Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2178940	06/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Champion Healthcare Llc	324 N Maple Street, Lebanon, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory test menu, the laboratory procedure manual, a lack of documentation, and staff interviews, the laboratory failed to verify the accuracy of 49 toxicology confirmation tests using liquid chromatography-tandem mass spectrometry (LC-MS/MS) at least twice a year in 2023 and 2024. The findings include: 1. A review of the laboratory test menu revealed the following 49 toxicology confirmation tests performed using LC/MS/MS: 6-MAM, a-Hydroxyalprazolam, Alprazolam, Amphetamine, Benzoylecgonine, Buprenorphine, Carisoprodol, Clonazepam, Codeine, Diazepam, Codeine, Diazepam, EDDP, Fentanyl, Flunitrazepam, Flurazepam, Gabapentin, Hydrocodone, Hydromorphone, JWH-018, Lorazepam, MDA, MDFA, Meperidine, Meprobamate, Methamphetamine, Methadone, Methylone, Methylphenidate, Morphine, Naloxone, Naltrexone, Norbuprenorphine, Norfentanyl, Norhydrocodone, Normeperidine, Noroxycodone 1, O-Desmethyltranadol, Oxazepam, Oxycodone, Oxymorphone, Phencyclidine, Phentermine, Prebabalin, THC-COOH, Temazepam, Tramadol, Tapentadol, and Zolpidem. 2. A review of the laboratory procedure titled "Proficiency Testing Protocols" revealed the following requirement: "Alternative Performance Assessment - This laboratory will perform split-sample testing with its reference laboratory for any assay which CLIA does not require PT testing at least semi-annually to determine the reliability of analytical testing. - Store all split-sample testing records in the designated PT manual." 3. No twice-yearly verification of accuracy documentation was available for all 49 analytes on the day of the survey, 06/04/2025. 4. The laboratory director and facility administrator confirmed the survey findings in an interview on 06/04/2025 at 3:00 p.m. .

D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality assessment (QA) policy and QA schedule, a review of laboratory records, and staff interviews, the laboratory failed to follow the quality assessment plan when the laboratory director did not review the required documents in 2023, 2024, and 2025. The findings include: 1. A review of the laboratory QA policy revealed, in addition to monthly quality control (QC) review, the following calendar for LC-MS/MS monthly QA reviews: January- Personnel files, LIS Validations February- Auto-Tune Review, QQA March- Complaints April- Master Stock, Incident Mgmt. May- Instrument Maintenance, Turnaround time June- Calibration Review, Glassware Cleaning July- Test Method review, Policy/Procedure review August- Standards Review, Check QC Review September- Target STD Review, ISTD Review October- Proficiency testing review November- QQA December- Yearly QA review 2. A review of laboratory records revealed no documentation of monthly QA assessments performed in 2023, 2024, and 2025. 3. The laboratory director and facility administrator confirmed the survey findings in an interview on 06/04/2025 at 3:00 p.m. .
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory records, and staff interviews, the laboratory failed to monitor room temperature and humidity in the area where Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) patient testing occurred in 2023, 2024, and 2025. The findings include: 1. Observation of the laboratory on 06/04/2025 at 08:45 a.m. revealed the Sciex 3200 LC-MS/MS (Serial Number- AA24771112) test system in use for drugs of abuse confirmatory patient testing. 2. A review of laboratory temperature logs revealed no documentation for room temperature for 182 of 365 days in 2023, 39 of 366 days in 2024, 30 of 154 days in 2025, and no documentation for humidity for 150 of 365 days in 2023, 169 of 366 days in 2024, and 31 of 154 days in 2025. 3. The laboratory director and facility administrator confirmed the survey findings in an interview on 06/04/2025 at 3:00 p.m. .

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of the laboratory and staff interviews, the laboratory failed to ensure they did not use expired reagents for their Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) system used for confirmatory drugs of abuse testing from March 1, 2025, to the day of the survey, June 4, 2025. The findings include: 1. Observation of the laboratory on 06/04/2025 at 08:45 a.m. revealed a Mystaire Basic Workstation Fume Hood (Serial Number MY241-308) in use for storing reagents and the Sciex 3200 LC-MS/MS (Serial Number- AA24771112) test system in use for drug of abuse confirmatory patient testing. The hood contained one solution labeled "MPAP, D 1-29-25, X 2-29-25". Two solutions, labeled "MPA Exp 3/14/25" and "MPB Exp 3/14/25," were observed to be in use on the LC-MS/MS system. 2. The laboratory director and facility administrator confirmed the survey findings in an interview on 06/04/2025 at 3:00 p.m. .
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of laboratory procedures, a lack of records, and staff interviews, the laboratory failed to follow its procedure for calibration checks and annual pipette calibration for pipettes used to prepare patient samples and reagents for toxicology testing in 2023 and 2024. The findings include: 1. Observation of the laboratory on 06/04/2025 at 08:45 a.m. revealed eight racked pipettes, including an Eppendorf Repeater M4 (Serial Number 138318E) and a Biopette Plus (Identification Number 0197). 2. A review of the laboratory procedure titled "Pipette Calibration" revealed the following requirements: " - For pipettes already in service, calibration checks are to be performed every six month using at least ten data points for each calibration run. - Automatic pipets, re-pipettes and automatic diluters must be checked for accuracy and precision before first put in use; at least annually after first use; if control (QC) problems develop. - Pipettes are sent to a reference laboratory for Calibration. Documentation of Calibration verification is filed with Pipette Calibration Schedule." 3. There was no documentation of calibration checks or pipette calibrations for 2023 and 2024 available on the survey date, 06/04 /2025. 4. The laboratory director and facility administrator confirmed the survey findings in an interview on 06/04/2025 at 3:00 p.m. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory procedures, review of laboratory records, lack of documentation, and staff interviews, the laboratory failed to follow its policy for documenting corrective action for out-of-range temperatures in 2023, 2024, and 2025. The findings include: 1. Observation of the laboratory on 06/04 /25 at 08:45 a.m. revealed two refrigerator/freezer units, a Vissani (Serial Number 112022_2009375) and a Haier (Serial Number FS559506) in use for reagent storage and patient sample storage. 2. A review of the laboratory procedure titled "Acceptable Temperature Ranges" revealed the following requirements: "Environment Temperature Refrigerators 2 - 8 C Freezer -20 or colder" and "CORRECTIVE ACTION If any of the temperatures are not within the acceptable range, adjust the available controls and document action on the temperature log. Monitor the temperature within 1-3 hours to determine if the adjustment was sufficient to meet the acceptable range. Re-read the temperature and document the results of the adjustment. Document any remedial action on the temperature log." 3. A review of laboratory temperature logs revealed the following: Freezer 2023- 99 of 180 recorded temperatures were out of range 2024- 156 of 307 recorded temperatures were out of range 2025- 71 of 134 recorded temperatures were out of range Refrigerator 2023- 9 of 182 recorded temperatures were out of range 2024- 8 of 82 recorded temperatures were out of range 2025- 2 of 41 recorded temperatures were out of range 4. There was no corrective action documented on the temperature logs for any of the out-of-range temperatures on the day of the survey, 06/04/2025. 5. The laboratory director and facility administrator confirmed the survey findings in an interview on 06/04/2025 at 3:00 p.m. .
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures, the lack of quality assurance (QA) review records, and staff interviews, the Laboratory Director failed to maintain the quality assurance program to assure the quality of the confirmatory drugs of abuse testing and identify failures in quality as they occurred in 2023, 2024, and to the date of the survey in 2025. The findings include: 1. A review of the laboratory Quality Assessment Policy, the Calendar of LC-MS/MS Monthly QA Reviews, and the Quality Control Program Policy revealed a requirement for Monthly QA reviews encompassing the pre-analytic, analytic, and post-analytic phases of testing. 2. There were no QA review records for 2023, 2024 and 2025 available on the day of the survey, 06/04/2025. 3. The laboratory director and facility administrator confirmed the survey findings in an interview on 06/04/2025 at 3:00 p.m. .