

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2113189	(X3) Date Survey Completed 08/19/2021
Name of Provider or Supplier Rppc Labs Llc	Street Address, City, State 26154 Woodward Avenue Ste 5, Royal Oak, MI	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Supervisor #2 (TS2), the laboratory failed to follow its policy to assess employee competency for 3 (Testing Personnel #1-#3) of 3 testing personnel listed on the CMS-209 form. 1. A review of the laboratory's "RPPC Personnel" policy revealed a section stating, "A formal performance evaluation is conducted at the end of the first six months of employment and each year of employment thereafter." 2. A review of the laboratory's personnel documentation revealed a lack of documentation of competency assessments for personnel hired at the RPPC Labs, LLC laboratory. 3. An interview on 8/18/21 at 11:49 am with TS2 confirmed the laboratory did not have documentation of competency assessments for testing at RPPC Labs, LLC.</p>
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Supervisor #2 (TS2), the laboratory failed to verify the accuracy of toxicology analytes that were not scored by</p>

the College of American Pathologists proficiency testing program for 1 (UT-C 3rd event in 2020) of 6 events reviewed. Findings include: 1. A review of the laboratory's "PT Exception Code/Ungraded Results" procedure revealed a section stating, "PT Exception Code/Ungraded Results appear in an evaluation to signify the PT for the analyte has not been graded. The laboratory must identify all of the analytes with an Exception Reason Code and investigate the acceptability of performance. If a PT Exception Code/Ungraded Results appears on the evaluation, the following protocol will be followed: 1. The technical supervisor will perform a self-evaluation of all PT Exception Code/Ungraded Results using the evaluation criteria in the participant summary. 2. This self-evaluation will be documented and reviewed by the laboratory staff. 3. The director will review and sign off on the self- evaluation. 4. All documentation will be retained for a period of two years." 2. A review of the laboratory's College of American Pathologists' proficiency testing documentation from the 2020 UT-C event revealed the "11- Unable to to analyze (documentation to be provided by the laboratory)" code, showing the proficiency testing company did not score the laboratory's results. There was a lack of documentation of the laboratory performing the self-evaluation in the participant summary. 3. An interview on 8/18/21 at 1:57 pm with TS2 confirmed the laboratory did not perform the self-evaluation for the UT-C event that was not scored by the proficiency testing provider.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

. A. Based on record review and interview with Technical Supervisor #2 (TS2), the laboratory failed to establish the storage stability of refrigerated or ambient urine specimens prior to testing patients since the testing began using the AB Sciex QTrap 4500 toxicology test system on 3/1/2016. Findings include: 1. A review of the laboratory's establishment of performance specifications "MPX-2 Validation" revealed it did not establish the storage stability for refrigerated or ambient urine samples for toxicology testing using the AB Sciex QTrap 4500 analyzer. 2. An interview on 8/18/21 at 1:45 pm with TS2 confirmed the laboratory did not have documentation of establishing the storage stability of refrigerated urine samples. B. Based on record review and interview with Technical Supervisor #2 (TS2), the laboratory failed to ensure the establishment of performance specifications of the laboratory-developed liquid chromatography mass spectrometry system met the laboratory's acceptance criteria before reporting patient toxicology results for 27 of 52 analytes on the laboratory's test menu. Findings include: 1. A review of the laboratory's test menu revealed the following analytes were tested by the laboratory: a. Alprazolam b. Hydroxalprazolam c. 7 aminoclonazepam d. Diazepam e. Nordiazepam f. Oxazepam g. Temazepam h. Lorazepam i. Meperidine j. Tapentadol

k. Methadone l. Fentanyl m. Norphentanyl n. Tramadol o. O-Desmethyltramadol p. Buprenorphine q. Norbuprenorphine r. Codeine s. Norcodeine t. Hydrocodone u. Norhydrocodone v. Dihydrocodeine w. Hydromorphone x. Morphine y. Oxycodone z. Noroxycodone aa. Oxymorphone bb. Naloxone cc. Naltrexone dd. Amobarbital-pentobarbital ee. Butalbital ff. Phenobarbital gg. Secobarbital hh. Carisoprodol ii. Mebrobamate jj. Zolpidem kk. Gabapentin ll. Pregabalin mm. Amphetamine nn. Methylphenidate oo. Ritalinic Acid pp. Phentermine qq. 6-MAM rr. Benzoyllecgonine ss. 3,4-Methylenedioxyamphetamine (MDA) tt. 3,4-Methylenedioxy-N-ethylamphetamine (MDEA) uu. 3,4-Methylenedioxymethamphetamine (MDMA) vv. Methamphetamine ww. Tetrahydrocannabinol (THC-COOH) xx. Methylone yy. Methcathinone zz. Methylenedioxypyrovalerone (MDPV) 2. A review of the laboratory's "LIQUID CHROMATOGRAPHY MASS SPECTROMETRY METHOD VALIDATION PLAN" revealed a section stating, "Calculated percent bias should be less than or equal to 20% to be acceptable (sufficient accuracy)." 3. A review of the laboratory's accuracy study revealed the following analytes did not meet the laboratory's accuracy criteria of less than or equal to 20% bias: a. 6-MAM b. Amphetamine c. Codeine d. Hydromorphone e. Norbuprenorphine f. Methamphetamine g. Hydroalprazolam h. Lorazepam i. MDA j. MDEA k. MDMA l. Meperidine m. Meprobamate n. Norbuprenorphine o. Nordiazepam p. Oxymorphone q. Tramadol r. Diazepam s. Methylone t. MDPV u. Norcodeine v. Norhydrocodone w. Noroxymorphone x. Noroxycodone y. Butabarbital z. O-desmethyltramasol aa. Ritalinic acid 4. An interview on 8/18/21 at 1:57 pm with TS2 and the Laboratory Manager confirmed the analytes listed above did not meet the laboratory's accuracy criteria.