Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0712129	10/08/2025
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the laboratory manager (LM), the testing personnel (TP) failed to attest to the routine integration of PT samples into the patient workload using the laboratory's routine methods for four out of six PT events. Findings: 1. Records for six PT events from 2024-2025 were reviewed. 2. In four of six PT events the names of the TP performing the PT testing were printed on the attestation form and not signed by each TP. 3. During the exit interview on 10/08/2025 at 2:35 PM, the LM confirmed that the TP did not sign the statement attesting to the routine integration of PT samples into the patient workload using the laboratory's routine methods in four out of six PT events.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) (b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the procedure manual, review of proficiency testing (PT) records, and interview with the laboratory manager (LM), the laboratory failed to ensure that PT samples were tested the same number of times that it routinely tested patient samples. Findings: 1. The laboratory had two instruments and tested for testosterone

	on a single instrument and for prostate specific antigen (PSA) on both instruments. 2. Patient samples were tested a single time. 3. Records for six PT events from 2024-2025 were reviewed. 4. The "Policy on Proficiency Testing" stated: a. "Three separate proficiency testing events will be conducted annually." b. "An event is defined as five samples being tested on two separate non- consecutive days prior to the due date established by the proficiency company." c. "The first day samples are tested will be considered day one. Within two to seven days of day one, the same five samples will be tested again and referred to as day two testing as scheduled by the lab manager." d. "Day two testing will be run by different staff than day one testing when able." 5. Records showed that for all PT events, each testosterone PT sample was tested twice on the single instrument and each PSA PT sample was tested twice on both instruments (for a total of four results). 6. During the exit interview on 10/08/2025 at 2:35 PM, the LM confirmed that PT samples were not tested the same number of times as patient samples were routinely tested.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the procedure manual, review of personnel records, and interview with the laboratory manager (LM), the laboratory failed to document initial training records on the designated training forms. Findings: 1. The "Personnel Competency Evaluation" stated that "The laboratory director evaluates the competency of testing personnel when a new method is begun using the FastPack Training Checklist and annually using the Personnel Evaluation Checklist." 2. The Laboratory Personnel Report listed 11 testing personnel (TP). Three of the 11 TP started testing since the previous recertification survey, did not have a completed "FastPack Training Checklist," but did have a completed "Personnel Evaluation Checklist" as an initial evaluation (TP# 7, 9, and 10). 3. During the survey on 10/08/2025 at 1:10 PM, the LM confirmed that since the previous survey, the initial training was documented on the "Personnel Evaluation Checklist" form instead of the "FastPack Training Checklist" form.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical

	parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration verification records and interview with the laboratory manager (LM), the laboratory failed to ensure that calibration verification was performed at least once every six months. Findings: 1. The laboratory had two instruments and tested for testosterone on a single instrument and for prostate specific antigen (PSA) on both instruments. 2. Records showed that calibration verification was performed for testosterone on 12/15/2023, 06/19/2024, and 09/17/2025. 3. Records showed that calibration verification was performed for PSA on both instruments on 12/15/2023 and 06/19/2024. One of the instruments was replaced and calibration verification performed on the new instrument on 04/25/2025. Calibration verification was then performed on both instruments on 09/17/2025. 4. During the exit interview on 10/08/2025 at 2:35 PM, the LM confirmed that calibration verification was not performed at least every six months for testosterone and PSA.
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the procedure manual, flow sheets, and patient records, and interview with the laboratory manager (LM), the laboratory failed to ensure that test results for one of three randomly selected patients were manually entered into the patient record. Findings: 1. Patient results were printed from the analyzer, affixed to a flow sheet, and then manually entered into the patient record. 2. The "Policy on Ensuring Quality Control in regards to Correct Entry of Patient Results" stated that "A representative working with each provider each day prior to closing will take the clipboard with the results and ensure the flow sheet and patient record match the correct result from the patient sticker that is printed by the analyzer." 3. Three randomly selected patients were chosen from the flow sheets to verify results in the patient record. 4. Results from one of the three randomly selected patients were not entered into the patient record. The patient was tested on 09/29/2025. 5. During the survey on 10/08/2025 at 2:20 PM, the LM confirmed that results from one of the three randomly selected patients were not manually entered into the patient record.
D5805	TEST REPORT CFR(s): 493.1291(c)

	(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 the procedure manual, review of test reports, and interview with the laboratory manager (LM), the test report included two different units of measurement. Findings: 1. The normal ranges for testosterone and prostate specific antigen (PSA) listed in the procedure indicated the unit of measurement for both analytes was ng/mL. 2. The test reports listed the units of measurement for both analytes as "ng/mL:mg/dL." 3. During the survey on 10/08/2025 at 2:20 PM, the LM confirmed that the laboratory recently changed their medical record software program which reported two different units of measurement for both testosterone and PSA results.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of the procedure manual, personnel records, and proficiency testing (PT) records and interview with the laboratory manager (LM), the personnel competency evaluations were not performed by a qualified technical consultant (TC), were not documented on separate checklists for each evaluation, and were not accurately reflective of tasks that were performed by the testing personnel (TP). Findings: 1. The "Personnel Competency Evaluation" procedure stated that "The laboratory director evaluates the competency of testing personnel when a new method is begun using the FastPack Training Checklist and annually using the Personnel Evaluation Checklist." 2. The competency evaluations for all TP performed in 2024 and 2025 were performed by TP# 11 and not the laboratory director (LD) who was also the qualified TC. There was no documentation to demonstrate that TP# 11 had the qualifications as a TC to be designated TC responsibilities. 3. A new "Personnel Evaluation Checklist" was not used for each competency evaluation. For example, the evaluation checklist for TP# 5 was originally completed on 03/18/2020 and then had the dates 03/15/2023, 03/16/2024, and 03/10/2025 written at the bottom with "observed by" and the signature of the evaluator implying that the checks from the original evaluation were still acceptable. 4. One of the items on the "Personnel Evaluation Checklist" was "Accurate test performance has been proven by successful proficiency testing." This item was checked as acceptable on the evaluations for the following: a. For TP# 3 on 08/22/2024 and 08/08/2025 when PT attestation statements showed that PT wasn't performed by TP #3 in 2024 and was performed on 09/02/2025 after the evaluation. b. For TP# 7 on their 6-month evaluation performed on 03/20

	/2025 when PT attestation statements showed that TP# 7 didn't perform PT until 09/20 /2025. c. For TP# 10 on their 6-month evaluation performed on 05/22/2025 when PT attestation statements showed that PT was never performed by TP# 10. 5. During the exit interview on 10/08/2025 at 2:35 PM, the LM confirmed that personnel competency evaluations were not performed by the LD in their role as qualified TC, were not documented on a separate evaluation checklist for each evaluation, and were not accurately reflective of tasks that were performed by the TP.