

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2007460	<b>(X3) Date Survey Completed</b> 11/07/2018
<b>Name of Provider or Supplier</b> Cpa - Mission Trails	<b>Street Address, City, State</b> 3333 Research Plaza, San Antonio, 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>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the procedure manual and review of Becton Dickinson (BD) training records it was determined that the laboratory failed to follow one of fifteen written procedures in the procedure manual. Findings include: 1. The laboratory failed to follow the written procedure titled "Proficiency Testing and Training Records" (signed and dated by the Laboratory Director/Technical Supervisor on 6/1/18). The procedure stated, "Training records for Thinprep and Surepath pap smears are maintained in the Procedure Manual for all testing personnel at this location". a. The Survey Team requested and the laboratory failed to provide BD SurePath Pap Test training records for Technical Supervisor #1.</p>
<b>D5411</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the BD SUREPATH IMPLEMENTATION GUIDE and</p>

certification records for the BD SurePath Pap Test it was determined that the laboratory failed to ensure that one of five Technical Supervisors had received the appropriate training to evaluate gynecologic specimens using the BD SurePath Pap Test, according to the manufacturer's instructions. Cross Refer to D5401 Findings include: 1. The BD SUREPATH IMPLEMENTATION GUIDE states that the "BD Surepath Morphology Training" must be completed for cytotechnologists and pathologists who evaluate BD SurePath prepared slides. 2. The Survey Team requested and the laboratory failed to provide morphology training records for one of five Technical Supervisors who performed diagnostic interpretations on BD SurePath Pap Tests. (See D5401)

**D9999**

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