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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D0278461 | (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 |
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| 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 Conditions were cited: D6063 493.1421 Condition: Laboratory Testing Personnel (Moderate complexity) D6168 493.1487 Condition: Testing Personnel (High complexity) 37881 A Validation revisit survey was conducted by desk review on August 1, 2025 for the survey ending on April 17, 2025 for Lower Keys Medical Center. The clinical laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories. Previously cited deficiencies were found to be corrected. |
| 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 reappoints 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 have competency evaluations on 15 out of 15 Technical Consultants for 2 (2023-2025) out of 2 years reviewed. Findings Included: 1. Review of FORM CMS-209 signed by the Laboratory Director on 04/10/2025 revealed 15 Technical Consultants for Moderate Complexity Testing. 2. Review of employee files for the 15 Technical Consultants no competency on their ability to be a Technical Consultant. 3. Review of policies</p> |

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| | <p>revealed that there was no policy to perform competency evaluations on Technical Consultants. 4. Interview on 04/17/2025 at 1:00 PM the Laboratory Director confirmed that he did not perform a competency evaluation for the 15 Technical Consultants.</p> |
| <p>D6063</p> | <p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory failed to have Florida Clinical Personnel licensure for 3 (See D6064) and verify the education of 1 (See D6065) out of 7 Testing Personnel who perform moderate complexity testing.</p> |
| <p>D6064</p> | <p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a)</p> <p>Each individual performing moderate complexity testing must-- (a) possess a current license issued by the State in which the laboratory is located, if such licensing is required; and</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to verify the State of Florida Clinical Personnel License of 3 (#MB, #MD and #MF) out of 7 Testing Personnel who perform moderate complexity testing. Findings Included: 1. Review of the FORM CMS-209 (signed and dated by the Laboratory Director on 04/10/2025) revealed 7 moderate complexity Testing Personnel. 2. Review of Testing Personnel Florida Clinical Personnel Licensure revealed no licenses for Testing Personnel #MB, #MD, and #MF. 3. Interview on 04/17/2025 at 11:00 AM Human Resources confirmed that they did not have the 3 State of Florida Personnel Licenses.</p> |
| <p>D6065</p> | <p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(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</p> |

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| | <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to verify the education of 1 (#MB) out of 7 Testing Personnel who perform moderate complexity testing. Findings Included: 1. Review of the FORM CMS-209 (signed and dated by the Laboratory Director on 04/10/2025) revealed 7 moderate complexity Testing Personnel. 2. Review of Testing Personnel education revealed no diploma for Testing Person #MB. 3. Interview on 04/17/2025 at 11:00 AM Human Resources confirmed that they did not have the diploma for Testing Person #MB.</p> |
| <p>D6079</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints 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 have competency evaluations on 4 out of 4 Technical Supervisors and 2 out of 2 General Supervisors for 2 (2023-2025) out of 2 years reviewed. Findings Included: 1. Review of FORM CMS-209 signed by the Laboratory Director on 04/10/2025 revealed 4 Technical Supervisors and 2 General Supervisors for High Complexity Testing. 2. Review of employee files for the 4 Technical Supervisors and the 2 General Supervisors revealed no competency on their ability to be a Technical Supervisor or General Supervisor. 3. Review of policies revealed that there was no policy to perform competency evaluations on Technical Supervisors or General Supervisors. 4. Interview on 04/17/2025 at 1:00 PM the Laboratory Director confirmed that he did not perform a competency evaluation for the 4 Technical Supervisors or 2 General Supervisors.</p> |
| <p>D6168</p> | <p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory failed to verify the education of 4 (#L, #N, #Q, and #S) out of 20 Testing Personnel who perform high complexity testing (See D6171).</p> |
| <p>D6171</p> | <p>TESTING PERSONNEL QUALIFICATIONS</p> |

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory failed to verify the education of 4 (#L, #N, #Q, and #S) out of 20 Testing Personnel who perform high complexity testing. Findings Included: 1. Review of the FORM CMS-209 (signed and dated by the Laboratory Director on 04/10/2025) revealed 20 high complexity Testing Personnel. 2. Review of Testing Personnel education revealed no diplomas for Testing Personnel #L, #Q, and #S. Testing Personnel #N had a foreign diploma with no foreign equivalency. 3. Interview on 04/17/2025 at 11:00 AM Human Resources confirmed that they did not have the 3 diplomas and 1 foreign equivalency.