

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0907702	(X3) Date Survey Completed 01/06/2026
Name of Provider or Supplier David B Hevert Md Pa	Street Address, City, State 3848 Fau Blvd Ste 210, Boca Raton, 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 David B Hevert MD PA on January 6, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document refrigerator 1, refrigerator 2 , Biorad freezer, Freezer ,room temperature, and humidity for October 2024 and 27 out of 30 days in April 2025. Findings included: 1. Review of Temperature and Humidity logs revealed the following: A. October 2024 had no documentation of temperatures for refrigerator 1, refrigerator 2, Biorad freezer, Freezer, room temperature, and humidity. B. April 2025 had 27 out of 30 days had no documentation for refrigerator 1, refrigerator 2, Biorad freezer, Freezer, room temperature, and humidity. 2. On 01/06/2026 at 5:11 PM, Testing Personnel A and the Office Manager confirmed there was no documentation of refrigerator 1, refrigerator 2, Biorad freezer, Freezer, room temperature and humidity for October 2024 and 27 out of 30 days in April 2025.</p>
D5447	CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(i)(g)

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to run two levels of controls for Free T4 (Thyroxine) on 1/8/2024 for 24 out of 24 patients reviewed. Findings included: 1. Review of Free T4 controls revealed the following: A. Biorad immunoassay control level 2 Lot: 40432 was run on 01/08/2024 for Free T4 B. No Biorad immunoassay control level 1 was ran on 01/08/2024. 2. Review of Free T4 Patient reports revealed the following: A. 24 patients were tested on 01/08/2024 for Free T4. 3. Review of Daily Controls policy read, "Daily controls of a known concentrations are processed each day of instrument use .If these fail to reproduce within the manufacturers acceptable limits remedial action must be followed and documented according to the instrument manufacturer." 4. On 01/06/2026 at 5:11 PM, Testing Personnel A and the Office Manager confirmed two levels of controls were not ran for Free T4 (Thyroxine) on 01/08/2024 prior to Patient testing.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to ensure that competency evaluations were performed by a qualified Technical Consultant for two (A and C) of three (A - C) Testing Personnel's competencies for 2024 and one (A) of three (A - C) Testing Personnel's competency for 2025; and the laboratory failed to have a policy for competency assessments. Findings Included: 1. Review of the Laboratory Personnel Report, signed and dated on 01/05/2026 by the Laboratory Director, listed the Laboratory Director was also the Clinical Consultant and the Technical Consultant; and there were three Testing Personnel. 2. Review of the personnel file for Testing Person A revealed, the Lab Personnel Evaluation Checklist on 11/24/2024 and 11/17/2025 were completed and signed by the Office Manager. 3. Review of the personnel file for Testing Person C revealed, the Lab Personnel Evaluation Checklist on 11/24/2024 was completed and signed by the Office Manager. 4. Review of the procedure manual showed there was no procedure on competency evaluations. 5. During an interview on 01/06/2026 at 11:30 AM, the Testing Person A confirmed the competency evaluations were performed by the Office Manager. 6. During an interview on 01/06/2026 at 5:30 PM, the Testing Person A acknowledged she did not find procedure on competency evaluations.