

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2153457	(X3) Date Survey Completed 08/14/2019
Name of Provider or Supplier Neoanalytics Laboratory	Street Address, City, State 25 S Raymond Ave Ste 204, Alhambra, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation of the reagents, controls and calibrators in the refrigerator and interview with the technical consultant, it was determined that the laboratory has been using reagents, solutions and other supplies that have exceeded their expiration date. The findings included: a. On the day of the survey (8/14/2019, 11:00) based on a direct observation, randomly selected materials inside the refrigerator, the following reagents, controls and calibrators were expired: Microgenics Corp. DRI Ecstasy Cal (750 mg/ml) Lot # 72778952, Exp.date 10/2018. DRI Ecstasy Cal (250 mg/ml) Lot # 72778949, Exp. date 9/2018. Total IgG THC (20 mg/ml), Lot # 72713744, and Exp. date 3/2018 MGC Primary DAU Control Set Lot # 72850720 Exp date 4/2019 DRI Multi Drug urine CAI 3 (TS), Lot # 72774503 Exp date 6/30/2019 Thermo Scientific Oxycodone Cal 100 Lot # 72772292 Exp Date 1/2019 Drug of Abuse Low, Lot # 73106161 Exp date 7/2019 Drug of Abuse High, Lot # 72791314 Exp date 8/2018 b. The technical consultant confirmed (8/14/2019, 11:00) that the controls, calibrators and other reagents were expired, but was inside the refrigerator which could have the potential to be used or being used. c. Based on the laboratory's annual testing declaration for 2018-2019 the laboratory analyzed and reported approximately 960 Toxicology tests that its accuracy could have been affected by the expired reagents, calibrators and controls used.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p>

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on direct observation of the reagents, controls and calibrators in the laboratory's refrigerator and interview with the technical consultant, it was determined that the laboratory did not follow written policies and procedures with regards to using reagents, controls and calibrators and other supplies not exceeding the expiration dates. The findings included: a. The laboratory's policy and procedure under title; "Test systems, equipment, instruments, reagents, materials and supplies." stated: "2. Reagents, solutions, control materials, calibration materials and other supplies shall not be used when they have exceeded their expiration date, have deteriorated or are substandard quality." 2. See D 5417.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on direct observation of the reagents, controls and calibrators in the laboratory's refrigerator and interview with the technical consultant, it was determined that; the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. See D 5417 and D 5791.