

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0425500	(X3) Date Survey Completed 03/09/2021
Name of Provider or Supplier Tasc, Inc	Street Address, City, State 700 S Clinton St, Chicago, IL	
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
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the technical consultant (TC1); the laboratory failed to ensure other patient-specific data are accurately and reliably entered into the patient's electronic medical records (EMR), affecting 2 out of 17 patients. Findings include: 1. The test requisitions and patients' electronic medical records (EMR) were reviewed. 2. The review of 17 patients' urine drug analysis test requisitions showed the following: Patient-B2's collection date: 09/27/2018; received in the laboratory: 09/28/2019 at 11:20 AM; Patient-D4's had 2 collection dates: 02/02/2020 and 02/20/2020; received in the laboratory: 02/21/2020 at 4:10 PM 3. The EMR (final) reports of the 2 patients listed in findings #2 revealed the following; Patient-B2's collection date: 09/27/2018, received in the laboratory: 10/02/2018 at 11:52 AM; Patient-D4's collection date: 02/02/20; received in the laboratory: 02/21/20 at 4:10 PM 4. The laboratory failed to ensure the information from the requisitions are accurately and reliably entered into the patients' EMR. 5. On a Recertification survey conducted on 03/09/2021 at 11:15 AM, the TC1 confirmed the above findings.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p>

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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the technical consultant (TC1), the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in transcribing patients' information into the electronic medical record (EMR) system, for 2 out of 17 patients. Findings include: 1. The laboratory's manual, patients' electronic reports, and requisitions were reviewed. 2. Review of 17 patients' urine drug requisitions revealed 2 patients' information were entered into their respective electronic records incorrectly. 3. The SOP failed to ensure a policy and procedure for monitoring and preventing errors when reporting patient information into their EMR. 4. On a Recertification survey conducted on 03/09/2021 at 11:15 AM, the TC1 confirmed the above findings

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on record review and an interview with the technical Consultant (TC1); the laboratory director (LD) failed to ensure verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method for urine drug analysis testing, prior to testing patients. Findings include: 1. The validation procedures, data, and results for the AU680 Chemistry analyzer were reviewed. 2. The laboratory began using the Beckman Coulter AU680 Chemistry analyzer for urine analysis for the following drugs of abuse on 07/07/2020. Amphetamine/Methamphetamine; Benzodiazepines; Barbiturates; Cocaine; Tetrahydrocannabinol (THC) Methadone; Ethanol Opiate Phencyclidine Ecstasy 3. The validation documentation records revealed the LD failed to provide written approval and signature for the precision, accuracy, linearity, and method comparison results of the new analyzer for testing the drugs listed in Findings #2, prior to testing patients. 4. On a Recertification survey conducted on 03/09/2021 at 11:15 AM, the TC1 confirmed the above findings.