

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2148459	(X3) Date Survey Completed 04/04/2019
Name of Provider or Supplier Chi St Vincent Oncology	Street Address, City, State 500 S University, Suite 815, Little Rock, 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: Through observation , a lack of documentation and interview with laboratory staff it was determined that the laboratory failed to define and monitor the conditions for proper storage of reagents and supplies consistent with manufacturer ' s instructions in one of two rooms in which supplies with storage temperature requirements were stored. Survey findings follow: A.On a tour of the facility conducted at approximately 1100 on 4/4/19, a flat of 100 BD EDTA blood collection tubes, lot # 8187713 expiration date 2019-12-31 , a flat of 100 BD SST blood collection tubes lot # 8255925 expiration date 2019-8-31 and a flat of 100 BD Na Citrate blood collection tubes lot # 8215583 expiration date 2019-5-31 all with storage temperature requirement of 4 degrees C. to 25 degrees C. were observed in a room separated from the main laboratory room by a closable door. B.Temperature and humidity records reviewed lacked documentation of data for the storage room mentioned above. C. Upon request, the laboratory was unable to provide documentation of room temperatures for the room identified above. D. In an interview on 4/4/19 at approximately 12:00 PM the technical consultant identified as number 2 on the CMS 209 form confirmed that room temperatures were not monitored for the storage room identified above..</p>

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Through observation and interview it was determined that the laboratory had 127 BD EDTA blood collection tubes and 118 BD Heparin blood collection tubes available for use that exceeded their date of expiration. Findings follow: A. During a tour of the laboratory on 4/4/19 at approximately 11:45 AM, the surveyor observed 127 BD 4.5 ml. EDTA, lot # 8099550, with an expiration date of 2019-1-31 and 118 BD Heparin blood collection tubes lot # 7279847 with an expiration date of 2019-3-31 in a storage cabinet in the laboratory. B. In an interview on 4/4/19 at approximately 12:30 PM, the technical consultant identified as number 2 on the CMS 209 form confirmed that the tubes identified above had exceeded their expiration date and were available for use.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Through review of the laboratory's policy and procedure for quality control, individual CBC quality control reports, lack of documentation and interview it was determined that the laboratory reported 48 patient CBC results without performing required quality control on one of 21 days of operation in July 2018. Findings follow: A. Review of the laboratory's policy and procedure for quality control revealed that at least two of three levels of quality controls must be within acceptable range before patient testing can be performed and patient results released. B. Review of individual quality control reports for 7/2/2018 revealed that abnormal high level control lot# 2180323 was recorded as giving unacceptable high results for hemoglobin and mean corpuscular hemoglobin analysis, normal level control lot # 2180322 was recorded with no values and only a flag of "DF" which indicated an analyzer malfunction, and abnormal low control lot # 2180321 was recorded with no values and only a flag of "DF" which indicated an analyzer malfunction. C. Review of patient CBC result reports revealed that CBC analyses were performed and reported on 48 patients identified as numbers 1 through 48 on the "Provider Schedule for Monday, 7/2/2018. D. In an interview on 4/4/19 at approximately 12:30 PM the technical consultant identified as number 2 on the CMS 209 form and the laboratory testing personnel identified as number 3 on the CMS 209 form confirmed that a CBC's were performed and reported on 7/2/18 without the required successful quality control results.