Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0666021	04/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Urological Associates, Pc	3319 Spring Street, Davenport, IA	

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 review of the Yearly Competency procedure, personnel competency assessment records, and confirmed by interview with Technical Consultant #1 (TC #1) and Testing Personnel #1 (TP #1) at 9:30 am on 04/16/2026, the laboratory failed to follow the competency procedures for one out of seven testing personnel in 2024 and 2025. The findings include: 1. The laboratory's Yearly Competency procedure stated the laboratory director will observe staff performing competency skills annually and will sign off competent staff after observation. 2. TC #1 stated that TP #1 performs PCR urine testing on the Pathnostics test system and semen analysis on the SQA Vision test system. 3. Review of competency assessment records for TP #1 showed the laboratory director did not perform and document competency assessment for semen analysis on the SQA Vision test system in 2024 or 2025. 4. At the time of the survey, TC #1 and TP #1 confirmed the laboratory did not follow written competency procedures for performing and documenting annual competency assessment for TP #1 on the SQA Vision test system in 2024 and 2025. THIS IS A REPEAT DEFICIENCY.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and confirmed by interview with Technical Consultant #1 (TC #1) at 10:20 am on 04/16/2026, the laboratory failed to take and document corrective action for 13 unacceptable PT scores from three out of seven PT testing events from 01/01/2024- 04 /16/2026. The findings include: 1. For 2024 testing event 1, the laboratory received unacceptable PT test scores for the following: *2024 Hematology/Coagulation event 1- hemoglobin (specimen HEM-05) and monocyte % (specimen HEM-04) 2. For 2025 testing event 1, the laboratory received unacceptable PT test scores for the following: *2025 Core Chemistry event 1- potassium (specimen CH-03) 3. For 2025 testing event 3, the laboratory received unacceptable PT test scores for the following: *2025 Core Chemistry event 3- alanine aminotransferase (ALT) (specimen CH-14) *2025 Hematology/Coagulation event 3- hemoglobin, hematocrit, lymphocyte %, mean corpuscular hemoglobin (MCH), mean corpuscular volume (MCV), neutrophil %, platelet, red blood cell (RBC) count, and white blood cell (WBC) count (specimen DXH-14) 4. At the time of the survey, TC #1 confirmed the laboratory did not take and document corrective action for the unacceptable PT test scores listed above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observations made during the survey, the TOSOH AIA-900 operator's manual, the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Application for Certification form, and confirmed by interview with Technical Consultant #1 (TC #1) at 9:15 am on 04/16/2026, the laboratory failed to ensure it did not use the denatured proprietary ethanol reagent beyond its expiration date for 326 out of 327 days of operation from 01/01/2025- 04/16/2026. The findings include: 1. Observations made during the survey revealed that the laboratory had in use denatured proprietary ethanol lot# 126247 (expiration 12/2024). 2. As part of instrument maintenance, the TOSOH AIA-900 operator's manual stated to replace the substrate in the tube with ethanol solution at the end of each work day. TC #1 stated the laboratory used denatured proprietary ethanol for the required ethanol solution. 3. The CLIA Application for Certification form indicated the laboratory's hours of operation are 7: 00 am- 4:00 pm on Monday- Thursday and 7:00 am- 3:00 pm on Friday. 4. At the time of the survey, TC #1 confirmed the laboratory used the expired ethanol reagent for 326 out of 327 days of operation from 01/01/2025- 04/16/2026.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel records, the Beckman Coulter DXH-520 performance

	verification records, and confirmed by interview with Technical Consultant #1 (TC #1) at 12:48 pm on 04/16/2026, the technical consultant failed to document training for the Beckman Coulter DXH-520 test system prior to reporting patient test results for three out of seven testing personnel (identifiers TP #1, TC #1, and TP #6). The findings include: 1. The laboratory began using the Beckman Coulter DXH-520 test system to perform patient testing in July 2024. 2. At the time of the survey, TC #1 confirmed the laboratory did not have training records on the Beckman Coulter DXH-520 test system for testing personnel identifiers TP #1, TC #1, and TP #6.