

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1096634	(X3) Date Survey Completed 04/02/2021
Name of Provider or Supplier Ameripath Lubbock 501(A)	Street Address, City, State 2001 West Rosedale Street, Fort Worth, 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 conducted 04/02 /2021. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives on 04/02 /2021. 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 State Health and Human Services Commission, Health Facility Compliance Arlington Group.
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's policy, Frozen Section Log, patient test reports and confirmed in interview, the laboratory failed to test and document the intended reactivity of toluidine blue stain for frozen section slides each day of use for 1 of 15 days in 2020 and 1 of 8 days in 2021. Findings: 1. Review of the laboratory's policy "Frozen Section Procedure" revealed: "6. PROCEDURE ... 3. Steps ... Document the acceptability of the stain quality on the Frozen Section Log. Toluidine Blue Stain Quality acceptability criteria: Nuclei Stain Blue With Crisp Clear Morphology; Polysaccharides are Purple." 2. Review of the laboratory's "Frozen Section Log" did not include for each day of use, documentation of the intended reactivity for the toluidine blue stain on the following days patients were tested and reported in 2020 and 2021: 12/04/2020 Patient ID: HS20-11928 01/22/2021 Patient ID: HS21-665 3.</p>

During an interview on 04/02/2021 at 12:15 pm, the QA Coordinators confirmed the above findings.