

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1084762	(X3) Date Survey Completed 07/11/2023
Name of Provider or Supplier Arizona Center For Cancer Care	Street Address, City, State 18699 N 67th Ave Ste 230, Glendale, AZ	
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
D3003	<p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory room #2 and interview with the technical supervisor (TS) #1 and testing personnel (TP) #1, the laboratory failed to be arranged to minimize contamination of patient specimens, equipment, and supplies. Findings: 1. Observation of the laboratory room #2 showed a small refrigerator containing food and drinks located next to one microtome and patient slides. 2. Observation of the laboratory room #2 showed one cabinet containing food and drinks. 3. Interview with the TS #1 and TP #1 on July 11, 2023 at 2:00 PM confirmed the laboratory failed to minimize contamination of patient specimens, equipment, and supplies.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the manufacturer's instructions, documentation of freezer temperatures, observation of Abbott Vysis Protease 1 reagent material stored in the freezer, and interview with the technical supervisor (TS) #1 and testing personnel (TP) #1, the laboratory failed to follow the manufacturer's instructions for storage of reagent material for 137 of 385 testing days since January 1, 2022 through June 30, 2023. Findings: 1. Review of the manufacturer's instructions for Abbott Vysis Protease 1 reagent for fluorescence in situ hybridization (FISH), showed the reagent must be stored at minus 8 degrees Celsius (C) to minus 20 degrees C. 2. Review of the laboratory's temperature chart showed a defined acceptable range of minus 20 degrees C to minus 25 degrees C. 137 of 385 testing days failed to meet the manufacturer's required minus 8 to minus 20 degree C range. 3. Observation of the laboratory freezer showed one box of Abbott Vysis Protease 1 reagent currently in use in the laboratory. 4. Interview with the TS #1 and TP #1 on July 11, 2023 at 2:00 PM confirmed the laboratory failed to properly monitor the freezer and store reagent materials consistent with the manufacturer's instructions. 5. The laboratory reports approximately 300 FISH tests annually.

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 on observation of 2 of 2 laboratory staff, review of formaldehyde monitoring documentation, and interview with the technical supervisor (TS) #1 and testing personnel (TP) #1, the laboratory director (LD) failed to provide a safe environment in which employees are protected from chemical and biological hazards. Findings: 1. Observation of 2 of 2 laboratory staff showed no laboratory personnel wearing formaldehyde monitoring badges. 2. Review of the formaldehyde monitoring badges documentation showed no monitoring for January 1, 2022 and to date July 11, 2023. 3. Interview with the TS #1 and TP #1 on July 11, 2023 at 2:30 PM confirmed the LD failed to ensure a safe environment in which employees are protected from chemical and biological hazards.