

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0925695	(X3) Date Survey Completed 01/09/2019
Name of Provider or Supplier Flor Mayoral Md Pa	Street Address, City, State 6705 Red Rd Ste 314, 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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record (hematoxylin and eosin Material Safety Data Sheet-MSDS) review and interview with testing person #1, laboratory failed to observe safety procedures to ensure protection from chemical materials. The findings include: On January 9, 2019 at 3:30 pm surveyor observed that testing person, #1 emptied about 300 to 400 ml (milliliter) of the hematoxylin stain (lot # 1524708) in regular laboratory sink and put the emptied gallon jar in the histopathology laboratory trash. HARLECO Gill modified Hematoxylin Solution # 3 MSDS review showed: A) - This material is considered hazardous by OSHA ((occupational safety and health administration) Hazard Communication Standard (29 CFR 1910.1200). B) - Environmental precautions: Avoid disposal of spilled material and runoff and contact with soil, waterways, drains, and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). C) - Spill: Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, watercourses, basement or confined areas. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Dilute with water and mop up if water-soluble or absorb with an inert dry material and place in an appropriate disposal container. D) - Disposal considerations-The information only applies to the material as supplied. The identification based on characteristic (s) or listing may not apply if the material has been used or otherwise contaminated. It is the</p>

responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with the applicable regulations. Disposal should be in accordance with applicable regional, national and local laws and regulations. Mercedes Medical safety data sheet review for eosin showed: - Precautionary statements; Dispose of contents/containers to an approved waste disposal plant. - Environmental precautions; Do not allow into any sewer, on the ground or into any body of water. Avoid release to the environment. - Waste treatment methods; Disposal of wastes-Disposal should be in accordance with applicable regional, national and local laws and regulations. During an interview on January 9, 2019, at 3:45pm, testing person #1 confirmed: - About emptying the hematoxylin, stain (lot # 1524708- about 300 to 400 milliliter) in regular laboratory sink and put the emptied gallon jar in the histopathology laboratory trash. - That is how laboratory always disposed of the chemicals into laboratory sink. Laboratory had provided the MSDS for hematoxylin and eosin via e-mail.

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, record review and interview with testing person #1, histopathology subspecialty laboratory had expired hematoxylin stain reagent. The findings include: On January 9, 2019 at 3:30 pm surveyor observed Hematoxylin, lot# 1524708 with expiration date 9/9/2017. During an interview on January 9 at 3:45 pm, testing person confirmed that the Hematoxylin, lot# 1524708 had expired on 9/9 /2017. Laboratory had provided the reagent log via e-mail.