

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0280247	(X3) Date Survey Completed 03/18/2020
Name of Provider or Supplier M Elena Kendall Md Pa	Street Address, City, State 318 Alhambra Cir, Coral Gables, 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	A recertification survey conducted on 03/18/2020 found that M Elena Kendall MD PA clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory failed to label reagents with correct lot numbers, expiration dates and manufacturers from January to March 2020. Findings include: 1-Observations taken while on tour on 3/18/2020 at 9:45 AM, revealed the following: -Half gallon of xylene with lot number 1613201, expiration date deleted with black marker. The flask label is from Mercedes Medical manufacturer. -Half gallon of isopropyl alcohol with lot number 1626321, expiration date altered with black marker to show 3/23. The flask label is from Mercedes Medical manufacturer. 2- Review of 2020 Reagent log revealed the following: - Xylene lot number 1613201 exp date 3/23. Review of 2018 reagent log revealed that the lot number listed match with the one used on 2018, with an actual expiration date of 11/11/2018. -Isopropanol Alcohol lot 1626321 exp date 3/23. Review of 2018 reagent log revealed that the lot number match the one for 2018, with an actual expiration date of 3/23/2019. During an interview on 03/18/2020 at 1:30 pm with laboratory director, she confirmed the label and reagent log mistakes listed above, she explained that the current supplier for those reagents is FAMIS.</p>

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and staff interview, the laboratory failed to remove Tissue-Tek O.C.T. Compound and Protocol Mounting Media Xylene reagents from the laboratory after the expiration. Findings include: 1-Observations taken while on tour on 3/18/2020 at 9:45 AM revealed that the laboratory had the following expired reagents: -2 bottles of 118 ml of Tissue-Tek O.C.T. Compound with lot number 6850-00 expired since March 2019. -1 bottle of 475 ml of Protocol mounting media Xylene with lot number 216558 expiration date 2/20. During an interview on 03/18/2020 at 1:30 pm with laboratory director, she confirmed the existence of the expired reagents.