

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2127353	(X3) Date Survey Completed 06/02/2023
Name of Provider or Supplier Heights Dermatology-Beaumont	Street Address, City, State 3485 Fannin Street, Beaumont, TX	
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 upon observations, review of policies and procedures, Material Safety Data Sheets (MSDS) and interview of facility personnel found that the laboratory failed to ensure that the laboratory had appropriate ventilation and storage for the six reagents and two stains used in the processing of patient tissue specimens for histopathology. The findings included: 1. Observations made during the tour the facility found that the laboratory had no ventilation system or chemical fume hood to provide adequate protection to testing personnel when using stains and reagents that produce harmful vapors. There was no flammable safety cabinet available to store flammable reagents . Reagents and stains stored in the cabinet were as follows: DMS Solutions Acetone lot 1271 Expiration 2023-09-28 Volu-Sol reagent Alcohol 95% lot VDN102 Expiration 2027-12-31 Platinumline 100% Reagent Alcohol lot 2236122 Expiration 2025-07-05 Volu-Sol Gill's Hematoxylin lot VCH196 Expiration 2024-04-30 EKI Acetic Acid, Glacial Lot 228506 Surgipath Hematoxylin Gill lot 080922 Expiration 2024-02-09 Platinumline Eosin Y Stain Solution lot 2310815 Expiration 2025-04-24 Volu-Sol Xylene lot 220207 Expiration 2027-05-31 Platinumline Xylenes lot 2300901 Expiration 2025-07-12 Platinumline Xylenes lot 2126009 Expiration 2024-03-23 EKI Ammonium Hydroxide lot 2223823 4 1 gallon containers of Platinumline 100% Reagent Alcohol lot 2236122 Expiration 2025-07-05 were also stored on the floor under the cabinet. 2. Review of policies and procedures found on page 4 under the heading STORAGE, USE AND HANDLING: "Reagents are stored according to manufacturer's instructions." 3. Review of MSDS sheets provided found under the heading Handling and Storage: Acetone - "Protect against physical damage. Store in a cool, dry, well -ventilated location, away from any area where the fire hazard may be</p>

acute. Outside or detached storage is preferred. Separate from incompatibles. Containers should be bonded and grounded to avoid static sparks. Storage and use areas should be No Smoking areas. Use non-sparking type tools and equipment, including explosion proof ventilation." Reagent Alcohol - " Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Keep away from open flames, hot surfaces or sources of ignition. Use only non-sparking tools. Keep in a dry, cool and well ventilated place. Keep container tightly closed. Keep away from Heat, sparks and flame. Flammables Area. Incompatible Materials, Acids, Ammonias, Peroxides, Acid Anhydrides, Acid Chlorides, Metals and Reducing Agents" Hematoxyline Gill III - "Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Store in a well ventilated place. Keep cool. Keep container tightly closed." Eosin Y Stain - "Wash thoroughly after handling. Use with adequate ventilation. Minimize dust generation and accumulation. Avoid contact with skin and eyes. Avoid ingestion and inhalation. Store in a cool, dry place. Keep container closed when not in use." Xylenes - "Keep container closed. Handle and open containers with care. Do not handle or store near an open flame, heat, or other sources of ignition. Do not pressurize, cut, heat, or weld containers. Empty product containers may contain product residue. Do not reuse empty containers without commercial cleaning or reconditioning. Store in a cool, well- ventilated place away from incompatible materials. Fireproof , Separated from strong oxidants and strong acids. Protect material from direct sunlight. Laboratory samples should be handled in a fume hood. {Provide mechanical ventilation of confined spaces. Use explosion proof ventilation equipment." Ammonium Hydroxide - "Use only under a chemical fume hood. Wear personal protective equipment as required. Do not get in eyes, on skin, or on clothing. Do not ingest. If swallowed, seek immediate medical assistance. Do not breathe mist /vapors/spray. Keep containers tightly closed in a dry, cool and well- ventilated place. Corrosives are, Incompatible materials, Strong oxidizing agents, Metals, Acids, Fluorine, Halogens." Acetic Acid - "Protect against physical damage. Store in a cool, dry, well -ventilated location, away from any area where the fire hazard may be acute. Outside or detached storage is preferred. Separate from incompatibles. Containers should be bonded and grounded to avoid static sparks. Storage and use areas should be No Smoking areas. Use non-sparking type tools and equipment, including explosion proof ventilation." 4. During interview of the histotechnician conducted June 2, 2023 confirmed that the laboratory did not have a ventilation system or chemical fume hood for use by testing personnel when handling stains and reagents that produce harmful vapors, and no flammable safety cabinet for the storage of flammable reagents.

D6084

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

This STANDARD is not met as evidenced by:

Based upon observations, review of policies and procedures, Material Safety Data Sheets (MSDS) and interview of facility personnel found that the laboratory failed to ensure that the laboratory had appropriate ventilation and storage for the six reagents

and two stains used in the processing of patient tissue specimens for histopathology.
(See D 3001)