

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0931269	(X3) Date Survey Completed 10/01/2026
Name of Provider or Supplier North Texas Medical Laboratory	Street Address, City, State 5420 Kell West Boulevard, Wichita Falls, TX	
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	An onsite initial certification survey was conducted on 10/01/2026. The laboratory was found to be in compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 direct observation, manufacturer's instructions, environmental logs, and confirmed in staff interview the laboratory failed to ensure the room humidity for 1 of 1 Olympus BX46 Clinical Microscope was maintained according to manufacturer's instructions for 1 of 1 month in 2025 (December) and 9 of 9 months in 2026 (January-September). Findings included: 1. During a tour of the laboratory director's office on 10/01/2026 at 10:09 AM, the surveyor observed an Olympus BX46 Clinical Microscope (Serial # 6G45608) on a desk. 2. Review of the Olympus BX46 Clinical Microscope instructions manual page 29 stated: "Item 9. Operating environment Specification ... Maximum relative humidity: 80% for temperatures up to 31 degrees C (88 degrees F), decreasing linearly through 70% at 34 degrees C (93 degrees F), to 50% relative humidity at 40 degrees C (104 degrees F)." 3. Review of the laboratory's environmental logs titled "TEMPERATURE MONITORING" from December 2025 through September 2026 revealed the laboratory failed to document and ensure the

	room humidity was maintained according to manufacturer's instructions of a maximum of 80%. 4. During an interview 10/01/2026 at 10:09 AM, the laboratory director after a review of records confirmed the laboratory failed to ensure the room humidity for 1 of 1 Olympus BX46 Clinical Microscope was maintained according to manufacturer's instructions for 1 of 1 month in 2025 (December) and 9 of 9 months in 2026 (January-September). Word Key: C- Celsius F- Fahrenheit
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: I. Based on review of laboratory policies, laboratory records, quality control records, annual test volume records, and confirmed in staff interview, the laboratory failed to define and document the intended reactivity for 1 of 1 Hematoxylin and Eosin (H & E) stain to ensure predictable staining characteristics of quality control slides for H & E staining on each day of patient testing for 215 of 215 days from December 2025 to September 2026. Findings included: 1. Review of the laboratory policy titled "Quality Control" revealed the laboratory failed to specify the intended reactivity for H & E stains to ensure predictable staining characteristics. 2. Review of laboratory records revealed that all histology, oral pathology and cytology specimens for the laboratory were sent to a reference laboratory for grossing and H&E staining, immunohistochemical and special staining. The slides were shipped back to the laboratory for pathological interpretation. 3. A review of the laboratory's "Daily Quality Control Log" from December 2, 2026, through September 30, 2026, revealed the following: The log had a column for "Stain Quality," each day stain quality was documented with a "checkmark" in the column and was initialed by the pathologist. The log did not specify if the "checkmark" column was indicated for H&E intended reactivity to ensure predictable staining characteristics. 4. According to laboratory records, the laboratory's annual volume was 1655 histology tests, 5 oral pathology tests and 60 cytology tests. 5. During an interview on 10/01/2026 at 10:05 AM, the laboratory director confirmed the laboratory failed to define and document the intended reactivity for 1 of 1 Hematoxylin and Eosin (H & E) stain to ensure predictable staining characteristics of quality control slides for H & E staining on each day of patient testing for 215 of 215 days from December 2025 to September 2026. II. Based on review of laboratory policies, laboratory records, quality control records, and confirmed in staff interview, the laboratory failed to define the intended reactivity for 19 of 19 special and immunohistochemical stains to ensure predictable staining characteristics of quality control slides each day of patient testing for 82 of 82 days from December 2025 to September 2026. Findings included: 1. Review of the laboratory policy titled "Quality Control" stated: "Special Stains: Special stains are performed by [XX], [XX] or other CLIA accredited lab. Upon review of the slides the stain quality control log is completed and retained. Corrective action is taken if necessary. The policy failed to specify the intended reactivity to ensure predictable staining characteristics for the following special and immunohistochemical stains used by the laboratory: Estrogen receptor (ER) GATA3 BerEP4 Claudin-4 D2-40 Calretinin Gross cystic disease fluid protein-15 (GCDFP-15) NKX2 MOC-31 Grocott-Gomoris Methenamine Silver (GMS) Periodic acid-Schiff (PAS) Trichrome 2A Iron P5/6 Cytokeratin (CK7) SOX10 Helicobacter pylori (H. pylori) CDB8 Kappa-Lambda

	2. Review of laboratory records revealed that all histology, oral pathology and cytology specimens for the laboratory were sent to a reference laboratory for grossing and H&E staining, immunohistochemical and special staining. The slides were shipped back to the laboratory for pathological interpretation. 3. A review of the laboratory's "Special Stains Quality Control Log" from December 4, 2026, through September 18, 2026, revealed the following: The log had a column for "Special Stain," to indicate the type of stain used on patient slides and another column labeled "Control Reactive" each day stain reactivity was documented with a "yes" in the column and was initialed by the pathologist. 4. Further review of the "Special Stains Quality Control Log" identified 183 patients who had special and immunohistochemical stains performed. 5. During an interview on 10/01/2026 at 10:05 AM, the laboratory director confirmed the laboratory failed to define the intended reactivity for 19 of 19 special and immunohistochemical stains to ensure predictable staining characteristics of quality control slides each day of patient testing for 82 of 82 days from December 2025 to September 2026.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on review of written laboratory procedures, review of annual test counts and staff interview, the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established and failed to establish a maximum workload limit for 1 of 1 testing personnel who performed primary cytology slide interpretations from December 2025 until the date of the inspection in October 2026. Findings included: 1. Review of the procedure manual found no written policy to ensure that the technical supervisor established a maximum workload limit for each testing personnel performing primary cytology slide interpretations. No workload limit was documented for the testing personnel who performed primary cytology slide interpretations from December 2025 until the date of the inspection in October 2026. 2. Review of the annual test counts found the laboratory reported performing 60 cytology slide interpretations. 3. During an interview on 10/01/2026 at 10:05 AM, the Laboratory Director confirmed the laboratory did not have a procedure to establish workload limits and did not establish a maximum workload limit for the pathologist performing primary cytology slide interpretations.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on review of written laboratory procedures, review of annual test counts and staff interview, the laboratory failed to establish written policies and procedures to reassess the workload limits at least once every six months for 1 of 1 testing personnel performing cytology slide interpretations from December 2025 until the date of the inspection in October 2026. Findings included: 1. Review of the procedure manual

	found no written policy to ensure that testing personnel workload limits were reassessed at least every six months for each testing personnel performing cytology slide interpretations. 2. Review of the annual test counts found the laboratory reported performing 60 cytology slide interpretations. 3. During an interview on 10/01/2026 at 10:05 AM, the Laboratory Director confirmed the laboratory did not reassess workload limits for the pathologist performing cytology slide interpretations at least once every six months.
D5639	CYTOLOGY CFR(s): 493.1274(d)(2)(i) (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday; This STANDARD is not met as evidenced by: Based on the review of laboratory procedures, review of annual test counts and interview of facility personnel, the laboratory failed to establish written policies and procedures to ensure 1 of 1 testing personnel examined no more than 100 slides in an eight-hour workday in December 2025 until the date of the inspection in October 2026. Findings included: 1. Review of the procedure manual found no written policy to ensure each testing personnel performing cytology slide interpretations reviewed no more than 100 slides in a 24-hour period. 2. Review of the annual test counts found the laboratory reported performing 60 cytology slide interpretations. 3. During an interview on 10/01/2026 at 10:05 AM, the Laboratory Director confirmed the laboratory did not have a procedure in place to ensure maximum workload limits for the pathologist performing cytology slide interpretations were not exceeded.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on the review of written laboratory procedures, review of annual test counts and staff interview, the laboratory failed to establish written policies and procedures to ensure that slide examination records were maintained for 1 of 1 testing personnel performing cytology slide interpretations to include the number of slides examined by each individual in a 24-hour period in December 2025 until the date of the inspection in October 2026. Findings included: 1. Review of the procedure manual found no written policy to ensure that slide examination records were maintained to include the total number of slides examined by each individual in a 24-hour period for each individual examining slides. 2. Review of the annual test counts found the laboratory reported performing 60 cytology slide interpretations. 3. During an interview on 10/01

	/2026 at 10:05 AM, the Laboratory Director confirmed the laboratory did not maintain records that include the number of slides examined in a 24-hour period for the pathologists performing cytology slide interpretations at least once every six months.
D5647	CYTOLOGY CFR(s): 493.1274(d)(4) (d)(4) Records are available to document the workload limit for each individual. (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload limit records, and staff interview, the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for the 1 of 1 testing persons performing cytology slide interpretations in December 2025 and to the date of the survey in October 2026. Findings included: 1. Review of laboratory policies and procedures revealed the laboratory failed to have written policies and procedures to ensure records were available to document the workload limit for testing personnel performing cytology slide interpretations. 2. The laboratory was asked to provide records of an established maximum workload limit for testing personnel performing cytology slide interpretations December 2025 and to the date of the survey in October 2026. None were provided. 3. During an interview on 10/01/2026 at 10:05 AM, the Laboratory Director confirmed the findings.
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c)(2) Must establish the workload limit for each individual examining slides; (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary; This STANDARD is not met as evidenced by: Based on the review of written laboratory procedures, review of annual test counts and staff interview, the technical supervisor failed to establish written policies and procedures to ensure that a maximum workload limit was established and reassessed at least once every six months for 1 of 1 testing personnel performing cytology slide interpretations in December 2025 until the date of the inspection in October 2026. Refer to D5633, D5637, and D5639.
D6131	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(4) (c)(4) Must perform the functions specified in 493.1274(d) and (e); This STANDARD is not met as evidenced by: Based on the review of written laboratory procedures, review of annual test counts and staff interview, the technical supervisor failed to establish written policies and procedures to ensure that slide examinations did not exceed the maximum count of 100 slides in 24 hours, workload limits were reassessed at least once every six months

and records were maintained for all testing personnel performing cytology slide interpretations to include the number of slides examined by each individual in a 24-hour period in December 2025 until the date of the inspection in October 2026. Refer to D5633, D5637, D5639, D5645 and D5647.