

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0163715	(X3) Date Survey Completed 04/17/2025
Name of Provider or Supplier Lower Keys Medical Center	Street Address, City, State 5900 College Rd, Key West, 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 validation survey was conducted at Lower Keys Medical Center on 04/15/2025 to 04/17/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6063 493. 1421 Condition: Laboratory Testing Personnel
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapporitions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to perform competency evaluations on 2 of 2 Technical Consultants for 2 of 2 years reviewed (2023-2025) . Findings Included: 1. Review of the FORM CMS-209 (signed by the Laboratory Director on 04/08/2025) revealed that the Laboratory Director was also a Technical Consultant and there were 2 other Technical Consultants. 2. Review of the competency evaluations revealed no competency evaluations for the 2 Technical Consultants for 2023-2025. 3. Review of the "ABG Competency" signed by the Laboratory Director on 02/04/2025 only referenced Testing Personnel Competency. 4. Interview on 04/17/2025 at 1:00 PM the Laboratory Director confirmed that he had not performed any competencies on the Technical Consultants.</p>

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on record review and interview, the Laboratory failed to verify the education of 1 (Testing Person #B) out of 9 Testing Personnel performing Blood gas testing. See D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory failed to verify the education of 1 (Testing Person #B) out of 9 Testing Personnel performing Blood gas testing. Findings Included: 1. Review of the Form CMS-209 signed and dated by the Laboratory Director on 04/08/2025 revealed 9 Testing Personnel who performed Blood Gas testing. 2. Review of Testing Personnel employment records revealed Testing Person #B did not have proof of education. 3. Interview on 04/17/2025 at 11:00 AM., the Human Resource representative confirmed that they did not have documentation of Testing Person #B's education.