

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0675621	<b>(X3) Date Survey Completed</b>  03/24/2023
<b>Name of Provider or Supplier</b>  Uthet Urology Tyler	<b>Street Address, City, State</b>  700 Olympic Plaza Circle Suite 700, Tyler, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An onsite survey conducted 03/24/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5783</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of laboratory policy calibration records, laboratory policy, laboratory patient test results, and confirmed in interview the laboratory failed to document corrective action for one of one Vitamin D calibration failure reviewed from January to May 2022. The findings include: 1. Review of the laboratory policy titled "Quality Assurance Program" section "Quality Control", bullet point three stated the following: "ALL QC results are recorded, even if a particular control value does not fall within the acceptable range. Any repeat controls or corrective action taken is documented." 2. A review of calibration records on the Architect i1000SR had the following Vitamin D failures with no corrective action documented. Assay Name - Calibration date/time - Status VitD_25-OH - 02.21.2022 / 09:20 - Failed Message: 1322 Assay (VitD_25-OH) Number (670) Calibration Failure, CV too large for Calibrator." 1 patient ran since the last acceptable QC on 2/18/2022 2027103263 3. In an interview on 3/24/2023 at 10:15 hours, in the laboratory, testing person 1 (TP1) confirmed that corrective action was documented for the above calibration failure. II. Based on a review of laboratory policy, laboratory quality control (QC) documents,</p>

patient test records, and confirmed in an interview, the laboratory failed to document corrective action for three of three control failures on the Architect i1000SR chemistry analyzer reviewed in May, July, and December 2022. The findings include: 1. Review of the laboratory policy titled "Quality Assurance Program", section "Quality Control"; bullet point three stated the following: "ALL QC results are recorded, even if a particular control value does not fall within the acceptable range. Any repeat controls or corrective action taken is documented." 2. Review of laboratory chemistry quality control documents, and patients tested, had the following quality control failures without documentation of corrective action taken to obtain a satisfactory QC result, or patient remedial action to the last acceptable QC. May 2022: 5/3/2022 - IA-MCC Level 2: 2Gen Test Expected 502.73 - 568.77 ng/dL Obtained - 874.03 ng/dL at 11:47 am Obtained - 447.2 ng/dL at 12.21 pm 5 patients ran since the last acceptable QC on 5/2/2022 2028880639 2028880871 2028884707 2028886909 2028825436 July 2022: 7/6/2022 - IA-MCC Level 2: 2GenTest Expected - 470.28 - 579.28 ng/dL Obtained - 460.83 ng/dL 2 patients ran since the last acceptable QC on 7/5/2022 2030445077 2030444102 December 2022: 12/14/2022 - IA-MCC Level 2- Free PSA Expected - 2.81 - 3.69 ng/mL Obtained - 1.865 ng/mL 9 patients ran since the last acceptable QC on 12/13/2022 2034581166 2034582161 2034582674 2034581659 2034584126 2034585838 2034586716 2034592901 2034593111 3. In an interview on 3/24/2023 at 10:23 hours, in the laboratory, testing person 1 (TP1) confirmed that corrective action was not documented for the above QC failures.