

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0675621	<b>(X3) Date Survey Completed</b>  09/15/2021
<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>	Based on a proficiency testing desk review survey performed on September 15, 2021, the laboratory was found to be out of compliance based on the following <b>CONDITION LEVEL DEFICIENCIES:</b> D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Association of Bioanalysts proficiency testing records, the facility failed to achieve successful</p>

	<p>performance in two of two consecutive testing events for the specialty Bacteriology, resulting in unsuccessful performance. Refer to D2020 and D2028.</p>
<b>D2020</b>	<p><b>BACTERIOLOGY</b> CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Association of Bioanalysts analysts, the facility failed to attain a score of at least 80 percent for Bacteriology in two of two consecutive testing events in 2021. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Association of Bioanalysts, the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for the specialty of Bacteriology in two of two consecutive events: 2021 AAB 1st event 67% 2021 AAB 2nd event 67%</p>
<b>D2028</b>	<p><b>BACTERIOLOGY</b> CFR(s): 493.823(e)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Association of Bioanalysts analysts, the facility failed to achieve an overall testing event score of satisfactory performance for two of two consecutive testing events in Bacteriology in 2021. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Association of Bioanalysts, the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for the specialty of Bacteriology in two of two consecutive events: 2021 AAB 1st event 67% 2021 AAB 2nd event 67%</p>
<b>D6000</b>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Association of Bioanalysts Institute proficiency testing records, the laboratory director failed to</p>

ensure successful participation in a HHS approved proficiency testing program for Bacteriology. Refer to D6016.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Association of Bioanalysts proficiency testing records, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for analyte Bacteriology for 2 of 2 events in 2021. Refer to D2020 and D2028.