

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2174706	(X3) Date Survey Completed 03/18/2022
Name of Provider or Supplier Southern Oncology Specialists	Street Address, City, State 146 Medical Park Road, Suite 250, Mooresville, NC	
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of 2020 and 2021 API (American Proficiency Institute) PT(proficiency testing) records, and interview with the laboratory supervisor 3/18/22, the laboratory failed to test PT specimens the same number of times as they test patient specimens. Findings: The laboratory's "Proficiency Testing" policy states, ".6. Replicate analysis of survey samples is acceptable only if patient specimens are routinely analyzed in the same manner.." Review of the "Quality Assessment" program revealed critical value ranges for the following: WBC(white blood cell): less than 2 and greater than 30,000 K/uL(cells per microliter); HGB(hemoglobin): less than 6 and greater than 20 g/dL(grams per deciliter); HCT(hematocrit): less than 18 and greater than 50 %(percent); Platelet: less than 50 and greater than 999,999 K/uL. Interview with the laboratory supervisor at approximately 3 p.m. confirmed all critical value results are repeated and verified prior to being reported. Review of the 2020 and 2021 API PT records revealed the laboratory failed to verify all critical value results obtained for the PT samples for 2 of 3 events in 2021. Examples include: a. 2021 1st event sample #4: HCT result of 17%; b. 2021 2nd event sample #9: HGB result of 5.6 g/dL and HCT result of 17%.</p>

D2009

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(1)

The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on review of laboratory's procedures, review of 2020 and 2021 API(American Proficiency Institute) PT(proficiency testing) records, and absence of documentation 3/18/22, the laboratory failed to ensure the testing personnel signed the attestation statements for 3 of 3 testing events in 2020. Findings: The laboratory's PT procedure stated, "...C. Submission of Proficiency Testing results...2. All personnel who performed the testing of survey materials must sign the attestation page..." Review of the 2020 and 2021 API PT records revealed the testing personnel failed to sign the attestation statements for the 2020 Hematology/Coagulation 1st, 2nd, and 3rd testing events.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions, review of laboratory hematology maintenance records, and absence of documentation 3/18/22, the laboratory failed to perform and document maintenance as required by the manufacturer. Findings: Review of the Sysmex XN-330 Troubleshooting manual stated for maintenance, "weekly(run cell clean auto)- Execute routine cleaning- the routine cleaning must be executed once every 1,000 analyses, or once a week. Routine cleaning consists of aspirating CELL CLEAN AUTO and rinsing the fluid line... Daily maintenance- Maintenance task- Shutdown...To maintain optimum instrument performance, periodic maintenance must be executed. When using the instrument on a continuous basis, execute 'Daily Maintenance' once every 24 hours..." Review of the Sysmex XN-330 maintenance records revealed maintenance documentation was unavailable for the following: a. There was no weekly maintenance documentation for all of 2020, January- July 2021, October- December 2021, and January 2022; b. There was no daily maintenance documentation prior to December 2020.