Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0712129	(X3) Date Survey Completed 08/10/2022
Name of Provider or Supplier Allaway And Parousis Urology Md Pa	**Street Address, City, State** 12234 Williams Road, Cumberland, MD	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant the laboratory did not follow policies for checking annual competency of testing staff. Findings: 1. Testing Person 1 and Testing Person 2 did not have competency checks performed for the year 2021 and 2020; and 2. this was confirmed with the technical consultant during interview the afternoon of survey.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values.

	(12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant, the units of measurement (patient testosterone test results)reported from the analyzer, used to enter test results and report the test results for the laboratory information system (LIS) were all different and not described in the laboratory written procedure. Findings: 1. The analyzer used the units NG/DL (nanogram per deciliter) to report patient testosterone results, the chart used the units NG/ML (nanogram per milliliter) to enter the test result into the patient chart and the patient report from the chart used the units PG/DL (picogram per deciliter) to report the patient test results. The units of measurement do not agree; and 2. This was confirmed with the technical consultant during interview the afternoon of survey.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant, the laboratory did not take corrective action when the temperature of the laboratory refrigerator failed to meet the laboratory's criteria for acceptability. findings: 1. The record the laboratory uses to document the daily temperature of the refrigerator (Laboratory Daily Environmental Log) did not include the upper and lower temperature limits for the refrigerator; 2. The temperature readings for February 2 and 7, 2022; January 13, 2022 and December 14 and 16, 2021 were 32 degrees Fahrenheit (at freezing). The temperature readings for January 29 and 31, 2022 were 30 degree Fahrenheit (below freezing); 3. Corrective actions, such as adjusting the thermostat, rechecking the temperature and observing or retesting reagents with fresh quality controls to ensure they were not deteriorated, was not performed and was not documented; and 4. This was confirmed during afternoon interview with the technical consultant.