

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0509648	<b>(X3) Date Survey Completed</b>  09/26/2018
<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>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists(CAP) proficiency testing records from 2017 and 2018, policies and procedures and staff interview, the laboratory failed to consistently review, evaluate and document corrective actions for proficiency testing results not graded by the proficiency testing agency. The findings included: 1. Review of CAP proficiency testing records from 2018 (3 testing events annually) found no documentation of review for analytes not graded by the proficiency testing agency as follows: a. CHPV-A 2018 Human Papillomavirus - Five of five results for the HR HPV Genotyping submitted by the laboratory were not graded by the proficiency testing agency and noted an exception Reason Code [26] = Educational challenge. b. HC6-B 2018 Chlamydia/GC by NAA - one of two results submitted by the laboratory were not graded by the proficiency testing agency and noted an Exception Reason Code [27]= Lack of participant or referee consensus. The laboratory submitted a result of POS FOR C. TRACHOMATIS for specimen HC6-10 using the Hologic Aptima Combo 2. A note written on the original evaluation read "HC-010 - possible sample problem". Review of the participants summary found that results submitted by laboratories testing specimen HC6-10 using the Hologic Aptima Combo 2 totaled 569 with 81 reporting positive and 488 reporting a negative result. c. Review of the Actions Laboratories Should Take when a PT Result is Not Graded as provided by the CAP Proficiency testing agency in the participants Data summary found that the laboratory should take the following actions for the Exception Reason Codes cited: "[26] - Educational Challenge - Response to the CAP is not required. Laboratory should document its review. [27] - Lack of participant or referee consensus - Document that the laboratory performed a self-evaluation and compared its results to the proper statistics supplied in the Participant Summary. If comparison</p>

is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested." d. There was no other documentation of assessment of proficiency testing results available for review. 2. Review of the laboratory policies and procedures found: a. In the laboratory's own written policy titled Participation in Proficiency Testing for Laboratories Performing Non-Waived Testing dated 01/01 /2006 revised 06/07/2018 found on page one under the heading ungraded challenges - "The laboratory will assess performance on PT results that were intended to be graded, but were not with the CAP PT exception investigation checklist. i. Reasons for ungraded challenges: ii. Results submitted after cut off date. iii. Did not submit results. iv. Did not complete result form correctly. v. Lack of consensus. vi. Laboratory did not complete result form correctly i.e. wrong method code. b. In the laboratory's own policy titled Quality Assurance dated 01/06/2014 revised 06/07/2018 - " Proficiency tests which do not correlate with other participants or referees are reviewed by the department supervisor and an exception report is written and reviewed by the Technical Supervisor." 3. Interview of testing person 3 listed on the CMS report 209 Laboratory Personnel report conducted on September 26, 2018 confirmed that there were no other documentation of assessment of proficiency testing available for review. He asked if the signature of the Technical Supervisor was not documentation of review.

**D5775**

**COMPARISON OF TEST RESULTS**  
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:  
Observations, review of Panther correlation study records and interview facility personnel found that the laboratory failed to perform comparison studies for common analytes tested on the two Hologic Panther analyzers at least twice yearly. Findings were as follows: 1. Observations made during the tour the facility found that the laboratory used two Hologic Panther systems for patient testing. 2. Review of Panther correlation study records for 2017 and 2018 found one of three expected correlation studies which was performed on August 24, 2018 (not yet evaluated). There were no additional records available for review that would indicate that the laboratory performed twice yearly correlation studies for the tests performed on the Hologic Panther in 2017. 3. Interview of testing person 3 listed on the CMS Report 209 conducted on September 26, 2018 at 10:54 AM confirmed that the laboratory failed to perform twice yearly correlation studies for the tests performed on the Hologic Panther in 2017.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Review of proficiency testing records, policies and procedures and interview facility personnel found that the laboratory director failed to ensure that proficiency testing reports were reviewed to evaluate the laboratory's overall performance. (see D 5221)