

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2083593	(X3) Date Survey Completed 07/15/2026
Name of Provider or Supplier Scotty Ortega, Md	Street Address, City, State 3001 N Faudree Road, Odessa, 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	The laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of an initial survey completed on July 15, 2026 and certification is recommended. Standard level deficiencies were cited.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of laboratory operations manual, instrument reagent change records, quality control (QC) records, and confirmed in interview, the laboratory failed to follow manufacturer's instructions to ensure the verification of quality control performance after reagent change on the Sysmex XN-530 for 14 of 26 reagent change records reviewed from October 2025 through June 2026. The findings included: 1. Review of the "Sysmex XN-L Series XN-530/XN-430/XN-330 Basic Operations Manual", chapter 3 "Performing Quality Control (QC)", section 3.22 "When QC analysis is performed" state the following: "QC is performed at the following times. Before Sample analysis After replacement/replenishment of reagents ..." 2. Review of the Sysmex XN-530 reagent replacement log and QC data included the following 14 days and time where reagent was changed without a QC verification afterwards: October 2025 10/22/2025 at 15:03, Sulfolyser reagent replaced November 2025 11/12/2025 at 09:00, Cellpack DCL reagent replaced December 2025 12/04/2025 at 16:58, Cellpack DCL reagent replaced 12/23/2025 at 15:03, Cellpack DCL reagent replaced January 2026 1/15/2026 at 09:40, Cellpack DCL reagent replaced February 2026 02/02/2026 at 11:42, Cellpack DCL reagent replaced 02/23/2026 at 16:01 Lysercell

WDF reagent replaced March 2026 03/03/2026 at 10:12, Cellpack DCL reagent replaced April 2026 4/06/2026 at 13:21, Cellpack DCL reagent replaced 4/10/2026 at 12:36, Fluorocell WDF reagent replaced 4/22/2026 at 17:08, Cellpack DCL reagent replaced May 2026 5/11/2026 at 17:25, Lysercell WDF reagent replaced June 2026 6/03/2026 at 10:18, Cellpack DCL reagent replaced 6/23/2026 at 13:52, Cellpack DCL reagent replaced 3. In an interview at 10:55 hours on 7/15/2026, in the laboratory, testing personnel 1 confirmed that QC was not verified after reagent replacement as required by the manufacturer.