

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2270323	(X3) Date Survey Completed 08/31/2023
Name of Provider or Supplier Urology Group Pc, The	Street Address, City, State 944 State Highway 77, Marion, AR	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test documentation and interviews with laboratory staff, the laboratory director and testing personnel failed to sign proficiency testing attestation statements for one of one testing events in 2023. Survey findings include: A. A review of proficiency testing documentation from 2022 and 2023 showed the laboratory director and testing personnel failed to sign the attestation statement on the First Testing Event of 2023 (one of three events). B. In an interview, at 11:50 a.m. on 8/31/23, the technical supervisor (as listed on the form CMS-209) confirmed the attestation statement listed above had not been signed by the laboratory director and testing personnel.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems</p>

identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Through a lack of policy and procedure and interview it was determined that the laboratory did not include written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic systems. Findings follow: A. Upon request, the laboratory could not produce policies and procedures that defined the mechanism to monitor, assess and correct problems identified in the postanalytic systems. B. In an interview on August 31, 2023, at 11:50 a.m. the technical supervisor verified that policies and procedures defining postanalytic quality assessment were not available.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on the lack of laboratory policies and procedures, lack of laboratory records, and interview it was determined that the Laboratory Director failed to ensure quality assessment programs were established in the general laboratory, preanalytic, analytic and postanalytic phases of testing. The Laboratory Director failed to establish and maintain a defined program to identify failures in quality. 1. Upon request, the technical supervisor failed to provide written policies and procedures of an established quality assessment program and failed to identify failures in quality. 2. During an interview on 8/31/23 at 11:58 a.m., the Technical Supervisor confirmed that there was no quality assurance policy available.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based upon review of personnel records, lack of documentation, and interview it was determined that the laboratory director failed to specify in writing the examinations and procedures that personnel are authorized to perform for one of one testing personnel for which records were presented. Findings follow: A. Upon request, the laboratory was unable to provide a written authorization to perform procedures signed by the laboratory director for the technical supervisor. B. In an interview on 8/31/23 at 11:59 a.m., the technical supervisor confirmed there was no written authorization to perform testing, signed by the laboratory director.