

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1003031	(X3) Date Survey Completed 05/28/2021
Name of Provider or Supplier Florida Clinical Laboratory Inc D/B/A	Street Address, City, State 27 E Hibiscus Blvd, Melbourne, 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
D5629	<p>CYTOLOGY CFR(s): 493.1274(c)(5)</p> <p>(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to follow written policies and procedures for the evaluation and comparison of three of six laboratory statistics and failed to document three of six required annual statistics for 2019 and 2020. Findings include: 1. The laboratory failed to follow the written procedure titled CYTOLOGY QUALITY MANAGEMENT-STATISTICAL DATA which stated: "Statistical Data is collected using the GenECyS Reporting Tool. Records are maintained on the following: a. # of specimens by specimen type b. # of specimens by diagnosis c. # of unsatisfactory specimens by diagnosis and client d. # of total cytology cases examined e. # of gyn cases where cytologic and histologic diagnoses are discrepant f. # of cases where a rescreen of a negative resulted in reclassification as a malignant or pre-malignant result g. # High grade cases researched for previous negatives." 2. The Survey Team requested and the laboratory failed to provide three of six required</p>

annual statistics for 2019 and 2020: a. # of specimens by specimen type b. # of specimens by diagnosis c. # of total cytology cases examined. 3. During an interview on April 13, 2021 at 3:40 the Cytology Supervisor confirmed that the numbers on the CYTOLOGY DIAGNOSTIC SUMMARY document failed to include the total number of cases that were evaluated. The numbers did not include the number of cases received from other locations and only included the number of cases that were accessioned at the laboratory being surveyed. a. The Survey Team requested and the Cytology Supervisor failed to explain the following disparities in 2019 statistical documents provided by the Cytology Supervisor: -QUALITY MANAGEMENT PERFORMANCE SUMMARY 2019: Total # Cases Reported: 126,621 Total # Cases Screened: 155,500 b. The Survey Team requested and the Cytology Supervisor failed to explain the following disparities in 2020 statistical documents provided by the Cytology Supervisor: -QUALITY MANAGEMENT PERFORMANCE SUMMARY 2020: Total # Cases Reported: 102,834 Total # Cases Screened: 128,992 - CYTOLOGY DIAGNOSTIC SUMMARY 2020: Total # Cases: 101,971 4. During an interview on April 14, 2021 at 11:00 AM the Laboratory Director/Technical Supervisor A confirmed these findings.