

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2301373	(X3) Date Survey Completed 04/21/2026
Name of Provider or Supplier Hca Florida South Bradenton Emergency	Street Address, City, State 6215 14th St W, Bradenton, 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 unannounced CLIA complaint survey, CCR #2026004244 was conducted at HCA Florida South Bradenton Emergency from 04/13/2026 to 04/21/2026. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2000 493.801 Condition: Enrollment and Testing of Samples, D6000 493.1403 Condition: Laboratory Director.
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 review of proficiency testing documentation and staff interviews, this laboratory (Lab A) received, tested and reported five of five proficiency testing (PT) samples for a remedial event from another lab (Lab B) with a different Clinical Laboratory Improvement Amendment (CLIA) Certificate of Accreditation number. (See D2013).
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4) (b)(5) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is

certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, this laboratory (Lab A) received, tested and reported five of five American Proficiency Institute (API) testing samples for a remedial event in 2026 in the Specialty of Chemistry (BG-01 through BG-05) from another laboratory (Lab B) with a different CLIA Certificate of Accreditation number. Findings included: 1. API test event, Chemistry - Core Remedial Event 84R documents were reviewed at Lab A. a. The API test event instructions had Lab B's name, address and API customer number on it. The due date was 01/09/2026 11:59:00 p.m. Eastern US time. b. Lab A's result summary printouts dated 01/06/2026, with a test date of 01/02/2026 included samples 2025 API-BG01/0, 2025 API-BG02/0, 2025 API-BG03/0, 2025 API-BG-04/0, and 2025 API-BG-05/0. c. The results from Lab A's result summary printouts for creatinine (Blood Gas) were hand written onto the API analyte worksheet. The results documented matched Lab A's result summary printouts. d. The API Attestation Statement dated 01/02/2026 was signed by Technical Consultant B as the Testing Person. e. The API Submitted Result Form had Lab B's CLIA#, address, and API customer number on it. The results were submitted 01/06/2026 at 10:42 a.m. Eastern US time. f. The API Performance Evaluation dated 01/06/2026 was signed as reviewed by Technical Consultant B on 01/06/2026 and the Lab Director on 01/14/2026. 2. Interview with Technical Consultant B on 04/13/2026 at 1:45 p.m. confirmed the above finding and stated the Chemistry remedial event was ordered under Lab B's CLIA ID because Lab A was unable to obtain the remedial event from its own PT provider and did not have its own API account.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of proficiency testing documentation, personnel records and staff interviews, the Laboratory Director failed to provide overall management and direction to ensure the laboratory adhered to the regulations pertaining to handling of proficiency testing (PT) samples to prevent PT referral. (See D6016).

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure that PT samples were tested as required and that the laboratory did not engage in PT referral for a remedial event from another laboratory (Lab B) with a different CLIA Certificate of Accreditation number. Refer to D2013.