Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2007027	03/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Anatomical Medical Laboratories, Inc	350 Ih-35e South, Denton, 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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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: I. Based on review of the CMS (Center for Medicaid & Medicare Services) 116 form, laboratory policy, proficiency testing records, and confirmed by staff interview, the laboratory failed to have documentation of evaluating the results of the peer reviews to determine accuracy for 1 of 1 event in 2021. Findings: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed histology procedures. 2. Review of the laboratory policy manual revealed the laboratory did not have a policy for performing twice annual accuracy assessments. 3. Review of the laboratory's twice annual accuracy assessment for 2021 revealed the

	following: Quality Review Form Accession No: S21-0018085 Date Completed: 03-01-2021 The form had 9 categories listed: patient data, gross description, microscopic description, diagnosis and comment, turn-around time, technical quality of slide(s), frozen section results (if applicable), includes appropriate CAP Cancer Care Protocol, and outside consultation. Patient data, gross description, microscopic description, and diagnosis and comment had two criteria: complete and comprehensible. Each criterion under the column "OK" had checkmarks. Turn-around time had the criteria: 1 days and under the column "OK" there was a checkmark. Technical quality of slide(s) had the criteria: slides and under the column "OK" there was a checkmark. Frozen section results (if applicable) had four options for selection: N/A, diagnosis deferred, diagnosis matches, false positive, false negative. "Diagnosis matches" was selected and under the column "OK" there was a checkmark. Includes appropriate CAP Cancer Care Protocol had three options for selection: yes, no, N/A. "Yes" was selected and the column under "OK" there was a checkmark. Outside consultation had the following selection options: yes, no, agree, disagree. For the "no" option under the column "OK" there was a checkmark. There was a line for comments. The comment stated "normal". The "Quality Review Forms" were signed by the peer reviewer. There was no documentation of the results from the peer reviewer being evaluated by the pathologist for accuracy. 4. During an interview on 03/30/2022 at 9:45 am, the Histology Supervisor confirmed the above findings. II. Based on review of laboratory policies, Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory records and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated histopathology procedures at least twice annually for 1 of 2 testing events in 2020. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not have a policy for performing twice annual accuracy assessments for histopathology procedures. 2. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed histopathology procedures. 3. Review of the laboratory's proficiency testing records for 2021 revealed the laboratory failed to verify the accuracy of histopathology procedures for 1 of 2 events in 2021. 4. During an interview on 03/30/2022 at 9:45 am, the Histology Supervisor confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation and staff interview, the laboratory failed to ensure reagents stored in secondary containers were labeled with proper identification, concentration, and poured/expiration dates. Findings: 1. During a tour of the laboratory on 03/30/2022 at 10:35 am, the surveyor observed the following on the counter next to the cryostat: 1 coplin jar labeled "Hema-Diff Thiazene [sic]; preparation date: 03/25/2022; expiration date: 04/30/2023; XX [initials]" 1 coplin jar labeled "37% Formaldehyde; preparation date: 03/25/2022; expiration date: 09/30 /2022; XX [initials]" 1 coplin jar labeled "Tap water, preparation date: daily" The laboratory failed to label all secondary containers with the lot numbers. The coplin jar with water failed to have preparation and expiration dates. Without proper labeling,

	the reagent could not be linked to an original container. The surveyor also observed the following staining tray with jars on the right side of the counter: Jar #1 labeled "H2O; change weekly" Jar #2 labeled "Gill 3; change weekly; XX [initials]" Jar #3 labeled "H2O; change weekly" Jar #4 labeled "H2O; change weekly; XX [initials]" Jar #5 labeled "NH3; change weekly" Jar #6 labeled "H2O; change weekly" Jar #7 labeled "Eosin; change weekly; XX [initials]" Jar #8 labeled "95% alcohol; change weekly; XX [initials]" Jar #9 labeled "100% alcohol; change weekly; XX [initials]" Jar #10 labeled "100% alcohol; change weekly; XX [initials]" Jar #11 labeled "Xylene; change weekly; XX [initials]" Jar #12 labeled "Xylene; change weekly; XX [initials]" The laboratory failed to label the secondary container with the lot numbers, concentration, and poured/expiration dates. Without proper labeling, the reagent could not be linked to an original container and therefore the expiration dates could not be determined. 2. During an interview on 03/30/2022 at 10:46 am, the Histology Supervisor confirmed the above findings.
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 review of the laboratory's policy, Quality Control (QC) logs, and confirmed in interview, the laboratory failed to document for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for Hematoxylin & Eosin (H&E) stain and Thiazine stain for 20 of 29 days in 2021 (05 /2021 through 12/2021) and 9 of 9 days in 2022 (01/2022 through 03/2022). Findings included: 1. Review of the laboratory's policy "H & E Staining Procedure for Frozen Sections" revealed: "Results: Nuclei Blue Cytoplasm Blue" Review of the laboratory's policy "Thiazene [sic] Quick Diff Stain" revealed: "Results: Nuclei----------Blue Cytoplasm----------Pink" 2. Review of the "H&E -THIAZENE [sic] QUALITY CONTROL CHECK" log revealed the following: The log had six columns titled "H&E", "THIAZENE" [sic], "HEME", "EOSIN", "MICROTOMY", and "CLARITY". Each day QC was documented with a "checkmark" under each column. The laboratory failed to specify what the "checkmark" indicated. The following dates in 2021 and 2022 were observed to be documented with a "checkmark": 2021 May: 21 June: 4 July: 9, 16, 23, 30 August: 6, 13, 20 September: 10, 17, 24 October: 15, 29 November: 5, 10, 12 December: 10, 17, 29 2022 January: 14, 21, 28 February: 4, 18 March: 3, 18, 25 The laboratory failed to document the staining characteristics for the H&E and Thiazine stains. 3. Review of test volume records provided by the laboratory included a total annual volume of 119 histopathology tests. 4. During an interview on 03/30/2022 at 10:12 am, the Histology Supervisor confirmed the above findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually

	after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of laboratory policy, personnel records, CMS (Center for Medicare & Medicaid Services) 209 form, and confirmed in interview, the technical supervisor (who was also the laboratory director) failed to evaluate and document the annual performances for 1 of 2 Testing Persons (TP-2) responsible for high complexity testing. Findings: 1. Review of the laboratory's policy "COMPETENCY TESTING INITIAL TRAINING AND COMPETENCY ASSESSMENT" revealed: "POLICY The performance of personnel responsible for the preparation and testing of tissue specimens for pathologic evaluation by a pathologist will be evaluated at least annually or semiannually during the first year of employment. Thereafter, evaluations are performed at least annually unless testing methodology or instrumentation changes, in which case, prior to the use the individual's performance must be reevaluated to include the use of new methodology or instrument." 2. Review of personnel training records for TP-2 revealed "Pathologist Performance Evaluation 2021" forms performed on 07/14/2021 and 01/26/2022. The annual competency assessment was performed by another pathologist supervisor who was NOT listed on the CMS 209 form and was NOT delegated to perform competency assessments. The technical supervisor failed to perform annual competencies on TP-2. 3. During an interview on 03/30/2022 at 9:45 am, the Histology Supervisor confirmed the above findings.