

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1034492	(X3) Date Survey Completed 08/27/2018
Name of Provider or Supplier Francisco Flores Md Llc	Street Address, City, State 14601 Sw 29th St Ste 206, Miramar, 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
D3001	<p>FACILITIES CFR(s): 493.1101(a)(1)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on observation and the interview with the testing person, the laboratory failed to provide adequate testing space for the histopathology testing by not having storage space for flammable chemicals, reagents and stains, and the slides and blocks storage. The findings include: On August 27, 2018 at 10AM, surveyor observed: 1- Metal cabinet with flammable, hazardous chemicals, reagents and stains in the employee breakroom. 2- Slides and blocks storage boxes for year 2014 and 2015, on top of the the employee breakroom cabinets. During an interview on 8/27/18, at 2:15 PM, the testing person confirmed that laboratory stored a- Flammable metal cabinet for hazardous chemicals and reagents in employee - break room. b- Slides and blocks storage boxes for year 2014 and 2015 on top of the employee - breakroom cabinets, as there was no adequate space in the laboratory.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the testing person, the laboratory director failed to: 1- Sign and date the procedure manual for histopathology laboratory. 2- Failed to include the turnaround time for test results in procedure manual, to have the</p>

corrective action and quality assessment for post-analytical test procedures. The findings include: On August 27, 2018 At 12:30PM, record review showed that director did not sign and date the procedure manual and procedure manual did not include the turnaround time for the histopathology laboratory testing. During an interview on 8/27/18, at 2:30 PM, the testing person confirmed that the laboratory director did not sign and date the procedure manual and procedure manual, did not include the turnaround time for the histopathology laboratory testing, and to have the corrective action and quality assessment for post-analytical test procedures.

D5609

HISTOPATHOLOGY
CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with testing person, the laboratory failed to have the complete records for the chemicals, reagents, and stains that would include the 'date opened' for two-year review period (2016 - 2018) for the subspecialty of histopathology testing. The findings include: On August 27, 2018, during a laboratory tour at 10AM, surveyor did not observe the 'date opened' on the reagent bottles. Reagent log review for two years (year 2016 to 2018) showed that there was no 'date opened' recorded for the reagents, chemicals, stains that were in use. An interview with the testing person at 2:15 PM confirmed that reagents, chemicals and stains that were opened and in use did not have the 'date opened' on the bottles and the reagent log did not have the complete documentation that would include the 'date opened' for the reagents, chemicals and stains that were in use.