

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0333745	(X3) Date Survey Completed 11/10/2022
Name of Provider or Supplier Southwest General Health Center	Street Address, City, State 18697 Bagley Road, Laboratory Services, Cleveland, OH	
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
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems in the postanalytic phases of cytology testing by monitoring the accuracy of final test reports. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic phases of testing by monitoring the accuracy of final test reports. 2. The Survey Team identified six random final test reports from June through November 2022 that documented the incorrect number of patient specimen slides on the final test report. Final test reports include: -NG-22-0000545 Test report: ThinPrep preparation slide, 5 additional slides Actual glass slides, ThinPrep preparation slide, 6 additional slides -NG-22-0000566 Test report: ThinPrep preparation slide, 5 additional slides Actual glass slides: ThinPrep preparation slide, 6 additional slides -NG22-0000651 Test report: ThinPrep preparation slide, 5 additional slides Actual glass slides: ThinPrep preparation slide, 6 additional slides -NG-22-0000769 Test report: ThinPrep preparation slide Actual glass slides: ThinPrep preparation slide, 2 additional slides -NG-22-0000783 Test report: ThinPrep preparation slide Actual glass slides: ThinPrep preparation slide, cell block preparation slides -NG-22-0000881 Test report: ThinPrep preparation slide</p>

Actual glass slides: ThinPrep preparation slide, 6 additional slides 3. During an interview on November 9, 2022 at 1:45 PM, these findings were confirmed with the Manager of Regulatory Compliance and Laboratory Manager.