

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2041010	(X3) Date Survey Completed 03/09/2022
Name of Provider or Supplier Baylor College Of Medicine	Street Address, City, State 333 N Texas Avenue, Webster, TX	
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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, the laboratory's twice annual accuracy check records, CMS 116 form, and confirmed in an interview found the laboratory failed to have documentation of evaluating and verifying the accuracy of the test results for 1 of 2 events in 2021 for 1 of 1 non-regulated analyte: surgical frozen section. The findings were: 1. Review of the laboratory's policy revealed no policy for evaluation and verification of the accuracy of test results twice annually for surgical frozen section. 2. Review of the laboratory's twice annual accuracy check records for surgical frozen section revealed the laboratory failed to perform 1 of 2 accuracy check events in 2021. 3. Review of CMS 116 form signed by LD on 3/8/2022 revealed the annual volume of frozen section was 6. 4. An interview with Assistant laboratory manager on 3/9/22 at 11:15 am in the lab confirmed the above findings. Key: CMS=Centers of Medicare and Medicaid Services LD=Laboratory Director .</p>