

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0507022	(X3) Date Survey Completed 10/21/2020
Name of Provider or Supplier Amarillo Urology Associates	Street Address, City, State 1900 Medi Park, Amarillo, TX	
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 review of the laboratory's policy and procedure, quality control logs, patient test logs, and interview, the laboratory failed to follow the laboratory's established quality control (QC) criteria for acceptable QC results and reported patient testing when QC failed. Findings follow. Review of the laboratory's Quality Assurance policy and procedure stated under "Quality Control Program" on page 4, "When a control is found to be outside of the specified range or expected result, the control will be re-ran. If the control is still outside of the specified range or expected result, further investigation will be initiated including contacting technical support for assistance if needed. Patient samples will not be tested until it has been resolved and the controls are within the specified range." Random review of quality control logs for Free PSA (Prostate Specific Antigen) performed on the Beckman Access 2 chemistry analyzer from 8/1/2020-9/01/2020 showed Biorad Level 1, Lot 40980, established QC range was 0.12-0.18, and was out of range 4 out of 21 days on the following dates of testing: 1. 08/14/2020 Biorad Level 1 result was 0.11 (out of range) 2. 8/17/2020 Biorad Level 1 result was 0.11 (out of range) 3. 8/18/2020 Biorad Level 1 result was 0.11 (out of range) 4. 08/20/2020 Biorad Level 1 result was 0.11 (out of range). Review of patient test logs from 8/15/2020-8/20/2020 showed 3 patients were reported on 8/14/2020 (patient IDs: 161636, 174035, and 117573), 4 patients were reported on 8/18/2020 (patient IDs: 139703, 137440, 95752, and 106871), and 5 patients were reported on 8/20/2020 (patient IDs: 135151, 174539, 170570, 142258, and 170306). Interview with testing personnel #16 on the CMS form 209 on 10/21/2020 at 1600 hours acknowledged when QC was out of range, he would compare to the control assay</p>

sheet (3 standard deviation range), peer data, or the new lot he was running in parallel to determine its acceptability.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of quality control records and interview, the laboratory failed to document the corrective action taken for repeated quality control (QC). Findings follow. Random review of QC logs for TSH (Thyroid Stimulating Hormone) performed on the Beckman Access 2 chemistry analyzer from 2/1/2020-2/29/2020 showed Biorad Level 1, Lot 40980, established QC range was 0.63-0.75, and was repeated 5 times on 02/07/2020: 1. at 7:56 the result was 0.78 2. at 13:30 the result was 0.77 3. at 13:31 the result was 0.76 4. at 13:31 the result was 0.74 5. at 13:31 the result was 0.78 6. at 13:32 the result was 0.77. Interview with testing personnel #16 on the CMS form 209 on 10/21/2020 at 1615 hours acknowledged he didn't put a note [into the system] on what steps were taken between runs.