

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2327763	(X3) Date Survey Completed 02/19/2026
Name of Provider or Supplier Halifax Health Db a Halifax Health - Freestanding	Street Address, City, State 577 N Williamson Blvd, Daytona Beach, 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 initial certification survey was conducted at Halifax Health Freestanding Emergency Department Ormond Beach on 2/10/26. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 with the Technical Consultant, the laboratory failed to evaluate and document the competency of 37 of 37 clinical consultants (CC #1 through CC #37) and 3 of 22 testing personnel (TP #K, TP #O, and TP #Q) reviewed. Findings include: 1. During an onsite initial survey on 2/10/26, a review of the laboratory's personnel records revealed no documentation of competency assessments for any of the 37 clinical consultants (CC #1 through CC #37) employed by the laboratory. 2. A review of the personnel records for 22 testing personnel (identified as TP #A through TP #V) on 2/10/26 revealed no documentation that competency assessments had been performed for three individuals: TP #K, TP #O, and TP #Q. 3. In an interview on 2/10/26 at 12:17 pm, the Technical Consultant (TC #1) confirmed that the laboratory had not performed or documented competency assessments for the 37 clinical consultants or for the three testing personnel.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency

specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Technical Consultant, the laboratory failed to follow the manufacturer's instructions for performing and documenting required daily and biweekly maintenance for 3 of 4 instruments reviewed (pocH-100i Hematology Analyzers #1 and #2, and Piccolo Analyzers #1 and #2). Findings include: 1. A review of the January 2026 maintenance logs for the pocH-100i Hematology Analyzer (Serial Number G8427; Identifier: Hematology #1) revealed the laboratory failed to document daily maintenance for 15 of 31 days (1/2, 1/6, 1/7, 1/8, 1/11, 1/12, 1/13, 1/14, 1/15, 1/20, 1/21, 1/22, 1/27, 1/28, and 1/31). Furthermore, biweekly maintenance was only documented on 1/4/26. 2. A review of the January 2026 maintenance logs for Piccolo Analyzer #1 revealed the laboratory failed to document daily maintenance for 10 days (1/1/26 through 1/8/26, 1/21/26, and 1/22/26). 3. A review of the January 2026 maintenance logs for Piccolo Analyzer #2 revealed the laboratory failed to document daily maintenance for 17 days (1/1/26 through 1/8/26, 1/13/26, 1/15/26, and 1/23/26 through 1/29/26). 4. In an interview on 2/10/26 at 2:00 pm, the Technical Consultant confirmed that the maintenance for these instruments had not been documented on the specified dates and that the laboratory had no other records demonstrating the maintenance had been performed.