

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1099838	(X3) Date Survey Completed 11/13/2019
Name of Provider or Supplier Softlanding Labs	Street Address, City, State 4531 W Harrison St, Hillside, IL	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on observation; review of laboratory procedures manuals and patients' test reports; and interview with General Supervisor #1; the laboratory failed to establish and follow written policies and procedures for Specimen referral. Findings: 1. On November 13, 2019 at 10:00 AM, the surveyor toured the laboratory facility. 2. The surveyor observed that there were 2 separate laboratories located at the facility. One on the 1st floor and the other on the 2nd floor. 3. There were 3 Mass Spectrometers in the 2nd floor laboratory where High Complexity Toxicology tests are performed. 4. Review of laboratory policies and procedures manuals revealed that the laboratory only performed High Complexity Confirmatory Toxicology testing, no screening. 5. Review of 4 patients test records revealed the following: a. BHS DRUG SCREEN was ordered for 4 of 4 patients b. Drug Screen results were reported for 4 of 4 patients test reports reviewed. c. Confirmed positive for the analyte was reported for 3 of 4 patients test reports reviewed. d. Both the 1st floor laboratory's and 2nd floor laboratory's name and address are documented on patient test reports. e. The surveyor could not determine which laboratory performed drug screening tests. 6. On November 13, 2019 at 10:30 AM, the General Supervisor told the surveyor that they do not perform any screening tests. He stated, "When we receive the specimen, we send it to the laboratory on the 1st floor for screening 1st. If it is positive, then the specimen gets sent to our laboratory for confirmation." 7. There were no written</p>

procedures for specimen referral. 8. On November 13, 2019 at 2:00 PM, the General Supervisor confirmed the surveyor's findings.

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 observation, review of patients' test reports, and interview with General Supervisor #1; the test report did not indicate the name and address of the laboratory location where the test was performed. Findings: 1. On November 13, 2019 at 10:00 AM, the surveyor toured the laboratory facility. 2. The surveyor observed that there were 2 separate laboratories located at the facility. One on the 1st floor, where drug screening tests are performed, and the other on the 2nd floor, where confirmatory toxicology tests are performed by mass spectrophotometry. 3. Review of patients' test reports revealed that both the 1st floor laboratory's and 2nd floor laboratory's name and address are documented on patient test reports. The surveyor could not determine which laboratory performed drug screening tests and which laboratory performed high complexity confirmatory toxicology tests. 4. On November 13, 2019 at 2:00 PM, the General Supervisor confirmed the surveyor's findings