Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0712129	10/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Allaway And Parousis Urology Md Pa	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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the daily patient worksheets, proficiency testing (PT) records, and interview with the testing person (TP), the laboratory failed to document the PT samples along with the regular patient workload. Findings: 1. The endocrinology PT records from the third event of 2022 through the third event of 2023 were reviewed for a total of four events. 2. Review of the daily patient worksheets showed that the original PT test results for all four events were not documented on the worksheet in the same manner as the patients. 3. During the survey on 10/19/2023 at 12:30 PM, the TP confirmed that the PT results were not being documented in the same manner as the patients.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods

	This STANDARD is not met as evidenced by: Based on review of the proficiently testing (PT) records and interview with the testing person (TP), the laboratory failed to ensure that the PT samples were routinely performed by all the TP who performed endocrinology testing. Findings: 1. The "Laboratory Personnel Report (CLIA)" (CMS-209 form) lists nine TP. All the TP have been at the lab for over a year and are trained to perform endocrinology testing. 2. The endocrinology PT records for 2022 and 2023, a total of four events were reviewed. Two of the nine TP performed the endocrinology PT during 2022 and 2023. 3. During the survey on 10/19/2023 at 12:30 PM, the TP confirmed that the PT samples were not rotated among all of the TP as required by CLIA.
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 review of the patients normal results on the worksheet, instrument printout, laboratory information system (LIS), and interview with the testing person (TP), the units of measurement for the patients with prostate-specific antigen (PSA) test results were all different and not described in the laboratory written procedure. Findings: 1. The patient worksheet listed the units for PSA as ng/ml (nanogram per milliliter), the instrument printout listed the units for PSA as ng/dl (nanogram per deciliter), and the LIS listed the units for PSA as pg/dl (picogram per deciliter). 2. During the survey on 10/19/2023 at 12:30 PM, the TP confirmed that the units for the normal patient reference ranges for PSA listed on the worksheet, instrument printout and LIS did not agree.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The

	laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the testing person (TP), the laboratory failed to have a written system that evaluates and compares the acceptable differences between the test results using two different instruments for the same test at the laboratory. Findings: 1. The laboratory has two Qualigen endocrinology analyzers used to report prostate-specific antigen (PSA) patient test results. 2. The TP explained that once the PT specimens were tested and the results submitted another TP re-ran the PT specimens for comparison between the two analyzers. These records were maintained in the PT binder. There was no evaluation comparing the two results to ensure that uniform results are reported from both analyzers. 3. During the survey on 10/19/2023 at 12:30 PM, the TP confirmed that there was no written protocol for performing and documenting the comparison, parameters of acceptability, and a protocol to follow when the results failed to meet the parameters of acceptability to ensure uniform results from both analyzers.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of final reports and interview with the testing person (TP), the laboratory failed to ensure that the final test report included the normal reference range values for the interpretation of the patient test results for prostate-specific antigen (PSA) and that the final test report included the address for testosterone (Testo) results. Findings: 1. The final test report for a patient with PSA results was reviewed. The report included the PSA value but not the normal patient reference range. The TP confirmed that this was missing from all the PSA patient reports. 2. The final test report for a patient with Testo results was reviewed. The report failed to include the address of the testing facility. The TP confirmed that the address of the testing facility was missing from all the Testo patient reports. 3. During the survey on 10/19/2023 at 12:30 PM, the TP confirmed that the normal patient reference range was missing from PSA final patient reports and the address of the testing facility was missing from the Testo final patient reports.