

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2140149	(X3) Date Survey Completed 06/05/2018
Name of Provider or Supplier Clarity Labs	Street Address, City, State 97 Mt Bethel Road, Warren, NJ	
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
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specifications (PS) and interview with the Laboratory Director (LD), the laboratory failed to have complete PS for Urine and Oral Fluid Drug tests performed on the AbSciex Triple Quad 4500 from January 2017 to the day of the survey. The finding includes: 1. A review of the PS for Analytical Specificity (AS) evaluating interfering substances and matrix interference revealed that the laboratory did not use blanks with and without the internal standard to evaluate AS. 2. The LD confirmed on 6/518 at 1:30 PM all PS were not established before reporting patients.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where</p>

the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Final Report (FR) and interview with the Laboratory Director (LD), the laboratory failed to report Immunoassay Screen (IS) result accurately from January 2017 to the date of survey. The findings include: 1. The Normal Range column on the FR had the cutoff limit. 2. The status column of the FR was inconsistent. Status for Specimen Validity referred to Normal/Abnormal and IS status referred to the patient result. 3. The LD confirmed on 6/5/18 at 12:35 pm that the FR did not have accurate information.

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:

Based on surveyor review of the Performance Specification (PS) records and interview with the Laboratory Director (LD) the LD failed to ensure PS were adequate to perform Validity testing for Urine Drug Screening tests on the Olympus AU 400 from January 1, 2017 to the date of survey. The findings include: 1. A review of Linearity revealed that Creatinine was linear from 1.25 to 23.05 but the laboratory's normal reference range was 20-350. 2. The Alternate Method Comparison Study for Creatinine revealed a Bias of 21.9%. 3. The LD confirmed on 6/5/18 at 1:40 pm that the LD did not ensure the PS were adequate.