

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1006416	(X3) Date Survey Completed 06/04/2025
Name of Provider or Supplier Thompson Oncology Group	Street Address, City, State 1915 White Avenue, Knoxville, TN	
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
D5461	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(g)</p> <p>(d)(6) Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, review of the reagent log, review of quality control records, and staff interview, the laboratory failed to perform quality control (QC) after changing reagents on the Sysmex XS-1000i complete blood count (CBC) analyzer in October 2023 and May 2025. The findings include: 1. Observation of the laboratory on 06.04.2025 at 9:00 a.m. revealed a Sysmex XS-1000i (Serial Number 70754) hematology analyzer used for complete blood count (CBC) patient testing. 2. A review of the Sysmex XS-1000i reagent log revealed that the laboratory changed reagents on the analyzer on 10.06.2023 at 4:45 p.m. and 05.14.2025 at 1:24 p.m. 3. A review of the Sysmex XS-1000i quality control records revealed no documentation that the laboratory ran QC after changing reagents on 10.06.2023 (QC lot 3261) and 05.14.2025 (QC lot 5090). 4. An interview with the technical consultant on 06.04.2025 at 12:30 p.m. confirmed the above survey findings.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)</p>

(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of policy, review of laboratory temperature/humidity log, lack of records, and staff interview, the laboratory failed to document corrective action for recorded humidity less than the laboratory's acceptable range for one of twenty days reviewed from February 2025. The findings include: 1. Observation of the laboratory on 06.04.2025 at 9:00 a.m. revealed a Sysmex XS-1000i (Serial Number 70754) hematology analyzer used for complete blood count (CBC) patient testing. 2. A review of the laboratory's "Reagent and Supply Management & Environmental Monitoring of Temperature and Humidity" policy revealed the following statements: "Record temperature and humidity readings and complete page 1 of the log. Record these readings at the start of the day, especially before refrigerators are opened and QC performed. Are the parameters recorded on the log in range? If the answer is NO for any parameters being out-of-range, document on page 2 of the log. Use the page 2 guide to determine if a Corrective Action Form is necessary." 3. A review of the laboratory's temperature and humidity log revealed an acceptable humidity range of 30-85 percent (%). The recorded humidity for 02.26.2025 was "28.8." On page 2 of the log, the laboratory failed to document unacceptable humidity for 02.26.2025. The review also revealed the following statement on page 2 of the log, "missing 2-26-25 documentation see corrective action. 4. Request for corrective action documentation revealed that no corrective action documentation for 02.26.2025 was available for surveyor review. 5. An interview with the technical consultant on 06.04.2025 at 12:30 p.m. confirmed the above survey findings. Word Key: QC = quality control

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (CMS 209), testing personnel (TP) records, and an interview with the technical consultant, the laboratory director failed to perform an annual competency assessment for one of eleven testing personnel in 2024. The findings include: 1. A review of the CMS 209 report revealed eleven testing personnel performing moderately complex patient testing for complete blood count. 2. A review of competency assessment records revealed that the laboratory director failed to perform annual competency on TP1, who is also the technical consultant (TC), as listed on the CMS 209 in 2024, as follows: -Direct observation of performance: observed on 04.19.2024 and 05.21.2024, initialed by TP1/TC -Review of QC: performed on 04.19.2024, initialed by TP1/TC -Monitoring, recording, and reporting

of tests: performed on 04.19.2024, initialed by TP1/TC -Direct observation of maintenance/function checks: observed on 04.19.2024, initialed by TP1/TC - Assessment of test performance using proficiency testing, blind, or previously analyzed samples: performed on 05.07.2024, initialed by TP1/TC -Assessment of test performance and problem-solving skills (cognitive) knowledge assessment: performed on 05.17.2024, initialed by TP1/TC -The Laboratory Director's signature obtained 06.19.2024 3. In an interview with TP1/TC on 06.04.2025 at 8:30 a.m., TP1/TC stated, "The laboratory director does not observe me doing anything on competency assessment," which confirmed the above survey findings.