Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2143452	01/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Ameripath Lubbock 501(A)	2010 W Katherine P Raines Suite #100, Cleburne, 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	The Regional Quality Manager was at the entrance conference conducted 01/10/2020. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the Regional Quality Manager on 01/10/2020. The laboratory was found to be in substantial compliance for the specialties /subspecialties for which it was surveyed. The standard level deficiency cited was discussed. The process for submitting the corrections was explained.
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, review of the laboratory's policy, and in interview with staff, the laboratory failed to label a secondary container of Toluidine Blue stain with its lot number and expiration date. Findings included: 1. During a tour of the laboratory on 01/10/2020 at 10:42 am, a white plastic container was observed to be stored on the counter that included a label: "Reagent Name: 1% TOLUIDNE [sic] BLUE; Lot No: [blank]; Conc: Predilute; Prep Date: 12/14/18; Exp Date: [lines through dates]; Prep By: [blank]; Store at: Room Temp 15-30C." 2. Review of "AP REAGENT LABELING HANDLING STORAGE AND LOT ACCEPTABILITY" (Document No: CSCQDAP871[1.1]; Effective Date: 03/01/2018) stated, "5. POLICY; 5.1. Reagent Labeling: Step 1: Action: Label all primary and secondary containers (purchased or prepared in-house) with the following: Identity/description of contents; Quantity and concentration or titer, if applicable; Date prepared in-house, changed

	/filtered or reconstituted by the laboratory, including staff initials;... Expiration date (at a minimum the month and year);...Lot or batch number; Storage requirements; Precautionary information." The laboratory did not label the observed secondary container of 1% Toluidine Blue stain with the lot number, expiration date, and staff initials. 3. The laboratory had an annual volume of 11 frozen sections. 4. During an interview on 01/10/2020 at 10:45 am, the Regional Quality Manager confirmed the laboratory did not label the secondary container of 1% Toluidine Blue stain with the lot number, expiration date, and staff initials.