

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0509648	<b>(X3) Date Survey Completed</b> 08/11/2021
<b>Name of Provider or Supplier</b> Gyn Path Services Inc	<b>Street Address, City, State</b> 7760 Alabama St, El Paso, 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>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by:</p> <p>II. Based on observations, review of temperature records ,laboratory policies and procedures, instructions available to clients submitting specimens for testing and interviews it was determined the laboratory failed to follow written policies and procedures for the collection, storage, handling and transportation of gynecologic specimens collected in Hologic PreservCyt solution using the manufacturer's specifications. Findings included: 1. Observations made in the specimen processing area of the laboratory conducted August 19, 2021 at 1:04 PM found gynecologic specimens collected in Hologic PreservCyt solution had been transported at temperatures outside of the manufacturer's specified storage of 15C (59F) and 30C (86F). 18 specimens were transported in refrigerated containers exceeding the minimum storage temperature of 15C. Container for Courier 3 held a thermometer which read 11.9C. It contained 18 PAP specimens in PreservCyt solution. 2. Review of temperature records for August 2021 for this container found: a. Temperature range was defined as 2-20 C. b. Temperatures were recorded three times each day as follows: Date Morning Afternoon Evening 08/02/2021 4 12 19 08/03/2021 5 13 19 08/04/2021 4 13 19 08/05/2021 5 13 19 08/06/2021 6 12 19 08/07/2021 7 15 08/09/2021 5 6 7 08/10/2021 6 11.9 There was no documentation available for review to define the time each of the specimens was placed into the container used for transport. 2. Review of the laboratory's written instructions for PAP test found under the heading</p>

Specimen Requirements: "Store vial with cytologic sample intended for ThinPrep Pap testing between 15C (59F) and 30C (86F) for up to 30 days. After 30 days, the sample is discarded as it is no longer valid for HPV testing." 3. Review of the laboratory's written procedure titled THINPREP Specimen Collection and Handling Guide (Rev. 02/01/2021) found on page 2 under the heading Storage and Transportation Instructions: "PreservCyt Solution: Storage: Store the PreserCyte Solution specimen at 15C (59F) and 30C (86F) for up to 30 days. Transportation: Transport the PreserCyte Solution specimen at 15C (59F) and 30C (86F) ." 4. Review of the Hologic ThinPrep 5000 instructions (AW-11239 Rev 2 8-2017) found on page 27: "Store Preservcyt Solution with cytologic sample intended for ThinPrep Pap testing between 15C (59F) and 30C (86F) for up to six weeks". 5. Interview of the General Supervisor conducted on August 10, 2021 at 1:36 PM confirmed that specimens were transported in the cooler with all specimens and delivered to the primary processing area in the main laboratory. PAP specimens were removed from containers and left in the processing area for accessioning. He stated "getting new coolers validated was next on his list but he hadn't gotten to that just yet".