

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2093550	(X3) Date Survey Completed 01/09/2020
Name of Provider or Supplier Duke City Recovery Toolbox	Street Address, City, State 125 Candelaria Road Nw Unit A, Albuquerque, NM	
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	The following deficiencies were cited during a validation survey completed on 01/09 /2020 for the federal requirements of 42 CFR Part 493 for Laboratories.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on the review of 2018-2019 proficiency test records, laboratory policy, and interview with the General Supervisor, the laboratory failed to ensure attestation statements were physically signed by the Laboratory Director and testing personnel. Findings are: A. Review of 2018-2019 proficiency test records revealed the laboratory director failed to physically sign attestations statements for 5 of 5 test events in 2018 and 4 of 4 in 2019. 1. CAP (College of American Pathologists) Proficiency testing program UT (Urine Toxicology) -A 2019, kit date 04/03/19 Undated electronic signature for both the Laboratory Director and Testing Person #1. UT-B 2019, kit date 08/21/19 Undated electronic signature for both the Laboratory Director and General Supervisor (as the testing person) UT-C 2019, kit date 11/14/19 Undated electronic signature for both the Laboratory Director and General Supervisor (as the testing person) DMPM (Drug Monitoring for Pain Management) - A, kit dated 03/07/18 Undated electronic signature for both the Laboratory Director and General Supervisor (as the testing person) DMPM, kit dated 09/12/18 Undated electronic signature for the Laboratory Director. The testing person did not sign. 2. API (American Proficiency Institute) Proficiency Program Chemistry - Miscellaneous (Urine Drug Screens) 2018-1 Electronic signature for the Laboratory Director on 05/09/18. 2018-2 Electronic signature for the Laboratory Director on 10/25/18. 2019-1 Electronic signature for the Laboratory Director on 05/03/19. 2019-2 Electronic signature for the Laboratory</p>

Director on 10/17/19. B. Review of the laboratory's Proficiency Testing Policy, reviewed by the Laboratory Director on 08/25/17, 08/07/18, and 08/16/18 indicated; "The Lab Director will review and sign all attestations, results, and corrective actions for each challenge. The lab personnel who perform testing, the Technical Supervisor and the Director and (sic) will review and sign results and corrective actions when applicable." C. During interview on 01/08/2020 at 08:30 am, the General Supervisor confirmed these findings.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on the review of manufacturer's instructions, laboratory policy, maintenance logs, quality assessment reviews, and interview with the General Supervisor, the laboratory failed to establish written policies for centrifuge function checks. Findings are: A. Review of the manufacturer's instructions for the Eppendorf Centrifuge 5430 used to spin urine samples revealed no requirements for function checks such as speed and timer checks. B. Review of the laboratory's Quality Management policy reviewed by the Laboratory Director on 08/16/19 indicated: "There is one clinical centrifuge (Eppendor [sic] Centrifuge 5430) in DCRT laboratory that is used to spin specimens during and after processing. Processed specimens are spun for 10 min at great (sic) or equal to 10,000 rpm before being transferred to auto-simpler vials for LC-MS-MS analysis. The centrifuges are maintained and serviced according to the directions and service schedule provided by the manufacturer." C. Review of the laboratory's 2018-2019 Centrifuge Logs revealed the laboratory performed weekly cleanings of the centrifuge but there was no documentation of speed and timer checks. D. Review of the May 2018 - July 2018 monthly quality assessment reviews under Pre-Analytical Parameters, Centrifuge, pipettes, thermometers maintenance revealed the following: 1. Findings - "Centrifuge and Pipettes should be services or calibrated yearly. Keep records in your Temperature Notebook." 2. Recommendations - "Send me details of your maintenance on these as you perform. If you (sic) policies do not list a specific speed for the Centrifuge, then you don't have to check it yearly, just clean."E. During interview on 01/09/20 at 09:00 am, the General Supervisor confirmed this finding.