

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2156354	(X3) Date Survey Completed 12/06/2019
Name of Provider or Supplier Phoenix Lab & Ancillary Services	Street Address, City, State 702 E Bell Rd Ste 112, Phoenix, AZ	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on lack of temperature logs for review and interview with the facility personnel, the laboratory failed to document the room temperature and humidity measurement of the room where testing occurred and failed to document the temperature of the refrigerator where test reagents are stored. Findings include: 1. No temperature logs, including room temperature, humidity and refrigerator temperature logs, were presented for review during the survey conducted on December 6, 2019. 2. The facility personnel confirmed that the temperature logs indicated above could not be located at the time of the survey. 3. The test volume under the sub-specialty of Toxicology is approximately 200 per year.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:
Based on review of the performance verification documentation for testing performed on the Indiko Plus analyzer and interview with the facility personnel, the laboratory failed to have the performance verification signed and approved prior to testing patient specimens. Findings include: 1. The laboratory began testing on the Indiko Plus toxicology analyzer in May 2019. The laboratory's approximate annual test volume is 200. 2. No documentation was provided for review to indicate the laboratory director or technical consultant analyzed, approved and signed the performance verification data for the analyzer prior to patient testing. 3. The facility personnel confirmed that the laboratory did not have a signed, approved copy of the performance verification as indicated above.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on review of patient test reports and interview with the facility personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are electronically interfaced from the analyzer to the Laboratory Information System (LIS) and from the LIS into the patients' Electronic Medical Record (EMR). Findings include: 1. The laboratory performs approximately 200 patient tests annually under the sub-specialty of Toxicology. 2. The laboratory performs testing on the Indiko Plus analyzer, and the test results are electronically transmitted from the analyzer to the LIS and from the LIS to the EMR. 3. No documentation was presented for review during the survey to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are electronically interfaced from the Indiko Plus analyzer to the LIS and from the LIS to the patients' EMR. 4. The facility personnel confirmed that the laboratory did not have a system in place to verify the accuracy of the patient test results that are electronically transmitted into the EMR.

D5805

TEST REPORT
CFR(s): 493.1291(c)

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 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 review of patient test reports and interview with the facility personnel, the laboratory failed to include on the test report the correct units of measurement for toxicology analytes tested on the Indiko Plus analyzer. Findings include: 1. The laboratory began patient testing in the sub-specialty of Toxicology in May 2019, with an approximate annual test volume of 200. The laboratory tests for the following analytes: Heroin (6-AM), Amphetamine (AMP), Benzodiazepine (BZO), Cocaine (COC), Opiate (OPI) and Oxycodone (OXY). 2. Two out of two test reports reviewed during the survey, from testing dates 8/15/19 and 10/24/19, were lacking the correct units of measurement for each test result. The Indiko Plus test system used by the laboratory issues the test result in ng/mL. The laboratory's test reports indicated the units of measurement as only "ng". 3. The facility personnel confirmed that the test reports reviewed during the survey were missing the correct units of measurement.