Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1088998	10/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ut Erlanger Women's Oncology	102 Central Avenue, Chattanooga, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), personnel records, American Proficiency Institute (API) proficiency testing (PT) records, and staff interviews, the laboratory failed to ensure that one of two testing personnel (TP) who performed hematology and chemistry patient testing also participated in proficiency testing in 2023 and 2024. The findings include: 1. Observation on 10/09/2024 at 8:30 a.m. revealed the laboratory used a Beckman Coulter DxH 520 hematology analyzer (ID: BG100552) and a Beckman Coulter AU 480 (ID: 2022120197) chemistry analyzer for patient testing. 2. A review of the FORM CMS-209 revealed two persons (TP1 and TP2) who perform moderately complex patient testing. 3. A review of the laboratory's personnel records revealed that TP1 and TP2 perform hematology and chemistry patient testing. 4. A review of the laboratory's 2023 and 2024 API PT attestation statements revealed that TP2 did not participate in any PT events (0 of 9 reviewed). 5. An interview with TP1 and the physician's office laboratory (POL) coordinator on 10/09/2024 at 3:30 p.m. confirmed that TP2 performed patient testing and did not participate in any PT events in 2023 and 2024.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the manufacturer instructions for use (IFU), a review of the laboratory's policies, environmental monitoring records, and staff interviews, the laboratory failed to define appropriate freezer temperature ranges and monitor freezer conditions, leading to the improper storage of quality control (QC) material used in chemistry testing for 18 of 18 months reviewed in 2023 and 2024. The findings include: 1. An observation on 10/09/2024 at 8:30 a.m. revealed that the laboratory used a Beckman Coulter AU 480 (ID: 2022120197) chemistry analyzer for patient testing. Two levels of Biorad Liquid Assayed Multiqual QC material (lot: 4596) were used to verify the test system's performance. The laboratory stored the QC material in a Frigidaire freezer (SN: BA02821407). 2. A review of the Biorad Liquid Assayed Multiqual IFUs revealed that the storage requirements are "-20 C to -70C." 3. A review of the laboratory's "Temperature Checking and Recording" policy (POL.063) revealed the following statements: - "It is recognized that some materials are only stable within certain prescribed temperature ranges and that some reagents are greatly influenced by small changes in temperature. For these reasons, it is necessary to verify that the correct temperatures are being maintained in all refrigerators and freezers used in the laboratory, as well as the ambient temperature of the laboratory itself." - "the temperatures of all refrigerators and freezers which contain either samples or reagents, and of the room itself, are to be recorded on a permanent record each day the office is open." 4. A review of the monthly "Laboratory Temperature Check Sheets" from April 2023 to October 2024 revealed the following: - The laboratory's stated acceptable freezer temperature range is "-15 to -25C." - The laboratory did not document freezer temps from April 2023 to September 2024. - The laboratory documented freezer temperatures warmer than -20C for all testing days in October 2024 (7 of 7). 5. An interview with TP1 and the POL coordinator on 10/09/2024 at 3:30 p.m. confirmed that the laboratory did not define freezer temperature ranges consistent with the manufacturer's instructions or verify that the correct temperatures were maintained, leading to the improper storage of QC materials in 2023 and 2024. Key: C = degrees celcius
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on laboratory observation, a review of laboratory policies, lack of documentation, and staff interviews, the laboratory failed to monitor chemistry testing quality control (QC) performance over time (18 of 18 months) in 2023 and 2024. The findings include: 1. An observation on 10/09/2024 at 8:30 a.m. revealed that the laboratory used a Beckman Coulter AU 480 (ID: 2022120197) chemistry analyzer for patient testing. Two levels of Biorad Liquid Assayed Multiqual QC material (lot: 4596) were used to verify the test system's performance. 2. A review of the laboratory's "Quality Control Procedure" (POL.9247) revealed the following statements: - "On a monthly basis Levy-Jennings charts for all QC will be printed including the statistical calculations such as SD and CV." - "QC is evaluated for trends. If a trend is noted, an investigation should begin and/or technical support should be contacted." - "Results will be reviewed by the Lab Designee and the Laboratory Director and corrective actions taken to address trends, shifts or other problems." 3. No Levy-Jennings charts for chemistry QC were available for review. 4. An interview with TP1 and the POL coordinator on 10/09/2024 at 3:30 p.m. confirmed the laboratory did not evaluate chemistry QC Levy-Jennings graphs for shifts and trends from April 2023 to October 2024.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of patient test reports, quality control (QC) records, laboratory policies, lack of documentation, and staff interviews, the laboratory failed to ensure complete blood count (CBC) QC met acceptability criteria before reporting patient test results and failed to document corrective actions for unacceptable QC on one of four days reviewed in 2023 and 2024. The findings include: 1. A random review of patient test records revealed that the laboratory performed CBC testing on 04/24/2023 at 8:16 a.m. (Patient: 03609681), 10/31/2023 at 8:30 a.m. (Patient: 03074628), 08/01 /2024 at 8:53 a.m. (Patient: 03586753), and 09/28/2024 at 8:17 a.m. (Patient: 02666289). 2. A review of the laboratory's CBC QC data for 04/24/2023 revealed the following: - The low (Lot: 069600) and high (Lot: 089600) levels of CBC QC showed unacceptable results at 6:30 a.m., 6:52 a.m., 6:57 a.m., and 7:10 a.m. - The CBC test system did not achieve acceptable QC results for all levels until 11:50 a.m. 3. A review of laboratories policies revealed the following: - The "Quality Assurance Plan" (POL.030) states that "the results of controls are verified for acceptability by testing personnel before reporting patient results" and that "corrective action is taken and documented for deficiencies identified through quality control measures." - The "Quality Control Procedure" (POL.9247) states that "if one or more controls fall outside of the established limits, patient testing should not be performed. (Troubleshooting protocol will begin and/or technical support will be contacted)." 4. No documentation of corrective actions or troubleshooting was available for 04/24 /2023. 5. An interview with TP1 and the POL coordinator on 10/09/2024 at 3:30 p.m. confirmed the findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)

	The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), testing personnel (TP) records, the laboratory's Quality Assurance (QA) policy, and staff interviews, the technical consultant failed to evaluate the competency of one of two testing personnel (TP) at least twice within their first year for hematology and chemistry testing. The findings include: 1. A review of the FORM CMS-209 revealed two persons (TP1 and TP2) who performed moderate complexity hematology and chemistry testing. TP1 was a new testing person listed since the laboratory's last survey. 2. A review of the laboratory's testing personnel records revealed the following: - TP1 began on 01/26 /2023. - TP1's first chemistry testing competency was on 03/15/2023. The next chemistry competency was over a year later (on 09/16/2024). - TP1's first and only hematology testing competency was on 02/29/2024. 3. A review of the "Quality Assurance Plan" (POL.030) revealed the following statement: - "Competency will be evaluated initially, at 6 months and annually thereafter." 4. An interview with TP1 and the POL coordinator on 10/09/2024 at 3:30 p.m. confirmed that TP1 did not have two chemistry and hematology competency assessments within their first year of testing.