

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0924715	(X3) Date Survey Completed 09/20/2021
Name of Provider or Supplier Urology Associates, Pc - Hendersonville	Street Address, City, State 107 Glen Oak Blvd, Suite 100, Hendersonville, TN	
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
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review of the Roche Light Cycler amplification analyzer quality control (QC) procedure, the light cycler QC log and interview with the general supervisor, the lab failed to follow their procedure for out of range QC from January 29, 2021 through September 7 2021. The findings include: 1. Review of the Roche Light Cycler amplification analyzer QC procedure 05.3 states "all amplification control results must be within range according to the control and specimen resolution log. If any control is out of range, it needs to be repeated along with any patient samples that were also run on the plate. All controls must pass before patient results can be reported out". 2. A random review of the Light Cycler amplification QC between January 29, 2021 through September 7, 2021 revealed 36 patients tested and 6 out of 71 QC runs had at least one analyte per run out of QC range. 3. Interview with the General Supervisor on September 20, 2021 at 2:30 p.m. confirmed the laboratory failed to follow their procedure for out of range QC from January 29, 2021-September 7, 2021.</p>
D6106	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p>

This STANDARD is not met as evidenced by:
Based on a review of the Point of Care (POC) procedure manual and an interview of the General Supervisor, the current laboratory director failed to sign/approve the laboratory POC procedure manual in 2019. Findings include: 1. Review of the procedure manual form for "Review by Laboratory Director" revealed a date of 2020, but no signature/approval by the current laboratory director. 2. Interview with the General Supervisor on September 20, 2021, at 11:30am, confirmed the procedure manual was not signed/approved by the current laboratory director in 2019.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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.

This STANDARD is not met as evidenced by:
Based on review of employee personnel records for 2019 and 2020 and interview with the General Supervisor, the laboratory's technical supervisor failed to document the six required criteria of personnel competency assessment as required by Centers for Medicare and Medicaid Services (CMS) The findings include: 1) Review of employee personnel records for 2019 and 2020 reveal 5 out of 14 testing personnel listed on the CMS 209 form did not have the six required criteria of competency assessment that include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, assessment of problem solving skills. 2) An interview with the General Supervisor on September 20, 2021 at 11:30 am confirmed 5 of 14 testing personnel were not evaluated during 2019 and 2020 using the six criteria for competency assessment required by CMS.