

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0410407	(X3) Date Survey Completed 11/19/2020
Name of Provider or Supplier St Peters Health	Street Address, City, State 2475 Broadway, Helena, MT	
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 review and interviews, the Pathology section failed to provide a safe environment in which employees are protected from chemical hazards with a certified fume hood. Findings: 1. Observation of the Pathology Section showed a lack of ventilation to remove xylene vapors on 11/17/20 and 11/18/20. A strong chemical smell could be detected in the Pathology section of the laboratory by both state surveyors. 2. Interview with Staff Member D, Testing Personnel (TP) confirmed the laboratory failed to provide proper ventilation to ensure personnel are protected from chemical hazards. 3. Observation of Pathology section showed the Biological Safety Hood II was being used for staining and excessive storage of chemical reagents on 11/17/20 and 11/18/20. Although the hood was not a fume hood and could not be certified, the storage of so many items under the hood can impact the performance of the hood operation. 4. Review of a hired hood certification contractor documentation for yearly certification states the NuAire Biological Safety Cabinet II located in the Pathology Laboratory, failed certification on 11/13/2020. There was no visible certification sticker on the hood. 5. During an interview on 11/18/20 with Staff Member B, General Supervisor (GS), he stated the levels for Xylene vapor monitoring badges had spiked above unacceptable ppm levels 14 months prior. 6. Review of Material Safety Data Sheet (MSDS) CSD/Startex (2010, January 20) Xylene, Technical DGSC pd 6810-1; Section 7 and Section 8 states to use Xylene with adequate ventilations; store in structures made for OSHA Class I C liquids and in containers that tightly close; ventilate to keep vapors below 50 ppm.</p>

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

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.

This STANDARD is not met as evidenced by:

Based on record review and interview, the Pathology section failed to document reagent expiration dates on reagent log(s). Findings: 1. Review of document labeled "Reagent 3D Hematoxylin Stain" lacked a column for recording expiration dates. 2. During an interview on 11/17/20 at 3:00 p.m. with the Staff Member C, technical supervisor (TS), confirmed the lack of documenting of the reagent expiration date.