Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2109508	06/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Champions Plaza Laboratories, Llc	305 Wells Fargo, Suite A4, Houston, TX	

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	An unannounced revisit survey was performed on 08/17/2023. The laboratory was found to be in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). ---------- An announced VALIDATION survey of the laboratory was conducted on June 27, 2023. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: D5300 - 42 C. F.R. 493.1240 Condition: Preanalytic systems D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Noted deficiencies and allegations of compliance/plans of correction were discussed with the laboratory representative(s) at the exit conference. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by:

	Based on surveyor's observations, review of laboratory's specimen stability establishment studies, instructions to clients, policies and procedures, quality assessment records and staff interview, the laboratory failed to identify, evaluate and correct problems in quality of the preanalytic systems. Findings included: 1. The laboratory failed to define and monitor specimen transport temperature for specimens received by the laboratory. Refer to D5311. 2. The laboratory's Quality Assessment failed to identify, assess and correct problems with pre-analytic systems. Refer to D5391.
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 review of laboratory's specimen stability establishment studies, instructions to clients, policies and procedures, surveyor's observations and staff interview, the laboratory failed to define and monitor specimen transport temperature for one of one specimen types received by the laboratory, urine. Findings included: 1. Review of laboratory's specimen stability establishment studies (completed on 08/02/2021) revealed the samples' stability was defined as 5 days at room temperature, and 14 days at 2-8C. The laboratory did not define the acceptable range for room temperature. 2. Review of laboratory's instructions to clients titled" Urine Collection Protocol" revealed: "In order to maintain sample stability, the sample must be stored in 2-8C refrigerator or at room temperature." And, "Place (biohazard) bag in FedEx packaging. No need for ice packs." 3. Review of laboratory's policy/procedure PRE2-0.1 Specimen Collection and Handling (implemented 02/01/2018, reviewed 04/08 /2022 and 04/10/2023) revealed: "STORAGE AND SHIPPING REQUIREMENTS OF SPECIMENS ... All specimens must be kept at room temperature in the client's office until courier pickup." There was no mention of transport temperature requirements. 4. Surveyor's observations on 06/27/2023 at 0955 and 1105 hours in the facility revealed the laboratory used a courier system to bring urine samples for testing from its clients. All samples were collected in the same collection plastic cup, packaged individually (each sample cup in a separate biohazard bag), and batched together in a larger plastic zipper bag. The bags were transported in the front seat of the courier's car and no coolers or ice packs were used. The observed samples were: a. 0955 hours courier run: Accession: 9790 9791 9792 9793 9794 9795 9796 9797 b. 1105 hours courier run: Accession: 9806 9807 9808 9809 9810 5. In an interview on 06/27/2023 at 1115 hours in the conference room, the laboratory's Technical Supervisor (as indicated on form CMS 209) confirmed that the laboratory did not define room temperature, and that the laboratory did not monitor specimen temperatures upon arrival to verify conformance with established specimen stability. Key: CMS - Centers for Medicare and Medicaid C - Degrees Celsius F - Degrees Fahrenheit
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 review of laboratory's quality assessment records for January to May of 2022 and January to March of 2023, the laboratory failed to recognize, assess and correct problems identified in the preanalytic systems. Refer to D5311.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory's specimen stability studies for its laboratory-developed toxicology test and staff interview, the laboratory failed to document proof to establish specimen's stability for two of two temperature studies completed in 2021. Findings included: 1. Review of laboratory's specimen stability studies (completed 08 /02/2021) for its laboratory-developed toxicology test revealed the laboratory documented specimen stability as % yield at room temperature and at 2-8C. The acceptability criteria for % yield was defined as >70%. The obtained data sets were as follows: a. Room temperature data set for: Day 0 Day 1 Day 3 Day 5 The studies did not include defined room temperature gradient. b. 2-8C temperature data set for: Day 14-1 Day 14-2 Day 14-3 2. Further review of the data revealed there was no documentation of establishing laboratory's claims of specimen's stability for Day 2 and 4 at room temperature, or Day 0 through Days 13 at 2-8C. 3. In an interview on 06 /27/2023 at 1130 in the conference room, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209) stated that the laboratory only tested stability establishment samples as indicated above and did not have proof of stability for each day of the established intervals. This confirmed the findings. Key: CMS - Centers for Medicare and Medicaid C - Degrees Celsius
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of laboratory's specimen stability studies for its laboratory-developed toxicology test, laboratory's quality assessment records and staff interview, the Laboratory Director failed to provide overall management and direction. Findings included: 1. Laboratory Director failed to ensure the laboratory's establishment studies were complete. Refer to D6086. 2. Laboratory Director failed to ensure laboratory's Quality Assessment identified and corrected problems in preanalytic systems. Refer to D6094.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 review of laboratory's specimen stability studies for its laboratory-developed toxicology test and staff interview, the Laboratory Director failed to ensure the laboratory's establishment studies were complete. Refer to D5423.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 review of laboratory's quality assessment records for January to May of 2022 and January to March of 2023, the Laboratory Director failed to ensure laboratory's Quality Assessment identified and corrected problems in preanalytic systems. Refer to D5391.