

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2157981	(X3) Date Survey Completed 04/24/2025
Name of Provider or Supplier Lee Health Coconut Point Clinical Laboratory	Street Address, City, State 23450 Via Coconut Point, Estero, 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 Lee Health Coconut Point on 04/21/2025 - 04/24/2025. The Laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5200 493.1230 Condition: General Laboratory Systems D6076 493.1441 Condition: Laboratory Director
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory failed to have competency evaluations to assess Pathologists performing Histopathology and Cytology for two years (4/2023-4/2025). See D5209.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on document review and interview, the laboratory failed to have competency evaluations to assess Pathologists performing Histopathology and Cytology for two years (4/2023-4/2025). This is a repeat citation from the 03/21/2023 Recertification survey. Findings included: 1. The accepted Plan of Correction signed by the Laboratory Director 04/10/2023 for the recertification survey ending 03/21/2023, showed for D5209 the corrective action was to have an updated system procedure and document review of the competency assessment at the end of the competency assessment period to ensure compliance. 2. The Professional Competency of Pathologists procedure approved by the Lab Director 04/15/2025 and 04/10/2023 showed Pathologists would have their professional competency assessed by the Medical Director (Laboratory Director) every six months for the first year of employment and annually thereafter. 3. The Quality Management System procedure approved by the Lab Director 01/28/2025 showed competency is assessed initially following training and on an annual basis thereafter. During the first year, competency will be assessed at least semiannually. 4. The CMS-209 Laboratory Personal Report signed by the Laboratory Director 04/11/2025 listed two Pathologists. Pathologist A- the Laboratory Director and Pathologist B who provided coverage as needed. The Administrative Histology Director stated on 04/21/2025 at 1:50 PM Pathologist B had begun employment at this Laboratory 11/2024. 5. Review of employee competency evaluation revealed no competency evaluations for Pathologist B who had been providing coverage since 11/2024. Competency evaluations for the Pathologists who provided coverage from 04/2023 to 11/2024 were requested, no competencies for this Laboratory were provided. The Administrative Histology Director confirmed on 04/21/2025 at 1:50 PM there were no competency evaluations performed at this Laboratory for Pathologist B or for the Pathologists who provided coverage from 04/2023 to 11/2024.

D5627

CYTOLOGY
CFR(s): 493.1274(c)(4)

(c)(4) Records of initial examinations and all rescreening results must be documented.

This STANDARD is not met as evidenced by:
Based on record review and interview the Laboratory failed to document who performed the initial screen of Cytology slides prior to 11/18/2024. Findings Included: Review of Policy "Cytology Screening, Reporting, Workload Limitations and Quality Management" signed by the Laboratory Director on 04/15/2025 revealed that the Staff Pathologists do not do any initial screening of Cytology slides. Patient reports dated from 03/2025, 06/2024, and 10/2023 were requested. No Patient initial screening results could be pulled for the 06/2024 and 10/2023 dates. Interview on 04/22/2025 at 2:00 PM the Administrative Histology Director stated that the Testing Person who performed the initial screening was not available for any Patient prior to 11/18/2024.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to be responsible for the overall operation and administration of the Laboratory for two of two years (4/2023-4/2025). See D6079.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

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 reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to be responsible for the overall operation and administration of the Laboratory for two of two years (04/2023-04/2025). Findings included: 1. The Laboratory failed to have competency evaluations to assess Pathologists performing Histopathology and Cytology for two years (4/2023-4/2025). This is a repeat citation (See D5209). 2. The Quality Management System procedure approved by the Lab Director 01/28/2025 stated job descriptions are maintained for each position and that training is provided based on job description. Training is considered complete when job specific competency has been demonstrated. 3. The CMS-209 Laboratory Personal Report signed by the Laboratory Director 04/11/2025 listed two Pathologists. Pathologist A- the Lab Director and Pathologist B who provided coverage as needed. The Administrative Histology Director stated on 04/21/2025 at 1:50 PM Pathologist B had begun employment at this laboratory 11/2024. No job description or training was provided for this Laboratory for Pathologist B. The Administrative Histology Director confirmed on 04/21/2025 at 1:50 PM there was no job description or training for this Laboratory for Pathologist B.