Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2326543	02/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Healthspan360	16922 Telge Road, Suite 2k, Cypress, 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 announced survey of the laboratory was conducted on 02/11/2026. The laboratory was found in substantial compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: A. Based on surveyor observations, review of laboratory's test establishment studies, patient test volumes and staff interview, the laboratory failed to document specimen transport device in its establishment studies for one of one molecular microbiology laboratory developed NexGen RT Polymerase Chain Reaction (PCR) Urinary Tract Infection (UTI) Panel test. Findings included: 1. Surveyor's observations on 02/11/2026 at 0945 hour in the laboratory revealed the laboratory received urine samples in BD (Beckton Dickinson) Vacutainer Urine C&S (culture and sensitivity) tube. 2. Review of laboratory's NexGen RT PCR UTI Panel establishment studies (approved 10/01/2025) revealed the laboratory established specimen stability as 7 days at temperatures ranging from -20 to 40C (Degrees Celsius), but the studies did not

	specify which specimen transport device was evaluated for acceptability. 3. Review of laboratory's submitted test volumes revealed the laboratory performed testing on approximately 80 patient samples from November 2025 through January 2026. 4. In an interview on 02/11/2026 at 1030 hours in the office, the laboratory's Technical Supervisor number one (as indicated on submitted Form CMS 209) confirmed the findings. B. Based on review of laboratory's policies/procedures, test establishment studies, patient test volumes and staff interview, the laboratory failed to document specimen transport stability study as per its own policy prior to start of patient testing for one of one laboratory developed Urine Toxicology Test Panel. Findings included: 1. Review of laboratory's Urine Toxicology Test Panel's establishment study policy "Temperature Stability Study" (document: MediaLab SOP No.22 number 707160.1953 22.TOX; effective: 11/25/2025) revealed: " Sample 5 will be utilized with a temperature logger to document temperature changes during transit and then tested at the lab" 2. Review of laboratory's Urine Toxicology Test Panel's establishment studies, completed and approved in September 2025, revealed there was no documentation of the laboratory's sample 5 transit temperature study prior to start of patient testing in October 2025. 3. Review of laboratory's submitted test volumes revealed the laboratory performed approximately 5760 urine toxicology tests from October 2025 through January 2026. 4. In an interview on 02/11/2026 at 1430 hours in the office, the laboratory's Technical Supervisor number two (as indicated on submitted Form CMS 209) confirmed the findings.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on surveyor's observations, review of laboratory's policies/procedures, new test establishment studies and staff interview the Laboratory Director failed to ensure that establishment studies were complete for two of two tests performed by the laboratory in 2025 and 2026, the NexGen RT Polymerase Chain Reaction (PCR) Urinary Tract Infection (UTI) Panel and the Urine Toxicology Test Panel. Refer to D5423 A and B.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) (b)(2) Verification of the test procedures performed and establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on surveyor's observations, review of laboratory's policies/procedures, new test establishment studies and staff interview the laboratory's Technical Supervisors one and two (as indicated on submitted Form CMS 209) failed to ensure that establishment studies were complete for two of two tests performed by the laboratory in 2025 and 2026, the NexGen RT Polymerase Chain Reaction (PCR) Urinary Tract Infection (UTI) Panel and the Urine Toxicology Test Panel. Refer to D5423 A and B.