

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  46D0679469	<b>(X3) Date Survey Completed</b>  05/10/2019
<b>Name of Provider or Supplier</b>  Brigham Young Univ Student Health Ctr	<b>Street Address, City, State</b>  1750 N Wymount Terrace Dr, Provo, UT	
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>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation and interview with the laboratory director, the director failed to sign and date as approved changes made to 5 of 5 procedures reviewed, (Director's responsibilities, Consultant's responsibilities, Laboratory Information System upgrades, and Thyroid Stimulating Hormone [TSH] Reflex testing for abnormal Free Thyroxine reference testing). Findings include: 1. Procedure manual review included pen and ink changes to procedures. Changes failed to include the director's signature and date of approval for the changes in the director's responsibilities procedure: A. Item #6 Ensure the general supervisor provided onsite supervision of high complexity test performance by testing personnel and Item #8 Specify in writing the responsibility and duties of each consultant (change from Supervisor) and lab employee engaged in the performance of pre-analytic, analytic, and post-analytic phases of testing. B. The pen and ink changes also included the deletion of item #14 and a change in item #15 that the laboratory director will delegate to the general supervisor the the following laboratory director's responsibilities: "A. Assure that all remedial action are taken whenever tests systems deviate from the laboratory's established performance specifications and C. Ensure the patient's test results are not reported if the system is not performing as expected." The changes did not include the signature and date the director approved the changes. C. Pen and ink changes were made to the Laboratory Information Systems upgrades and release notes without the director's signature and date of approval. E. Pen and ink changes were made to the Reference laboratory process for Thyroid Stimulating Hormone reflex testing for abnormal Free thyroxine tests without the signature and date of approval. 2. In an interview with the director on 05/10/2019 at approximately</p>

3:00 P.M. the director confirmed he had not approved the pen and ink changes made by the former technical consultant.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on direct observation, patient test reports review and interview with staff, the laboratory failed to establish a procedure for Laboratory Information System server maintenance sessions that affected test report information for 7 of 26 reports reviewed that failed to include the name and location for where tests were performed. Findings include: 1. Direct observation of test reports printed failed to include the name and address of the laboratory where testing was performed stating "Practice Name" for reports 737504 on 05/18/2017; 727968 on 08/28/2017; 693027 on 11/01/2017; 341793 on 01/29/2018; 823464 on 03/22/2018; 645457 on 07/11/2018; and 0998359878 on 10/18/18. 2. In an interview conducted on 05/10/2019 at approximately 6:00 P.M. staff stated the laboratory server had been serviced earlier in the day without having prior notification from the information technology staff what areas may be affected by the service process. The service affected one work station where reports were being generated. Laboratory staff were unaware the report header had been removed from the test report until printing the requested reports. Staff confirmed they did not have a policy for what to review after LIS maintenance to ensure there were no unintended consequences.