

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2123842	(X3) Date Survey Completed 06/06/2018
Name of Provider or Supplier Mid - Florida Pathology Llc	Street Address, City, State 120 East North Blvd Ste 102, Leesburg, 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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on a record and interview, the laboratory failed to obtain State of Florida Clinical Laboratory licensure in the subspecialty of Cytology prior to reporting patient test results. Findings: Review of an "Internal Quality Control" memo signed by the laboratory directory read, "We identified while performing QA duties and getting ready for inspection that we were reporting cytology cases from the Leesburg location and cytology specialty was not added to that CLIA license." Cytology results were reported out from 6/20/17 through 5/23/18. During an interview on 6/06/18 at 9:15 AM, Quality Assurance (QA) Coordinator stated that when they applied for a new license for the location they forgot to add the specialty of cytology.</p>
D5645	<p>CYTOLOGY CFR(s): 493.1274(d)(3)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document and maintain records of the total number of slides examined by each individual during each 24 hour</p>

period and the number of hours spent examining slides. Findings: Review of the laboratory's procedure titled "Cytology Workload" showed the "Adopted Date" of the procedure was 4/12/18, and that the procedure was signed and dated by the laboratory director on 4/12/18. Review of the laboratory's cytology workload logs showed that the laboratory failed to record the number of cytology slides examined by each individual and the amount of time spent examining slides from 6/20/17 through 11/01/17. The laboratory failed to record the amount of time spent on their "Non-Gyn Daily Slide QC" from 11/02/17 to 4/01/18. During an interview on 6/06/18 at 12:19 AM, Quality Assurance Coordinator acknowledged that they did not record cytology workload before 11/02/17 and that the "Time Screening" was added to the "Non-Gyn Daily Slide QC" on 4/13/18.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to follow a written policy to monitor access and correct problems for their quality assessment (QA) program. Findings: Review of laboratory's quality assessment logs showed that the laboratory failed to document any quality assessment activity from 6/20/17 to 12/31/17. During an interview on 6/06/18 at 11:40 AM, QA Coordinator stated they had not done any QA checklists before 1/01/18.