

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1080385	(X3) Date Survey Completed 02/11/2020
Name of Provider or Supplier Prc Associates Llc	Street Address, City, State 1671 Clyde Morris Blvd, Daytona Beach, FL	
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
D0000	A recertification survey was conducted on February 11, 2020. PRC Associates LLC is NOT in compliance with 42 CFR, Part 493 Requirements for Laboratories.
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory had not tested chemistry proficiency testing samples the same number of times that it tests patient samples for two of four American Proficiency Institute (API) testing events reviewed. Findings included: A record review of 2018 and 2019 API Chemistry proficiency testing (PT) was conducted on February 11, 2020. The analytes tested are: Creatinine, pH, Amphetamines, Barbiturates, Benzodiazepine, Cannabinoids, Cocaine Metabolites, MDMA (3,4-Methylenedioxymethamphetamine), Methadone, Opiates, Oxycodone, Phencyclidine, and Alcohol. The first event of 2018 showed the samples UDS01, UDS02, UDS03, UAD01, UAD02, and UAD03 were tested on 4/24/2018 and 4/26/2018. The API "Submitted Results Form" showed the results were submitted electronically on 5/1/2018. The review of the second event in 2019 showed the samples UDS04, UDS05, UDS06, UAD04, UAD05, and UAD06 were tested on 10/16/2019, 10/17/2019, and 10/22/2019. The API "Submitted Results Form" showed the results were submitted electronically on Oct 22, 2019. Review of the policy titled "Proficiency Testing" states "Proficiency test samples must be tested the same number of times that patient samples are routinely tested. The laboratory must use the same procedures for both patient samples and PT samples. Do not run PT samples multiple times if patient samples for that testing are not routinely run multiple times". The interview with the Technical Supervisor on 2/11/20 at 11:30am confirmed the PT samples were run multiple times.</p>

<p>D5209</p>	<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 lack of records and interview, the laboratory failed to follow their procedures to document annual competency evaluations for one of one Testing Persons on staff for two of two years reviewed (2018-2019). Findings include: At the time of survey, the Technical Supervisor was unable to provide documentation of Competency Assessment for 2018 and 2019. The facility policy titled "Competency" states "New personnel as assessed initially during training, at 6 months, and at least annually thereafter by the Laboratory Director or designee". The interview with the Technical Supervisor on 2/11/20 at 11:30am confirmed the competency assessments had not been completed.</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to ensure testing personnel were competent and that competency was maintained. Findings include: The Laboratory Director failed to ensure all testing personnel that perform moderate complexity testing had competency evaluations in 2018 and 2019. (See D5209)</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and staff interview, the Laboratory Director failed to ensure testing personnel were competent and that competency was maintained. Findings include: The Laboratory Director failed to ensure all testing personnel that perform high complexity testing had competency evaluations in 2018 and 2019. (See D5209)