

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2125579	(X3) Date Survey Completed 04/27/2021
Name of Provider or Supplier Oxford Mediplex Laboratory	Street Address, City, State 1400 Highway Drive, Oxford, AL	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the installation and validation records for the EPOC analyzer, Serial Number (SN)10020, and an interview with the Point of Care Testing (POCT) Supervisor, the laboratory failed to ensure the manufacturer's performance specifications for accuracy and precision were validated, and the Laboratory Director's review and approval was documented before patient testing began. This affected one of one instruments in use at this facility. The findings include: 1. A review of the installation procedures for the EPOC analyzer, SN 10020 revealed validation of the reportable range. Two additional folders included documentation of ten runs each of the Level 1 and Level 3 quality controls (QC). However, there was no documentation the data was analyzed and evaluated to confirm the accuracy and precision of the instrument as stated in the manufacturer's performance specifications. 2. The validation and installation records also failed to include the Laboratory Director's (or a qualified Technical Consultant's) signature and date indicating review and approval of the new procedures before patient testing began on 3/26/2020. The surveyor noted the review of the reportable range study was only signed by the POCT Supervisor. 3. During an interview on 4/27/2021 at 4:00 PM (with the new and the retiring Laboratory Managers present), the POCT Supervisor confirmed she had signed the EPOC (SN 10020) validation, and stated the Laboratory Director has</p>

"looked" at the documents. The Supervisor further stated she had not realized the laboratory was required to validate accuracy and precision (and the QC data could have been utilized for this) before patient testing began. SURVEYOR IS #32558
Licensure and Certification Surveyor