

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2081203	(X3) Date Survey Completed 06/03/2019
Name of Provider or Supplier Meditest Laboratories	Street Address, City, State 17971 Skypark Circle, Unit 33e, 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory director, it was determined that the laboratory failed to assure no expired laboratory supplies or reagents were used. The findings included: a. The refrigerator which stored international standard (IS) materials had kept one ampoule of IS for (+/-) Proposyphene D11 purchased from Cerrilliant. b. The lot number for this expired IS was FE0511204 and expired in June 2017. c. The laboratory director affirmed (6/3/19 @ 10:55 AM) that the laboratory kept the expired IS ampoule in the refrigerator.</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's Daily Control Report records and interview with the laboratory director, it was determined that the laboratory failed to ensure the test results and other patient-specific data were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. The findings included: a. The laboratory used Agilliant Quad to perform drug screen and confirm the analyte when drug detected and provided concentrations for the confirmed analyte. b. The laboratory used laboratory information system (LIS), Labdaq, to interface and receive the testing data, and generate test result with necessary information in the reports. c. Reviewed the laboratory Daily Control Reports (DCR), a printed report identified by Name: QC 1 ST 400, Acc # 63733, Lot Number 12072015 Lot Expires 1/1/2020 with Control # QC_1_ST_400. d. Under "Daily Control Report" wording, an "Accession Range 63733 to 63733), no run date was noted on the report except printed 6/3/2019 11:11 AM at the bottom left side. e. "Results still pending" in printed 4 times on this DCR where LIS normally identified "Run by HM on 5/24/2019 1:05 PM". f. This report showed all the testing results for each drug analyte listed on the report. g. Inconsistency was noted that a complete results reported for this Daily Control Report, but the wording of "Results still pending" alerted on the report. h. The laboratory director affirmed (6/3/19 @ 11: 25 AM) that LIS acted strangely. i. The laboratory failed to ensure test results and other patient-specific data were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's patient test report records and interview with the laboratory director, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct the problems in post-analytic system. The findings included: a. The laboratory established and performed in house Tracking Procedures, quality assessment (QA), to ensure the accuracy of the patient test reports in a timely manner. b. The laboratory failed to follow written policies and procedures to do Tracking Procedures for the year of 2018 to assure the accuracy of patient test result reports. c. The laboratory director affirmed (6/3/19 @ 1:45 PM) that the laboratory failed to follow its written policies and procedures to perform its quality assessment, Tracking Procedures in 2018.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records, and interview with the laboratory director, it was determined that the laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the pre-analytic, analytic, and post-analytic phases of testing. The findings included: See D-5415, D-5791, and D-5801