

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0484493	(X3) Date Survey Completed 10/13/2020
Name of Provider or Supplier Ameripath Lubbock 501(A)	Street Address, City, State 800 W Randol Mill Rd, Arlington, 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	<p>The Quality Assurance Coordinator and Laboratory Director were at the entrance conference conducted 10/13/2020. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the Quality Assurance Coordinator and Laboratory Director on 10/13/2020. 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.</p>
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 the laboratory's policy, Quality Control (QC) logs, and confirmed in interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) QC for 39 of 39 days in 2019 (random review 11/2019 through 12/2019) and 49 of 49 days in 2020 (random review 08/2020 through 10/2020). Findings: 1. Review of the laboratory's policy Quality Control Evaluation of Tissue Pathology Slides revealed: "10. Local Addendum -Quality Control Evaluation of H & E Stains 1. The pathologist will evaluate the quality on the H&E stain daily. 2. The pathologist will be given the "Pathologist daily H/E QC stain log" and an H&E control slide daily. 3. Upon completion of the pathologist evaluation he/she will put a</p>

check in the appropriate box if the quality of the stain is acceptable and a (-) if the stain is unacceptable. 4. If the quality of the stain is unacceptable, the pathologist will alert the Histology Lab and the lab will make the appropriate adjustments to the stain. 5. A control slide will then be re-submitted." The policy did not define intended reactivity of the H&E stain to ensure predictable characteristics. 2. Review of the "DERMATOLGOY H E Daily Review Log" revealed the following: The log had a row for "Stain acceptable" and each day QC was documented with "checkmark" in the column. The bottom of the log stated that a checkmark meant the "parameter indicated was checked as expected", but it did not specify what expected meant. The following dates in 2019 and 2020 (random review) were observed to be documented with "checkmark": 2019 November: 1, 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 18, 19, 20, 21, 22, 25, 26, 27, 29 December: 3, 4, 5, 6, 9, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24, 26, 30, 31 2020 August: 1, 2, 3, 4, 8, 9, 10, 11, 14, 15, 16, 17, 18, 21, 22, 23, 24, 25, 28, 29, 30 September: 3, 4, 5, 6, 7, 10, 11, 12, 13, 14, 19, 20, 21, 24, 25, 26, 27, 28, 31 October: 1, 2, 5, 6, 7, 8, 9, 12, 13 The laboratory failed to document the staining characteristics for the H&E stain. 3. Review of test volume records provided by the laboratory included a total annual volume of 6,000 histopathology tests. 4. During an interview on 10/14/2020 at 11:25 am, the Quality Assurance Coordinator confirmed the above findings.