

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1066386	<b>(X3) Date Survey Completed</b>  01/10/2018
<b>Name of Provider or Supplier</b>  Ameripath Texas, Inc	<b>Street Address, City, State</b>  2501 S State Hwy 121 Suite 1210, Lewisville, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6115</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(2)</p> <p>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on review of 417 gynecologic cases and corresponding final test reports from September through December 2017, and interview it was determined that the the Technical Supervisor failed to verify the accuracy of five gynecologic cytology test reports. Findings include: 1. TP17-200145 09/28/17 ThinPrep LABORATORY DIAGNOSIS: Satisfactory for Evaluation; Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for Evaluation; Scant Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory for Evaluation; Scant Cellularity 2. TP17-316404 10/05/17 ThinPrep LABORATORY DIAGNOSIS: Satisfactory for Evaluation; Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for Evaluation; Scant Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory for Evaluation; Scant Cellularity 3. TP17-316577 10/0517 ThinPrep Imaged LABORATORY DIAGNOSIS: Satisfactory for Evaluation; Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for Evaluation; Scant Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory for Evaluation; Scant Cellularity 4. TP17-411219 10/18/17 SurePath FocalPoint LABORATORY DIAGNOSIS: Satisfactory for Evaluation; Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for Evaluation; Scant Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory for Evaluation; Scant Cellularity 5. TP17-200181 12/27/17 Conventional LABORATORY DIAGNOSIS: Satisfactory for Evaluation; Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS:</p>

Unsatisfactory for Evaluation; Scant Cellularity TECHNICAL SUPERVISOR  
DIAGNOSIS: Unsatisfactory for Evaluation; Scant Cellularity 6. The Technical Supervisor confirmed the Survey Team findings at 12:30 PM on January 10, 2018.

**D9999**

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