

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D1053655	(X3) Date Survey Completed 12/12/2022
Name of Provider or Supplier Chi Saint Joseph Cancer Care Center - London	Street Address, City, State 165 London Mountain View Drive, London, KY	
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	A recertification survey was conducted on 12/12/2022 and the facility was found not to be in substantial compliance with the laboratory requirements at 42 CFR Part 493, with deficiencies cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on interview, record review, and review of the facility's policies, it was determined that the facility failed to follow its written policies for competency assessment for two (2) of seven (7) testing personnel (TP #6 and TP #7). The findings include: Review of the facility's policy titled, "Competency Assessment", effective 06 /2015 and last reviewed 02/2022, revealed a comprehensive competency assessment is conducted upon all new hires in the laboratory prior to starting patient testing and prior to reporting results. Further review revealed all personnel are evaluated for competency, as it is an "ongoing process and is occurring continuously throughout the year by the administrative laboratory manager and designated personnel who meet the requirements for Moderately Complex testing general supervisors, technical consultants or directors". Review of a 2020 proficiency testing attestation statement, dated 11/19/2020, compared against the personnel competency assessment records, revealed no documentation of competency assessments for TP #6 and TP #7. Review of a 2021 proficiency testing attestation statement, dated 07/30/2021, compared against the personnel competency assessment records, revealed no documentation of competency assessment for TP #7. Interview with the Laboratory Director, on 12/12</p>

/2022 at 12:30 PM, revealed he examined the proficiency testing attestation forms and competency assessment records referenced above, and confirmed there were no competency assessments performed for TP #6 and TP #7.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on observation, interview, and record review, it was determined the facility failed to implement a system to evaluate the relationship between tests performed at the facility, and at the main hospital, to ensure consistent results were produced for patients who came to the facility for weekly chemotherapy treatments. The findings include: A review of the facility's procedure manual, reviewed on 01/2022, revealed there was no documented procedure regarding performance of the required comparison tests. A concurrent observation and interview with the Laboratory Director (LD), on 12/12/2022 at 12:45 PM, revealed that since 10/25/2022, when a new electronic medical record (EMR) system was implemented, testing could only be performed at the facility when either the LD or other laboratory testing personnel (TP) were on site. Further interview revealed the LD and TP were the only authorized users for the new EMR, which was interfaced to the laboratory instrument. Continued interview with the LD revealed that patients who came to be treated at the facility when there was no authorized TP on site would have their blood specimens drawn and sent to the main hospital laboratory for testing. Patients that came to the facility for their weekly chemotherapy treatments could be tested at either location. The surveyor observed the hematology instrument in use at the facility was a Coulter ACTDiff2. Per the LD, the hematology instrument in use at the hospital was a Sysmex. When asked whether the laboratory performed comparisons between the Coulter ACTDiff2 instrument in use at the facility and the Sysmex instrument in use at the hospital, the LD stated no.