Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2152636	05/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Boyett Healthcare Of Tennessee, Pllc	801 Hill Street, Springfield, TN	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of the manufacturer instructions for use (IFU), lack of documentation, and staff interview, the laboratory failed to follow the manufacturer's instructions for performing external quality control on the drug test cups used for patient toxicology screening in 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory on 05/07/2024 at 9:30 a.m. revealed Identify Diagnostics Drug Test Cups (Lot: 2306049) used for toxicology screening of patient urine specimens. 2. A review of the Identify Diagnostics Drug Test Cups IFU revealed the following: - "Test each new lot and shipment by using external quality control materials (positive and negative), with each new untrained operator, monthly for storage, and as otherwise required by your lab internal quality system procedures." 3. There was no documentation of external quality control testing available for the Identify Diagnostics Drug Test Cups. 4. An interview with the Laboratory Director and General Supervisor on 05/07/2024 at 2:00 p.m. confirmed the laboratory did not perform external quality control on the Identify Diagnostics Drug Test Cups used for patient toxicology testing.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when

	appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observations of the laboratory and clinic storage room, a review of the laboratory procedures, and staff interviews, the laboratory failed to follow its policy for labeling 4 of 23 patient urine toxicology samples. The findings include: 1. Observation on 05/07/2024 at 9:30 a.m. revealed twenty-three urine sample cups in the hallway between the laboratory and storage room. One urine cup did not contain any identifying information. Three urine cups had a patient name on the label. 2. A review of the laboratory procedure titled "Specimen Collection and Handling" revealed the following statement: -"Every patient sample must have two identifiers and be properly clearly labeled and packaged with the correct patient information." 3. An interview with the Laboratory Director and General Supervisor on 05/07/2024 at 2: 00 p.m. confirmed that the laboratory failed to follow its policy for labeling patient urine specimens when four of the specimens observed during the survey did not contain two identifiers.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) 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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on laboratory observation, lack of documentation, and staff interviews, the laboratory failed to establish a system for monitoring and documenting urine specimen validity for patient toxicology testing using liquid chromatography-mass spectrometry (LC/MS) in 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory on 05/07/2024 at 9:30 a.m. revealed an Agilent 6410 Triple Quadrupole LC/MS analyzer (ID: SG1131106) performing drugs-of-abuse toxicology confirmation testing on urine specimens. 2. In 2022, 2023, and 2024, there were no records for monitoring the validity and acceptability of urine specimens for LC/MS toxicology testing. 3. An interview with the Laboratory Director and General Supervisor on 05/07/2024 at 2:00 p.m. confirmed the laboratory did notestablish a system to monitor urine specimen validity prior to LC/MS toxicology testing.