

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0950842	(X3) Date Survey Completed 11/15/2024
Name of Provider or Supplier Chi St Vincent North	Street Address, City, State 2215 Wildwood Avenue, Sherwood, AR	
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
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: Review of the "Frozen Section Procedure", a review of cryostat temperature log, review of patient reportes, and interviews with laboratory staff, determined the laboratory failed to monitor temperatures to ensure reliable test system operation. Survey findings include: A) The "Frozen Section Procedure" states, "The proper operating temperature of the cryostat is -17 degrees Celsius(C) to -30 degrees C." B) The cryostat temperature log used to monitor the daily operating temperature of the cryostat states the acceptable range of the cryostat is -17 to -25 degrees C. C) In an interview on 11/15/24 at 10:15 a.m. the laboratory employee #1 (as listed on a separate staff identification list) stated that the specimen courier logs the cryostat temperature every day because the pathologist is on call and is only present on days when frozen section procedures are anticipated. D) Review of the cryostat temperature log for June 2024 revealed that cryostat temperatures were not documented on Monday, 6/17/24. E) Review of patient reports revealed that on Monday, 6/17/24, a frozen section was performed on brain tissue from patient B00183688. F) In an interview at 10:27 a.m. on 11/15/24, laboratory employee #1 (as listed on the staff identification list) confirmed the cryostat temperatures were not documented on 6/17/24.</p>