

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0977077	(X3) Date Survey Completed 01/28/2021
Name of Provider or Supplier Idaho Urologic Institute	Street Address, City, State 2855 E Magic View Dr, Meridian, ID	
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
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on record review of Estradiol validation, and an interview with the laboratory manager on 01/28/2021, the laboratory director failed to ensure the verification procedures for the analyte Estradiol were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. The findings include: 1. A record review of the new analyte validation study for Estradiol revealed that the laboratory director failed to approve the validation prior to testing patient specimens. 2. An interview with the laboratory manager on 01/28/2021 at 11:10 AM confirmed the laboratory director failed to review, sign, and approve the validation study prior to testing patient specimens. 3. The laboratory reports performing 490 Estradiol patient tests from the time Estradiol was validated on August 23, 2019 to the time of the current survey on 01/28/2021.</p>