GYN PT™

2018 Laboratory Enrollment Booklet

ASCP GYN PT and Lab Comparison™

The Centers for Medicare & Medicaid Services (CMS) has approved ASCP's GYN PT™ gynecologic cytology proficiency testing program under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, applicable sections of Subparts H and I.

Experienced ASCP customer service staff are at your service to answer questions, amend enrollments and assist with date changes. Call ASCP toll free at 312.541.4999.

The American Society for Clinical Pathology is a not-for-profit medical society.

- **ASCP's Mission:** To provide excellence in education, certification, and advocacy on behalf of patients, pathologists, and laboratory professionals.
- ASCP is an ACCME-accredited provider of *AMA PRA Category 1 Credit™* for physicians with a special recognition of exemplary compliance and listing as a "Best of Practices" provider by the ACCME.
- ASCP provides online education to address the needs of pathologists and technologists at www.ascp.org.

The Centers for Medicare & Medicaid Services (CMS) has approved the American Society for Clinical Pathology's gynecologic cytology proficiency testing program under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 for 2018.

According to CLIA regulations at §493.855(a) participation in an approved program is required when one becomes available: ***"The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by CMS ..."*** Therefore, each individual cytotechnologist and pathologist involved in the examination of gynecologic cytology specimens must enroll in a CMS-approved cytology proficiency testing program. Individual results are available through Laboratory Directors or CMS.

For a complete description of Federal CLIA regulations that apply to cytology proficiency testing visit:

Centers for Disease Control and Prevention: **https://www.cdc.gov.clia**

Centers for Medicare and Medicaid Services: **http://www.cms.gov/clia**

In order to ensure that proficiency testing occurs during the 2017 calendar year, all laboratories examining gynecologic cytology specimens must enroll in a CMS-approved GYN Proficiency Testing Program whether or not the actual PT event occurs in the laboratory.

- **ASCP** GYN PT™ enrollment begins **July 2017 for the 2018 calendar testing year.**
  Early enrollment increases your opportunity to receive your choice of testing date.

2018 ASCP GYN Proficiency Testing begins January 1, 2018 and ends December 31, 2018.
Re-testing events may extend into the first quarter of 2019 as necessary.

REVIEW ALL PAGES IN THIS ENROLLMENT BOOKLET

Refer to the following instructions to aid in the completion of the various forms.
Contact ASCP with questions related to the enrollment or testing process at 312.541.4999.

ORDER INFORMATION

- **SELECT THE PT PROGRAM FOR YOUR LABORATORY**
- **Note Part A:** General Laboratory Base Site Fee. Complete Parts B, C and D:
- **Part B:** GYN CLIA Certificate Site Registration Fee
- **Part C:** Individual Participant Fee
- **Part D:** Proctoring Options
- Sum the fees for the Grand Total for your institution for the 2018 annual **ASCP** GYN PT™ Proficiency Test
- Select 3 potential testing dates for ASCP GYN PT™ testing in your laboratory. ASCP will attempt to match one of your choices with an available testing date. Early enrollment will increase the chances of having your prefered testing date accommodated.

CONTACT, PAYMENT AND SHIPPING INFORMATION

CONTACT INFORMATION

- Provide Laboratory Director's name, address and contact information. If appropriate, provide an alternative contact person and their information. This information will be utilized for all communications regarding ASCP GYN Proficiency Testing.

PAYMENT INFORMATION

- Acceptable payment options include check, credit card (VISA/MASTERCARD/AMEX) or purchase order. Payment may be sent with enrollment or ASCP can invoice your institution.

SHIPPING INFORMATION

- Provide the preferred laboratory address for correspondence. Provide a secondary shipping address if address differs from laboratory address. Testing materials will be sent to the attention of the proficiency testing Proctor 1 selected by the Laboratory Director. Be sure to include the laboratory's CLIA number to ensure proper identification of the laboratory.

To ensure that the CMS PT Referral Policy is adhered to, please review the CMS PT Referral Policy located on page 19 of the 2018 Proctor Instructions prior to completing the GYN PT Enrollment form.

PROCTOR SELECTION PROCESS AND PROCTOR INFORMATION

- After carefully reviewing the Proctor Selection Process, fill out the Proctor Information Form(s) if choosing to use in-house Proctors. A minimum of two (2) Proctors must be selected for your institution.
- Verify that attestation statements have been signed and dated by the Laboratory Director and each Proctor.
- Return the Proctor Information Form with your enrollment information.

PARTICIPANT ENROLLMENT

A Participant Enrollment Form must be completed for each professional (cytotechnologist or physician) who examines gynecologic cytology preparations in your laboratory. Include all full-time, part-time, locum tenens and on-call personnel. Pathology residents and fellows are required to enroll in the ASCP's CMS-approved Proficiency Testing Program if they perform the final review/sign-out of GYN cases.

PARTICIPANT NAME

- Print the participant's full legal name
- If applicable, please indicate all other names used by the participant on certification or licensure information

Physicians

- Indicate whether the physician is a D.O. or M.D.
- Indicate whether the physician performs primary or secondary screening according to the guidelines given.
- Provide the Medical License number or State License number for the state where the test will be taking place (only one).

Cytotechnologists

- Indicate ASCP Board of Certification (BOC) number, HEW number or State License number (only one needed).

TESTING LOCATION

- Provide information regarding where the participant will be taking the proficiency test. If the participant listed will NOT be taking the proficiency test at the primary testing location listed, provide the name and address of the laboratory location where he or she will be taking the test.

ADDITIONAL PLACES OF EMPLOYMENT

- If the participant is evaluating GYN challenges at 2 or more labs, provide the information requested so that ASCP can provide required proficiency testing documentation to all labs identified.

CHALLENGE TYPES

- Indicate all GYN Prep types **routinely** evaluated: **C**=Conventional, **T**=ThinPrep, **SP**=SurePath
- *PT test sets will contain 100% of the GYN preparation type indicated as routinely evaluated.*

ATTESTATION STATEMENT, ENROLLMENT CHECKLIST AND SUBMISSION INSTRUCTIONS

- The Laboratory Director must sign the attestation statement regarding the Participant Enrollment Forms.
- Review checklist to verify that all listed items are completed and returned to ASCP for proper processing of enrollment.
- Review the ASCP contact information and enrollment return instructions.

Any institution may choose to have ASCP Proctors administer the PT test for an additional fee. If the Laboratory Director decides to choose in-house Proctors to administer the ASCP GYN Proficiency Test on-site, the following criteria should be considered when reviewing potential candidates:

- It is required that the laboratory select a minimum of two Proctors, a primary Proctor (referred to as Proctor 1) and one alternate (Proctor 2). Proctor 1 should be someone who is not taking the on-site PT exam on the same day that it is being administered in your laboratory. **A cytotechnologist or pathologist can only be Proctor 1 if they take the on-site PT at another laboratory or on a different date.**

Suggestions for personnel who could serve as Proctor 1 include:

> **NOTE:** A primary Proctor (referred to as Proctor 1) should be someone who is not taking the on-site PT exam on the same day that it is being administered in your laboratory. A cytotechnologist or pathologist can only be Proctor 1 if they take the on-site PT at another laboratory or on a different date.

Clerical staff, Office Manager, Cytology Preparatory Technician, Histotechnologist, Clinical Laboratory Supervisor, Laboratory Manager, Laboratory Supervisor from another department, Quality Assurance Director, or Corporate Compliance Officer.

- It is recommended that at least one of the Proctors be familiar with microscopy and can spot-check any challenges for residual dots if challenges need to be cleaned at the facility.
- A cytotechnologist or pathologist who is taking the on-site PT exam at the laboratory can function as Proctor 2 providing Proctor 1 administers the PT exam to them prior to testing the remaining participants. **PROCTORS CAN NOT PROCTOR THEIR OWN TESTING EVENT.** Proctor 2 can then assist Proctor 1 in administering the PT exam to the other participants. Example: The morning of the test, Proctor 1 assigns the appropriate Test Challenges Box to the Cytology Supervisor, who will function as Proctor 2. After Proctor 2 has completed the test, he/she is then available to assist Proctor 1 in administering the PT test to the other PT test participants.
- Laboratories with a large number of PT participants may want to select more than two (2) Proctors to facilitate the smooth administration of the PT exam. Proctors can determine in advance how they will coordinate shared responsibilities.
- A comprehensive Proctor training document must be reviewed within 30 days of your scheduled testing event and is available online at http://www.ascp.org/proficiencytesting/
- Following review of this material, the Proctor is required to pass a 20 question online quiz to be certified as an ASCP GYN PT Proctor.
- Testing materials will NOT be shipped to the facility until the primary Proctor (Proctor 1) successfully passes the online proctor quiz. If the primary proctor (Proctor 1) does not achieve a passing score of 90% or better within the two attempts, another primary Proctor Proctor 1) must be selected and ASCP notified to add them to the testing event.

PROCTOR RESPONSIBILITIES

Proctors will NOT be responsible for the grading of any proficiency testing forms and do not have the answers to test sets. All scoring takes place at ASCP.

The selected Proctors must be able to carry out the following responsibilities and acknowledge that they accept the following duties:

- Review the Proctor orientation training document and successfully complete the Online Proctor Quiz
- Unpack testing supplies and verify that:
    1. Security seals are intact on Test Challenge Boxes and
    2. All testing materials listed on the Packing Slip arrived in good condition
- Follow ASCP protocol for handling damaged PT Test Challenge Boxes
- Immediately notify ASCP of missing test materials or if security seals on Test Challenge Boxes were broken
- Provide basic instructions to PT test participants
- Match pre-labeled Proficiency Test Result Forms to each appropriately identified participant
- Assign the correct type of PT Test Challenge Box to each participant
- Ensure that each participant completes the PT within 2 hours or less
- Ensure that the PT Challenges are not altered in any way during the test except for the addition of ink dots to indicate cells for review by secondary screening pathologist participants
- Collect Proficiency Test Result Forms at the conclusion of each participant test and ensure the confidentiality of participant responses during and after the testing process
- If necessary, remove all dots from completed PT Challenges and reassign Test Challenge Boxes to the next cytotechnologist or primary-screening pathologist participant
- Sort all pre-screened, dotted PT Test Challenge Boxes by noting type of Challenge preparation for distribution to pathologist participants who require pre-screened cases for their PT exam
- Assign Test Challenge Boxes to secondary screening pathologists randomly from the appropriate group of pre-screened and dotted Test Challenge Boxes, matching the preparation types indicated on the pre-labeled Proficiency Test Result Forms for the pathologist(s)
- Monitor the integrity of the testing environment
- Ensure that each participant fills out the PT result form completely and accurately including Start and Stop Times
- Copy and distribute ASCP GYN PT Participant Evaluation Forms to PT participants
- Sign attestation statement that the ASCP protocol for administration of the GYN PT exam was followed
- Repack all PT Test Challenge Boxes, Proficiency Test Result Forms, evaluation forms, and Proctor attestation statement in the provided EXPRESS shipping container and call for pickup immediately upon completion of testing
- Report any problems with the PT process to ASCP PT personnel toll free at 312.541.4999
- Ensure that the integrity environment is maintained (no discussion of cases before, during or after testing event; no utilization of reference materials; and no photography of cases)

A. GENERAL LABORATORY TESTING SITE BASE FEE (Select One)

ASCP GYN PT™ - A stand-alone GYN proficiency test that fulfills federal CLIA requirements. (PT18-GLASS) $ 995.00 **Subtotal:** $_____

ASCP GYN PT and Lab Comparison™ - A complete solution for PT compliance and lab accreditation. There are two components - one shipment of ASCP GYN PT™ and a separate shipment at a different date of the Laboratory Comparison program, which consists of 12 glass slides for interlaboratory comparison, which fulfills CAP/LAP lab accreditation requirements. (PTLC18) $1350.00 **Subtotal:** $_____

CAP Laboratory Accreditation No. (required for reporting): _____

B. GYN CLIA CERTIFICATE SITE REGISTRATION FEE ONLY (No Testing)

Calculate total cost @ $500 per site X _____ sites = $_____
(PTCLIA18)

List site only 10-digit CLIA #'s here: 1_____ 2_____ 3_____
4_____

Subtotal: $_____

C. INDIVIDUAL PARTICIPANT FEE

"All CLIA certified laboratories must ensure that each individual performing gynecologic cytology examinations is enrolled in a CMS-approved cytology proficiency testing program..."

$90 x _____(total # of Cytotechnologists/Pathologists at Laboratory) (PT-GLASS-PART) **Subtotal:** $_____

The number of participants above must match the number of individuals submitted on the Participant Enrollment Forms.

D. PROCTORING OPTIONS (Select One)

☐ **Option 1:** If you do not wish to use in-house Proctors, ASCP can send a trained Proctor to your facility. A fee of $500 for this service is due with enrollment. Additional expenses (air, hotel, per diem) will be invoiced post testing. (PTPRC118)

☐ **Option 2:** The Laboratory Director will designate Proctors from our facility or a neighboring facility. No additional fee. **Subtotal:** $_____

Total Cost for Annual PT (A + B + C + D): $_____

Please indicate your top three testing dates (month/day) in order of preference for your 2018 **ASCP** GYN PT™ Testing. ASCP will schedule your testing for ONE of these dates.

1_____ 2_____ 3_____

If ASCP GYN PT and Lab Comparison™ is chosen please indicate your top three dates (month/day) in order of preference for your Lab Comparison review. ASCP will schedule your lab review for ONE of these dates.

1_____ 2_____ 3_____

CONTACT INFORMATION

Laboratory Director _____

Laboratory Director's e-mail _____

Phone _____ Fax _____

Institution _____

Laboratory CLIA Number _____

Address _____

Address _____

City _____ State _____ ZIP_____

Alternative Contact_____

Alternative Contact's e-mail _____

Phone _____ Fax _____

PAYMENT INFORMATION* *(Remember: Payment or PO must accompany enrollment)*

☐ Check Enclosed (payable to ASCP)

☐ Purchase Order # _____

**For your protection, ASCP no longer gathers credit card info via mail or fax. Please call to give ASCP your credit card information.*

SHIPPING INFORMATION (where test sets should be sent, if different from above)

☐ CHECK HERE IF SAME AS ABOVE

Institution _____

Laboratory CLIA Number _____

Address _____

Address _____

City _____ State _____ ZIP_____

If Proctor Option 1 was selected on Page 4, Section D, ASCP will provide Proctors at an additional fee. Do not complete this form.

If Proctor Option 2 was selected, this form must be completed. The Laboratory Director must choose a minimum of two (2) Proctors from the participating institution or another institution. The Laboratory Director must sign the Proctor certification statement below and each listed Proctor must sign and date their agreement to accept the responsibilities of being a Proctor.

As Laboratory Director, I hereby certify that the individuals selected as Proficiency Testing Proctors meet the criteria specified and are capable of performing responsibilities as described on Page 5.

Laboratory Director's Signature _____ Date _____

Proctor 1 (All Testing Materials will be shipped to the attention of Proctor 1)

Proctor Name _____ Title _____

Phone _____ Fax _____ Email _____

Address _____

City/State/Zip _____

I accept the responsibility of performing the duties of the Proficiency Testing Proctor.

Proctor 1 Signature _____ Date _____

NOTE: A primary Proctor (referred to as Proctor 1) should be someone who is not taking the on-site PT exam on the same day that it is being administered in your laboratory. A cytotechnologist or pathologist can only be Proctor 1 if they take the on-site PT at another laboratory or on a different date.

Proctor 2

Proctor Name _____ Title _____

Phone _____ Fax _____ Email _____

Address _____

City/State/Zip _____

I accept the responsibility of performing the duties of the Proficiency Testing Proctor.

Proctor 2 Signature _____ Date _____

For larger laboratories, more than two proctors may be advisable. Make copies of this page to add information about proctors as needed.

Complete this form for each participant enrolling in ASCP GYN PT™ or ASCP GYN PT and Lab Comparison™.

Please note that all information related to GYN Proficiency Testing is handled by employees of ASCP with confidentiality.
All testing results are sent directly to CMS and the Laboratory Director.
Under no circumstances are individual results shared or discussed with an unauthorized individuals.

PARTICIPANT INFORMATION:

- **NAME**: First_____ M.I._____ Last_____
- **Other name(s) used** (maiden name, change of name)

  (1) _____ (2) _____ (3) _____
- **CMS PTR#** (if known): _____
- **Physician details:** 1. **Circle one** that applies: **M.D.** or **D.O.**

  2. **Check one** category of **Primary** or **Secondary** screener as defined:
  - ☐ A. **Primary** Screener of GYN materials (even if one case/year)
  - ☐ B. **Secondary** Screener (always screens pre-dotted GYN challenges)

  3. Please provide **one license number** as noted below (used by ASCP as a unique identifier only)

  A. Medical Licensure Number _____
  B. State Licensure Number (where PT testing will occur) _____
- **Cytotechnologist details:** (Note: new graduates who passed the ASCP Board of Certification exam for 2016 **are not required** to take a CMS-approved GYN proficiency test in 2016)

  1. Please provide **one credentialing number** as noted below (used by ASCP as a unique identifier only)

  A. ASCP BOC#: _____ B. HEW _____ C. State Licensure Number(s) _____

- ***ASCP PROVIDES A CHOICE OF GYN PREPARATION TYPES. TEST SETS WILL CONTAIN 100% OF THE CHOSEN PREP TYPE. SELECT ONE PREPARATION TYPE MOST ROUTINELY EVALUATED BY THIS INDIVIDUAL:***

  C=Conventional **T**=ThinPrep **SP**=SurePath

- **IS THIS PERSON TESTING AT THIS LOCATION? CIRCLE YES or NO** If NO, please indicate where will testing occur:

  Laboratory Director _____
  Institution _____
  Address _____
  Address _____
  City _____State_____ZIP_____

IS ENROLLEE CURRENTLY EVALUATING GYN CHALLENGES AT TWO OR MORE LABS? CIRCLE YES or NO

If YES, provide information for each lab for ASCP to forward testing results to the Lab Director.

Laboratory Director _____

Institution _____

Address _____

Address _____

City _____State_____ZIP_____

Approximately 30 days prior to testing, ASCP will send a verification letter to your institution listing each individual enrolled in ASCP GYN PT™. You will have the opportunity to amend participants at that time.

ATTESTATION STATEMENT

I hereby affirm that the information provided on the participant testing logs included with this enrollment is true and complete, and includes the names of all individuals who diagnose, screen or review gynecologic cytology specimens at this laboratory

In addition, I hereby attest that I will ensure that all proficiency testing is done in an independent manner without the utilization of reference materials. I also acknowledge that I am aware that the photography of any testing materials is prohibited.

Signature of Laboratory Director _____ Date _____

ENROLLMENT CHECKLIST

- ☐ Order Information Form
- ☐ Contact, Payment and Shipping Information Form
- ☐ Proctor Information Forms (if applicable)
- ☐ Participant Enrollment Forms for all personnel evaluating GYN specimens
- ☐ Attestation Statement
- ☐ Payment check (if not paying by purchase order or credit card)
- ☐ Fax or mail pages 6-10

SUBMISSION INSTRUCTIONS

Make a copy of all enrollment materials for your records

To submit enrollment by:

Phone
312.541.4999, ext 3902 (international callers: 312.541.4890)
Monday-Friday (8:30am–5:00pm CT)
Have your email address and credit card available.

Fax*
312.541.4472
Please include email address and a copy of your purchase order with the registration form anytime.

Mail*
ASCP
3462 Eagle Way
Chicago, IL 60678-103
Include email address, a check payable to ASCP, or a completed purchase order.

*For your protection, ASCP no longer gathers credit card info via mail or fax.
Please call to give ASCP your credit card informations.