

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2157981	<b>(X3) Date Survey Completed</b>  03/21/2023
<b>Name of Provider or Supplier</b>  Lee Health Coconut Point Clinical Laboratory	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Lee Health Coconut Point Clinical Laboratory on 03/20/2023 - 03/21/2023. The laboratory was surveyed under 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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: Based on interview with the Histology Manager and review of the Laboratory Personnel Report (Form CMS-209), Pathologist competency evaluations, and policy and procedures, the laboratory failed to have competency evaluations for 2 out of 2 years (2021-2023) reviewed. Findings Included: Review of the CMS-209 signed by the Lab Director on 03/17/2023 revealed there were 2 Pathologists. Pathologist #A was the Laboratory Director and Pathologist #B provided coverage in the Laboratory Director's absence. Review of employee competency evaluation revealed no competency evaluations for Pathologist #B. Pathologist #B had been providing coverage since 07/2021. Review of the policy and procedure titled "Professional Competency of Pathologists" revealed "Pathologist will have their professional competency assessed and reviewed by the Medical Director(s) monthly and/or quarterly via the Quality Management and Quality Improvement program." During an interview on 03/21/2023 at 10:00 AM, the Histology Manager confirmed the laboratory was using peer review as the only form of competency evaluation.</p>
<b>D5477</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(4)(g)</p>

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on interview with the Laboratory Manager and review of "Microbiology Supply Request" the laboratory failed to document the lot number and expiration of the media for the visual check and sterility for 10 (March 2023, February 2023, October 2022, September 2022, August 2022, May 2022, March 2022, January 2022, October 2021, and June 2021) out of 20 months (March 2023, February 2023, December 2022, November 2022, October 2022, September 2022, August 2022, July 2022, June 2022, May 2022, March 2022, February 2022, January 2022, December 2021, October 2021, September 2021, July 2021, June 2021, May 2021, and March 2021 ) reviewed. Findings Included: Review of "Microbiology Supply Request" logs revealed the lot number and expiration of the media was not recorded for March 2023, February 2023, October 2022, September 2022, August 2022, May 2022, March 2022, January 2022, October 2021, and June 2021). The Laboratory Manager confirmed on 03/21/2023 at 2:30 PM the logs did not always capture the lot numbers and expirations.

**D5601**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on interviews with the General Supervisor and Histology Manager and review of H & E (Hematoxylin & Eosin) stain logs, the laboratory failed to document H & E stain quality for frozen specimens and failed to document a negative control for Cytokeratin (AE1/AE3) Antibody (IHC stain) for 4 (September 2021, April 2022, October 2022, and January 2023) out of 4 months reviewed. Findings Included: Review of H & E stain quality logs revealed the Pathologist who reviewed the stain quality did not document if it was acceptable or not in September 2021, April 2022, October 2022, and January 2023. The Histology General Supervisor confirmed during an interview on 03/20/2023 at 5:15 PM, the Histology Tech documents H & E stain quality for frozen sections and not the Pathologist. Review of the policy "Cytokeratin (AE1/AE3) Antibody," last reviewed by the Lab Director on 01/03/2023, showed "Positive tissue (with negative element) controls are utilized." The Histology Manager confirmed on 03/21/2023 at 10:30 AM, they do not run a separate negative quality control tissue in some IHC stains.

**D5633**

**CYTOLOGY**

CFR(s): 493.1274(d)(1)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

This STANDARD is not met as evidenced by:

Based on interview with the Histology Manager, lack of workload limits, and lack of workload limit policy, the laboratory failed to establish and follow written policies for the Technical Supervisor to establish maximum workload limits for each Pathologist who performed primary screening for 2 (2021-2023) out of 2 years reviewed.

Findings Included: Review of policies and procedures revealed no policy for the Technical Supervisor to establish maximum workload limits for each Pathologist performing primary screening of cytology slides. Interview with the Histology Manager on 03/21/2023 at 11:00 AM confirmed no policy was established and no maximum workload limits were set for performing primary screening.

**D5805**

**TEST REPORT**

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on interview with the Histology Manager and review of Histology final reports, the laboratory failed to have the correct address of the laboratory location where testing was performed for 3 (7H, 8H, and 9H) out of 9 (1H, 2H, 3H, 4H, 5H, 6H, 7H, 8H, and 9H) Histology reports reviewed. Findings Included: Review of 3 (7H, 8H, and 9H) Histology final reports showed the slides were read at the laboratory. When the "Case Assignments" were pulled for these 3 reports, it was revealed they were read at a different location than the final report stated. During an interview on 03/21/2023 at 12:00 PM the Histology Manager confirmed the location on the report of where the slides were read was incorrect.