

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D1094598	<b>(X3) Date Survey Completed</b>  09/27/2021
<b>Name of Provider or Supplier</b>  Ez Clinical Lab	<b>Street Address, City, State</b>  557 Cranbury Rd, Suite # 2, East Brunswick, NJ	
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>D5309</b>	<p>TEST REQUEST CFR(s): 493.1241(e)</p> <p>If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Test Requisitions (TR) and interview with the Laboratory Director (LD), the laboratory failed to ensure that information from the patient's test request form was transcribed accurately into the laboratory information system from November 2020 to the date of the survey. The finding includes: 1. A review of TR for COVID Antibody (AB) tests revealed COVID IgM AB was not performed when requested. 2. The LD confirmed on 9/27/21 at 2:15 pm the laboratory did not ensure TR were transcribed accurately.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to follow their PM policy for "Installing Validating and Calibrating Laboratory Equipment" for all analytes performed on the Dimension EXL and Advia Centaur XPT analyzers from October</p>

2020 to the date of survey. The findings include: 1. The PM stated "When a new instrument or test method is introduced, the following must be performed. 1. Accuracy, 2. Precision, 3. Linearity, 4. Calibration, 5. Verification of Reference Range, 6. Correlation Study." 2. There was no documented evidence that "Verification of Reference Range" was performed. 3. The LD confirmed on 9/27/21 at 2:00 pm that the above mentioned procedure was not performed.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

a) Based on surveyor review of the Performance Specification (PS) records and interview with the Laboratory Director (LD), the LD failed to ensure that PS were adequate to perform Endocrinology, Chemistry and Virology tests performed on the Dimension EXL and Advia Centaur XPT analyzers from October 2020 to the date of survey. The findings include: 1. The laboratory did not verify Patient Normal Range on the Dimension EXL and Advia Centaur XPT analyzers . 2. The laboratory did not perform a Method Comparison on the Dimension EXL with a comparable testing method. 3. There was no documented evidence that PS was performed for Blood Urea Nitrogen run on the Dimension EXL. 4. The LD confirmed on 9/27/21 at 11:15 am that not all PS were not adequate. 35471 b) Based on surveyor review of the PS records and interview with the LD, the LD failed to ensure that PS were adequate to perform Virology tests on the BioRad CFX96 PCR analyzer from November 2020 to the date of survey. The finding includes: 1. There was no documented evidence the software used in the BioRad to generate results was verified when transferred from the instrument database to the database used for result review. 2. The LD confirmed on 9/27/21 at 2:00 pm that PS were not adequate.