Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1088998	07/10/2026
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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing (PT) records and staff interviews, the laboratory failed to retain the signed attestation statement for 2 years (1 of 15 events reviewed for 2024, 2025, and 2026). The findings include: 1. A review of the laboratory's API PT records on the survey date (07/10/2026) revealed that the signed attestation statement for the Chemistry Core 2025 Event 1 was not retained. 2. An interview with the laboratory liaison on 07/10/2026 at 3:00 p.m. confirmed the survey findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (Form CMS-209), laboratory procedure, personnel records, and staff interviews, the laboratory failed to follow the established procedure for annual competency assessment for 1 of 4 testing personnel (TP) in 2025. The findings include: 1. A review of the Form CMS-209 completed for the survey on 07/10/2026 revealed that the laboratory director served as the technical consultant, and four

	testing personnel performed moderately complex patient testing. 2. A review of the laboratory procedure titled "Competency Evaluation" (POL.024A) revealed, "For Non-Waived Testing, use of all 6 elements must be assessed annually by the technical consultant or the Laboratory Director". 3. A review of the laboratory's personnel records revealed no documentation of an annual competency assessment for TP 2 in 2025. 4. An interview with the laboratory liaison on 07/10/2026 at 3:00 p.m. confirmed the survey findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, and staff interview, the laboratory failed to evaluate 6 non-graded scores for the Bilirubin, total (BILI, total) analyte for 3 of 6 events reviewed for 2025 and 2026. The findings include: 1. Observation of the laboratory on 07/10/2026 at 8:35 a.m. revealed the Beckman Coulter AU480 (serial number 2022120197) instrument used for chemistry patient testing, which included BILI, total analyte. 2. A review of the laboratory's API PT records revealed the following non-graded scores for the BILI, total analyte: 2025 Chemistry-Core 2nd Event: Samples CH-07, CH-09, CH-10 2025 Chemistry-Core 3rd Event: Samples CH-12, CH-15 2026 Chemistry-Core 1st Event: Sample CH-05 Documentation of the evaluation of the non-graded scores was not available on the date of the survey (07/10/2026). 3. An interview with the laboratory liaison on 07/10 /2026 at 3:00 p.m. confirmed the survey findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of the Centers for Medicare and Medicaid (CMS) Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), lack of records, and staff interviews, the laboratory failed to verify the accuracy of the urine total protein analyte in 2025, with approximately 87 patients reported. The findings include: 1. Observation of the laboratory on 07/10/2026 at 8:35 a.m. revealed the Beckman Coulter AU480 (serial number 2022120197) instrument used for chemistry patient testing, including the urine total protein analyte. 2. A review of the Form CMS-116 completed for the survey date (07/10/26) revealed that the laboratory listed urine total protein as a test performed. 3. The laboratory did not have records for the verification of accuracy studies for the urine total protein analyte for 2025. 4. An interview with the laboratory liaison on 07/10/26 at 3:00 p.m. confirmed the survey findings. An electronic interview with the laboratory liaison on 07/13/2026 at 1:03 p.m. confirmed the laboratory performed 87 patient tests for urine total protein in 2025.

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of instrument validation records, a lack of documentation, a review of the laboratory procedure manual, instrument report, and staff interviews, the laboratory failed to evaluate the normal reference ranges for the Thyroid Stimulating Hormone (TSH), Cancer Antigen 125 (CA-125), Carcinoembryonic Antigen (CEA), Free Thyroxine (FreeT4), and Beta-human chorionic gonadotropin (bHCG) analytes for the Access2 instrument used for patient testing since April 2026. The findings include: 1. Observation of the laboratory on 07/10/2026 at 8:35 a.m. revealed the Access2 instrument (serial number 574055) used for patient testing for TSH, CA-125, CEA, FreeT4, and bHCG analytes. During the observation, the testing person 1 stated that patient testing began in April 2026. 2. A review of the laboratory's instrument validation records for the Access2 instrument revealed no documented normal reference range studies for any of the analytes. 3. A review of the laboratory's procedure titled "Operation of the Beckman Coulter Access 2 Immunoassay System," approved by the laboratory director for use on 04/09/2026 in section "VIII. Reporting Results," revealed the following normal ranges: TSH-0.340-5.600 uIU/mL CA-125 0-35 U/mL CEA-0.1-5.0 ng/mL FreeT4- 0.54-1.24 ng/dL bHCG-0.0-5.0 mIU/mL 4. A review of the Access2 "Continuous Sample Report" instrument report printed for patients reported on 06/23/2026 revealed the following: Patient 03340385: Ca-125 Patient 03807967: TSH, FreeT4 Patient 03574503: TSH, Ca-125 Patient 01396080: TSH, Ca-125, and FreeT4 5. An interview with the laboratory liaison on 07/10/2026 at 3:00 p.m. and a subsequent phone interview on 07/13/2026 at 11:57 a.m. confirmed the survey findings. Word Key: uIU/ml- micro-International Units per milliliter U/mL- units per milliliter ng/mL- nanograms per milliliter ng/dL- nanograms per deciliter mIU/mL- milli-international units per milliliter
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical

	parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of the Centers for Medicare and Medicaid (CMS) Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), manufacturer's user guide, instructions for use, package inserts, lack of records, and staff interviews, the laboratory failed to perform calibration verification at least every six months for analytes with less than three calibrators that spanned the reportable range for analytes performed (8 of 8 reviewed) on the Beckman Coulter AU480 chemistry instrument in 2024, 2025, and 2026. The findings include: 1. Observation of the laboratory on 07/10/2026 at 8:35 a.m. revealed the Beckman Coulter AU480 instrument (serial number 2022120197) used for chemistry patient testing. 2. A review of the Form CMS-116 completed for the survey (07/10/2026) revealed an estimated annual test volume for the chemistry specialty as 77,316. 3. A review of the manufacturer's User's Guide in Chapter 8, section 8.12.2, "ISE CALIBRATION," revealed that the ISE module for Sodium (Na), Potassium (K), and Chloride (Cl) analytes required calibration every 24 hours using a high standard and a low standard. 4. A random review of the manufacturer's analyte instructions for use revealed the following: Albumin, Glucose, and Magnesium calibration was performed with the Chemistry Calibrator (CAT#DR0070). Alkaline Phosphatase and Aspartate Transferase (AST) calibration was performed with the System Calibrator (CAT#66300X). 5. A review of the manufacturer's package inserts revealed the following: Chemistry Calibrator (CAT#DR0070), lot# 6101K41 /6102K41, included two-point calibrators for Albumin, Glucose, and Magnesium. System Calibrator (Cat#66300X) lot# 1126, included one-point calibrators for Alkaline Phosphatase and AST. 6. No documentation of calibration verification studies with three or more points was available for any of the analytes performed on the Beckman Coulter AU480 instrument for 2024, 2025, or 2026. 7. An interview with the laboratory liaison on 07/10/2026 at 3:00 p.m. confirmed the survey findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (Form CMS-209), laboratory personnel records, and staff interviews, the technical consultant failed to evaluate testing personnel competency assessments for 4 of 4 testing personnel (TP) in 2025 and 2026 that performed complete blood count with differential (CBC), chemistry, endocrinology, and immunology patient testing on the DxH520, Au480, and Access2 instruments. The findings include: 1. Observation of the laboratory on 07/10/2026 at 8: 35 a.m. revealed the following instruments: DxH520 (serial number 8379956) was

	used for CBC patient testing. Au480 (serial number 2022120197) was used for chemistry patient testing. Access2 (serial number 574055) was used for patient testing in chemistry, endocrinology, and immunology. 2. A review of the Form CMS-209 completed for the survey on 07/10/2026 revealed that the laboratory director served as the technical consultant, and four testing personnel performed moderately complex patient testing. 3. A review of the laboratory personnel competency assessment records revealed that the laboratory director/technical consultant indicated on Form CMS-209 was not the evaluator for the following: TP 1- Semiannual competency assessment was initialed by TP 3 as the assessor/evaluator/trainer. Competency Assessment Log 6-month dated 03/20/2026 for the DxH520 and Au480. Au480 Competency Checklist dated 03/20/2026 and was signed by the laboratory director /technical consultant on 03/23/2026. CBC Annual Competency Worksheet dated 03/20 /2026 and was signed by the laboratory director/technical consultant on 03/23/2026. TP 2- Annual competency assessment was initialed by TP 1 as the evaluator. Au480 Chemistry Annual Competency Worksheet dated 04/09/2026 and was signed by the laboratory director/technical consultant on 04/15/2026. CBC Annual Competency Worksheet dated 04/09/2026, and was signed by the laboratory director/technical consultant on 04/15/2026. TP 3- Semiannual competency assessment was initialed by TP 1 as the assessor. Competency Assessment Log dated 03/20/2026 for the DxH520, Au480, and Access2 instruments. Assessor initials were TP 1. TP 4: Initial Competency Assessment was initialed by TP 1 as the assessor/evaluator/trainer. Competency Assessment Log dated 06/24/2026 for the DxH520, Au480, and Access2. Au480 Competency Checklist dated 06/24/2026 and was signed by the laboratory director/technical consultant on 06/26/2026. 4. An interview with the laboratory liaison on 07/10/2026 at 3:00 pm confirmed the survey findings.