

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0962429	(X3) Date Survey Completed 10/11/2022
Name of Provider or Supplier Christus Southeast Texas Orthopedic Specialty Ctr	Street Address, City, State 3650 Laurel Ave, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
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: Based on direct observation of the surveyor, the review of the manufacturer's insert, the laboratory's refrigerator logs from June 2021 to September 2022, patient results, and confirmed in an interview found the laboratory failed to document temperatures for the proper storage of reagents for three of 50 days reviewed. for i-STAT blood analyzer. The findings were: 1. Direct observation of the surveyor on 10/11/2022 at 9:30 am in the lab revealed the laboratory performed CHEM8+ cartridges on one of one i-STAT blood analyzer (SN: 339794). 2. Direct observation of the surveyor on 10/11/2022 at 9:32 am in the lab revealed the laboratory had no CHEM8+ cartridges at the room temperature. All Chem8+ cartridges were stored in the refrigerator. 3. Review of the manufacturer's insert titled i-STAT CHEM8+ Cartridge (Art: 765874-00 Rev. A Rev. Date: 26-Feb-2020) under p.6 Storage Condition revealed "Refrigeration at 2 to 8 C (35 to 46 F) until expiration date." 4. Review of the laboratory's refrigerator logs for temperatures from June 2021 to September 2022 revealed no documentation of</p>

refrigerated temperatures on 12/23/2021, 12/30/2021, and 9/23/2022. 5. Review the laboratory's patient results for the above dates revealed 3 patients had CHEM8+ testing performed on i-STAT blood analyzer. 12/23/2021 SPEC: 1223:PC00160R 12/30/2021 SPEC: 1230:PC00196R 9/23/2022 SPEC: 0923:PC00230R 6. An interview with the Point-of-care coordinator (POCC) on 10/11/2022 at 12:18 pm in the office confirmed the above findings.