Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2091956	04/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ut Medical Group, Inc	877 Jefferson Ave, Chandler Building, 4th Fl &, Memphis, 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
D0000	A complaint survey was completed on April 9, 2024. The laboratory was found NOT to be in compliance with the following 42 CFR PART 493, Requirements for Laboratories. The complaint was substantiated. The laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: CFR 493.801 Condition: Enrollment and testing of samples CFR 493.1441 Condition: Laboratories performing high complexity testing; laboratory director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records, and staff interview, the laboratory failed to ensure that proficiency testing (PT) samples were not referred to another laboratory for analysis. (Refer to D2013).
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4) The laboratory must not send proficiency testing samples or portions of proficiency

	testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of proficiency testing records, and staff interviews, the laboratory failed to ensure Sudden Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) proficiency testing samples were not sent to another laboratory for analysis for four of four testing events. The findings include: 1. Observation of the laboratory on 4/09/24 at 10:00 am revealed no testing for SARS-CoV-2 was being performed. 2. A review of the laboratory's College of American Pathologists (CAP) PT records revealed the laboratory was enrolled in SARS-CoV-2 testing. The PT results printouts displayed the name, address and CLIA number for another laboratory (44D2090400). Attestation statements were signed by testing personnel working at CLIA number 44D2090400 for the following events: 2022 event two: COV2-04, COV2-05, COV2-06 2023 event one: COV2-01, COV2-02, COV2-03 2023 event two: COV2-04, COV2-05, COV2-06 2024 event one: COV2-01, COV2-02, COV2-03 3. Interview with the quality manager and lead histotech on 04/09/24 at 4:30 pm confirmed the following: The SARS-CoV-2 samples enrolled under CLIA 44D2091956 were performed by the laboratory with CLIA number 44D2090400.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory policy, lack of records, and staff interviews, the laboratory failed to follow the safety procedure for monitoring Xylene exposure for personnel in 2023 and 2024. The findings include: 1. Observation of the laboratory on 04/09/2024 at 10:15 am revealed a container labeled "Xylene" on the counter in the frozen section room. During the observation, testing persons nine and ten stated exposure to Xylene was not monitored. 2. A review of the laboratory policy titled " Formaldehyde and Xylene Monitoring" revealed "Vapors are monitored by badges worn by employees" and that badges are evaluated by an outside agency. 3. Documentation for Xylene badge monitoring was not available on the date

	of the survey (04/09/2024). 4. Interview on 04/09/2024 at 3:45 pm with the pathology manager confirmed the laboratory failed to follow the procedure for monitoring employee exposure to Xylene in 2023 and 2024.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of the laboratory, patient test record review, and staff interview the laboratory used Hematoxylin stain after the manufacturer expiration date in 2024. The findings include: 1. Observation of the laboratory on 04/09/2024 at 10:45 am revealed Hematoxylin stain (lot 158304) stored in the laboratory with an expiration date of 03/31/2024. During observation, testing person nine stated the expired Hematoxylin was being used to stain tissue in frozen section procedures. 2. A review of patient test records revealed the laboratory used the expired Hematoxylin for patient SH24-1058 reported on 04/01/2024. 3. Interview on 04/09/2024 at 3:45 pm with the pathology manager confirmed the laboratory used expired Hematoxylin stain in 2024 for patient testing.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient frozen section reports, lack of records, and staff interviews, the laboratory failed to document Hematoxylin and Eosin (H&E) stain quality for staining performed in the "Frozen Section" room for one of one dates reviewed in 2024. The findings include: 1. Laboratory observations were performed on 04/09/2024 at 10:45 am. Observation of the section of the laboratory referred to as the "Frozen Section" room revealed H&E stains used for staining tissues removed during surgical procedures. Also observed was a microscope used for evaluation of the tissue after staining. During observations, testing person nine stated that H&E stain quality was not documented for the slides that were processed in the "Frozen Section" room. 2. A review of patient frozen section reports revealed patient SH24-1058 reported on 04/01/2024. Documentation of H&E stain quality was not available on the date of the survey (04/09/2024). 3. Interview on 04/09/2024 at 3:45 pm with the pathology manager confirmed the laboratory failed to document H&E stain quality for patient testing in the "Frozen Section" room of the laboratory.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f)

	(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of records, and staff interviews, the laboratory failed to retain records of stain lot numbers, dates in use, and stain quality assessment documentation when shipments were received or lot numbers changed for reagents and stains used the "Frozen Section" room of the laboratory in 2023 and 2024. The findings include: 1. Observation of the laboratory on 04/09/2024 at 10:45 am revealed H&E stains and other chemicals used for processing patient tissue removed during surgical procedures. During the observation, testing person nine stated that the laboratory did not retain records of stain and reagent lot numbers or documentation of stain quality when lot numbers change. 2. Interview on 04/09/2024 at 3:45 pm with the pathology manager confirmed the laboratory failed to retain records of lot numbers, dates in use, and stain quality assessment or reagents used in the "Frozen Section" room of the laboratory in 2023 and 2024.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of final patient test reports and staff interviews, the laboratory failed to ensure the correct address of the facility that performed the professional component of patient testing was included on the final patient test report (13 of 13 reports reviewed) in 2023 and 2024. The findings include: 1. A review of final patient test reports revealed the following reports that did not include the correct address of the facility that performed the professional component of patient testing: SHBM23-3 reported on 01/17/2023 SH23-668 reported on 03/14/2023 SH23-991 reported on 04 /14/2023 SH23-2258 reported on 08/04/2023 SH23-2719 reported on 09/13/2023 CH23-457 reported on 12/12/2023 CH24-17 reported on 01/25/2024 CH24-73 reported on 03/12/2024 SH24-1026 reported on 04/02/2024 CH24-104 reported on 04 /02/2024 SH24-913 reported on 04/03/2024 CH24-106 reported on 04/04/2024 SH24-1058 reported on 04/05/2024 2. Interview on 04/09/2024 at 3:45 pm with the pathology manager confirmed the laboratory failed to ensure the correct address of the facility where the professional component of patient testing was performed was included on the final patient test report in 2023 and 2024.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441

	The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's CAP PT records and staff interview, the Laboratory Director failed to provide overall management and direction of the laboratory. (Refer to D6089)
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's CAP PT records, and staff interview, the Laboratory Director failed to ensure SARS-CoV-2 proficiency testing samples were not sent to another laboratory for analysis for four of four PT events. (Refer to D2013)