



STRONGERTOGETHER

2017 Proctor Instructions

ASCP GYN Proficiency Test Administration Booklet

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SECTION A

ASCP GYN PROFICIENCY TEST ADMINISTRATION:

PROCTOR INSTRUCTIONS

I. PROCTOR RESPONSIBILITIES PRIOR TO TEST ADMINISTRATION

- A. Review all of the Proctor Training Manual 30 days prior to the testing date.
- B. Successfully complete Proctor Quiz at least one week prior to the test date (see quiz information in this document).
- C. Print Proctor Training Certificate for documentation through the ASCP online education portal.
- D. Define shared duties among Proctors. Proctors should discuss how Proctor responsibilities will be shared during the administration of the test, prior to the scheduled on-site test date.
- E. Determine test schedule. In cooperation with the Laboratory Director, the Proctor will determine the timing of the proficiency test for all participants.
 1. The test should be administered within the laboratory's normal working hours as much as possible to mimic the normal working environment.
 2. Ask the Laboratory Director to inform you if there are specific times that certain individuals need to take the test. For example, pathologists may cover other facilities in the morning and need to take the test in the afternoon, or a part-time cytotechnologist may only work in the afternoon or weekend.
 3. It is recommended that you establish specific scheduled test times for each individual participant and inform them of the schedule in advance of the test, so they may plan their daily work activities accordingly.
- F. Review the procedures you will use to assign and handle Test Challenge Boxes for each participant, ensuring you are comfortable with procedures and have **contacted ASCP with any questions prior to the date of test administration**.
- G. Gather or make arrangements for test-related supplies: dotting pens; Challenge cleaning supplies; microscope for reviewing Challenges for residual dots, etc.
- H. Review attachments to this document to become familiar with their content and use.
- I. Review the **Proctor Test Administration Checklist** which will be used at the time of testing to track all aspects of the testing process, verify that procedures were followed, and document any broken Challenges.

TO ENSURE COMPLIANCE WITH CMS' PT REFERRAL POLICY, ALL TESTING INDIVIDUALS MUST COME TO THE "SLIDES" (TEST BOXES). TESTING MATERIALS CANNOT BE TRANSPORTED TO TESTERS AT OTHER FACILITIES/LOCATIONS.

II. PROCTOR RESPONSIBILITIES DURING TEST ADMINISTRATION

A. Receipt of Test Materials

1. Testing materials should arrive by either Fed-Ex or UPS Courier delivery two business days before the scheduled test date. (Testing materials for proficiency tests scheduled on a Monday will arrive at the laboratory on the previous Thursday.) This allows additional time to handle shipping delays and client needs, and may allow for additional testing time, as long as a Proctor is available to administer the test.

DO NOT DESTROY THE SHIPPING BOX – IT WILL BE USED FOR THE RETURN SHIPMENT.

2. Testing materials will be sent to the shipping address listed on the laboratory enrollment form to the attention of Proctor #1. ASCP cannot ship to P.O. Boxes.
3. If proficiency testing materials do not arrive one or two days before the scheduled test date **call ASCP at 312.541.4999 ext 3902 immediately for shipment tracking.**



B. Verification of Test Documents

Verify that the following documents are contained in the material box, contact ASCP at 312.541.4999 ext 3902 immediately with any questions or concerns.

1. Chain of Custody Record
2. Proctor Test Administration Checklist
3. Proctor Test Administration Instructions
4. Proficiency Test Instructions for Participants
5. Proficiency Testing Result Forms
6. PT Scoring Charts
7. Proficiency Test Process Evaluation Form
8. Add New Participants Form
9. Participant Excused Absence Form
10. Procedure for Cleaning Challenges & Handling Broken Test Challenges
11. Fed-Ex or UPS Pre-addressed Return Shipment Label
12. ASCP Security Envelope (to be used for the return of documents)

C. Verification and Inspection of Test Challenge Boxes

1. Verify that all Test Challenge Boxes have been received by reviewing the Chain of Custody Record (See attachment A, page 21 of this document) to check that the total number and GYN PREP Type of Test Challenge Boxes received match the total number and the types of boxes listed.
 - a. The GYN PREP Type of Test Challenge Box is determined by looking at the bar code label on the outside of the cardboard box. The bar codes refer to the type of Challenges each participant is eligible to receive for their proficiency test, based on enrollment information about the type of Challenges they examine in the laboratory.
 - b. The Test Challenge Boxes are labeled as follows:
 - i. "C" for conventional Pap smear test Challenges
 - ii. "T" for ThinPrep Challenges
 - iii. "SP" for SurePath Challenges
2. **Instruct laboratory personnel not to open the Test Challenge Boxes. The security seal must be intact when the official Proctor(s) opens the boxes to inspect for damage.** This is verification that participants did not examine test Challenges prior to the start of the proficiency test. If the security seal has been broken, the Test Challenge Boxes cannot be used for the test. *Notify ASCP immediately so that replacement Test Challenge Boxes can be shipped overnight.*
3. The Proctor(s) should break the Security Seal and open each Test Challenge Box to examine the 10 glass test Challenges inside the Styrofoam Challenge holders for evidence of damage or breakage. If any of the Challenges are damaged or broken, refer to the Handling Broken Test Challenges procedure. *Notify ASCP immediately so that replacement Test Challenge Boxes can be shipped overnight.*
4. Based upon enrollment information provided by your facility, ASCP will pre-determine the sufficient number of Test Challenge Boxes necessary to test all proficiency test participants in the allotted time. This determination will be based on the following formula, with a minimum of one (1) Box for every four (4) participants:

Number of Cytotechnologists & MD/Pathologists performing primary screening	Number of ASCP GYN PT™ Test Challenge Boxes
1 to 20	1 Box for every 2 primary screening individuals
21 and above	1 Box for every 3 primary screening individuals



EXAMPLE #1 Matching Test Challenge Boxes received with Chain of Custody Record

There are 6 Test Challenge Boxes, including 1 with the “C” bar code prefix and 5 with the “T” bar code prefix listed on the **sample Chain of Custody Record**. In unpacking a real shipment box you would verify that there are 6 cardboard boxes sealed with a security seal, including 1 boxes labeled with a “C” bar code prefix, and 5 boxes labeled with a “T” bar code prefix.

5. For the testing event, and especially if participants have been added, verify that the number and GYN PREP Type of Test Challenge Boxes received are adequate for the cytotechnologists (Cytotech) and Primary screening pathologists (MD) listed on the ASCP PT Participant Test Log to test on the dates available.

REMEMBER—THE TEST CHALLENGE BOXES DO NOT NEED TO BE SHIPPED BACK TO ASCP UNTIL THE DAY AFTER THE SCHEDULED TESTING DATE. THEREFORE, ADDITIONAL TESTING CAN BE SCHEDULED FOR THE NEXT MORNING PRIOR TO RETURNING THE MATERIALS TO ASCP IF NECESSARY.

EXAMPLE #2 Determining whether the number and type of Test Challenge Boxes received for the test is adequate to test all participants

There are 6 Test Challenge Boxes, including 1 with the “C” bar code prefix and 5 with the “T” bar code prefix listed on the sample Chain of Custody Record. In unpacking a real shipment box you would verify that there are 6 cardboard boxes sealed with a security seal, including 1 boxes labeled with a “C” bar code prefix, and 5 boxes labeled with a “T” bar code prefix.

There are 12 Cytotechs and 1 primary screening MD* participant listed in the sample **ASCP PT Participant Test Log (page 24 of this document)**. Three of the Cytotechs require “C” boxes and 9 require “T” boxes. The primary screening MD* requires a “T” box. There are only 6 Test Challenge Boxes, including 1 with the “C” bar code prefix and 5 with the “T” bar code prefix sent for this sample test.

This is an adequate number of Test Challenge Boxes since the test Challenges can be cleaned and reassigned to the other participants. One of the “C” boxes can be cleaned of dots and assigned to another Cytotech requiring the “C” GYN PREP Type bar code pre fix; one of the “T” boxes can be cleaned of dots and assigned to another Cytotech requiring the “T” GYN PREP Type bar code prefix; and one of the “T” boxes can be cleaned of dots and assigned to the primary screening MD* requiring the “T” GYN PREP Type bar code prefix. See EXAMPLE #5 & 6 for methods used to reassign Test Challenge Boxes.

Note: MD indicated Primary Screening MDs.*

D. Storage of Test Materials

1. After the Proctor has inspected the test materials to verify their condition and ensure that all are present, the testing materials must be placed in a locked and secure location to be retrieved by the Proctor just prior to the start of the proficiency test.
2. *Materials must be secured before and between each testing event.*



E. Documentation of Participants

1. **Review the ASCP Participant Test Log** included with the test materials and check it against those available to participate in the test at the pre-scheduled date and time.
2. **Verify the identity** of each test participant by checking a facility ID badge or government issued photo-ID if the individual is unknown to you.
3. **Add New Participants:** If there are PT participants present on the scheduled test date who have not been enrolled by the laboratory or registered by ASCP prior to the scheduled on-site test, the Proctor must ensure the following:
 - a. The laboratory director completes the **Add New Participants Form (see sample form on page 30 of this document)** with all of the required information and returns the **Form** with payment.

NOTE: NEWLY BOARD CERTIFIED CYTOPATHOLOGISTS, NEWLY CERTIFIED ANATOMIC PATHOLOGISTS AND NEWLY GRADUATED CYTOTECHNOLOGISTS WHO PASSED THEIR EXAM WITHIN THE SAME CALENDAR YEAR ARE EXEMPT FROM GYN PT TESTING THAT SAME CALENDAR YEAR.

- b. Fax this form to ASCP as soon as possible at 317.569.0221.
 - c. Call ASCP if you have any questions about whether there are enough Test Challenge Boxes containing the appropriate GYN PREP Type bar code to test the added-on PT participant or if you need any assistance with the enrollment process.
 - d. Extra blank **Proficiency Testing Result Forms** will be included in the testing packet for these “last minute” PT participants. Make sure the pertinent participant information is written onto the **Proficiency Testing Result Form** to ensure that the PT participant score is accurately recorded.
 - e. Write the new participant’s full name on the **ASCP PT Participant Test Log**. If you receive a Participant Test Record # (PTR#) from ASCP, or the participant already has PTR #, record this number on the test log. Otherwise record the ASCP registry number for cytotechnologists or State medical license number for pathologists. Record the bar code number of the assigned Test Challenge Box in the appropriate column.
4. Documenting Absences: The Proctor shall ensure that the Laboratory Director completes:
 - a. **The Participant Excused Absence Form** for those participants who miss the exam.
 - b. Documents any unexcused absence from the test event.

PROCTORS WHO ARE ALSO TESTING INDIVIDUALS MUST TEST FIRST AND HAVE A CERTIFIED PROCTOR OVERSEEING THEIR TESTING EVENT. PROCTORS MAY NOT PROCTOR THEMSELVES.

F. Review Information with Proficiency Test Participants

1. Review the following instructions and documents with all PT participants. This can be done in a group setting or individually as tests boxes are assigned.
 - a. **ASCP Proficiency Test Instructions**
 - b. **PT Scoring Chart and Guide** to ensure all participants understand how their PT test will be graded. Participants need a score of 90% to successfully complete the test.
2. Inform participants that a **maximum of two (2) hours** is provided to complete the ten (10) Challenge exam. Proctors can document legitimate time spent away from the test for special circumstances. Contact ASCP customer service at 800.267.2727 for any questions or concerns.
3. Emphasize that the test Challenges are to be diagnosed independently, and there should be no discussion of the test Challenges with other participants during the exam, after the exam with participants who have not yet taken the test, or until the testing materials have been shipped to the **ASCP GYN PT™** location and left the testing facility. Contact ASCP customer service at 800.267.2727 for any questions or concerns.



Example of Non-Compliance: Independent Review

GYN PT Testing was conducted on the pre-scheduled GYN PT testing date. Upon completion of the testing event, the QA/QC Director reviewed all completed GYN PT answer sheets in conjunction with the glass slide test boxes to identify variations in answers rendered on the same test boxes. Once variations were identified, the glass slides were pulled and reviewed to determine the correct response. Findings were discussed with the testers and the original answer sheets were given back to the Proctor to send to the GYN PT Provider for scoring.

Infraction: Violation of testing integrity. Test Challenges are to be diagnosed independently and there should be no discussion of challenges with participants during the exam, after the exam with participants who have not yet tested, or until the testing materials have physically left the testing facility.

CMS Ruling: The Clinical Laboratory Improvement Amendments (CLIA) sanction, in the form of a Civil Money Penalties (CMP), was issued. The CLIA Regulations at §493.1834 specifies the range of CMPs from \$50 - \$10,000 per day of non-compliance or per violation. Each slide may be considered a violation. The involved Proctor was no longer allowed to serve as a Proctor at that location or any other. In addition, the testing location was required to utilize high-level individuals outside the cytology department to serve as Proctors or pay for onsite proctoring to be done by the GYN PT Provider.

What other option(s) would have been compliant?: Only option was to allow no discussion of challenges with participants during the exam, after the exam with participants who have not yet tested, or until the testing materials have physically left the testing facility. Educational intervention could happen upon return of the GYN PT Testing results.

4. Inform participants that they may not refer to textbooks, atlases, or other reference materials during the test.
5. Ensure that test participants have a **black** pen to mark the bubbles on the **PT Result Form**.
6. Remind test participants to use **dotting pens** for marking the test Challenges containing ink that can be removed by alcohol. Instruct them not to use paint or some other medium for marking the Challenges that cannot be easily removed.
7. Instruct participants to **sign** the attestation statement at the bottom of the **PT Result Form** at the conclusion of the test, attesting they diagnosed the cases independently.

G. Distributing Test Documents and Supplies

1. Provide each participant with the following documents. Please see PT Test Administration Packet sample:
 - a. **Proficiency Test Instructions**
 - b. **Proficiency Test Scoring Chart and Guide**
 - c. **Important Test Details**
 - d. **Proficiency Testing Result Form**—Ensure that each participant signs the statement verifying they have read and understood all directions regarding the test.
 - e. **ASCP PT Process Evaluation Form**
2. Provide the following physical supplies as needed:
 - a. Dotting pens—participants are required to use dotting pens to mark the PT test Challenges with ink that can be removed by alcohol, since dots will need to be removed prior to assigning the Test Challenge Box to the next primary screener or to returning to ASCP.
 - b. Supplies to clean challenges, e.g. alcohol, paper towels, gauze, to wipe the Challenges clean between primary screenings by Proctors or to remove unwanted dots by cytotechnologists.

c. **Black** ink pens to mark answers on the **Proficiency Test Result Form**.



H. Distributing Test Challenges Boxes

1. Proctors will assign the Test Challenge Boxes to the **Primary screeners first**, since they will be prescreening and dotting the test Challenges for the secondary screeners / pathologist participants. Some pathologists may be primary screeners and can receive their test sets with the initial distribution as noted below.
2. Using the **ASCP PT Participant Test Log**:
 - a. Refer to the “GYN PREP Type Prefix” column to determine the type of test box to distribute to each participant.
 - b. The Proctor will record the bar code prefix and number of the Test Challenge Box assigned to each participant under the “Test Box Assigned” column.
3. Pathologists who perform primary screening of gynecologic cytology Challenges without prescreening and dotting by a cytotechnologist are denoted as “ P” on the Participant Test Log and as “Screeener Type: P” on the **Proficiency Testing Result Form**.
 - a. Assign the Test Challenge Boxes to the MD* pathologists following the same guidelines described above (assigning Test Challenge Boxes that have not been prescreened or dotted by the cytotechnologist).
 - b. If a pathologist screens previously unevaluated Challenges at any time in their daily practice, they **must** be assigned a previously unevaluated Test Challenge Box.
4. If time allows, each Test Challenge Box may be assigned to up to four different Cytotech or primary screening MD* participants requiring the same GYN PREP Type bar code prefix, if the test Challenges are cleaned of dots prior to assignment to each of the participants.
5. The same prescreened and dotted Test Challenge Boxes can be assigned to multiple pathologists requiring the same GYN PREP Type bar code prefix as long as sufficient time to take each test is provided. **No discussion or sharing of answers for any set is permitted.**
6. **To ensure compliance with CMS’ PT Referral Policy, all testing individuals MUST come to the “slides” (Test Boxes). Testing materials CANNOT be transported to testers at other facilities/locations.**

Example of Non-Compliance: CMS PT Referral Policy

GYN Proficiency Testing documentation was pulled for review during an annual laboratory inspection. The documentation revealed that the one set of GYN PT testing materials were being utilized by multiple hospital satellites, with the Proctor transporting the GYN PT testing materials to each satellite location rather than having the testers go to the slides. The Hospital was cited by the accrediting body for violation of the CMS PT Referral Policy and was reported to CMS for review.

Infraction: Violation of CMS PT Referral Policy. The GYN PT glass slide testing materials cannot be transported offsite to the other hospital satellites. The Testers must GO TO the location that the glass slides were shipped to.

CMS Ruling: CMS ruled that the PT Referral Policy was violated and the imposition of a Civil Money Penalty per infractions (slide) was under consideration. Scores were changed to 0% for all individuals involved in the PT Referral and all individuals were required to retest within 45 business days.

What other option(s) would have been compliant?: Option 1) Have all testing individuals travel to one location for testing (location where slides are shipped to). Option 2) Purchase GYN PT Testing for each location.

EXAMPLE #3 Assigning and Recording Test Challenge Boxes on Participant Test Log

In the **sample ASCP PT Participant Test Log** included with these instructions, Cytotech participant Number 1, PTR # CMS00100, may be assigned a Test Challenge Box with the “T” bar code prefix. You would record the Test Challenge Box number with a “T” bar code prefix that you gave to PTR# CMS00100 in the “Test Box Assigned” column on the same row, listed here as T442.

I. Receiving Completed Test Challenge Boxes

When a cytotechnologist turns in their completed **Proficiency Testing Result Form** and Test Challenge Boxes to the Proctor:

- a. Verify each participant has completed all of the **required information** on the form, such as the **start and finish time for the test, the Test Challenge Box number, inked in all the bubbles for the test results, and signed the attestation statement at the bottom of the form.**
- b. Take each Test Challenge Box returned and perform **one** of three functions:
 - i. Sort all prescreened and dotted PT Test Challenge Boxes by box prefix (C versus T versus SP) for distribution to pathologist participants who require prescreened and dotted cases for their PT exam. Then assign Test Challenge Boxes to those pathologists **randomly** from the appropriate group of prescreened and dotted Test Challenge Boxes, matching the GYN PREP Types indicated on the pre-labeled **Proficiency Test Result Forms** for the pathologist(s). **Pathologists cannot request a Test Challenge Box screened by a specific cytotechnologist. – OR –**
 - ii. Remove the dots from the test Challenges and assign the Test Challenge Box to another cytotechnologist who requires the same GYN PREP Type bar code; – **OR** –
 - iii. If no other cytotechnologists or pathologists require a Test Challenge Box with the same GYN PREP Type bar code, check the Styrofoam Challenge holders to ensure they contain all 10 Challenges. Clean the Challenges following the **Cleaning Proficiency Test Challenges** protocol, and return the Test Challenge Box to the shipping container for return to ASCP. Place the completed **Proficiency Testing Result Form** in the Security envelope.

J. Redistributing Completed Test Challenge Boxes

1. For Pathologists designated as “secondary screeners”:
 - a. If a pathologist requires a Test Challenge Box with the same GYN PREP Type bar code prefix as that completed by a cytotechnologist, then **randomly** assign a prescreened and dotted Test Challenge Box and **provide a copy of the cytotechnologist’s completed Proficiency Testing Result Form to that pathologist.**
 - b. Verify the identity of the pathologist, distribute the preprinted **Proficiency Testing Result Form** with their name on it, and record the Test Challenge Box number on the **ASCP PT Participant Log** as described above.
 - c. Follow this procedure until all pathologists have received Test Challenge Boxes.
 - d. If multiple pathologists receive the same Test Challenge Box screened by the same cytotechnologist, keep the dots made by the cytotechnologist on the Challenge, and provide a copy of the accompanying **Proficiency Testing Result Form** completed by the cytotechnologist to the pathologist taking the test. **DO NOT** pass the pathologists’ completed test result forms on to the other pathologists taking the proficiency test.
 - e. If a pathologist was originally scheduled to receive a prescreened and dotted Test Challenge Box but decides during the exam that he/she wants a previously unevaluated Test Challenge Box, remove the dots from a Test Challenge Box with the appropriate GYN PREP type, and assign to the pathologist following the steps detailed in section H.



EXAMPLE #4 Assigning Prescreened and Dotted Test Challenge Boxes to Pathologists

In the sample **ASCP PT Participant Test Log** included in these instructions, Cytotech participant number 1, PTR # CMS00100 was assigned Test Challenge Box C442. When PTR# CMS00100 completed that test box it was assigned to pathologist (MD) participant number 14, PTR # CMS00113, who is eligible to review GYN PREP Type “C” prefix Test Challenge Boxes. Notice that “Prescreened C442” has been recorded in the “Test Box Assigned” column for PTR# CMS00113. The test box number was filled in for illustration purposes only in this sample test. When you are performing the test assignments yourself, you will need to record the actual test box number you assigned.

2. For Cytotechnologists:

- a. If another cytotechnologist requires a Test Challenge Box with the same GYN PREP Type bar code prefix as that completed by the initial cytotechnologist, then remove the dots from the test Challenges following the **Cleaning Test Challenges** protocol.
- b. Verify the identity of the cytotechnologist, distribute the **Proficiency Testing Result Form** with their name preprinted on it, and record the Test Challenge Box number assigned on the **ASCP PT Participant Log** as described in above.
- c. Follow this procedure for other cytotechnologists until all have been assigned Test Challenge Boxes.
- d. **DO NOT** pass on the **Proficiency Testing Result Form** completed by the initial cytotechnologist when subsequent cytotechnologists receive the same Test Challenge Box. Ensure all dots have been removed prior to distributing the test Challenges to the next participant. It may be necessary to check the Challenges microscopically to ensure that all dots have been removed.

EXAMPLE #5 Reassigning Test Challenge Boxes to Additional Cytotechnologist Participants

There are 12 cytotechnologist participants (Cytotech) listed in the sample **ASCP PT Participant Test Log** included with these instructions. Looking at the column labeled “GYN PREP Type Prefix” you will see that three of the Cytotech participants require “C” boxes and 9 require “T” boxes. The laboratory received 6 Test Challenge Boxes, 1 with “C” bar code prefix and 5 with “T” bar code prefix, in the shipment for this sample test described in Example #1. So, more than one of the “T” bar code prefix Test Challenge Boxes and the “C” bar code prefix Test Challenge Box will need to be reassigned to other Cytotechs.

Looking at the “Test Box Assigned” column on the sample **ASCP PT Participant Test Log**, Test Challenge Box C445 was initially assigned to Cytotech participant 3, PTR # CMS00102. After PTR# CMS00102 completed the box, the dots were removed and Test Challenge Box C445 was reassigned to Cytotech participant 11, PTR # CMS00110. Test Challenge Box C982 was initially assigned to Cytotech participant 4, PTR # CMS00103. Test Challenge Box C982 was then reassigned to Cytotech participant 9, PTR # CMS00108 after the dots were removed.



EXAMPLE #6 Reassigning Test Challenge Box to MD*

In the “Cytotech/MD or MD*” column on the sample **ASCP PT Participant Test Log** included with these instructions, MD participant number 15, PTR# CMS00114 is a MD* requiring a Test Challenge Box with a “T” bar code prefix. Any unscreened Test Challenge Box with a “T” bar code prefix may be assigned to this participant. Notice the “Test Box Assigned” column does not list “prescreened” for the “T” prefix listed for this participant. In this sample test Cytotech participant 2, PTR # CMS00101 was initially assigned Test Challenge Box T443. After the dots were removed Test Challenge Box T443 was reassigned to PTR# CMS00114.

K. Monitoring the Testing Environment

Proctors **must** monitor the environment of the testing location throughout the test to ensure confidentiality of test results.

1. Do not allow test participants to discuss test Challenges at any time during the testing process.
2. Participants are not to alter the test Challenges in any way except for the addition of ink dots to indicate cells of interest for review by the pathologist.
3. Proctors must keep completed Proficiency Testing Result Forms in the Security envelope with them at all times, until they are packed in the return shipping container. Completed Proficiency Test Result Forms **must not** be removed from the security envelope for any reason.

Example of Non-Compliance: Monitoring

GYN PT Testing was conducted on the pre-scheduled GYN PT testing date with all but one of the testers completing the testing process. The last tester was not available to test during the week, but could test on Saturday, a day the Primary Proctor was not scheduled to work. Rather than changing the Proctor’s work schedule or requesting an extension from the PT Provider, the Proctor provided the Tester with instructions on how to take the test (self-proctoring), as well as how to package their answer sheet with those of the other testers and ship back to the GYN PT Provider on Saturday.

Infraction: Violation of testing integrity. The Tester was not proctored by a certified proctor throughout the testing process and the Tester had access to the answer sheets of the other testers.

CMS Ruling: Scores were changed to 0% for the Saturday Tester and the individual was required to retest within 45 business days. The involved Proctor was no longer allowed to serve as a Proctor at that location or any other.

What other option(s) would have been compliant?: Option 1) Called PT Provider and asked for an extension so that testing could take place with Proctor during the work week. Option 2) Had another trained and certified Proctor administer the test on Saturday. Option 3) Return completed testing materials and schedule a makeup test for the Tester at a later date.

L. Finalizing the Testing Process

Check with each test participant to gather all supplies, documents and Test Challenges Boxes related to the proficiency test, including:

1. **Test Challenge Boxes**—confirm that each box contains all 10 glass Challenges
2. **Proficiency Testing Result Forms** with:
 - Correct test box identified
 - Start and finish times indicated

- Signature and date

3. **ASCP PT Process Evaluation Forms**



III. PROCTOR RESPONSIBILITIES AFTER TEST ADMINISTRATION

A. Make copies of the following records related to your Proficiency Test.

These records must be kept for a minimum of two (2) years onsite at your facility:

1. **ASCP PT Participant Test Log**
2. **Add New Participant Forms**
3. **Participant Excused Absence Forms**
4. **Proficiency Testing Result Forms** for each participant
5. **Proctor Test Administration Instructions**
6. **Proctor Test Administration Checklist**—review to assure all steps have been completed.

B. Verify that documents contain all required signatures prior to return shipment to ASCP, including:

1. Laboratory Director signature on the **ASCP PT Participant Test Log**
2. Laboratory Director signature on the **Add New Participants Form**
3. Laboratory Director signature on the **Participant Excused Absence Form**
4. Participant signatures on the **Proficiency Testing Result Forms**
5. Proctor's signatures on the **Proctor Test Administration Checklist**

C. Gather all materials for return shipment to ASCP, including:

1. **Chain of Custody Record**
2. **Test Challenge Boxes**
3. **Add New Participant Forms**
4. **Participant Excused Absence Forms**
5. **ASCP PT Participant Test Log**
6. **Proficiency Testing Result Forms** for each participant. Be sure to compare the number of **Proficiency Testing Result Forms** collected to the number of test participants listed on the **ASCP PT Participant Test Log** to determine whether you have collected them all. In the sample test log on page 24, there are 16 PT participants taking the test at this location since MD participant 17, PT registry # CMS00116 was tested at another laboratory location
7. **ASCP PT Process Evaluation Forms**
8. **Proctor Test Administration Checklist**

D. Package materials in the original shipment box for return to ASCP:

1. Place the following forms into the **ASCP Security Envelope** and **confirm before sealing**:
 - a. **ASCP PT Participant Test Log**. Original signed copy.
 - b. **Proficiency Testing Result Forms**. Original signed copy.
 - c. **ASCP PT Process Evaluation Forms**
 - d. **Proctor Test Administration Checklist**. Original signed copy.
 - e. **Add New Participant Forms**. Original signed copy.
 - f. **Participant Excused Absence Form**. Original signed copy.



2. Re-pack all test materials in the original shipping box for return:
 - a. PT Test Challenge Boxes
 - b. **Chain of Custody Record** (should be outside the security envelope)
 - c. ASCP Security Envelope containing the documents listed above in **D.1.**
 - d. Re-pack materials with any protective packaging included, seal the box well with packing tape, completely fill out the prepaid return Fed-Ex or UPS air bill that was enclosed with your test materials for return shipment, and affix it to the package.
 - e. Retain a copy of the airbill with the airbill number for tracking purposes.
 - f. **Call FedEx @ 1-800-463-3339 or UPS @ 1-800-742-5877 for U.S. Domestic Shipments (dependent on your enclosed air bill). Call your local FedEx or UPS office if you are outside the U.S. Testing materials must be returned NO LATER THAN the end of the day following the scheduled testing date.**
 - g. Note that late or unreturned testing materials may invalidate the testing event and may result in a failing score.

IMPORTANT TEST DETAILS!

This information must be passed on to the testing individuals.

- Each individual is to use their own pre-labeled test form answer sheet.
- All **ASCP GYN PT™** boxes, by law, must have at least one case from each Response Category (A, B, C, D).
- If you make an error on the answer sheet place an "X" through the incorrect response(s) and initial next to the "X".
- Secondary screening Physicians are to receive **pre-dotted Challenges AND a copy of the Cytotechnologist's answers for that box.**
- All testing locations/offices are to be accessible to the Proctor(s) during the entire testing event.
- Double check your answer sheet before turning it in to Proctor.
 - Make sure you only have one answer per case
 - Make sure that you have provided an answer for each case
 - Make sure that you have at least one case from each Response Category
 - Make sure that you indicate the correct **ASCP GYN PT™** test box number on the test form
 - Make sure that you indicated both the START and FINISH times on the test form
 - Make sure that you signed and dated the test form
- Testing Results will arrive within 15 business days from the date the testing materials arrive back at ASCP.

THIS CONCLUDES THE PROCTOR TEST ADMINISTRATION INSTRUCTIONS.

Question? Please contact ASCP Customer Service at 800.267.2727.

IV. PROCTOR QUIZ INSTRUCTIONS

This section provides information on taking a quiz to verify training, and receiving your Certificate of Participation for documentation as a certified **ASCP GYN PT™** Proctor.

- After thorough review of the Proctor Instructions for Administration of the **ASCP GYN PT™**, a twenty (20) question quiz is required to document that the Proctor responsibilities have been understood.
- This quiz is “open book”; you may refer back to materials as necessary.
- Take the Proctor Quiz that is available in two formats: 1) online at ascp.org **OR** 2) by paper copy (attached below) that you may fax back to ASCP for scoring.
- Successfully complete the training (30 days prior to the test date) and quiz (one week prior the test date) prior to the administration of the Proficiency test.

A. ONLINE QUIZ

1. ASCP prefers that Proctors take the online test which allows for instant scoring feedback and immediate printing of the **Proctor Certificate of Successful Participation**.
2. The primary Proctor will receive instructions regarding accessing the online Proctor quiz approximately 30 days prior to your test date from ASCP. Call 800.267.2727 with any questions. NOTE: usernames and Passwords are CaSe sEnSiTiVe. When contacting ASCP, please include each Proctor Name, Facility Name, Facility Site Number (if known) and scheduled Proficiency Test date (if known).
3. The Online Proctor Quiz can be accessed via the internet at ASCP’s online education portal at www.ascp.org.
4. Instructions for taking the online test are available online and should be reviewed prior to taking the test by clicking on the My Education tab in Education.
5. Upon successful completion (score of 90% or better) you will be able to print your **Proctor Certificate of Successful Participation** from the Certification & Transcripts tab.
6. If you receive less than a 90% score, you will be allowed to re-take the online test a second time.
7. If after a second attempt, a score of 90% was not achieved, the laboratory will need to select a different Proctor and repeat the processes outlined in this packet.
8. Provide a copy of the certificate to the Laboratory Director. This certificate, or a copy, is to be kept readily accessible for any inspecting agency or unannounced monitoring during the testing event. This certificate will serve to verify, to inspecting agencies, that you are qualified to administer the ASCP on-site proficiency test.

B. PAPER QUIZ

1. If you choose to take the Paper Quiz, you may do so and fax back the completed quiz to ASCP for scoring at 317.569.0221, Attention: ASCP Proctor Training.
2. Feedback on scoring will be provided by email or fax within one week of ASCP’s receipt along with a **Proctor Certificate of Successful Participation**.
3. The hard copy version of the Proctor Test includes an attestation statement for the Proctor’s signature verifying that all test questions were answered independently.
4. If the test was completed successfully with a passing score of at least 90%, ASCP will send a **Proctor Certificate of Successful Participation** by email or fax.
5. If a score of 90% is not achieved on the first test, a second test is required.
6. If after a second attempt, a score of 90% was not achieved, the laboratory will need to select a different Proctor and repeat the processes outlined in this packet.

C. DEFINITIONS TO BE USED FOR PROCTOR QUIZ QUESTIONS 15 - 20:

1. *Compliant = Meets and/or exceeds all components of CLIA '88 relative to cytology proficiency testing, complies with CMS' PT Referral Policy and meets the ASCP Proctor requirements as outlined in the Proctor Information.*
2. *Non-Compliant = Fails to meet all components of CLIA '88 relative to cytology proficiency testing, does not comply with CMS' PT Referral Policy OR does not comply the ASCP Proctor requirements as outlined in the Proctor Information.*



2017 ASCP GYN PT™ PROCTOR QUIZ

Attestation Statement: I certify that I answered all questions on the Proctor test independently.

Signature of Proctor: _____

Date: _____

Proctor Name: Scheduled Test Date:		
Proctor Phone:	Proctor Email:	
Lab/Facility Name:		
Lab Director Name:	Lab Phone:	
Lab Address:		
Lab Address:		
City:	State:	Zip:



CIRCLE THE MOST APPROPRIATE ANSWER

QUESTION 1

- 1. What documents are to be distributed to each Testing Participant?**
 - a. Proficiency Testing Result Form only
 - b. Proficiency Testing Result Form and Proficiency Testing Instructions only
 - c. Proficiency Testing Result Form, Proficiency Testing Instructions, Proficiency Testing Scoring Sheet & Guide, Supplemental Important Test Details and PT Process Evaluation Form
 - d. Proficiency Testing Result Form and Proficiency Testing Instructions and PT Process Evaluation Form only

QUESTION 2

- 2. Which of the following documents need to be copied and retained by the laboratory for a minimum of 2 years?**
 - a. ASCP PT Participant Test Log
 - b. Proficiency Testing Results
 - c. Participant Excused Absence Forms
 - d. All of the above.

QUESTION 3

- 3. If the Primary Proctor is also a testing individual, they are allowed to proctor their own test if they have passed the proctor exam?**
 - a. True.
 - b. False

QUESTION 4

- 4. In accordance with the Federal CLIA requirements, all Test Challenge boxes must have how many Test Challenges from each “diagnostic response category” of A, B, C or D?**
 - a. No requirement exists
 - b. At least one
 - c. Only one
 - d. At least two

QUESTION 5

- 5. Secondary-screening Physicians may select which Cytotechnologist prescreens their Test Challenge box**
 - a. True
 - b. False

QUESTION 6

- 6. Test Materials must be stored in a locked and secure location**
 - a. Before, between and after each segment of the Proficiency testing event - if split into multiple days or time periods
 - b. Prior to the start of the Proficiency testing event
 - c. Does not need to be stored in a locked and secure location
 - d. After all testing has been completed



QUESTION 7

- 7. When monitoring the GYN PT Testing Environment, which of the following scenarios is not acceptable:**
- a. Proctor passing along a prescreened and dotted Test Challenge Box and a copy of the Proficiency Testing Result Form, which contains the answers of the Cytotechnologist, to a testing Secondary-Screening Physician
 - b. Utilizing the same Test Challenge Box for multiple physicians if there is sufficient time for taking the test and they all require the same GYN PREP Type prefix Test Challenge Box
 - c. Testing Participants photographing problematic test challenges for future discussion
 - d. Utilizing a different prescreened and dotted Test Challenge Box for each Physician as long as the GYN PREP Type prefix on the Test Challenge Box is matched to the requirements of each testing Physician participant

QUESTION 8

- 8. If a Testing Participant has made an error on the Proficiency Testing Result Form, the Proctor should instruct the Testing Participant to:**
- a. Ignore the error and proceed with marking the correct Response Category (A, B, C, D)
 - b. Make an X through the incorrect response(s) and initial next to the X
 - c. Call ASCP for a new Proficiency Testing Result Form
 - d. Make the X bigger for the correct Response Category (A, B, C, D)

QUESTION 9

- 9. Upon receipt of completed Test Challenge Boxes from Testing Participants, Proctors are responsible for all of the following except:**
- a. Verification that testing participants have completed all the required information on the Proficiency Testing Result Form
 - b. Removing dots from Test Challenges and assigning to another Cytotechnologist
 - c. Randomly assigning prescreened and dotted Test Challenge boxes to secondary-screening Physicians, matching GYN PREP types indicated on the pre-labeled Proficiency Testing Result Form for the pathologist(s)
 - d. Grading the GYN PT testing event for each Testing Participant

QUESTION 10

- 10. If the Testing Participant is approaching the 2-hour testing limit, the Proctor should:**
- a. Warn them how many minutes are remaining for their testing event and stop the testing event at 2 hours whether or not the Testing is complete
 - b. Wait to see if they need more time and then allow an additional 8 minutes per Test Challenge remaining in their box.
 - c. Recommend adjusting the start and stop time to reflect 2 hours of testing time
 - d. Allow them to complete the testing event and ignore the 2-hour testing limit

QUESTION 11

- 11. As a GYN PT Provider, ASCP reserves the right to conduct unannounced visits to any testing facility and monitor the GYN proficiency testing process.**
- a. True
 - b. False



QUESTION 12

12. It is the Proctor's responsibility to verify the following:

- a. That answers are provided for all test challenges and only one answer is provided for each test challenge
- b. That the start and stop times are identified, the test box number is correct and the answer sheet is signed by the tester
- c. A and B are correct
- d. None of the above

QUESTION 13

13. If a testing individual does not feel well, it is up to the Primary Proctor to determine whether or not an additional 15 minutes can be added on to the allotted 2-hour testing time.

- a. True
- b. False

QUESTION 14

14. Who of the following are required to participate in the GYN Proficiency Testing event?

- a. All practicing individuals (physicians and cytotechnologists) who examine or interpret gynecologic cytology specimens (Pap smears)
- b. Newly graduated cytotechnology students who have completed and passed the boards within that calendar year
- c. Newly certified Anatomic Pathologists within that calendar year
- d. Newly board-certified CytoPathologists within that calendar year

INDICATE WHETHER OR NOT THE FOLLOWING SCENARIOS ARE COMPLIANT VERSUS NON-COMPLIANT WITH GYN PT TESTING REGULATORY REQUIREMENTS AND PROTOCOL

DEFINITIONS TO BE USED FOR PROCTOR QUIZ QUESTIONS 15 - 20:

- *Compliant = Meets and/or exceeds all components of CLIA '88 relative to cytology proficiency testing, complies with CMS' PT Referral Policy and meets the ASCP Proctor requirements as outlined in the Proctor Information.*
- *Non-Compliant = Fails to meet all components of CLIA '88 relative to cytology proficiency testing, does not comply with CMS' PT Referral Policy OR does not comply the ASCP Proctor requirements as outlined in the Proctor Information.*

QUESTION 15

15. Primary and secondary Screeners were enrolled for GYN PT testing at White Hospital. On the day of the testing, the Proctor started with the primary screeners, having the last primary screener dot their box of test challenges for the secondary screening Physician. A copy of the primary screener's answer sheet was provided with the glass slide test challenges to the secondary screening Physician. During the testing event the Physician noted a test challenge that was originally categorized as Negative (Category A) by the primary screener when, in fact, it contained cells consistent with HSIL (Category D). Upon completion of his testing event, the secondary screening Physician reviewed the discrepant test challenge with the primary screener prior to turning all testing materials into the Proctor for return to the GYN PT Provider.

- a. Compliant
- b. Non-compliant



QUESTION 16

- 16.** Hospital A has two other locations (Hospitals B and C) that have CLIA numbers that list cytology as a test commonly performed. Rather than purchasing a separate GYN PT Proficiency test for each location, the QA Director schedules a date for all Testers to come to Hospital A for testing.
- a. Compliant
 - b. Non-compliant

QUESTION 17

- 17.** In order for the annual GYN Proficiency test to fulfill both the regulatory requirements, as well as count towards the cytology department's monthly in-house education, all cytology personnel sat at the multi-headed microscope reviewing the test challenges together. Testing individuals were encouraged to render their own diagnostic response (category), even if it differed from the consensus of the group.
- a. Compliant
 - b. Non-compliant

QUESTION 18

- 18.** In addition to serving as a reference laboratory, Education Laboratory housed a well-known and respected Cytotechnology program. During the most recent scheduled GYN PT Proficiency test, one of the Testers noted a great example of a rare cancer on one of the GYN PT test challenges. Upon completion of his testing event, the Tester proceeded to take microphotographs of the test challenge to add to his teaching materials.
- a. Compliant
 - b. Non-compliant

QUESTION 19

- 19.** Dr. Smith typically performs secondary screening only on GYN cytology materials. This year, however, he was called in to review a STAT GYN specimen without the aid of a primary screening cytotechnologist. Since he typically performs secondary screening and this was only a one time occasion, he will still take his GYN Proficiency test this year as a secondary screener.
- a. Compliant
 - b. Non-compliant

QUESTION 20

- 20.** A Medical Center on the east coast employs 48 individuals within the Cytopathology department, all of which are required to participate in annual GYN Proficiency testing. Rather than trying to find one date that works for everyone, the Medical Center purchases two different GYN PT testing events one month apart, enrolling 22 Testers in the first event and 26 Testers in the second event.
- a. Compliant
 - b. Non-compliant

SECTION B

ASCP GYN PT™ Cytology Proficiency Test Test Administration Packet For

EXAMPLE HOSPITAL 9000

The following documents are included as examples only
An additional set of documents related to your testing event will be included
with your **ASCP GYN PT™** Shipment.

Contact **ASCP**: Phone: 312.541.4999 • Fax: 312.541.4472 • Hours of operation: Mon–Fri, 8:00 A.M.–5:00 P.M. EST



TEST ADMINISTRATION PACKET CONTENTS CHECKLIST

Document	Document Title	Check
01	Chain of Custody Record	
02	Instructions for Lab Director	
03	Proctor Test Administration Checklist	
04	Participant Test Log	
05	Participant Test Instructions	
06	PT Scoring Charts and Guide	
07	Add New Participant Forms	
08	Participant Excused Absence Form	
09	Cleaning & Handling Challenges Protocol	
10	Proficiency Testing Result Forms	
11	ASCP GYN PT™ Process Evaluation Forms	
12	Security Envelope	

CHAIN OF CUSTODY¹ RECORD
 ~ Cytology Proficiency Testing ~

From: ASCP - Indianapolis
 833 West Carmel Drive
 Carmel, IN 46032
 1-312-541-4999
 1-317-569-0221 (fax)

EXAMPLE CHAIN OF CUSTODY RECORD
Attn: PROCTOR
CLIA#: 000000000
Site#: 0000000
Testing Date: 01/01/2014

No.	Box ID	No.	Box ID	No.	Box ID
1		6		11	
2		7		12	
3		8		13	
4		9		14	
5		10		15	

(1) Sent by ASCP (signature):
Date:
Comments:
(2) Received by Proctor (signature):
Date:
Comments:
(3) Sent by Proctor (signature):
Date:
Comments:
(4) Received by ASCP (signature):
Date:
Comments:

¹ "Chain of custody" is a set of procedures used to provide an accurate written record that can be used to trace the possession of proficiency test slides from ASCP to the recipient laboratory and back to ASCP. The process ensures the integrity of the proficiency testing process. Chain of custody means the PT slides: 1) are in your actual possession, or 2) are in your view, after being in your physical possession, or 3) were in your possession and then you locked the slides in a secure location, or 4) are in a secure area. Until you relinquish the slides to someone else and have documented the transfer, you are responsible to ensure that no one is able to tamper with the slides. Proctor must complete (2) Received by/Date and (3) Sent by/Date, include signature.



SITE INFORMATION

CLIA #: _____

ASCP Site#: _____

Lab Name: _____

Lab Director: _____

Address: _____

Phone: _____

Fax: _____

PT Test Date: _____

Test Participants: _____

Proctors: _____

INSTRUCTIONS FOR LABORATORY DIRECTOR

1. Make any corrections or additions to the information printed below. Cross out the name of any individual who is no longer employed at this laboratory.
2. All individuals who evaluate gynecologic cytology specimens must be listed. Include all fulltime, part-time and on-call employees.
3. A unique national proficiency testing registration number (PTR#) is assigned to each proficiency test participant by ASCP during the enrollment process. Each participant will keep their unique national PTR # for the duration of their enrollment in the ASCP program, or any other CMS-approved program.
4. Cytotechnologists "Cytotech" receive the proficiency test Challenges first since they screen and dot the Challenges for the pathologist participants, "MD S or DO S". Pathologists who screen Pap test Challenges instead of a cytotechnologist are designated as "MD P or DO P" for the purposes of this test. They will be designated as a "Primary Evaluator" on the Proficiency Testing Result Form preprinted label. They will be assigned Test Challenge Boxes that have not been screened or dotted by the cytotechnologist.
5. If a participant is being tested at this facility indicate "Y" for yes in the "Test Here" box. If not tested here indicate "N" for no and write in the name of the alternate testing location.
6. The "ASCP GYN PREP Type Prefix" is determined by looking at the label on the outside of the cardboard Test Challenge Box. The labels refer to the type of Challenges each participant is eligible to receive for their proficiency test, based on enrollment information about the type of Challenges they routinely examine in the laboratory. The boxes are labeled as follows: "C" for conventional Pap smear test Challenges, "T" for ThinPrep Challenges, and "SP" for SurePath Challenges.
7. In the "Test Box Assigned" column, the PT Proctor will write in the test box number (as identified by the label on the box) that corresponds to the Test Challenge Box given to each participant.
8. The Laboratory Director will **review and sign** the completed **ASCP GYN PT™ Participant Test Log**, attesting to its accuracy. The laboratory is required to keep a copy of this participant test log for 2 years from the date of the test. Please fax **ONLY** the signed **ASCP GYN PT™ Participant Test Log** to ASCP @ 317.569.0221.

I hereby certify that the information provided on this participant testing log is true and complete, and includes the names of all individuals who diagnose, screen or review gynecologic cytology specimens at this laboratory, under this CLIA number.

Signature of Laboratory Director Date

PROCTOR TEST ADMINISTRATION CHECKLIST

Prior to Test Administration

Proctor #1 - Receive testing materials

- Proctor #1 - Unpack and verify that Security Seals on test boxes are unbroken and all testing materials are present, to include:
 - Glass Challenge Test Boxes
 - Proficiency Testing Documents
- Store testing materials in a locked and secure location

During Test Administration

- Define shared duties among Proctors
- Determine and assign time schedule for testing event (2 hour window per test)
- Document late enrollees, if applicable, by completion of the **Add Participant Enrollment Form**
- Provide dotting pens, black ink pens and other supplies as needed to test participants
- Review Participant Proficiency Test Instructions, **Proficiency Testing Result Forms and PT Scoring Charts & Guide** with participants, and provide **ASCP GYN PT™ Process Evaluation Forms**
- Assign Test Challenge Boxes to primary screeners according to protocol
- Upon receipt of EACH test form, review to ensure the correct test box indicated, that START and FINISH times have been completed correctly, and that the form is signed and dated.
- Receive and re-distribute Test Challenge Boxes and Proficiency Testing Result Forms to secondary screeners according to protocol on page 8 of the Proctor Instructions
- Clean PT Challenges and handle and document broken Challenges according to protocol- use the form on this page to document broken Challenges
- Document excused absences, if applicable, by completion of the **Participant Excused Absence Form**

After Test Administration

- Verify all required signatures on documents
- Copy all PT documents and retain in the laboratory for 2 years
- Package Test Challenge Boxes and all original, completed and signed PT documents for return to ASCP in the original box the materials arrived in
- Have all Proctors sign off on this document and send the original back to ASCP
- Call FedEx @ 1-800-463-3339 or UPS @1-800-742-5877 for U.S. Domestic Shipments (dependent on your enclosed air bill). Call your local FedEx or UPS office if you are outside the U.S.

DOCUMENT BROKEN TEST CHALLENGES HERE

Test Challenge Box #	Challenge #	Broken in Shipment	Broken During Test	Repaired	Returned to ASCP



CLIA Provider #: #####	PT Test Date: Jan 1, 2006
Laboratory Name: XYZ L	Laboratory Director: M. Smith MD
Address: 1234 W. 5 th ST.	
Address: Anywhere, USA	
Phone: 317.888.8888	Proctor: Alison Smith, CT (ASCP)

Number	Registration Number (PTR#)	Participant First and Last Name	Cytotech/ MD/DO S or MD/DO P	Test Here Y or N (If N list alternate test location)	GYN PREP Type Prefix	Test Box Assigned
1	CMS00100	Barbara Carey	CYTOTECH	Y	C	C442
2	CMS00101	Linda Miller	CYTOTECH	Y	T	T443
3	CMS00102	Susan Brown	CYTOTECH	Y	T	T445
4	CMS00103	Alex Duncan	CYTOTECH	Y	C	C982
5	CMS00104	Michael Fry	CYTOTECH	Y	T	
6	CMS00105	Ruth Rayon	CYTOTECH	Y	T	
7	CMS00106	Pia Green	CYTOTECH	Y	T	
8	CMS00107	David Constella	CYTOTECH	Y	T	
9	CMS00108	Bruce [redacted]	CYTOTECH	Y	C	C982
10	CMS00109	Ann Zachary	CYTOTECH	Y	T	
11	CMS00110	[redacted] Black	CYTOTECH	Y	T	T445
12	CMS00111	Donna [redacted]	CYTOTECH	Y	C	C982
13	CMS00112	[redacted] Zeta	MD	Y	C	
14	CMS00113	Rachel Shawnee	MD	Y	T	T442
15	CMS00114	Young Lee	MD	Y	T	T443
16	CMS00115	Zeta Lebow	MD	Y	C	
17	CMS00116	Andrew Thompson	MD	N. ST. ELSEWHERE, USA		

ASCP GYN PT™ PARTICIPANT TEST LOG

I hereby certify that the information provided on this participant testing log is true and complete, and includes the names of all individuals who diagnose, screen or review gynecologic cytology specimens at this laboratory, under this CLIA number.

Signature of Laboratory Director

Date



PARTICIPANT PROFICIENCY TEST INSTRUCTIONS

1. Review the **ASCP GYN PT™ Program PT Scoring Chart and Guide** to ensure you understand how your PT test will be graded. A passing score is 90%.
2. Check all preprinted information on the **Proficiency Testing Result Form**, including your name, registration number (PTR#), laboratory test location, **ASCP GYN PT™ PREP TYPE** for the type of test you will receive, and whether you are a cytotechnologist (Cytotech), pathologist (MD S) or a pathologist who examines gynecologic cytology Challenges without prescreening or dotting by a cytotechnologist (MD P = Primary evaluator).
3. Make any changes necessary by crossing out the incorrect information and writing in the correct information. Please inform the Laboratory PT Proctor if there is an error in the **ASCP GYN PT™ GYN PREP type** or Cytotech/"MD S" or "MD P" information since this could change the type of Test Challenge Box you will be assigned for the test.
 - a. The "**ASCP GYN PT™ PREP Type**" was determined from the Laboratory Enrollment Form indicating the types of GYN cases you examine. The **ASCP GYN PT™ PREP Type** barcode prefix includes: "C" for conventional Pap smear Challenges, "T" for ThinPrep Challenges, and "SP" for SurePath Challenges.
4. Record the Test Challenge Box assigned to you in the space provided on the **Proficiency Testing Result Form**.
5. Record the "Test start time" in the space provided on the **Proficiency Testing Result Form** when you begin the test. The Laboratory PT Proctor will collect your test when the 2-hour limit is up, even if you have not marked all your answers. If you need to interrupt the proficiency test for an unscheduled STAT laboratory procedure, for example to read frozen section biopsies or perform Fine Needle Aspirations, or for any other reason, inform the Proctor of your absence and record the time you were absent from the test in the "Comments" section. You have a total of 2 hours to complete the test. The time you spent away from the microscope will not be counted in the 2-hour time limit. These instructions are based upon CMS directives and CLIA '88 regulations.
6. The test Challenge label contains a number from 1 to 10. The pertinent patient history such as age and LMP are also provided on the test Challenge label.
7. (Cytotech) **CYTOTECHNOLOGISTS**: Screen all 10 proficiency test Challenges and dot each Challenge by the procedures you routinely follow in your laboratory. Your test Challenges may be passed on to a pathologist for their proficiency test. Use a dotting pen containing ink that can be easily removed by alcohol, since your test Challenges may need to be cleaned of dots prior to assignment to another test participant.
8. (MD S) **PATHOLOGISTS**: Review/screen all 10 test Challenges that have been prescreened and dotted by a cytotechnologist, observing the same process you routinely follow in your laboratory. If you decide that you would rather have a test set that has not been previously evaluated by a cytotechnologist, inform the Proctor so they can assign you a Test Challenge Box with undotted Challenges. Proctors have been instructed to assign Test Challenge Boxes with the appropriate. GYN PREP Type prefix in a random fashion to pathologist participants. Pathologists cannot request a Test Challenge Box that has been prescreened and dotted by a *specific* cytotechnologist. These instructions are based upon CMS directives and CLIA '88 regulations.
9. (MD P= Primary evaluators) **PATHOLOGISTS** performing primary screening of gynecologic cytology Challenges without prescreening or dotting by a cytotechnologist: Observe the same process for screening the test Challenges that you routinely follow in the laboratory. The Test Challenge Box you receive will not be prescreened and dotted by a cytotechnologist. Your test Challenges will not be forwarded to another pathologist for review. These instructions are based upon CMS directives and CLIA '88 regulations.
10. Using a **black ink pen**, fill in the boxes on the **Proficiency Testing Result Form** that correspond to your answers for each Challenge, labeled 1 to 10. The response criteria for each answer category are included on the test result form. Please review these response criteria to make sure you understand how to mark each category prior to beginning the proficiency test.



11. Response categories mandated by CMS and CLIA '88 for the gyn proficiency test include:
 - a. A = Unsatisfactory for diagnosis due to: Scant cellularity, air drying, obscuring material (blood, inflammatory cells, or lubricant).
 - b. B = Negative—includes: Normal, negative or within normal limits; Infection other than Human Papillomavirus (HPV) (e.g., *Trichomonas vaginalis*, changes or morphology consistent with *Candida* spp., *Actinomyces* spp. or Herpes simplex virus); Reactive and reparative changes (e.g., inflammation, effects of chemotherapy or radiation).
 - c. C = Low Grade Squamous Intraepithelial Lesion—includes: Cellular changes associated with HPV; Mild dysplasia/CIN-1.
 - d. D = High Grade Lesion and Carcinoma—includes: High grade squamous intraepithelial lesions which include moderate dysplasia/CIN-2 and severe dysplasia/carcinoma in-situ/CIN-3; Squamous cell carcinoma; Adenocarcinoma and other malignant neoplasms.
12. Do not discuss the proficiency test cases with anyone during the test, or after the test with anyone who has not yet taken the test. You must determine the diagnosis on the test Challenges independently. Test participants may not refer to textbooks, atlases, or any other reference materials during the test. These instructions are based upon CMS directives and CLIA '88 regulations.
13. Each proficiency test Challenge is checked for breakage, coverslipping quality and overall condition prior to each laboratory PT shipment. If you feel that a Challenge did not make a good test Challenge because of poor staining or coverslipping and you would like this Challenge to be reviewed by the ASCP staff, please make a comment on the **ASCP GYN PT™ Process Evaluation Form**.
14. Take care with the proficiency test Challenges. In the event that a test Challenge is broken, immediately inform the Laboratory PT Proctor who has instructions on how to handle this event so that testing may continue. **ASCP will charge the site \$200 for each broken PT Challenge.**
15. After you have completed the proficiency test and recorded all your answers by filling in the corresponding boxes on the **Proficiency Testing Result Form**, record the "Test finish time" in the space provided on the test form.
16. In accordance with CMS and/or CLIA '88, review all information on the **Proficiency Testing Result Form** to ensure all requested information has been entered, including the test start and finish time and any comments regarding time away from the test for STAT procedures or other reasons, the Test Challenge Box number, and signed statement that you understand all test instructions. REMEMBER: Every **ASCP GYN PT™** test box, by law, must contain at least one case of every response category (A, B, C, D).
17. As required by CMS and/or CLIA '88, sign and date the **Proficiency Testing Result Form** on the line below the attestation statement indicating that all cases were diagnosed independently by you.
18. Return the Test Challenge Box and completed **Proficiency Testing Result Form** to the Laboratory PT Proctor.
19. Complete the **ASCP GYN PT™ Process Evaluation Form** and return it to the Laboratory PT Proctor.
20. Please note that photographing, photocopying or reproducing Challenges or other copyrightable materials in any way is not permitted.
21. Clarify all questions regarding the on-site PT exam with the Proctor prior to the beginning of the test. If there are questions that the Proctor cannot answer, request that the Proctor contact ASCP prior to the beginning of the PT exam to receive clarification.
22. Results will be sent to the Laboratory by ASCP within 15 business days of receipt by ASCP of the testing materials.

ASCP GYN PROFICIENCY TESTING™ PROGRAM SCORING CHARTS AS MANDATED BY CMS & CLIA '88

PT SCORING CHART FOR CYTOTECHNOLOGISTS

Point Value per Case (10-Challenge Test)

PARTICIPANT RESPONSE

Correct Response	A UNSAT	B NEG	C LGSIL	D HGSIL/CA
A UNSAT	10	0	5	5
B NEG	5	10	5	5
C LGSIL	5	0	10	10
D HGSIL/CA	0	-5	10	10

PT SCORING CHART FOR PATHOLOGISTS

Point Value per Case (10-Challenge Test)

PARTICIPANT RESPONSE

Correct Response	A UNSAT	B NEG	C LGSIL	D HGSIL/CA
A UNSAT	10	0	0	0
B NEG	5	10	0	0
C LGSIL	5	0	10	5
D HGSIL/CA	0	-5	5	10



PT SCORING CHART GUIDE 10-CHALLENGE TEST AS MANDATED BY CMS & CLIA '88

- There is a different scoring chart for cytotechnologists and pathologists.
- A passing score is 90%. A maximum of 10 points are awarded for a correct response and a maximum of minus five points (-5) for an incorrect response on a 10-Challenge test.
- The individual's score for the testing event is determined by adding the point value achieved for each Challenge preparation, dividing by the total points for the testing event and multiplying by 100.
- For example, if the correct answer for test Challenge #1 is "response category D HGSIL/CA" and a cytotechnologist participant selected "response category B NEG" as the correct answer, then the cytotechnologist's point value on that Challenge would be calculated as -5 points. Assuming that the cytotechnologist answered the other 9 test Challenges correctly, the cytotechnologist's PT test score would be 85%, a failing score. (9 Challenges x 10 points = 90 points + (-5) points = 85 points)
- In another example, the correct answer for test Challenge #2 is "response category C LGSIL" and a pathologist participant selected "response category D HGSIL/CA" as the correct answer. The point value for this Challenge is 5 points. Assume the other 9 Challenges were answered correctly. The pathologist participant's score is 95%, a passing score. (9 Challenges x 10 points = 90 points + 5 points = 95 points)
- For another example, the correct answer on test Challenge #3 is "response category B NEG" and a cytotechnologist participant selected "response category D HGSIL/CA" as the correct answer. The point value for this Challenge is 5 points. The correct answer for test Challenge #4 is "response category C LGSIL" and the same cytotechnologist participant selected "response category A UNSAT" as the correct answer. The point value for this Challenge is 5 points. The other 8 Challenges were answered correctly. The cytotechnologist participant's score is 90%, a passing score. (8 Challenges x 10 points = 80 points + 5 points + 5 points = 90 points)
- **REMINDER: YOU MAY NOT CONFER WITH ANY OTHER PARTICIPANT ABOUT PROFICIENCY TEST CHALLENGES. ALL CHALLENGES MUST BE DIAGNOSED INDEPENDENTLY.**

RESPONSE CATEGORIES USED FOR THE ASCP GYN PROFICIENCY TEST™ (PT) AND ABBREVIATIONS USED FOR THE SCORING CHART AS MANDATED BY CMS & CLIA '88

- A = UNSAT = Unsatisfactory for diagnosis due to: Scant cellularity, Air drying, Obscuring material (blood, inflammatory cells, or lubricant).
- B = NEG = Normal or Benign Changes - includes: Normal, negative or within normal limits; Infection other than Human Papillomavirus (HPV) (e.g., Trichomonas vaginalis, changes or morphology consistent with Candida spp., Actinomyces spp. or Herpes simplex virus); Reactive and reparative changes (e.g., inflammation, effects of chemotherapy or radiation)
- C = LGSIL = Low Grade Squamous Intraepithelial Lesion - includes: Cellular changes associated with HPV; Mild dysplasia/CIN-1.
- D = HGSIL/CA = High Grade Lesion and Carcinoma - includes: High grade squamous intraepithelial lesions which include moderate dysplasia/CIN-2 and severe dysplasia/carcinoma in-situ/CIN-3; Squamous cell carcinoma; Adenocarcinoma and other malignant neoplasms.



IMPORTANT TEST DETAILS!

This information must be passed on to the testing individuals.

- Each individual is to use their own pre-labeled test form answer sheet.
- All **ASCP GYN PT™** boxes, by law, must have at least one case from each Response Category (A, B, C, D).
- If you make an error on the answer sheet place an “X” through the incorrect response(s) and initial next to the “X”.
- Secondary screening Physicians are to receive **pre-dotted Challenges AND a copy of the Cytotechnologist’s answers for that box.**
- All testing locations/offices are to be accessible to the Proctor(s) during the entire testing event.
- Double check your answer sheet before turning it in to Proctor.
 - Make sure you only have one answer per case
 - Make sure that you have provided an answer for each case
 - Make sure that you have at least one case from each Response Category
 - Make sure that you indicate the correct **ASCP GYN PT™** test box number on the test form
 - Make sure that you indicated both the START and FINISH times on the test form
 - Make sure that you signed and dated the test form
- Testing Results will arrive within 15 business days from the date the testing materials arrive back at ASCP.

CMS-approved GYN Proficiency Testing Result Form



This Result Form can only be used by the laboratory whose name is printed in this box. If you need to make a change or have other questions, please call 1-800-267-2727 for assistance.

Please do not write comments on this form. Any concerns should be e-mailed to assessment@ascp.org.

PTR #: _____

08055

8/20/2011

Name: _____

Prep Type: _____ Screener Type: _____

If Participant is absent for testing event, complete the following: Excused Unexcused

Test Slide Box #:

--	--	--	--	--	--	--

If applicable (MD ONLY) Prescreened by PTR#:

--	--	--	--	--	--	--	--

* Secondary-screening Physicians are to get pre-screened slides AND a copy of the pre-screening Cytotech's completed test form

Test Start Time: :

Test Finish Time: :

TEST RESULTS: Select the correct box below

Case No.	UNSAT	NEG	LSIL	HG & ABOVE
1	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
2	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
3	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
4	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
5	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
6	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
7	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
8	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
9	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
10	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D

I have read, understood and followed the ASCP Gyn PT™ Instructions as presented to me by the Laboratory PT Proctor.

I hereby attest that the cytology proficiency test slides were independently diagnosed by me in the same manner as patient specimens, to the extent allowed by testing policies.

Participant Signature

Date

ASCP GYN PT™ Process Evaluation

Test Slide Box #: _____

 Site # (if desired):
 On-site PT exam date: / /

Fill in the box that corresponds to your degree of agreement with the statement, with 1 being strongly agree to 5 being strongly disagree.

Process Evaluated	Scale				
	Strongly Agree				Strongly Disagree
	1	2	3	4	5
1. Written ASCP GYN PT Instructions were clear. Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. The Proctor gave clear instructions for taking the test. Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. The criteria for the four response categories, A, B, C and D contained on the Proficiency Testing Result Forms were clear. Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. The information contained in the PT Scoring Charts was clear. Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. The test slides were well stained and coverslipped. (If you thought a slide was poorly stained or coverslipped and would like ASCP staff to review, include the Test Slide Box number and the slide label number.) Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Test Slide Box #: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Slide Label #: <input type="text"/> <input type="text"/>					
6. The test Slides contained the morphologic criteria necessary to accurately categorize the response category as A, B, C or D. Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

IF YOU HAVE ADDED ANY PERSONNEL WHO EVALUATE GYNECOLOGIC CYTOLOGY SPECIMENS BUT WHO HAVE NOT ALREADY TAKEN A PROFICIENCY TEST FOR THE CURRENT YEAR, YOU MUST ENROLL THEM AT LEAST TWO WEEKS BEFORE THE SCHEDULED TESTING DATE.

Please provide payment information and complete an Add Participant Enrollment Form for each employee not listed on the Participant Enrollment Log provided.

Refer to the following instructions to aid in the completion of this form. Contact ASCP with questions related to the enrollment process for new employees at 312.541.4999 ext 3902.

ADD PARTICIPANT ENROLLMENT FORM

PARTICIPANT INFORMATION

- Print the participant's full legal name and, if applicable, please indicate all other names used by the participant on certification or licensure information
- Please indicate the following:

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 and State License number for the state where the test will be taking place

Cytotechnologists

- Indicate ASCP Board of Certification (BOC) number and State License number(s)

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 below, provide the name and address of the laboratory location where they will be taking the test.

ADDITIONAL PLACES OF EMPLOYMENT

- If the participant is evaluating GYN Challenges at two (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 testing will be comprised of one or more of the GYN preparation types indicated as routinely evaluated.
- The GYN Prep type chosen for testing does not affect what Prep types may be evaluated at your facility or the validity of your Proficiency Test.



COMPLETE A COPY OF THIS FORM FOR EACH PARTICIPANT YOU ARE ADDING TO YOUR EXISTING ENROLLMENT FOR THE ASCP GYN PROFICIENCY TEST.

All information related to GYN Proficiency Testing will be handled by employees of ASCP with utmost confidentiality and discretion. Under no circumstances will an individual's results be shared or discussed with an unauthorized individual. All testing results will be sent directly to the CMS and the Laboratory Director.

PARTICIPANT INFORMATION

First Name M.I. Last Name
Other name(s) used (maiden name, change of name)
1 _____ 2 _____ 3 _____

PHYSICIAN *(must complete the information below)*

- M.D. - D.O. *(please check)*
- Please check ONE category that applies:
 - Primary Screener of GYN materials (even if one case/year)
 - Secondary Screener (always screens pre-dotted GYN materials)
- Medical Licensure Number _____
- or State Licensure Number (where PT testing will occur) _____

CYTOTECHNOLOGIST *(must complete the information below)*

- ASCP/BOC# _____ or HEW # _____
- or State Licensure Number(s) _____
- (If no Licensure Number, please provide Social Security number or Driver's License number)*

Will participant be testing AT THIS LOCATION? YES / NO If NO, at which location will he/she be testing?

Laboratory Director: _____
Laboratory/Hospital: _____
Laboratory/Hospital Address: _____
City/State/Zip: _____

IS ENROLLEE CURRENTLY EVALUATING GYN Challenges MORE THAN ONE LAB? YES / NO

If YES, provide the following information for each lab. ASCP will forward testing results to each site indicated.

Laboratory Director: _____
Laboratory/Hospital: _____
Laboratory/Hospital Address: _____
City/State/Zip: _____

CIRCLE THE GYN PREP TYPE ROUTINELY EVALUATED BY THIS INDIVIDUAL:
(this should be the Prep Type Evaluated the Majority of the Time)

C=conventional T=ThinPrep SP=SurePath

PT TEST WILL BE COMPRISED OF 100% OF THE GYN PREPARATION TYPE INDICATED AS ROUTINELY EVALUATED

Questions? Please contact ASCP Customer Service at 800.267.2727



PLEASE COMPLETE PAYMENT INFORMATION BELOW AND HAVE THE LABORATORY DIRECTOR SIGN THE ATTESTATION STATEMENT. SUBMIT THIS PAGE AND THE ADD PARTICIPANT FORM(S) TO ASCP AT LEAST TWO WEEKS PRIOR TO YOUR SCHEDULED TESTING DATE.

- Indicate the number of participants to be added and calculate the total fees due.
\$85 (PTPART17) x _____ (number of new participants) Total added participant fees: _____
- Payment or PO must accompany enrollment. Acceptable payment options include check, credit card (VISA/MASTERCARD/AMEX) or purchase order.

o Check Enclosed (payable to ASCP)

o Purchase Order # _____

o I want to pay by credit card. Please call me at _____ . Date/Time _____

IMPORTANT!

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

To submit enrollment for new participants by MAIL:	ASCP Proficiency Testing Enrollment 833 W Carmel Dr Carmel IN 46032
To submit enrollment for new participants by FAX:	317.569.0221

ATTESTATION STATEMENT

I hereby affirm that the information provided on the Add Participant form(s) included with this form is true and complete, and completes the enrollment of all individuals who diagnose, screen or review gynecologic cytology specimens at this laboratory.

Signature of Laboratory Director

Date

ASCP GYN PT™ PARTICIPANT EXCUSED ABSENCE FORM

CLIA #: _____ ASCP Site#: _____
Lab Name: _____ Lab Director: _____
Address: _____ Phone: _____
_____ Fax: _____
Test Participants: _____

Please complete the form below for those PT participants who were unable to take the ASCP on-site PT exam on the scheduled date, or while the test Challenges were still at the laboratory, and return in the Security Envelope with the other completed testing materials (unused forms do not need to be returned). Please note that make-up PT exams need to be scheduled as soon as possible. If you do not yet know which make-up options the participant will choose, send this form in the Security Envelope now, and follow-up with a faxed (317.569.0221) completed form as soon as possible. Questions? Please contact ASCP at 800.267.2727.

1. BOX A—write the participant's complete first and last name in this box.
2. BOX B—Record the participant's PTR# in this box.
3. BOX C—Write "Yes" for excused absence and "No" for unexcused absence from the on-site PT exam. Participants with unexcused absences receive an automatic failing score (0) and must take the retest at the ASCP Testing Center in Indianapolis, IN not more than 45 days after the receipt of the notification of receiving score of less than 90%.
4. BOX D—If the participant has an excused absence and plans to schedule a make-up test at ASCP, make a checkmark in this box. If the participant does not have an excused absence, this is their only option for taking a retest. Please indicate top three (3) choices for make-up testing dates. If scheduling a retest for an UNEXCUSED absence, please indicate three (3) choices for retesting that fall within 45 calendar days of receiving the notification of score of 0%.
5. BOX E—If the laboratory plans to schedule a second on-site **ASCP GYN PT™** exam for multiple participants with **excused absences** to take the make-up test, make a checkmark in this box. Please indicate three (3) choices for make-up testing dates.
6. BOX F—If the participant has an excused absence and works at another facility where the make-up test will be taken make a checkmark in this box.
7. BOX G—Record the name and address of the laboratory facility where the participant will be taking the make-up test in this box. An Adding New Participants form will need to be completed and signed by the Laboratory Director of the make-up test laboratory location. Please fax the **Adding New Participants form** to ASCP@ 317.569.0221 as soon as possible.

The following participants did not take the ASCP on-site proficiency test on the schedule date:

Signature of Laboratory Director

Date



CLEANING TEST CHALLENGES

PURPOSE: All Proficiency Test participants who perform primary screening must review Challenges without dots. When PT Challenge Boxes are shared among multiple cytotechnologists or pathologists who perform primary screening, the Challenges must have all ink dots removed prior to assignment and review by the next participant to ensure that no participant benefits from residual ink dots. Challenges must also be cleaned and ink dots removed prior to returning to ASCP.

MATERIALS:

1. Coplin jar of 100% alcohol
2. Gauze squares
3. Paper towels
4. Microscope with 4X objective

PROCEDURE:

1. Dip each Challenge into a Coplin jar of 100% alcohol, being careful not to immerse the label into the alcohol solution.
2. Lay the Challenge on a surface covered with paper towels. Carefully wipe the Challenge with gauze squares until all evidence of dots and fingerprints is removed.
3. Microscopically review each Challenge under a 4X objective to ensure all dots have been removed. This is the only way to precisely assess that no residual ink dots remain.
4. Return all Challenges to the Styrofoam Challenge holder inside the test Challenge box in their original order.
5. Assign the cleaned test Challenge box to the next participant, or place the cleaned box in the shipping container to return to ASCP.

HANDLING BROKEN TEST CHALLENGES

PURPOSE: This procedure describes what a proctor should do if a proficiency test Challenge is broken before, during, or after it has been examined. It assures a satisfactory testing event. In the event of broken Challenges, the proctor will need to determine whether an adequate number of Test Challenge Boxes is available to test all participants, and assign equivalent replacement test Challenge boxes for participants to use in place of the broken Challenges.

CHALLENGES BROKEN DURING SHIPMENT:

1. If a proficiency test (PT) Challenge is broken on the label end or some other area that does not contain cells, and can be repaired with a piece of glass Challenge repair tape that does not interfere with microscopic interpretation, then:
 - a. The participant may continue the test.
 - b. Record the Test Challenge Box and Challenge number of the repaired Challenge at the end of **Proctor Test Administration Checklist** to alert us that the damaged Challenge was repaired.
2. If the PT Challenge cannot be repaired to a functional state:
 - a. Remove the entire Test Challenge Box with the broken Challenge from the testing process.
 - b. Replace the broken Challenge in the Styrofoam Challenge holder for return shipment. If necessary place the broken Challenge pieces in a small bag or container labeled with the Test Challenge Box label number.
 - c. Substitute an equivalent replacement Test Challenge Box with the same **ASCP GYN PT™** PREP Type label prefix for assignment to the test participants, following the test administration protocol.
 - d. If a substitute Test Challenge Box with the same **ASCP GYN PT™** PREP Type label prefix is not available, call ASCP @ 312.541.4999 ext 3902 for suggested courses of action.
3. Please complete the “Broken Challenges” section at the end of the **Proctor Test Administration Checklist**.
4. The laboratory will not be charged a fee for a Challenge broken through no fault of its own.



CHALLENGES BROKEN AT THE TESTING SITE BEFORE TEST CHALLENGE BOXES ASSIGNED:

1. Follow all applicable procedures listed above under “Challenges Broken During Shipment”.
2. The laboratory will be charged **\$200 per broken Challenge**.

CHALLENGES BROKEN AT THE TESTING SITE AFTER TEST CHALLENGE BOXES ASSIGNED:

1. If a PT Challenge is broken beyond repair during the test but it has not yet been examined:
 - a. Remove the entire Test Challenge Box with the broken Challenge from the testing process.
 - b. Assign the participant with the broken Challenge an equivalent replacement Test Challenge Box.
Follow the procedures listed above under “Challenges Broken During Shipment”.
2. If a Challenge is broken in a Test Challenge Box assigned to a pathologist participant (MD or DO), an equivalent Test Challenge Box with the same **ASCP GYN PT™** TEST Type label prefix must be assigned that has been prescreened and dotted by a cytotechnologist.
 - a. Write the new Test Challenge Box number on the **Proficiency Testing Result Form** and on the **ASCP GYN PT™** Participant Testing Log.
 - b. Record the new start time on the **Proficiency Testing Result Form**.
 - c. Complete the “Broken Challenges” section at the end of the **Proctor Test Administration Checklist**.
 - d. The laboratory will be charged **\$200 per broken Challenge**.
3. If a PT Challenge is broken beyond repair during the test, and it has already been examined by the participant:
 - a. Instruct the participant to continue with the test.
 - b. After the participant has completed the test, remove the entire Test Challenge Box with the broken Challenge from the testing process.
 - c. Replace the broken Challenge in the Styrofoam Challenge holder for return shipment. If necessary place the broken Challenge pieces in a small bag or container labeled with the Test Challenge Box label number.
 - d. Complete the “Broken Challenges” section at the end of the **Proctor Test Administration Checklist**.
 - e. The laboratory will be charged **\$200 per broken Challenge**.

CHALLENGES BROKEN AT THE TESTING SITE AFTER TESTING COMPLETED, BUT PRIOR TO RETURN

1. Replace the broken Challenge in the Styrofoam Challenge holder for return shipment. If necessary place the broken Challenge pieces in a small bag or container labeled with the Test Challenge Box label number.
2. Complete the “Broken Challenges” section at the end of the **Proctor Test Administration Checklist**.
3. The laboratory will be charged **\$200 per broken Challenge**.