

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1093166	(X3) Date Survey Completed 12/28/2018
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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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on API (American Proficiency Institute) proficiency testing record review for two-year period (years 2017 and 2018), and interview with testing person #2, the laboratory failed to rotate proficiency testing (PT) events to include all testing personnel who routinely performed patient testing for: - 4 out of 4 events for urine cocaine and opiates. - 2 out of 2 events for urine cannabinoids. - 2 out of 2 events for urine PH (a numeric scale used to specify the acidity or basicity). The findings include: On December 28, 2018 at 1:30pm surveyor reviewed API proficiency testing records for years 2017 and 2018. Record review revealed that testing person #2 did not perform proficiency testing for: A) 4 out of 4 proficiency testing events (years 2017 and 2018) for cocaine and opiates - urine toxicology test analytes. B) 2 out of 2 proficiency testing events (year 2017) for cannabinoids (urine toxicology test analyte) and urine PH (urine chemistry test). During an interview on December 28, 2018, at 3:00pm, testing person #2 confirmed findings A and B.</p>
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory</p>

results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:

Based on the record review of one patient (test order date 12/12/18, test run date 12/28/18 for urine cocaine and opiates) and interview with the testing person #2, laboratory failed to have type of specimen, time of specimen collected, test ordered, and the name of the ordering physician on test requisition form (test order). The findings include: On 12/28/18 at 2pm, surveyor reviewed one test requisition form (test order) and test report record for urine cocaine and opiates for the test order date 12/12/18 and test date of 12/28/18. It showed that: A- Requisition form did not include the test ordered, type of specimen, time of specimen collected, and the name of the ordering physician. B- Hand written date for specimen collection was not clear. During an interview on December 28, 2018 at 3:00 PM, testing person #2 confirmed that: (a) Test requisition form (test order date 12/12/18, test run date 12/28/18 for urine cocaine and opiates) did not have type of specimen, time of specimen collected, the test ordered, and the name of the ordering physician. (b) Hand written date for specimen collection was not clear.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

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.

This STANDARD is not met as evidenced by:

Based on the observation, record review and interview with the testing person #2, laboratory failed to follow the specimen labeling as per laboratory procedure manual for 30 out of 30 urine specimens for cocaine and opiates- drug screening. The findings include: On December 28, 2018 at 2:15pm surveyor observed 30 urine specimens for urine drug (cocaine and opiates) screening that had only first and last name of the patient, with no date, time, tech initials, or unique patient identification number to match with requisition forms. Two specimens had the names with the running ink. Procedure manual review under patient test management described: "Correct and timely labeling is critical. All specimens should contain the proper information: date, time, tech initials, unique patient identification number. Make sure you use a black pen that does not run when wet. Always: 1-Confirm the patient's full name. 2-Label the specimen completely before patient leaves drawing area. 3-Note the condition of specimen if unacceptable. 4-Assign it a lab accession number if applicable". During an interview on December 28, 2018, at 3:00pm, testing person #2 confirmed that 30 urine specimens collected for drug (cocaine and opiates) screening had: I- Only the

first and last names of the patient. II- No other information to match the requisition form or as described in the laboratory procedure manual- to include date, time, tech initials, unique patient identification number, or accession number. III- Two specimens had the names with the running ink.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on observation and record review from 1/ 2017 to 12/28/2018 and interview with testing person #2, laboratory failed to: - log correctly (April and May 2018), and record (October 2018) the daily temperature and humidity, refrigerator and freezer temperatures. The findings include: On December 28, 2018 at 11: am surveyor reviewed the laboratory temperature worksheets, instrument maintenance and quality control records for years 2017 and 2018. It showed that: I- Room temperature, humidity, refrigerator temperature and freezer temperature record dates were April 12, 2018 while instrument maintenance records and test controls run dates were April 15, 2018. II- Room temperature, humidity, refrigerator and freezer temperature record dates were May 5, 2018 while instrument maintenance records and test controls run dates were May 6, 2018. III No records of room temperature, humidity, refrigerator and freezer temperature for October 21 and 28, 2018. During an interview on December 28, 2018, at 3:00pm, testing person #2 confirmed: A) Findings I and II and that the temperature and humidity records did not match with the instrument maintenance and test control run dates. B) Finding III, that laboratory did not record the room temperature, humidity, refrigerator and freezer temperature for October 21 and 28, 2018.

D5787

TEST RECORDS

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on the urine cocaine and opiates tests record review for 6 out of 6 patients and interview with the testing person #2, laboratory failed to include the identity of testing person. The findings include: On 12/28/18 at 2pm, surveyor reviewed 6 patient test reports for urine cocaine and opiates screening tests. The instrument print out - test report did not include the testing person identity for all 6-test reports reviewed. During an interview on December 28, 2018 at 3:00 PM, testing person #2 confirmed that urine cocaine and opiates screening test instrument print out - test report for all six patients did not include the testing person identity.

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 the record review and interview with the testing person #2, laboratory failed to report the patient test results in timely manner by: Running the specimens collected from 12/12/18 to 12/20/18, on 12/28/18 and then to be waiting the results to be verified by physician in EMR (Electronic medical records) for cocaine and opiates-drug screening tests. The findings include: On December 28, 2018 at 2:00pm surveyor reviewed: A) Six patients test reports (urine cocaine and opiates- drug screening) for specimen collection dates 12/12/18, 12/14/18, 12/17/18, 12/17/18, 12/18/18, and 12/20/18 with the test run date of 12/28/18. During an interview on December 28, 2018, at 3:00pm, testing person #2 confirmed that the laboratory ran the urine drug screening tests(cocaine and opiates) for the collection dates from 12/12/18 to 12/20/18 on 12/28/18 for the six patients reviewed. The results then to be scanned in to EMR and then to be verified by the physician.