

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2084683	(X3) Date Survey Completed 07/09/2018
Name of Provider or Supplier Baker Direct Medical Care	Street Address, City, State 1345 Hwy 343, Neon, KY	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review, observation, and staff interview on 07/09/2018, the laboratory failed to monitor and document temperatures for the storage of the drugs of abuse testing reagents and storage of urine specimens prior to testing. Findings include: Manufacturer's Instructions for the storage of testing reagents is 2-8 degrees Centigrade. The laboratory failed to document refrigerator temperatures from 02/06 /2018 when the instrument was installed. Based on observation, the laboratory stored urine samples in the freezer prior to testing. There was no documentation of temperatures for the freezer from when the laboratory started patient testing 02/12 /2018. Interviews with the Laboratory Director and testing personnel at 2:00 PM on 07 /09/2018, revealed the laboratory failed to have a system in place to ensure refrigerator and freezer temperatures were monitored and documented daily.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following</p>

for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and staff interview on 07/09/2018, the laboratory failed to include a positive and negative control material for the Buprenorphine drug of abuse for six of six days of patient testing. Findings include: Record review revealed Buprenorphine results were reported on 02/27/2018, 03/29/2018, 04/27/2018, 05/24/2018, 06/19/2018, and 06/26/2018. There was no evidence of positive and negative control materials tested on these days. An interview with the testing personnel at 2:00 PM 07/09/2018, revealed the laboratory failed to have a system in place to ensure positive and negative control materials were run and documented on all days of patient testing.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on record review and staff interview on 07/13/2018, the laboratory director failed to enroll the laboratory with an approved proficiency testing agency for toxicology samples. Findings include: Record review failed to reveal confirmation of enrollment for proficiency testing samples for drugs of abuse. Interview with the laboratory director at 2:00 PM on 07/09/2018, revealed the laboratory was not enrolled in proficiency testing for nine drugs of abuse being tested on patients.