Surgical Pathology

Analytes/procedures in bold type are regulated for proficiency testing by the Centers for Medicare & Medicaid Services

Performance Improvement Program in Surgical Pathology PIP (PIP1)

Category 1 CME

Program	PIP	Challenges per Shipment
Surgical pathology case review for one pathologist	▮	10
Surgical Pathology Option: PIP1 (For each additional pathologist within the same institution)		

Note: The PIP1 Program may be ordered only in conjunction with PIP.

Product Information

The Performance Improvement Program in Surgical Pathology (PIP) is designed by pathologists for the education of pathologists in general surgical pathology. This program provides a practical approach to continuing education in surgical pathology and gives pathologists a method to assess their diagnostic skills and compare their performance with that of their peers.

Each quarterly shipment will contain ten unknown cases with patient histories. PIP case selections represent a variety of neoplastic and non-neoplastic lesions, including inflammatory and infectious diseases, and will be made from various sites, encompassing essentially all organ sites.

The participant selects the appropriate diagnosis from a master list provided with each case. Also included in each mailing is a review of the case features with diagnostic highlights and educational questions. Participants are asked to return to the CAP the completed questionnaire with their diagnoses and answers to the educational questions. A certificate for CME credit is mailed to the pathologist, and a report tabulated with peer group responses will follow. The slides become the property of the PIP subscribers.

PIP is designed for educational purposes only. The program is unsuitable for proficiency testing or grading because of the large number of blocks used for each case and their inherent variability and because rare or newly described lesions are often included.

Pathologists can earn a maximum of 40 CME credits (Category 1) per pathologist for completion of an entire year (see Chapter 3, Continuing Education). For those institutions with multiple pathologists interested in participating in PIP and obtaining their own CME credits, the PIP1 option is available.

Product Fulfillment Group PIP

Online Virtual Biopsy Program VBP, VBP1

Program	VBP	Challenges per Shipment
Online virtual biopsy case review	▮	5

Category 1 CME

Online Virtual Biopsy Program Option: VBP1 (For each additional pathologist within the same institution)
Note: The VBP1 may be ordered only in conjunction with VBP.

Product Information

The Online Virtual Biopsy Program (VBP) is designed as an educational program for participants to assess and improve their diagnostic skills in surgical pathology. Using digital image technology to simulate the use of a microscope in evaluating slides enables the use of a wide variety of case materials and provides all participants with identical diagnostic challenges. This VBP is designed as an educational activity and is not designed for proficiency testing.

Four online activities will be available in 2008, each containing five diagnostic challenges. Each challenge will consist of one or more digital images derived from a single case, plus clinical history and other pertinent information. Participants will be able to manipulate the digital slide images by scanning throughout the slide field and changing the magnification. Some cases may also include gross, radiographic, or endoscopic images. Participants will receive immediate feedback as they select diagnoses from a master list and answer educational questions.

Case selections will be made from selected organ systems and may include a variety of specimen types (e.g., core biopsies, endoscopic biopsies, curettings, aspirate smears). The 2008 online VBP activities will focus on the following organ sites:

Activity	Course
2008-A	Liver biopsy
2008-B	Gynecologic biopsy
2008-C	Prostate biopsy
2008-D	Surgical pathology biopsy

Pathologists can earn a maximum of 10 CME credits (Category 1) for completion of an entire year. For those institutions with multiple pathologists interested in participating and obtaining their own CME credits, the VBP1 option is available.

For information on computer requirements and continuing medical education, please see Chapter 3, Continuing Education.

Online Dates (Participants will be notified by mail when each online activity is available.)

NSH/CAP HistoQIP HQIP

Stain/Tissue	HQIP	Challenges per Shipment A	Challenges per Shipment B
H&E–Skin (excision, non-neoplastic tissue)	▮	1	
H&E–Uterus, to include endometrium and myometrium	▮	1	
Grocott methenamine silver (GMS) – Control tissue	▮	1	
Verhoeff–van Gieson (VVG) - Lung (excision, non-neoplastic tissue)	▮	1	
Cytokeratin 20–Colorectal adenocarcinoma	▮	1	
H&E–Breast (to include non-neoplastic parenchyma)	▮		1
H&E–Spleen	▮		1
Reticulin–Liver wedge or needle biopsy	▮		1
Mucicarmine–Mucin-producing adenocarcinoma	▮		1
HMB45 (or comparable melanoma marker, excluding S100 protein)–Melanoma	▮		1

Product Information

The HistoQIP Program is designed as an educational program to improve the preparation of histologic slides. Participants will receive an evaluation specific to their laboratory, an educational critique, and a participant summary report that includes peer comparison data, evaluators' comments, and performance benchmarking data.

Twice each year, participating laboratories will submit one stained and coverslipped glass slide from five different cases (2 H&E-stained slides, 2 special stains, and 1 immunohistochemical stain). All submitted slides will be recuts of specific surgical tissue types or positive control tissue that will vary from one challenge to the next. Submitted slides will be evaluated for histologic technique by an expert panel of histotechnologists, histotechnicians, and pathologists, using uniform grading criteria. The following areas will be evaluated: fixation, tissue processing and embedding, microtomy, staining, and coverslipping.

This Survey provides an education activity that includes reading material found in the Final Critique and online learning assessment questions. All laboratory staff can participate individually and earn free CE credit without leaving the laboratory.

Predictive Markers

Analytes/procedures in **bold** type are regulated for proficiency testing by the Centers for Medicare & Medicaid Services (CMS).

Category 1 CME

Immunohistochemistry MK (MK1)

Procedure	MK	Challenges per Shipment
Immunohistochemistry	▮	4
Immunohistochemistry Option: MK1 (For each additional pathologist within the same institution)		

Note: The MK1 Program may be ordered only in conjunction with Survey MK.

Product Information

Survey MK is designed as an educational program for laboratories performing immunohistochemistry procedures for diagnostic support. Participants are asked to stain slides with antibodies to suggested "markers," using the remaining slides for an H&E stain and appropriate negative controls, and provide interpretation.

Each shipment will contain unstained, treated glass slides with brief clinical histories.

Pathologists can earn a maximum of four CME credits (Category 1) for completion of an entire year (see Chapter 3, Continuing Education). For those institutions with multiple pathologists interested in participating in Survey MK and obtaining their own CME credits, the MK1 option is available.

Product Fulfillment Group MK

HER2 Immunohistochemistry, Tissue Microarray HER2

Analyte	HER2	Challenges per Shipment
HER2	▮	40

Product Information

Each shipment will contain four ten-core tissue microarray slides, which participants are asked to stain for *HER2* using immunohistochemistry procedures and to provide interpretations.

CD117, ER, CD20, EGFR Immunohistochemistry, Tissue Microarray PM1, PM2, PM3, PM4

Analyte	PM1	PM2	PM3	PM4	Challenges per Shipment
CD117	▮				10
Estrogen Receptor (ER)		▮			10
CD20			▮		10
Epidermal Growth Factor Receptor (EGFR)				▮	10

Product Information

Surveys PM1, PM2, PM3, and PM4 are designed for laboratories performing immunohistochemistry procedures for predictive markers. Participants are asked to stain one ten-core tissue microarray slide for the assigned "marker" using immunohistochemistry procedures and provide interpretation.

Cytopathology

Analytes/procedures in **bold** type are regulated for proficiency testing by the Centers for Medicare & Medicaid Services (CMS).

Interlaboratory Comparison Program in Non-Gynecologic Cytopathology NGC (NGC1)

Program	NGC	Challenges per Shipment
Non-gynecologic cytopathology case review—glass slides	▮	5
Non-gynecologic cytopathology case review—online	▮	4 per year

CNGC includes one Laboratory response and two additional individual participants – pathologists or cytotechnologists

Cytopathology Options: NGC1 (For each additional pathologist or cytotechnologist within the same institution)

Note: The NGC1 Program may be ordered only in conjunction with NGC.

Product Information

The Interlaboratory Comparison Program in Non-Gynecologic Cytopathology (NGC) is designed as an educational opportunity for participants to assess their screening and interpretive skills. Because NGC cases are chosen for their educational value, the NGC Program is unsuitable for proficiency testing.

Each quarterly shipment will include five specimens on glass slides with patient histories. Cases include fine needle aspirations and exfoliative specimens representing a variety of conditions, both benign and malignant. Reference interpretations and laboratory peer performance, along with concise cytologic features and pertinent references, are available ***within 20 minutes by fax***, providing rapid educational feedback, peer comparison, and time to further review the material before returning the slides to the CAP.

NGC Shipments will contain instructions for accessing online virtual microscopy cases (four per year), which use digital image technology to simulate the use of a microscope. Online images will consist of rare and unusual non-gynecologic cases with ancillary information when appropriate. Participants will be able to manipulate the images by scanning across the slide, moving between planes (where appropriate), and changing the magnification. Participants will receive immediate feedback as they select interpretations from a master list and answer educational questions.

Pathologists can earn a maximum of 22 CME credits (Category 1) and cytotechnologists can earn a maximum of 22 CE credits/hours for completion of an entire year: twenty credits for glass slide review and two credits for online case review (see Chapter 3, Continuing Education).

The NGC Program includes a laboratory response and two individual response forms. For institutions with multiple pathologists or cytotechnologists interested in participating in the glass slide portion of the NGC Program and obtaining his/her own credits/hours, the NGC1 option is available. The four online cases may be accessed and completed for two CME/CE credits by all staff in a participating institution independent of the number of NGC1 options ordered.

Product Fulfillment Group NGC

Slide sets must be returned by a trackable method within the time period stated in the kit instructions. Laboratories not returning their slides on time will forfeit subsequent shipments and may be ineligible to enroll in future cytopathology programs.

Laboratories subject to CLIA should enroll in one of the PAP PT programs (see page 190). For laboratories not subject to CLIA, the PAPCE1, PAPKE1, PAPME1, and PAPJE1 programs meet the CAP Laboratory Accreditation Program requirement for participation in a peer educational program.

Interlaboratory (PAP Education) Comparison Program in Gynecologic Cytopathology PAPCE1, PAPKE1, PAPME1, PAPJE1

Procedure	PAPCE1	PAPKE1	PAPME1	PAPJE1	Challenges per Shipment
Each module includes the following slide types:					
Conventional	▮			▮	5 slides + 2 online cases
ThinPrep®			▮	▮	5 slides + 2 online cases
SurePath™		▮		▮	5 slides + 2 online cases

APAPCE1, APAPKE1, APAPME1, APAPJE1 (for each pathologist or cytotechnologist within the same institution)

Product Information

The Interlaboratory Comparison Program in Gynecologic Cytopathology (PAP) is designed as a peer educational opportunity for participants to assess their screening and interpretive skills. Each semi-annual shipment will include five ungraded specimens on glass slides with patient histories. For PAPCE1, the ungraded slides will be conventional preparations. For PAPKE1 and PAPME1, the slidesets will contain pure liquid-based slides reflective of the module chosen at enrollment. For PAPJE1, the slidesets will be a combination of conventional, ThinPrep®, and SurePath™ slides. Reference interpretations and laboratory performance profiles are available ***within 20 minutes by fax***, providing rapid educational feedback, peer comparison, and time to further review the material before returning the slides to the CAP.

Each shipment will also contain instructions to access two online virtual microscopy cases (four per year), which use digital image technology to simulate the use of a microscope. Online images will present diagnostic challenges incorporating Bethesda terminology. Participants will be able to manipulate the images by scanning across the slide, moving between planes, and changing the magnification. Participants will receive immediate feedback as they select interpretations from a master list and answer case-related educational questions.

Pathologists can earn a maximum of 12 CME credits (Category 1) and cytotechnologists can earn a maximum of 12 CE credits/hours for completion of an entire year: ten credits for glass slide review and two credits for online case review (see Chapter 3).

The PAP Education base program includes one laboratory response form. For each pathologist or cytotechnologist to participate in the 10-case glass slide portion of the PAP Program and obtain his/her own credits/hours, an APAP option (APAPCE1/APAPKE1/APAPME1/APAPJE1) should be ordered. The four online cases may be accessed and completed for two CME/CE credits by all staff in a participating institution independent of the number of APAP options ordered.

Slide sets must be returned by a trackable method within the time period stated in the kit instructions. Laboratories not returning their slides on time will forfeit subsequent shipments and may be ineligible to enroll in future cytopathology programs.

CMS APPROVED CYTOLOGY PROFICIENCY TESTING PROGRAM

2008 Gynecologic Cytology PT Program PAP PT

Procedure	PAPCPT	PAPKPT*	PAPMPT*	PAPJPT	PPTENR	Challenges per Shipment: Proficiency Testing	Education A	Education B
Conventional	▮	▮	▮	▮		10 slides	5 slides + 2 online cases	5 slides + 2 online cases
ThinPrep®			▮	▮				
SurePath™		▮		▮				
PAP PT Laboratory Enrollment					▮			

APAPCPT, APAPKPT, APAPMPT, APAPJPT (for each pathologist or cytotechnologist on the same testing date within the same institution)

** The PAPKPT and PAPMPT slidesets will contain ten liquid-based slides only.*

*** Per CLIA '88 regulations, all laboratories must be enrolled in an approved cytology proficiency-testing program and all individuals must be tested by an approved program.*

The PAP PT Laboratory Enrollment Only is designed for laboratories that possess a CLIA license to perform gynecologic cytology but have personnel that are testing at another location. The laboratory must be enrolled in a proficiency-testing program in order to be compliant with CLIA '88, even though personnel are not testing at that location.

Product Information

PAP PT builds on the PAP Program that you trust and includes ***two*** components: a CMS-approved Cytology Proficiency Testing (PT) Program and an educational Interlaboratory Comparison Program in Gynecologic Cytopathology. ***To order the PAP PT Program, you must obtain an enrollment packet from the CAP by calling 800-323-4040 option 1 or by downloading the packet from www.cap.org.***

The PAP PT Program mailing will occur on one of 24 test sessions based on participant preference and space availability. Successful completion of the PAP PT Program satisfies an individual's 2008 cytology PT requirement per CLIA.

Participation in the two education mailings (the Interlaboratory Comparison Program in Gynecologic Cytopathology or PAP Education) meets the CAP Laboratory Accreditation Program requirement for participation in a peer educational program. Each of the two education mailings will include five glass slides. Reference interpretations and laboratory performance profiles for the five glass slides are available ***within 20 minutes by fax***, providing rapid educational feedback, peer comparison, and time to further review the material before returning the slides to the CAP. Laboratories may choose either Education Series 1 or Education Series 2 ship dates.

Each education mailing will also contain instructions to access two online virtual microscopy cases (four per year), which use digital image technology to simulate the use of a microscope. Online images will consist of diagnostic challenges incorporating Bethesda terminology. Participants will be able to manipulate the images by scanning across the slide, moving between planes, and changing the magnification. Participants will receive immediate feedback as they select interpretations and answer case-related educational questions.

Pathologists can earn a maximum of 12 CME credits (Category 1) and cytotechnologists can earn a maximum of 12 CE credits/hours for completion of an entire year: ten credits for glass slide review and two credits for online case review (see Chapter 3).

PT Event Date Choices: see shipping calendar at end of catalog

Online Digital Slide Program in Fine Needle Aspiration FNA (FNA1)

Category 1 CME

Program	FNA	Challenges per Shipment
Online digital slide fine needle aspiration case review	▮	5

Online Digital Slide Program in FNA Option: FNA1 (For each additional pathologist within the same institution)
Note: The FNA1 Program may be ordered only in conjunction with FNA.

Product Information

The Online Digital Slide Program in Fine Needle Aspiration (FNA) is an educational program for pathologists and experienced cytotechnologists to assess and improve their diagnostic skills in non-gynecologic fine needle aspirations. Using digital image technology to simulate the use of a microscope in evaluating slides enables the use of a wide variety of case materials and provides all participants with identical diagnostic challenges. This FNA program will focus on diagnostic dilemmas encountered by pathologists in practice and is designed as an educational activity. It is not suitable for proficiency testing.

Two online activities will be available, each activity containing five diagnostic challenges. Each challenge will consist of one or more digital images derived from a single case, plus clinical history and other pertinent information. Participants will be able to manipulate the digital slide images by scanning throughout the slide field, moving between planes (where appropriate), and changing the magnification. Participants will receive immediate feedback as they select interpretations from a master list and answer educational questions.

Selections of ancillary studies such as immunohistochemical stains, molecular tests, and/or flow cytometry will be available as appropriate.

Pathologists can earn a maximum of 5 CME credits (Category 1) and cytotechnologists can earn a maximum of 5 CE credits/hours for completion of an entire year. For those institutions with multiple pathologists and/or cytotechnologists interested in participating and obtaining their own CME/CE credits, the FNA1 option is available.

Product Fulfillment Group FNA

Human Papillomavirus for Cytology CHPVD, CHPVM, CHPVK, CHPVJ

New

Analyte	CHPVD	CHPVM	CHPVK	CHPVJ	Challenges per Shipment
HPV	▮	▮	▮	▮	5

Note: These Surveys are intended for cytopathology labs that have their own CLIA number and are performing HPV testing. Each product will meet regulatory requirements for vial identification.

Product Information

Surveys CHPVD, CHPVM, CHPVK, and CHPVJ are designed for laboratories performing nucleic acid amplification for HPV. Each shipment will include simulated cervical specimens.

Survey CHPVD Digene® Specimen Transport Medium™ (STM)
Survey CHPVM ThinPrep® Preservcyt® transport media
Survey CHPVK SurePath™ Preservative Fluid transport medium
Survey CHPVJ Digene, Preservcyt, and/or SurePath transport medium

Product Fulfillment Group CHPV

Specialty Anatomic Pathology

Analytes/procedures in **bold** type are regulated for proficiency testing by the Centers for Medicare & Medicaid Services (CMS).

Neuropathology Program NP (NP1)

Program	NP	Challenges per Shipment
Neuropathology case review ***Now on CD-ROM***	▮	8
Neuropathology Option: NP1 (For each additional pathologist within the same institution)		

Note: The NP1 Program may be ordered only in conjunction with NP.

Product Information

The Neuropathology Program is designed as an educational program for anatomic pathologists, neuropathologists, and trainees to assess and improve their diagnostic skills and to learn of new developments in neuropathology.

Each shipment contains a CD-ROM with eight cases that cover the spectrum of neoplastic and non-neoplastic disorders affecting the central and peripheral nervous systems, including infectious, degenerative, developmental, demyelinating, traumatic, toxic-metabolic, vascular, and neuromuscular diseases. Four of the eight cases in each shipment comprise a mini-symposium focused on a specific problem area in neuropathology. The other four cases cover a variety of nervous system diseases.

For each case, pertinent clinical and laboratory information and several microscopic images are provided. Some cases also include radiographic and/or gross images. Following review of the case materials, participants answer a series of questions directed at diagnosis, interpretation, and pathophysiology.

All participants receive on the CD-ROM a critique including diagnosis, focused discussion and review, and selected references for each case. Participants can also download case materials from the CD-ROM for educational purposes. The NP cases are selected for their educational value; the case selection and evaluation process make the program unsuitable for proficiency testing or grading.

Pathologists can earn a maximum of eight CME credits (Category 1) for completion of an entire year (see Chapter 3, Continuing Education). For those institutions with multiple pathologists interested in participating and obtaining their own CME credits, the NP1 option is available. Survey NP1 will include only a result form and CME form for an additional pathologist within the same institution.

Product Fulfillment Group NP

Autopsy Pathology AU (AU1), AUCD (AUCD1)

Category 1 CME

Program	AU	AUCD	Challenges per Shipment
Autopsy case analysis	▮		6
Autopsy case analysis (CD-ROM)		▮	6

Autopsy Pathology Option:
AU1 (For each additional pathologist within the same institution)
Autopsy Pathology CD-ROM Option:
AUCD1 (For each additional pathologist within the same institution)

Note: The AU1 Program may be ordered only in conjunction with Survey AU. The AUCD1 Program may be ordered only in conjunction with Survey AUCD.

Product Information

Participants in the program will receive detailed discussions of challenging autopsy cases. Each shipment of Survey AU will include six cases, each consisting of a case description and illustrative 35mm gross and/or microscopic slides, with questions directed at aspects of interpretive analysis, differential diagnosis, pathophysiology, cause of death, and quality assurance. In addition, each case will include a PowerPoint summary slide highlighting the key teaching points of each case. Survey AU1 will include only a Result Form and CME form for an additional pathologist within the same institution. To provide participants with immediate feedback, detailed discussions with current references will be included in the original mailing.

Each shipment of Survey AUCD will include the same six cases as above, but instead of 35mm slides, the images will be provided on a CD-ROM. Survey AUCD1 will include only a Result Form and CME form for an additional pathologist within the same institution. To provide participants with immediate feedback, detailed discussions with current references will be included in the original mailing.

Pathologists can earn a maximum of 12 CME credits (Category 1) for completion of an entire year (see Chapter 3, Continuing Education). For those institutions with multiple pathologists interested in participating and obtaining CME credit, the AU1 and AUCD1 options are available. Surveys AU and AUCD are designed for educational purposes and are not suitable for proficiency testing.

Cytogenetics and Molecular Pathology

Analytes/procedures in **bold** type are regulated for proficiency testing by the Centers for Medicare & Medicaid Services (CMS).

ACMG/CAP Fluorescence In Situ Hybridization – Breast Cancer (*HER2* Gene Amplification) CYH

Procedure	CYH	Challenges per Shipment
HER2 gene amplification for breast cancer	▮	10

Product Information

Survey CYH is designed for clinical laboratories that perform fluorescence in situ hybridization (FISH) using chromosome-specific *HER2* DNA probes. Participants will use their own chromosome-specific DNA probes and FISH methodology to process and score a series of interphase nuclei for each specimen.

Each mailing will consist of two five-core tissue microarray slides that offer a combined total of ten paraffin-embedded breast tissues specimens. A duplicate set of H&E stained tissue microarray slides will be provided with the shipment.

ACMG/CAP FISH For Paraffin-Embedded Tissue – CYJ, CYK, CYL

				Challenges per Shipment	
Gene/Region of Interest	**CYJ (Glioma tissue)**	**CYK (Sarcoma tissue or pediatric neoplasm)**	**CYL (Lymphoma tissue)**	**A**	**B**
1p/19q	▮			1	1
MYCN		▮		1	
ALK			▮	1	
CHOP		▮			1
MYC			▮		1

Product Information

These Surveys are designed for clinical laboratories that perform fluorescence in situ hybridization (FISH) using chromosome-specific DNA probes in paraffin-embedded tissue (see CYF for FISH in cell suspension specimens). Participants will use their own chromosome-specific DNA probes and FISH methodology to process and score a series of interphase nuclei for each specimen. All specimens will be 4-micron tissue sections mounted on positively charged glass slides. One hematoxylin-eosin stained slide will also be provided with each challenge for reference.

The first mailing (CYP-A) will include one challenge each for CYJ, CYK, and CYL. CYJ-A will consist of four unstained slides from paraffin-embedded tissue representing a neurological cancer specimen (glioma). Participants are to use FISH probes for detection of deletions within 1p36 and 19q13 band regions. CYK-A will consist of two unstained slides from paraffin-embedded tissue representing a pediatric neoplasm. Participants are to use FISH probes to detect aberrations of the *MYCN* gene (2p24.3). CYL-A will consist of two unstained slides from paraffin-embedded tissue representing a lymphoma specimen. Participants are to use FISH probes to detect rearrangement of the *ALK* gene (2p23).

The second mailing (CYP-B) will include one challenge each for CYJ, CYK and CYL. CYJ-B will consist of four unstained slides from paraffin-embedded tissue representing a neurological cancer specimen (glioma). Participants are to use FISH probes for detection of deletions within 1p36 and 19q13 band regions. CYK-B will consist of two unstained slides from paraffin-embedded tissue representing a sarcoma tissue. Participants are to use FISH probes to detect aberrations of the *CHOP* (*DDIT3*) gene (12q13). CYL-B will consist of two unstained slides from paraffin-embedded tissue representing a lymphoma specimen. Participants are to use FISH probes to detect rearrangement of the *MYC* gene (8q24.1).

Product Fulfillment Group CYP

In Situ Hybridization ISH

Procedure	ISH	Challenges per Shipment
In situ hybridization	▮	1
Kappa lambda	▮	1

Note: Brightfield in situ *hybridization for* HER2 *is now offered in ISH2*

Product Information

Survey ISH offers laboratories performing clinical *in situ* hybridization tests the opportunity to objectively evaluate their performance for targets including human papillomavirus (HPV) and Epstein-Barr virus (EBV). Information including the conditions of slide pretreatment, probe type, hybridization conditions, and detection systems will be used to facilitate interlaboratory comparison of methods and standardization. Laboratories performing FISH for interphase chromosomal targets in paraffin sections should refer to CY Surveys.

Each shipment for *in situ* hybridization analysis will include a set of treated glass slides upon which are mounted one or more formalin-fixed, paraffin-embedded sections of either cell pellets or tissues containing the nucleic acid target of interest, along with appropriate information for direct testing. Each shipment will also contain one challenge for kappa-lambda mRNA. The kappa-lambda challenge will include a set of glass slides.

Product Fulfillment Group ISH

New

In Situ Hybridization, *HER2* ISH2

Analyte	ISH2	Challenges per Shipment
HER2 gene amplification for breast cancer	▮	10

Product Information

Survey ISH2 is designed for clinical laboratories that perform brightfield in situ hybridization (ISH) for *HER2*.

Each mailing will consist of two five-core tissue microarray slides that offer a combined total of ten unique paraffin-embedded breast tissue specimens.

Product Fulfillment Group ISH

Molecular Oncology MO, MO2, MO3

Procedure	MO	MO2	MO3	Challenges per Shipment
Molecular analysis (cells, frozen tissue, or DNA)	▮			2
Molecular analysis, double volume (cells, frozen tissue, or DNA)		▮		2
Molecular analysis (paraffin sections)			▮	2

Product Information

Survey MO is designed for laboratories performing molecular analysis of leukemias and lymphomas. Survey MO2 contains additional sample vials to accommodate laboratories performing RNA testing in addition to DNA testing. Survey MO3 is for laboratories performing molecular analysis of leukemias and lymphomas on paraffin sections. *Note: Laboratories performing immunophenotyping on patients with leukemia and/or lymphoma should refer to Survey FL3 on page 151 and Survey MK on page 186.*

Each shipment of Survey MO will include two sample vials containing a snap frozen cell pellet, frozen tissue specimen, or DNA. From each pellet or frozen tissue specimen, at least 100 µg of DNA can be extracted for Southern blot analysis and/or amplification of antigen receptor (B- and T-cell) gene arrangement or selected (B- and T-cell) translocations (eg, *bcr*). Survey MO2 will contain four sample vials (two per specimen). Each shipment of Survey MO3 will contain four 10-micron paraffin sections per specimen.

Product Fulfillment Group MO

Minimal Residual Disease MRD

Analyte	MRD	Challenges per Shipment
Minimal residual disease	▮	2

Product Information

Survey MRD is designed for laboratories that perform minimal residual disease testing in cancer patients. The Survey is specifically designed for laboratories monitoring chronic myelogenous leukemia by measuring the quantity of *BCR/ABL1* transcripts at diagnosis and during or after therapy. The MRD Survey is also applicable for monitoring acute leukemia for *BCR/ABL1*.

Each shipment of Survey MRD will include three sample vials, each holding a frozen cell pellet or extracted RNA. The first sample will typically be a baseline sample, while samples two and three will represent follow-up samples.

Microsatellite Instability MSI

Analyte	MSI	Challenges per Shipment
Microsatellite instability (paraffin sections)	▮	1

Product Information

Survey MSI is designed for laboratories performing microsatellite analysis of paraffin-embedded colorectal carcinoma (or other HNPCC-related tumors) by DNA amplification.

Each shipment will include one H&E slide and two or more 10-micron unstained sections on glass slides to be used to isolate DNA from tumor and normal tissue for microsatellite instability analysis.

Sarcoma Translocation SARC

Analyte	SARC	Challenges per Shipment
Sarcoma translocation	▮	1

Product Information

Survey SARC is designed for laboratories performing molecular analysis of sarcoma translocations by RT-PCR. The participants may perform testing on the sample for any sarcoma translocation, including *EWS/EGR,* t(21;22); *EWS/FL11*, t(11;22); *EWS/WT1*, t(11;22); *FUS/CHOP*, t(12;16); *PAX3/FKHR*, t(2,13); *PAX7/FKHR*, t(1;13); *PDGFB/COL1A1*, t(17;22); *SYT/SSX1*, t(X;18); *SYT/SSX2*, t(X;18); and *SYT/SSX*, NOS.

Each shipment of Survey SARC will include one snap frozen cell pellet or extracted RNA from which the participant will be able to extract approximately 5 to 10 micrograms of RNA.