Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2134889	11/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Propath Associates	1500 S Main, 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	The Peer Reviewer, QA Manager, and QA Specialist were at the entrance conference conducted 11/12/2019. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the Peer Reviewer, QA Manager, QA Specialist on 11/12/2019. 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 Health and Human Services Commission, Health Facility Compliance Arlington Group.
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 laboratory policy, quality control (QC) records, patient test records, and confirmed in interview, the laboratory failed to define intended reactivity to ensure predictable staining characteristics of Hematoxylin & Eosin (H&E) stain for 1 of 1 day in 2018 (December) and 4 of 4 days in 2019 (January). Findings: 1. Review of the laboratory's policy "Frozen Section Procedure" revealed: "REPORTING 1. Quality of stain must be evaluated before rendering a frozen section diagnosis. Document frozen section H&E stain quality on the Frozen Room Routine Maintenance form (attachment A)." The procedure failed to define the staining characteristics for intended reactivity (positive or negative) for the H&E stain. 2. A random review of the "H & E QC Log by Client" log in 2018 and 2019 revealed the following: The log had a H & E QC column for "Satisfactory/Unsatisfactory" that was

	to be circled as documentation of QC. The following dates were circled "Satisfactory": 12/10/2018 01/08/2019 01/09/2019 01/10/2019 01/28/2019 The laboratory failed to document the staining characteristics for the H&E stain. 3. During the exit interview at 12:08 pm, the QA Manager, QA Specialist, and Peer Reviewer, confirmed the laboratory failed to define intended reactivity to ensure predictable staining characteristics of H&E stain.