

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0048872	<b>(X3) Date Survey Completed</b>  02/20/2023
<b>Name of Provider or Supplier</b>  Lsu Student Health Center	<b>Street Address, City, State</b>  16 Infirmery Road Room 121, Baton Rouge, LA	
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>	A Recertification Survey was conducted on February 20, 2023 at LSU Student Health Center-CLIA # 19D0048872. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard level deficiencies were cited.
<b>D2010</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and proficiency testing records, as well as interview with laboratory personnel, the laboratory failed to test Proficiency Testing (PT) samples the same number of times that patients are routinely tested for two (2) of three (3) Hematology events reviewed. Findings: 1. Review of the laboratory policy "Proficiency Testing" revealed "The PT samples are treated as a patient sample." 2. Further review of the laboratory's American Proficiency Institute (API) records with raw data revealed the laboratory tested Hematology PT samples more times than patients are routinely tested. a) 2022 Hematology/Coagulation - 1st Event -Sample #1 tested 3/14/2022 at 11:08 AM - Sample #1 tested 3/14/2022 at 11:11 AM -Sample #2 tested 3/14/2022 at 11:12 AM - Sample #2 tested 3/14/2022 at 11:14 AM -Sample #3 tested 3/14/2022 at 11:16 AM - Sample #3 tested 3/14/2022 at 11:18 AM -Sample #4 tested 3/14/2022 at 11:21 AM - Sample #4 tested 3/14/2022 at 11:23 AM -Sample #5 tested 3/14/2022 at 11:24 AM - Sample #5 tested 3/14/2022 at 11:26 AM b) 2022 Hematology/Coagulation - 3rd Event -Sample #11 tested 11/14/22 at 1:26 PM -Sample #11 tested 11/14/22 at 1:28 PM -Sample #11 tested 11/14/22 at 1:53 PM -Sample #12 tested 11/14/22 at 1:31 PM - Sample #12 tested 11/14/22 at 1:32 PM -Sample #12 tested 11/14/22 at 1:47 PM - Sample #13 tested 11/14/22 at 1:34 PM -Sample #13 tested 11/14/22 at 1:36 PM - Sample #13 tested 11/14/22 at 1:50 PM -Sample #14 tested 11/14/22 at 1:38 PM -</p>

Sample #14 tested 11/14/22 at 1:40 PM -Sample #14 tested 11/14/22 at 1:45 PM -  
Sample #15 tested 11/14/22 at 1:45 PM -Sample #15 tested 11/14/22 at 1:43 PM 3. In  
interview on February 20, 2023, Testing Personnel 1 said that they would normally  
repeat samples once if flags were present on the instrument printout. She confirmed  
the lab tested the PT samples identified multiple times.

**D5221**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy, proficiency testing records, and interview with laboratory personnel, the laboratory failed to perform an evaluation for results "not graded" for four (4) of four (4) proficiency testing events reviewed. Findings: 1. Review of the laboratory's "Proficiency Testing" policy revealed "When results are returned to the laboratory, the supervisor will review along with the laboratory staff and the laboratory medical director. If there are failures or not graded due to lack of referee consensus, they are investigated, evaluated, corrected and reviewed by all laboratory personnel and the laboratory medical director." 2. Further review of the policy revealed no information for evaluation of results to include, but not limited to, those not graded for reasons other than lack of referee consensus or declared as educational. 3. Review of the laboratory's 2022 proficiency testing results from the American Proficiency Institute revealed the following "not graded" results without documentation of review by the laboratory: a) 2022 Microbiology - 1st Event i) Urine Culture MIC/Zone Diameter Value - UR-01 -Agar disk diffusion/CLSI/Amoxicillin /Clavulanic acid -Agar disk diffusion/CLSI/Ampicillin -Agar disk diffusion/CLSI /Nitrofurantoin -Agar disk diffusion/CLSI/Norfloxacin -Agar disk diffusion/CLSI /Tetracycline b) 2022 Hematology/Coagulation - 1st Event i) Educational Blood Cell Identification -Basophil (DIF) (%) DIF-01 -Eosinophil (DIF) (%) DIF-01 - Lymphocyte (DIF) (%) DIF-01 -Monocyte (DIF) (%) DIF-01 -Neutrophil, segmented (DIF) (%) DIF-01 -Platelet estimate (DIF) DIF-01 -Blood cell ID (Educational) -ECI-01 -ECI-02 -ECI-03 -ECI-04 -ECI-05 c) 2022 Hematology/Coagulation - 2nd Event i) Educational Blood Cell Identification -Basophil (DIF) (%) DIF-02 -Eosinophil (DIF) (%) DIF-02 -Immature Cell (DIF) (%) DIF-02 -Lymphocyte (DIF) (%) DIF-02 - Lymphocyte, reactive (DIF) (%) DIF-02 -Monocyte (DIF) (%) DIF-02 -Neutrophil, band (DIF) (%) DIF-02 -Neutrophil, segmented (DIF) (%) DIF-02 -NRBC/100 WBC (DIF) (%) DIF-02 -Platelet estimate (DIF) DIF-02 -Unclassified Cell (DIF) (%) DIF-02 -Blood Cell ID (Educational) -ECI-06 -ECI-07 -ECI-08 -ECI-09 -ECI-10 ii) Microscopy/Urine Sediment -Vaginal Wet Preparation - VA-02 d) 2022 Hematology /Coagulation - 3rd Event i) Blood Cell Identification -Blood Cell Identification - BCI-14 ii) Educational Blood Cell Identification -Basophil (DIF) (%) DIF-03 -Eosinophil (DIF) (%) DIF-03 -Immature Cell (DIF) (%) DIF-03 -Lymphocyte (DIF) (%) DIF-03 - Lymphocyte, reactive (DIF) (%) DIF-03 -Monocyte (DIF) (%) DIF-03 -Neutrophil, band (DIF) (%) DIF-03 -Neutrophil, segmented (DIF) (%) DIF-03 -NRBC/100 WBC (DIF) (%) DIF-03 -Platelet estimate (DIF) DIF-03 -Unclassified Cell (DIF) (%) DIF-03 -Blood Cell ID (Educational) -ECI-11 -ECI-12 -ECI-13 -ECI-14 -ECI-15 4. In interview on February 20, 2023, Testing Personnel 1 confirmed that there was no documentation of evaluation for the identified results.

**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 record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D2010.

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D5221.