

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0895548	(X3) Date Survey Completed 10/30/2018
Name of Provider or Supplier Accatur Diagnostics Ii Llc	Street Address, City, State 18102 Sky Park South, Ste F, Irvine, CA	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2017 proficiency testing evaluations from CAP (College of American Pathologists), laboratory proficiency testing records, and patients Toxicology tests reports; and interview with laboratory personnel, the laboratory failed to verify the accuracy of testing at least twice annually. Findings include: a. The laboratory used LC/MS (Liquid chromatography/Mass spectrophotometry) methodology to test for 47 different drugs. b. The laboratory chose to participate in CAP's proficiency testing program, "DMPM, Drug Monitoring for Pain Management", as the means to satisfy the requirement to verify the accuracy of testing at least twice annually. 1) For 2 out of 2 testing events, CAP provided no samples for 20 drugs: MDEA 2-Hydroxyethylflurazepam a-Hydroxytriazolam Diazepam Flunitrazepam Lorazepam Triazolam Phencyclidine (PCP) Gabapentin 6-Acetylmorphine Norpropoxyphene maleate Propoxyphene Carisoprodol Meprobamate Zolpidem Amitriptyline Desipramine Doxepin Imipramine Nortriptyline 2) For 1 out of 2 testing events, CAP provided no samples for 19 drugs: MDA MDMA Methamphetamine Aminoclonazepam a-Hydroxyalprazolam Alprazolam Clonazepam Nordiazepam Oxazepam Temazepam Codeine Fentanyl Hydrocodone Meperidine Norfentanyl oxalate Normeperidine Oxycodone Tramadol THC 3) For 1 out of 2 events, CAP reported code "40", "Results for this kit were not received": Amphetamine c. Laboratory personnel affirmed (10/30/18) the laboratory had no alternate method for verifying testing accuracy; and thus, the failure to at least twice annually verify the accuracy of testing for the aforementioned drugs. d. The</p>

reliability and quality of results reported for these 40 drugs could not be assured. Based on the stated annual test volume, the laboratory reported a total of approximately 705 results in 2017. .

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on the cumulative and serious nature of the deficiencies cited, the Laboratory Director is herein cited at the Condition level for deficient practice in providing overall management and direction. Findings include: a. Under the Laboratory Director's management, the laboratory failed to at least twice annually verify the accuracy of testing for each analyte. b. See D5217 c. Under the Laboratory Director's management, the laboratory failed to ensure a sufficient number of licensed individuals performed high complexity testing and analysis. d. See D6168 and D6170. .

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
Based on the severity of the deficiency cited, the laboratory is herein cited at the Condition level for failing to ensure a sufficient number of individuals with required qualifications to perform high complexity testing. See D6170. .

D6170

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(a)

Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:
Based on observation and interviews with laboratory personnel and review of test records, it was determined that the individual operating the LC/MS test system didn't have a license for clinical laboratory testing, a California State requirement for performing high complexity testing. Findings include: a. Laboratory personnel affirmed (10/30/18) the individual performing all the "wet work" hands-on operation of the LC/MS system including reviewing QC data to determine assay acceptability, was nonlicensed to perform clinical laboratory testing. b. Laboratory personnel affirmed (10/30/18) the licensed person was not onsite during testing to perform "wet work" and had responsibility limited to review of final results for reporting. c. The reliability and quality of results reported could not be assured when testing was

performed by unlicensed personnel. Based on the stated annual test volume, the laboratory reported a total of approximately 705 results each year. Patient test reports selected at random for review from 2017 are as follows: Accession #
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