

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2112655	(X3) Date Survey Completed 05/02/2018
Name of Provider or Supplier Lld Laboratories, Llc	Street Address, City, State 249 East Nc Highway 54, Suite 310, Durham, NC	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2016, 2017, and 2018 AAB (American Association of Bioanalysts) proficiency testing records 5/2 /18, the testing personnel and laboratory director failed to attest that proficiency samples for each test event were tested in the same manner as patient specimens. The laboratory's "Proficiency Testing" policy states "... Procedure: Receiving & Testing ... 3. All attestation forms should be signed by the testing personnel and medical director /designated individual. ..." Review of 2016, 2017, and 2018 AAB proficiency testing records revealed the laboratory failed to ensure that attestation statements were signed by the testing personnel and the laboratory director or designee for the 2016 3rd Q test event, the 2017 1st, 2nd, and 3rd Q test events, and the 2018 1st and 2nd Q test events. Names had been typed on the attestation statements, but the attestation statements were not signed by the testing personnel and laboratory director or designee.</p>
D6139	<p>CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1457(c)</p> <p>The clinical consultant must ensure that reports of test results include pertinent information required for specific patient interpretation.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of manufacturers' instructions and random review of 6 patient test reports (#7223, #5425, #5545, #4475, #871, #4408) on 5/2/18, the clinical consultant failed to ensure that patient urine drug screen test reports included pertinent information required for result interpretation. Review of manufacturer's product inserts revealed the assays should be used to determine the presence or absence of the analyte tested, and should not be used to quantify the amount of analyte. Examples: 1. The Lin-Zhi International, Inc. LZI Amphetamines 500 Enzyme Immunoassay product insert states "... Limitations 1. A positive result from the assay indicates only the presence of amphetamines. The test is not intended for quantifying these single analytes in samples. 2. A positive result does not necessarily indicate drug abuse. 3. A negative result does not necessarily mean a person did not take amphetamines. ... 7. The test is not for therapeutic drug monitoring. ... Results: Qualitative: The cutoff calibrator ... is used as a reference for distinguishing positive from negative samples. A sample with a change in absorbance ... equal to or greater than that obtained with the cutoff calibrator is considered positive. A sample with a change in absorbance ... lower than that obtained with the cutoff calibrator is considered negative. Semi-Quantitative: The semi-quantitative mode is for the purpose of enabling laboratories to determine an appropriate dilution of the specimen for verification by confirmatory methods such as GC/MS or LC/MS or permitting laboratories to establish quality control procedures. ..." 2. The Lin-Zhi International, Inc. LZI Oxycodone Enzyme Immunoassay product insert states "... Limitations 1. A positive result from the assay indicates only the presence of oxycodone. The test is not intended for quantifying these single analytes in samples. 2. A positive result does not necessarily indicate drug abuse. 3. A negative result does not necessarily mean a person did not take illegal drugs. ... 7. The test is not for therapeutic drug monitoring. ... Results: Qualitative: The cutoff calibrator ... is used as a reference for distinguishing positive from negative samples. A sample with a change in absorbance ... equal to or greater than that obtained with the cutoff calibrator is considered positive. A sample with a change in absorbance ... lower than that obtained with the cutoff calibrator is considered negative. Semi-Quantitative: The semi-quantitative mode is for purposes of (1) enabling laboratories to determine an appropriate dilution of the specimen for verification by a confirmatory method such as GC/MS, LC/MS or (2) permitting laboratories to establish quality control procedures. ..." Random review of 6 patient test reports (#7223, #5425, #5545, #4475, #871, #4408) revealed the laboratory reported a numerical result in ng/mL (nanograms per milliliter) for the drugs detected in the patient urine specimens, with the interpretation listed as "POSITIVE". The cutoff value for each drug was also included on patient reports. The drugs which were tested but not detected in the patient specimen were reported as "Not Detected". During interview at approximately 5:30 p.m., the general supervisor stated that some providers wanted the numerical values included on patient test reports, so the numerical values had not been removed. At approximately 5:50 p.m., he stated IT (information technology) personnel had removed the numerical values from the patient reports generated by this laboratory.