Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2265416	08/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Z2 Scientific Llc	2954 Mallory Circle Suite 208, Celebration, FL	

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 CLIA recertification survey was conducted at Z2 Scientific LLC on July 22, 2025 to August 28, 2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: 2000 Enrollment and Testing of Samples
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to enroll proficiency testing for Pan-Adenovirus, Klebsiella Pneumoniae, Strepreptoccous Pneumoniae, Haemophilius Influenza, Haemophilus Influenza Type B, Human Adenovirus, Rotavirus, Klebsiella Aerogenes, Enterohemmoragic Verotoxin E.coli, SHV type Extended-Spectrum B-Lactamase (SHV), Vancomycin-Resistant Enterococcus (VAN A/B), Ureaplasma Urealyticum, and Haemophilus Ducreyi in Microbiology for 1st and 2nd Event in 2025. Findings Included: 1. Review of test menu revealed: Sexually Transmitted Infection panel included Van A/B , Ureaplasma Urealyticum , Haemophilus Ducreyi and SHV. Respiratory Pathogens Panel included Pan-Adenovirus, Klebsiella Pneumoniae, Strepreptoccous Pneumoniae, Haemophilius Influenza and Haemophilus Influenza Type B. Urinary tract infection Panel included Klebsiella Aerogenes. Gastrointestinal Pathogens (GI) panel included Human

	Adenovirus, Rotavirus and Enterohemmoragic Verotoxin E.coli. 2. Review of American proficiency testing revealed the following: Microbiology 1st and 2nd proficiency testing events of 2025 did not include these subspecialties: Pan-Adenovirus, Klebsiella Pneumoniae, Streptococcus Pneumoniae, Haemophilius Influenza, Haemophilus Influenza Type B, Human Adenovirus, Rotavirus, Klebsiella Aerogenes, Enterohemmoragic Verotoxin E.coli, SHV type Extended-Spectrum B-lactamase (SHV), Vancomycin-resistant Enterococcus (VAN A/B), Ureaplasma Urealyticum,and Haemophilus Ducreyi. 3. On 7/25/2025 at 2:27 PM, the Laboratory Assistant confirmed 13 subspecialties were not enrolled in Microbiology for 1st and 2nd Event in 2025.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform annual competency in 2024 for 1 (Testing Person #C) out of 4 Testing Personnel and 1 out of 1 Technical Supervisor, and six month competency assessments in 2024 for 2 (Testing Person #D, Testing Person #E) out of 4 Testing Personnel. Findings Included: 1. Review of the CMS-209 Laboratory Personnel Report signed and dated by the Laboratory Director on 07/25/2025 revealed the laboratory had one Technical Supervisor, who was also Testing Person #B, and three additional Testing Personnel (#C, #D, and #E). 2. Review of Competency Assessments revealed: The Technical Supervisor did not have documentation of annual competency for 2024. Testing Person #C did not have documentation of annual competency for 2024. Testing Person #D and Testing Person #E did not have documentation of 6 month competency assessments for 2024. 3. During an interview on 07/25/2025 at 2:09 PM, the Laboratory Assistant confirmed the failures to maintain documentation of competencies in 2024 for the Technical Supervisor, and Testing Personnel #C, #D, and #E.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to label 5 of 5 bottles in a box used for molecular testing. Findings Included: 1. On 07/22/2025 at 12:00 PM, there were 5 bottles in a box next to the biological cabinet hood used for molecular testing. All 5 bottles contained liquid solutions and were not labeled to identify the liquid content, preparation or expiration dates. 2. Review of the laboratory's Standard Operations Procedure revealed no documentation of a policy or

	procedure for labeling bottles to identify what the solution was, the preparation date, and expiration date. 3. During an interview on 07/25/2025 at 2:09 PM, the Laboratory Assistant confirmed the 5 bottles used for molecular testing had no labels.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to run negative controls for Gastrointestinal Pathogens (GI) panel from January 2025 to July 2025 and January 2024 to December 2024, Sexually Transmitted Infection (STI) panel for February 2024, April 2024, May 2025, and June 2025, and Urinary Tract Infection (UTI) panel for February 2024, April 2024, May 2025 and June 2025 in Polymerase Chain Reaction (PCR) testing. Findings Included: 1. Review of Urinary Tract Infection (UTI) Panel Quality Control (QC) revealed: UTI Negative controls were not run in February and April of 2024. UTI Negative controls were not run in May and June of 2025. 2. Review of Gastrointestinal Pathogens (GI) Panel QC revealed: GI Negative controls were not run from January to December of 2024. GI Negative controls were not run from January to July 2025. 3. Review of Sexually Transmitted Infection (STI) Panel QC revealed: STI Negative controls were not run for February and April of 2024. STI Negative controls were not run for May and June of 2025. 4a. Review of UTI qPCR Testing Validation read, "NTC-No template control (nuclease-free water) added during Real time Polymerase Chain Reaction (RT-PCR) reaction set-up (target & internal control: cycle threshold (Ct) values should be undetermined." 4b. Review of STI Multiplex Real-Time RT-PCR reaction set-up read, "NTC-No Template Control (NTC) during qPCR reaction set-up as a qPCR contamination control." 5. Review of Laboratory Statistics /Usage revealed the following: 2,324 patients were tested for UTI PCR testing from 5/1/2024 to 7/21/2025. 27 patients were tested for GI PCR testing from 5/1/2024 to 7/21/2025. 214 patients were testing for STI PCR testing from 5/1/2024 to 7/21/2025. 6. On 07/25/2025 at 2:27 PM, the Laboratory Assistant confirmed negative quality control was not done for GI panel from January 2025 to July 2025, and January 2024 to December 2024, STI panel for February 2024, April 2024, May 2025 and June 2025, and UTI panel for February 2024, April 2024, May 2025 and June 2025 in PCR testing.