

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0641487	(X3) Date Survey Completed 07/02/2019
Name of Provider or Supplier Cytopath Inc	Street Address, City, State 1004 First Street North, Suite 200, Alabaster, AL	
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
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on the desk review of materials submitted with the laboratory's Allegation of Compliance it was determined that the laboratory failed to maintain the identity of the personnel who performed the search for prior negative cases for 18 of 23 current high grade squamous intraepithelial lesion (HSIL) and malignant cases from June through August 2018. Findings include: 1. The Survey Team reviewed laboratory records titled FIVE YEAR RETRO-REVIEW OF CURRENT HSIL/CA PAP CASES from June through August 2018. The records failed to identify the personnel who performed the search on 18 of 23 current HSIL and malignancies for prior negative cases. Cases include: - COSO-18-5002 - COSO-18-5300 - COSO-18-6076 - COSO-18-6411 - COSO-18-6464 - COSO-18-6660 - COSO-18-6677 - COSO-18-6783 - COSO-18-6832 - COSO-18-6861 - COSO-18-7053 - COSO-18-7460 - COSO-18-7486 - COSO-18-7619 - CMWO-18-364 - CMWO-18-599 - CMWO-18-632 - CMWO-18-635</p>
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