Cov-2 IgG assay with a 28 day frequency as defined by the manufacturer for six out of eight months reviewed in 2022. Findings include: Review of the insert for the Access SARS CoV-2 IgG assay revealed that a calibration is required every 28 days. -Review of calibration records revealed that the laboratory performed calibration in 2022 as follows: 01/17/2022 to 02 /07/2022: 21 days. 02/07/2022 to 03/07/2022: 28 days. 03/07/2022 to 04/07/2022: 31 days. 04/07/2022 to 05/09/2022: 32 days. 05/09/2022 to 06/09/2022: 31 days. 06/09 /2022 to 07/18/2022: 42 days. 07/18/2022 to 08/18/2022: 31 days. 08/18/2022 to 10/13 /2022: 56 days. During an interview on 11/08/2022 at 01:25 PM, Testing Personnel # A, confirmed that the calibrations were performed in the days listed above and not following the frequency required by the manufacturer for 6 out of 8 months.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. This STANDARD is not met as evidenced by: Based on record review and interview, the Quality Assessment (QA) failed to identify and correct that the freezer temperature for the storage of Biorad Liquichek Immunoassay Plus Control levels 1 and 3 was out of the acceptable range for 425 out of 458 days reviewed. The QA failed to have corrective actions for refrigerator temperature for thawed Biorad Liquichek Immunoassay Plus Control levels 1 and 3 storage that were outside of the acceptable range for 18 out of 321 days reviewed. Findings include: -Review of Biorad Liquichek Immunoassay Plus Control levels 1 and 3 insert revealed a storage acceptable temperature range for frozen control of -20 to -70C and for the thawed and used control an acceptable temperature range of 2-8C. Review of Freezer temperature logs for 2021 and 2022 revealed that the temperatures were outside of the acceptable range as listed below: 2021: February 11 days, March, 22 days, April 22 days, May 20 days, June 22 days, July 20 days, August 22 days, September 21 days, October 19 days and December 21 days. 2022: January 21 days, February 20 days, March 23 days, April 20 days, May 21 days, June 22 days, July 13 days, August 17 days, September 20 days, October 21 days and November six days. Review of Refrigerator temperature logs for 2021 and for 2022 (July to November) revealed the following days that temperature was outside of the acceptable range: 03 /05/2021, 03/08/2021, 03/19/2021, 03/29/2021, 03/31/2021, 04/08/2021, 04/09/2021, 04/12/2021, 04/13/2021, 04/14/2021, 05/27/2021, 06/21/2021, 07/07/2021, 10/14 /2021, 10/15/2021, 07/05/2022, 10/24/2022 and 11/08/2022. During an interview on 11/08/2022 at 01:07 PM, the testing personnel A confirmed that there were no corrective actions for the temperatures outside of the acceptable range.