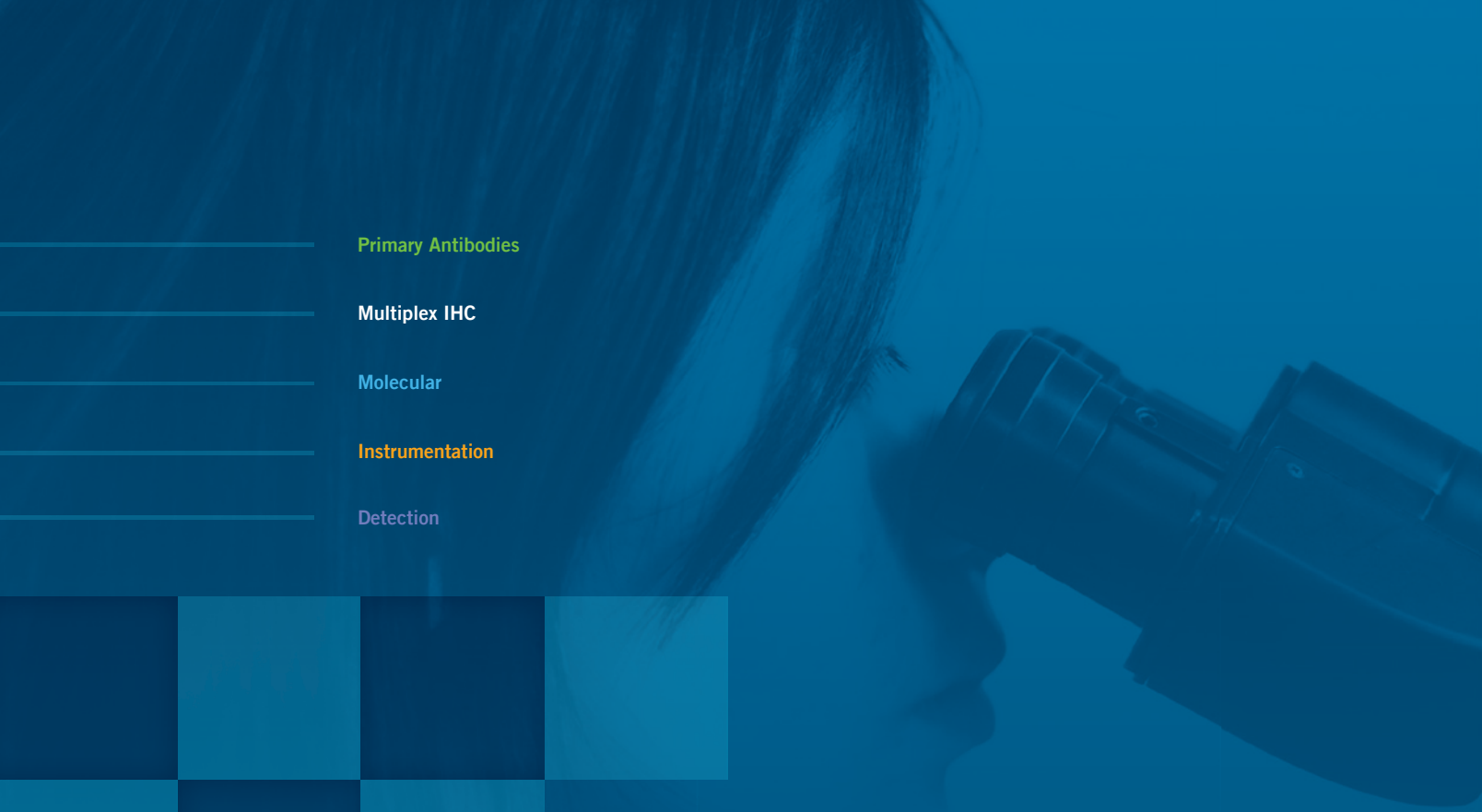
Product Catalog

BIOCARE MEDICAL

Supplement 2012

www.biocare.net



Primary Antibodies

Multiplex IHC

Molecular

Instrumentation

Detection

Fighting Cancer

One Slide at a Time

Contact Customer Service
7:00 am - 5:00 pm PST
Toll Free 800-799-9499
customerservice@biocare.net

Contact Biocare Medical
Toll Free 800-799-9499
Local 925-603-8000
Fax 925-603-8080

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24/7 Live Technical Support
Toll Free 800-799-9499 **Option 3**
techsupport@biocare.net

BIOCARE MEDICAL

4040 Pike Lane, Concord, CA 94520

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Ordering Information

How to Place an Order

Contact customer service, orders may be submitted via phone, fax, email or standard mail. Please provide the following information on your purchase order or correspondence: Purchase order number; Name, telephone number, shipping address (No P.O. boxes) and billing address (If applicable); Name of product, catalog number, and quantity; Credit card number, expiration date and name exactly as it appears on the credit card.

Place an Order Internationally

To order outside the USA, please contact the Biocare Medical international distributor closest to you. For a list of current international distributors visit us online at www.biocare.net.

Payment Methods

Payments must be made in U.S. dollars. Methods of payment are as follows: MasterCard, VISA, American Express or by check, drawn on a U.S. bank, made payable to “Biocare Medical, LLC”.

Conditions of Sale

All prices are quoted in U.S. dollars, exclusive of state and county tax, where applicable. Prices are subject to change without notice.

Credit Terms

Net 30 upon approval. Overdue accounts are subject to finance charges.

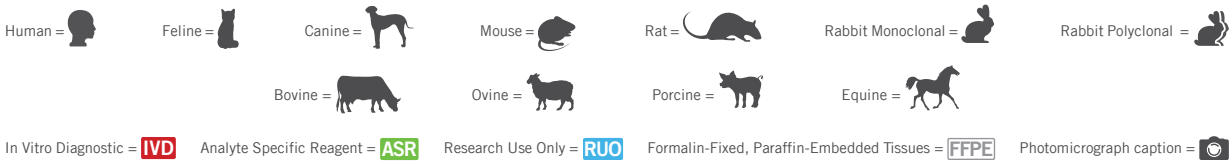
Shipping & Priority Delivery

Shipments are F.O.B. Concord, CA. Freight and handling charges must be prepaid and are added to the invoice. Priority and Saturday delivery are available on request.

Returns

If you are not completely satisfied with the performance of a product, you may return it to Biocare Medical for a refund or replacement, at our discretion. Returns can only be accepted with a return identification number and authorization. Contact Customer Service for assistance in returning products. (Returns not caused by unsatisfactory product performance must be approved by Biocare in advance and made within 30 days of delivery and will be subject to a 30% restocking fee.)

Image Identification Key

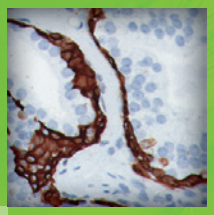


Product Size Key

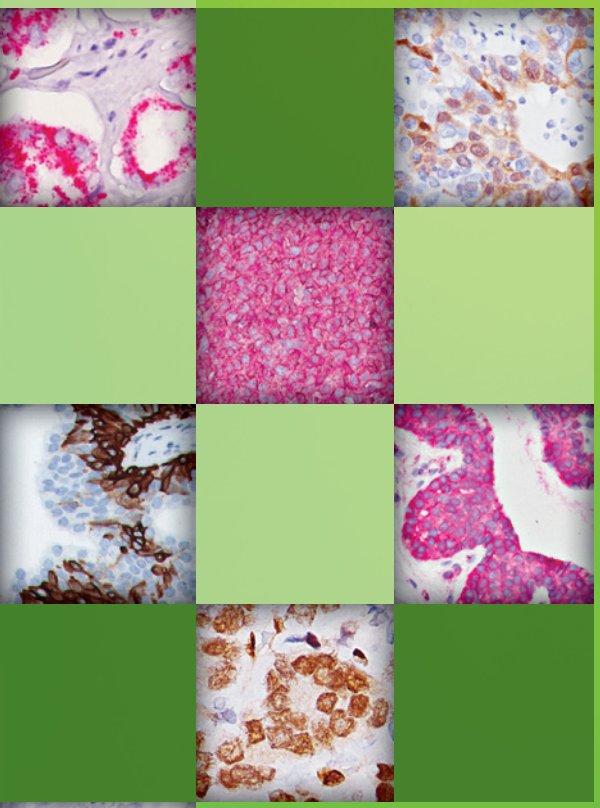
Letter	Volume
A, AK	0.1 ml
B, BK	0.5 ml
C, CK	1.0 ml
G5	5.0 ml
AA, G, KG	6.0 ml
G10	10 ml

Letter	Volume
G20	20 ml
H, G25, KH	25 ml
JJ, R	50 ml
G80	80 ml
L, LX, S	100 ml
L10	110 ml

Letter	Volume
LL	200 ml
M, M-RVS, MX	500 ml
MM, MMRTU	1000 ml
BULK	2.5 L
G1, GL	1 gallon
G4	4 gallons



Primary Antibodies

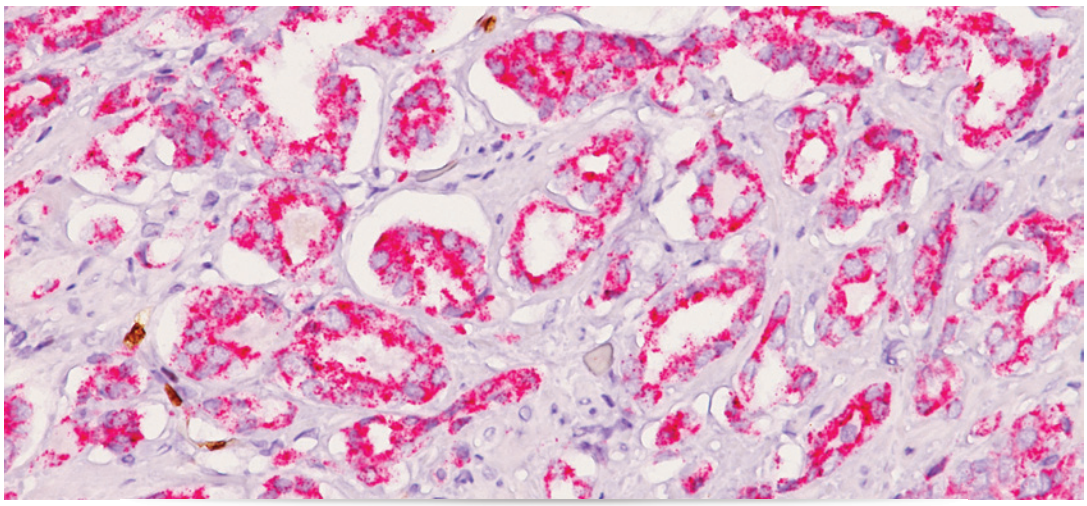


Biocare Medical's dedicated Research & Development Team pride themselves on developing the most sensitive and highly specific antibodies which are suitable for use in the anatomical pathology laboratory. We are routinely expanding our antibody offerings to include key antibodies that are critical to cancer and infectious disease diagnosis. We provide exclusive, licensed antibodies such as ERG, p63 and PAX8, which are crucial aids in diagnostic decision making. All Biocare antibodies are optimized for immunohistochemical procedures for use on FFPE tissues. They are formulated to provide maximum sensitivity while concurrently minimizing the amount of background staining. Available in both prediluted and concentrated formats, we also offer a concise list of antibodies that are optimized for our automated slide stainer, the intelliPATH™, and for the Ventana Medical Systems instrumentation. Our antibodies are readily available in a number of formats, thus making them accessible to all laboratories that perform IHC.

- Most prediluted antibody solutions are available in 6 ml or 25 ml dropper bottles, and are designed to work in tandem with Biocare Detection Systems

- Most concentrates are available in 0.1 ml, 0.5 ml and 1.0 ml sizes. Each antibody is shipped with an informative data sheet indicating the recommended protocol

AMACR, 2X ASR FFPE



Prostate cancer stained with AMACR, 2X antibody

AMACR (P504S) protein is expressed in prostatic adenocarcinomas, but not in benign prostatic tissue. It has also been found to be expressed in some premalignant lesions of the prostate: high-grade prostatic intraepithelial neoplasia (PIN) and atypical adenomatous hyperplasia. AMACR can be used as a positive marker for prostate cancer and may be useful to confirm small foci of prostate carcinoma in needle biopsies. AMACR stains the majority of prostate cancer; however, AMACR has been shown to stain many other types of carcinomas such as hematomas, breast carcinomas, pancreatic and islet tumors.

Clinical Relevance

- Definitively identifies prostate cancer - does not stain normal pancreas or normal prostate glands
- A known diagnostic marker for Barrett's esophageal cancer

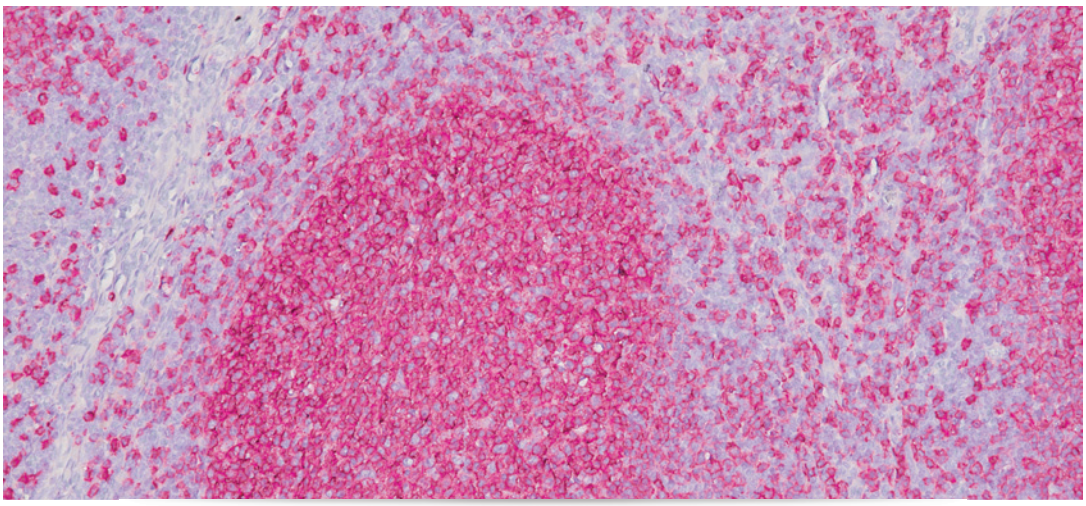
Ordering Information

Concentrate	APA 3016 AA

Specifications

Clone	13H4
Isotype	Rabbit IgG
Reactivity	N / A
Control	N/A

CD20 (P) RUO FFPE FARMA



Dog tonsil stained with CD20 (P) antibody

This antibody has been optimized to work with Biocare Medical's PromARK™ detection products for animal tissues. CD20 is a 33 kDa leukocyte surface antigen consisting of four transmembrane regions and cytoplasmic N- and C-termini. CD20 is expressed primarily on B-cells but has also been detected on both normal and neoplastic T-cells. This gene encodes a B-lymphocyte surface molecule which plays a role in the development and differentiation of B-cells into plasma cells. CD20 has been tested and confirmed on multiple mammalian tissues including feline, canine, bovine, porcine, equine, ovine and human, but does not cross-react in mouse or rat tissues.

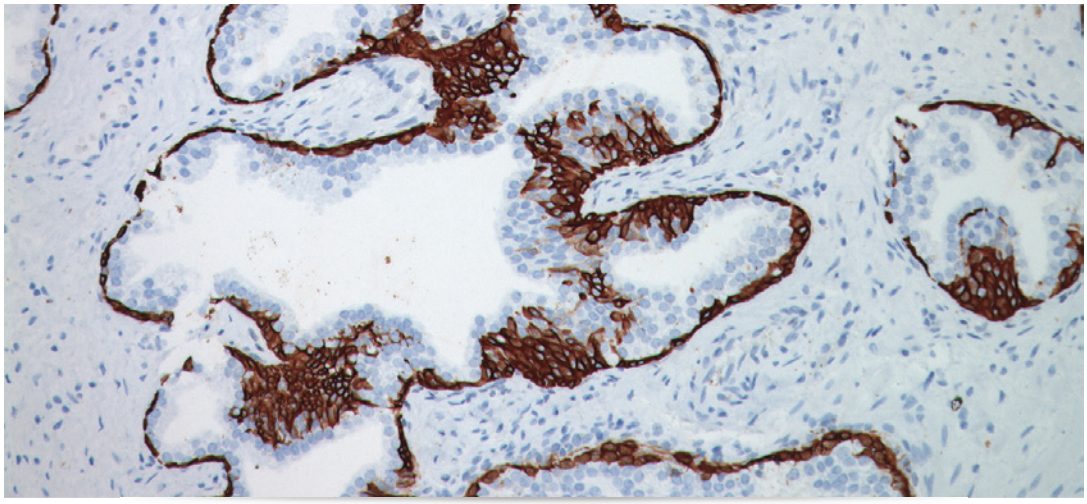
Ordering Information

Concentrate	ACR 3004 A, B

Specifications

Clone	N/A
Isotype	N/A
Reactivity	
Control	Tonsil or B-cell Lymphoma

Cytokeratin 5 (CK5) IVD FFPE



Prostate glands stained with Cytokeratin 5 (CK5) antibody

CK5 is a type II intermediate filament protein that is expressed in active basal layers of most stratified squamous epithelia. CK5 tissue distribution is in many non-keratinizing stratified squamous epithelia as well as basal cells in prostate glands and myoepithelial cells in mammary glands. CK5 is also expressed in most epithelial and biphasic mesotheliomas.

Studies have shown CK5/6 to be a specific marker for lung squamous carcinoma and mostly negative for lung adenocarcinoma. In a published study, rabbit monoclonal CK5 antibody was compared to mouse monoclonal CK5/6. CK5 was 84% sensitive and 100% specific for lung SqCC, compared to CK5/6 (80% sensitivity and 97% specificity). CK6 mRNA has been detected in lung adenocarcinomas and thus CK5 alone may be a more specific marker than CK5/6. The CK5 predilute has been optimized for lung squamous cell carcinoma; other tumors have not been tested.

Clinical Relevance

- 84% sensitive and 100% specific for lung squamous carcinoma (SqCC)

Ordering Information

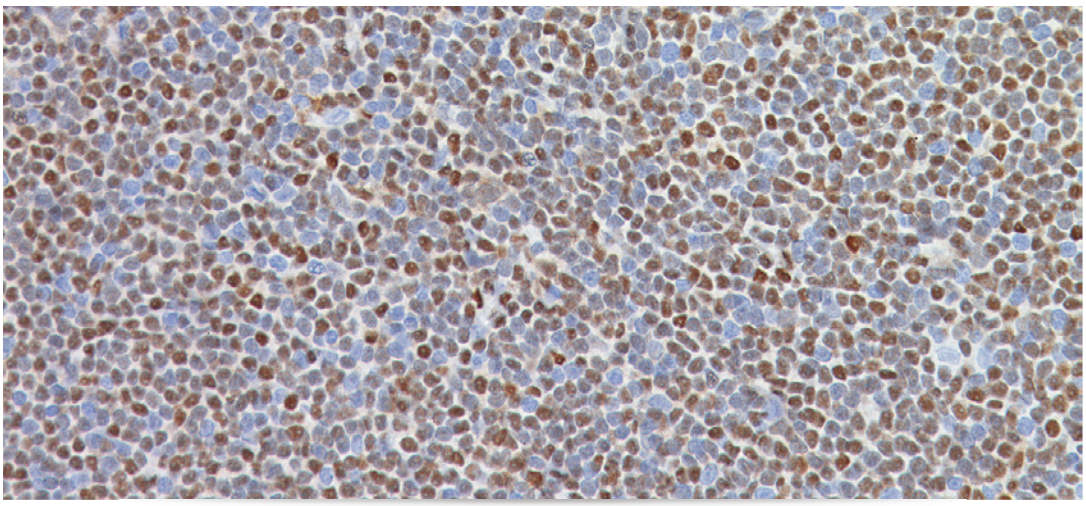
Concentrate	CME 430 A, B	**Predilute**	PME 430 AA

Specifications

Clone	EP1601Y
Isotype	N/A
Reactivity	
Control	Lung SqCC, some Breast Cancers or normal Prostate, Skin

Cyclin D1

IVD FFPE



Mantle cell lymphoma stained with Cyclin D1 antibody

This rabbit monoclonal antibody recognizes a protein of 36 kDa, identified as Cyclin D1 (also known as BCl-1 or PRAD-1). Cyclin D1 is a regulatory subunit of certain protein kinases thought to advance the G1 phase of the cell cycle. Cyclin D1 used in tandem with CD5, CD10 and CD23 is the most reliable immunohistochemical marker for mantle cell lymphoma. Cyclin D1 is also expressed in invasive breast cancer. Due to the superior technology in the development of this antibody, its binding capacity is superior to mouse monoclonal antibodies and is virtually background free.

Clinical Relevance

- Use in tandem with CD5, CD10 and CD23 as a marker for mantle cell lymphoma

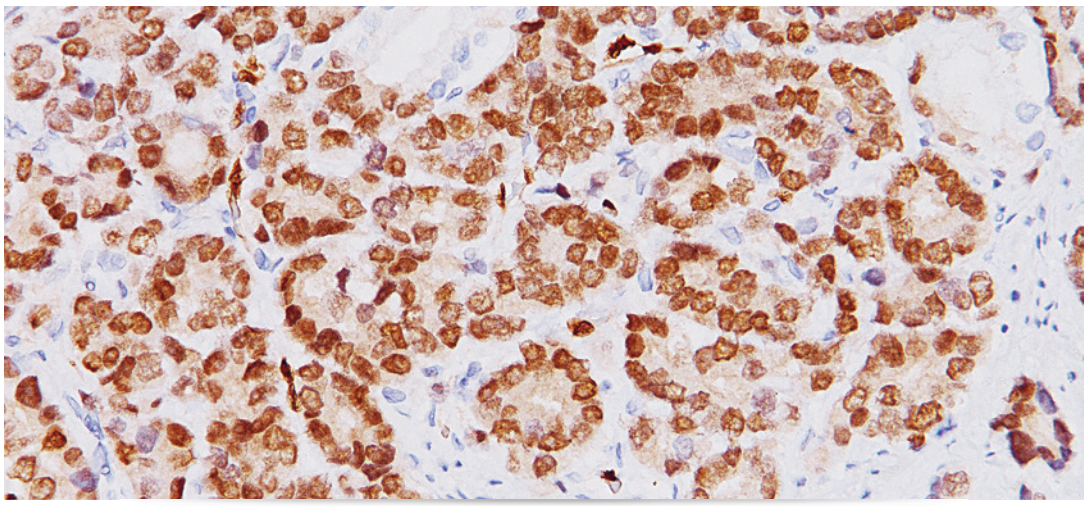
Ordering Information

Concentrate	CME 432 A, C	**Predilute**	PME 432 AA

Specifications

Clone	EP12
Isotype	Rabbit IgG
Reactivity	
Control	Mantle Cell Lymphoma, Breast Cancer

ERG IVD FFPE



Prostate cancer stained with ERG antibody

The TMPRSS2:ERG fusion gene is the most frequent gene rearrangement in prostate cancers, occurring in 45-65% of North American patients. A mouse monoclonal anti-ERG antibody was developed with 99.9% specificity for detecting prostatic adenocarcinomas. There is a strong correlation between the expression of the ERG protein and the presence of TMPRSS2:ERG rearrangement and a 96.5% concordance of ERG positive prostatic intraepithelial neoplasia (PIN) and ERG positive carcinoma in prostatectomy specimens. *Note: ERG [9FY] was developed by the Center for Prostate Disease Research in association with the Henry M. Jackson Foundation, Rockville, Maryland. Patent Pending.*

Clinical Relevance

- 99% specific for prostate carcinoma with clone 9FY
- ERG has been recently used in detecting endothelial malignancies, such as Kaposi sarcoma
- ERG high grade PIN may indicate the need for subsequent biopsy

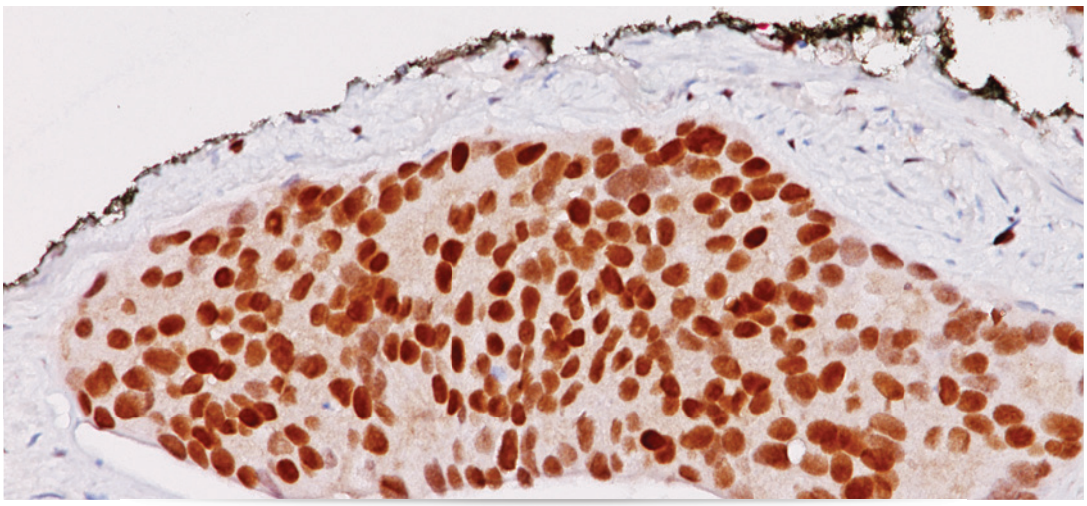
Ordering Information

Concentrate	CM 421 A, C	**Predilute**	PM 421 AA	**VP Echelon**	VP 421 G

Specifications

Clone	9FY
Isotype	IgG1
Reactivity	
Control	ERG+ Prostate Cancer and/or PIN glands

ERG, 2X (M) IVD FFPE



ERG Translocation in prostate biopsy

The TMPRSS2:ERG fusion gene is the most frequent gene rearrangement in prostate cancers, occurring in 45-65% of North American patients. A mouse monoclonal anti-ERG antibody was developed with a 99.9% specificity for detecting prostatic adenocarcinomas. There is a strong correlation between the expression of the ERG protein and the presence of TMPRSS2:ERG rearrangement and a 96.5% concordance of ERG positive prostatic intraepithelial neoplasia (PIN) and ERG positive carcinoma in prostatectomy specimens. ERG, 2X (M) may be combined with AMACR, 2X (RM) to form a primary antibody cocktail.

Clinical Relevance

- 99% specific for prostate carcinoma with clone 9FY
- ERG high grade PIN may indicate the need for subsequent biopsy
- ERG has been recently used in detecting endothelial malignancies, such as Kaposi sarcoma

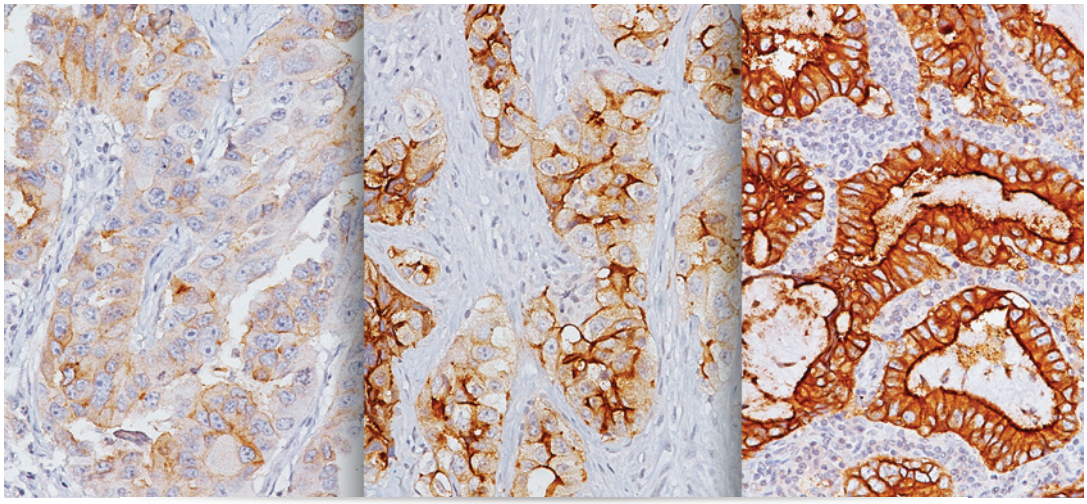
Ordering Information

Predilute	API 3017 AAK

Specifications

Clone	9FY
Isotype	IgG1
Reactivity	
Control	ERG+ Prostate Cancer and/or PIN glands

Folate Receptor Alpha (FRalpha) Kit IVD FFPE



Lung adenocarcinoma, [26B3.F2] from left to right: 1+ staining, 2+ staining, 3+ staining

The Folate Receptor Alpha IHC Assay Kit is intended for use in IHC procedures for the identification of Folate Receptor alpha (FRalpha) expression in FFPE tissue sections. Mouse anti-human Folate Receptor alpha monoclonal antibody [26B3.F2] specifically recognizes the alpha isoform of Folate Receptor. FRalpha is primarily expressed in the apical surface of some polarized epithelial cells of normal tissues (such as kidney, lung, breast, and salivary glands) and on many cancer cells of epithelial origin; namely, ovarian cancer, thyroid cancer, non-small cell lung adenocarcinoma (NSCLC) and endometrial cancer. In the most widely studied tumor, epithelial ovarian cancer, expression of FRalpha increases with tumor stage, and is associated with decreased survival. However, in NSCLC, FRalpha has been shown to be specific for adenocarcinomas relative to squamous cell carcinoma and other histologic subtypes, and increased expression has been correlated to increased survival.

Clinical Relevance

- A positive prognostic indicator for Stage I and Stage II lung adenocarcinomas
- A negative prognostic indicator for ovarian, endometrial and breast cancers

Ordering Information

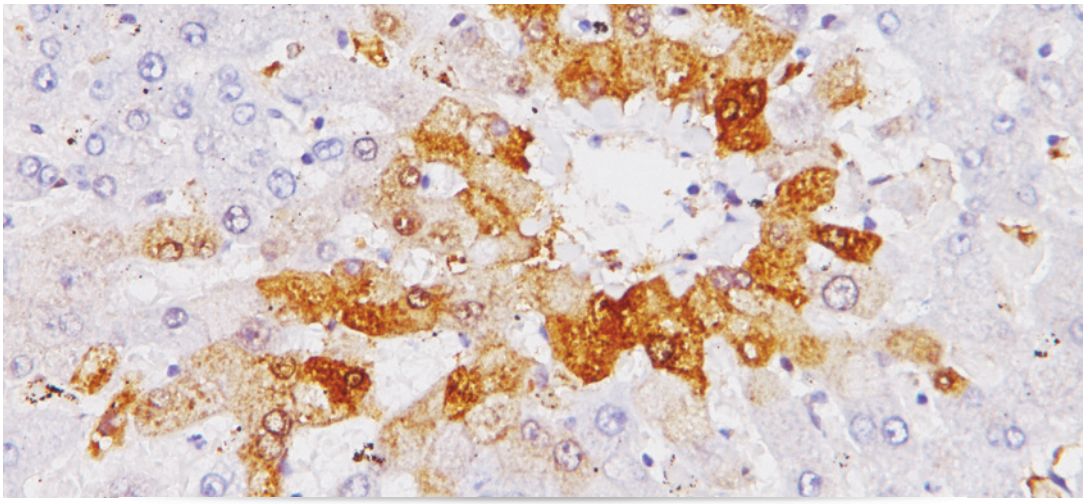
Predilute	BRI 4006K AA	**intelliPATH™**	IPI 4006K G10

Specifications

Clone	26B3.F2
Isotype	IgG1
Reactivity	
Control	Lung Adenocarcinomas or Ovarian Serous Papillary Adenocarcinoma

Glutamine Synthetase

IVD FFPE



Liver stained with Glutamine Synthetase antibody

Glutamine Synthetase (GS) catalyzes the synthesis of glutamine, which is the major energy source of tumor cells. Accumulation of GS was first found through analyzing increased ubiquitinated protein in hepatocellular carcinoma (HCC) and its stepwise increase in expression from precancerous lesions to early advanced HCC. Liver biopsy for HCC detection is largely restricted to small hepatocellular lesions, which are often morphologically challenging, requiring careful distinction between dysplastic nodules (high-grade) and well-differentiated HCC. When a panel of GS, Heat Shock Protein 70 and Glypican 3 is used, if any 2 of the 3 are positive, the sensitivity and specificity for the detection of early and HCC-G1 was 72% and 100% respectively.

Clinical Relevance

- Differentiate between benign and malignant hepatocellular carcinomas
- Distinguish between astrocytic and oligodendroglial tumors

Ordering Information

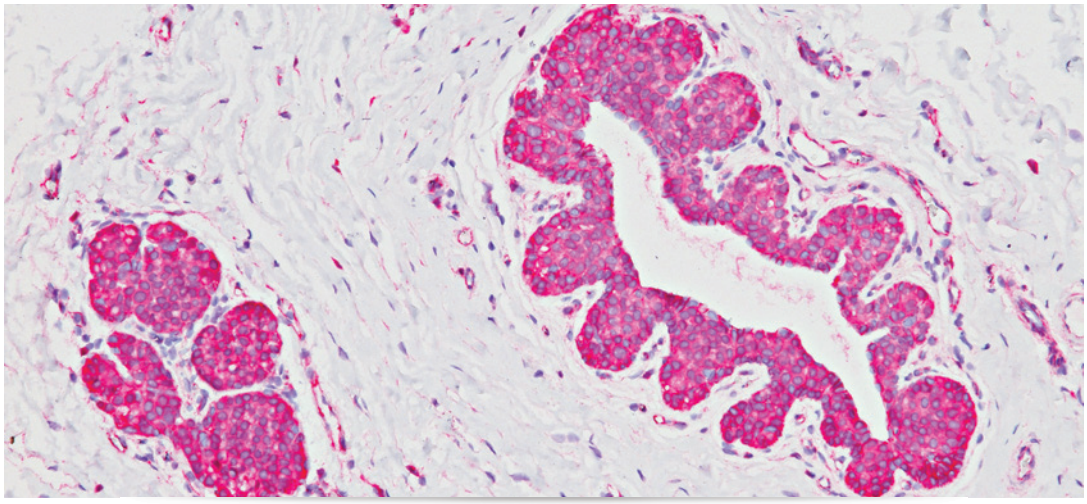
Concentrate	ACI 3009 A, B	**Predilute**	API 3009 AA

Specifications

Clone	6/Glutamine Synthetase
Isotype	IgG2a
Reactivity	
Control	Hepatocellular Carcinoma

p120 Catenin

IVD FFPE



Lobular breast carcinoma *in situ* stained with p120 Catenin antibody

p120 is a proliferation-associated nucleolar protein found in most human malignant tumors, but not in resting normal cells. p120 expression could be a prognostic marker for resected Stage I lung adenocarcinoma. In colorectal cancer the altered localization of p120 catenin corresponds with loss of cytoplasmic localization of E-cadherin and has been associated with an increase in tumor stage and lymph node metastasis.

Studies have shown accurate categorization of ductal vs. lobular neoplasia in the breast was achieved with p120 staining. p120 expression further clarifies the separation of low-grade ductal carcinoma *in situ* from lobular neoplasia. E-cadherin, a negative membrane marker for lobular neoplasia, is useful in the distinction of ductal neoplasia vs. lobular but can be difficult to interpret.

Clinical Relevance

- p120, combined with E-cadherin, can aid in categorization of ductal vs. lobular neoplasia
- p120 can be particularly useful in identifying early lesions of lobular neoplasia

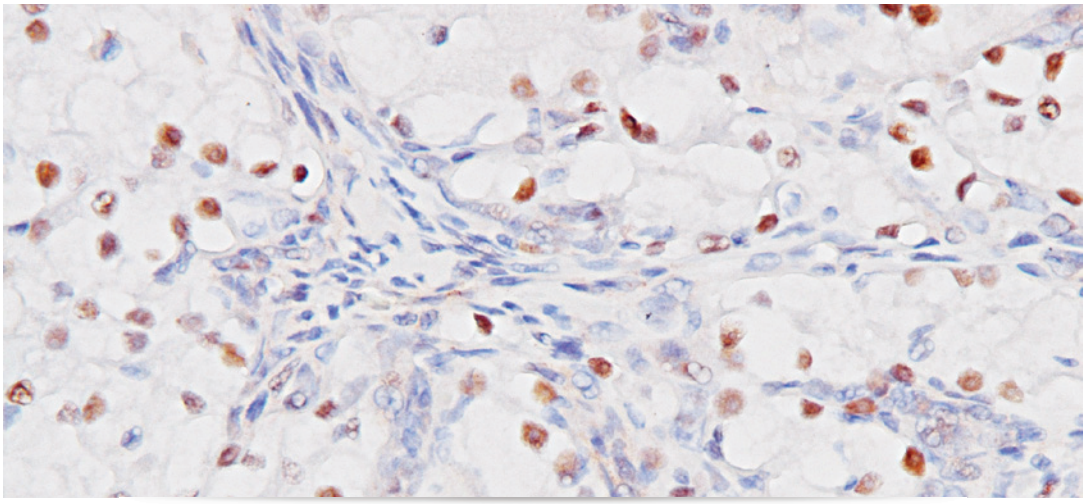
Ordering Information

Concentrate	ACI 3008 A, B	**Predilute**	API 3008 AA

Specifications

Clone	98/pp120
Isotype	IgG1
Reactivity	
Control	Breast Cancer

PAX8 (M) IVD FFPE



PAX8 expressed in clear cell renal carcinoma

PAX8 is a member of the paired box (PAX) family of transcription factors, which plays critical roles during fetal development and cancer growth. PAX8 is expressed in a high percentage of renal cell carcinomas and ovarian cancers.

This mouse monoclonal PAX8 antibody [BC12] has been designed to target restricted epitopes, and exhibits higher specificity and provides sharper staining than our PAX8 rabbit polyclonal antibody. This mouse monoclonal antibody does not stain B-cells, nor does it recognize epitopes of pancreatic origin and neuroendocrine cells in stomach and colon. The expression of the mouse monoclonal PAX8 target antigens was found in normal kidney, thyroid and cervix, but not in normal ovary. PAX8 stains nuclei exclusively and performs well in formalin-fixed paraffin-embedded tissues.

Clinical Relevance

- PAX8, in combination with RCCm, will stain over 85% of metastatic renal cell carcinomas
- PAX8, in combination with CD10, will stain 67% of metastatic renal cell carcinomas

Ordering Information

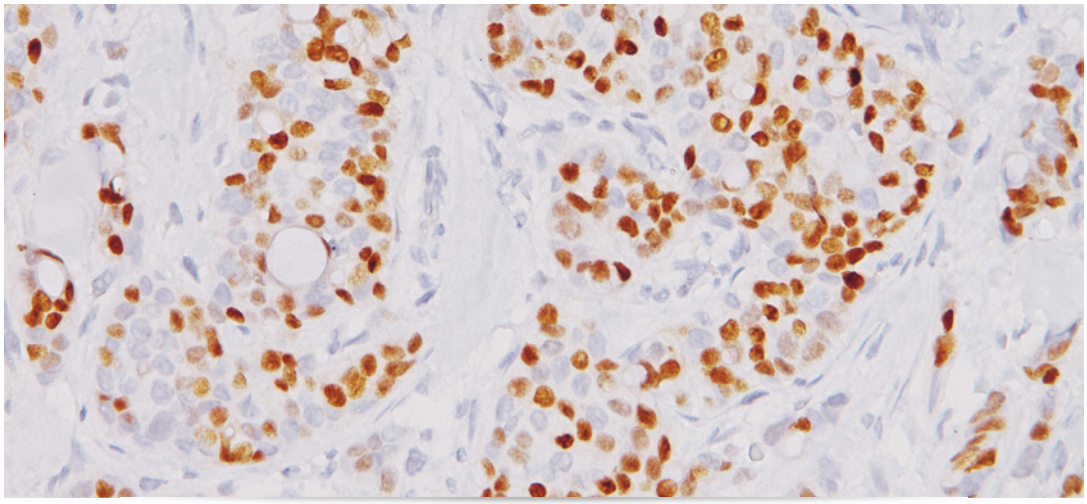
Concentrate	ACI 438 A, B, C	**Predilute**	API 438 AA	**VP Echelon**	AVI 438 G

Specifications

Clone	BC12
Isotype	IgG1
Reactivity	
Control	Normal Kidney, Renal Cell or Serous Ovarian Carcinomas

Progesterone Receptor [16]

RUO ASR FFPE



Breast cancer stained with Progesterone Receptor [16] antibody

Progesterone Receptor (PgR) content of breast cancer tissue is an important parameter in the prediction of prognosis and response to endocrine therapy. PgR clone 16 is directed against the human progesterone receptor molecule. A prokaryotic recombinant protein, corresponding to the N-terminal region of the A form of human progesterone receptor, was used as the immunogen. Antibody characterization studies demonstrated that PgR clone 16 reacts with both A and B forms of human progesterone receptor in Western blotting procedures.

Ordering Information

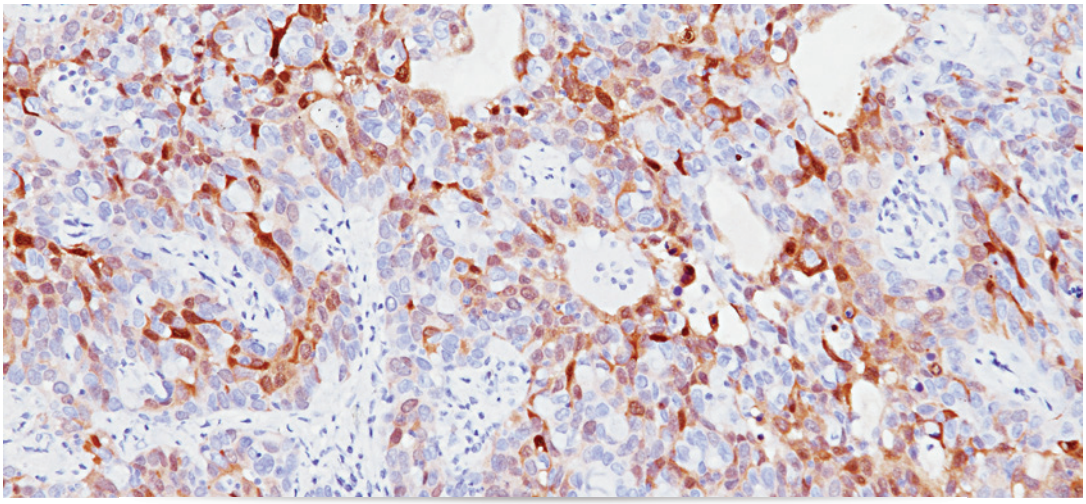
Concentrate	CM 424 A, C	**Predilute**	PM 424 AA	**intelliPATH™**	IP 424 G10

Specifications

Clone	16
Isotype	IgG1
Reactivity	
Control	PR+ Breast Carcinoma

S100P

IVD FFPE



Bladder cancer stained with S100P antibody

Placental S100 (S100P) is a member of S100 protein family, which functions as extracellular and/or intracellular regulators of diverse cellular processes. S100P expression has been detected in human tumor cell lines and tissues derived from breast, prostate, pancreas, lung and colon, and is associated with a malignant phenotype, hormone independence and resistance to chemotherapy. Over-expression of S100P promoted tumorigenesis and metastasis in diverse cancer models. Recent studies have shown that S100P is highly expressed in both the cytoplasm and nucleus of cells in poorly differentiated bladder cancers. S100P has been shown to be negative in the vast majority of renal cell and prostate carcinomas; thus S100P can be used in the differential diagnosis of bladder, prostate and renal cell carcinomas.

Clinical Relevance

- Highly expressed in poorly differentiated bladder cancers
- Useful for differential diagnosis of bladder, prostate and renal cell carcinomas

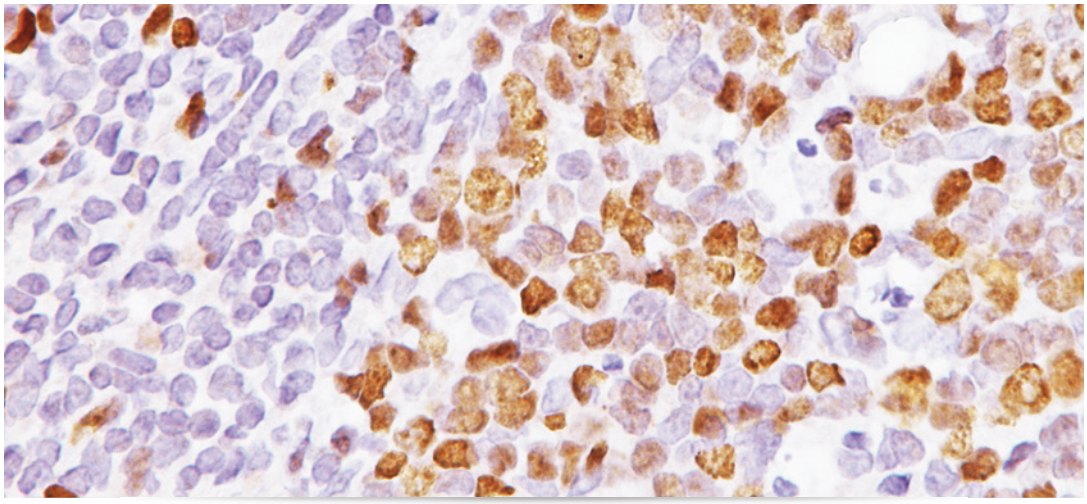
Ordering Information

Concentrate	ACI 3010 A, B	**Predilute**	API 3010 AA

Specifications

Clone	N/A
Isotype	N/A
Reactivity	
Control	Bladder Cancer

Topoisomerase II alpha (Topo IIa) IVD FFPE



Tonsil stained with Topoisomerase II alpha antibody

Topoisomerase II alpha (Topo IIa) plays important roles in the synthesis and transcription of DNA and is reported to be a sensitive and specific marker of late S-, G2- and M-phases in transformed and developmentally regulated normal cells. Topo IIa has been implicated in drug resistance of tumor cells and has been shown to be over-expressed in many human cancers. Topo IIa has been shown to have prognostic and predictive value in breast, colon, prostate, ovarian and bladder cancers. This product can be used for qualitative IHC with normal and neoplastic formalin-fixed, paraffin-embedded tissue sections, to be viewed by light microscopy.

Clinical Relevance

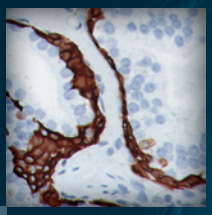
- Decreased expression of Topo IIa is linked to resistance to several chemotherapy drugs
- Topo IIa has prognostic and predictive value in cancers including breast, colon and prostate

Ordering Information

Concentrate	ACI 3015 A, B	**Predilute**	API 3015 AA

Specifications

Clone	EP93
Isotype	Rabbit IgG
Reactivity	
Control	Breast Cancer or Tonsil

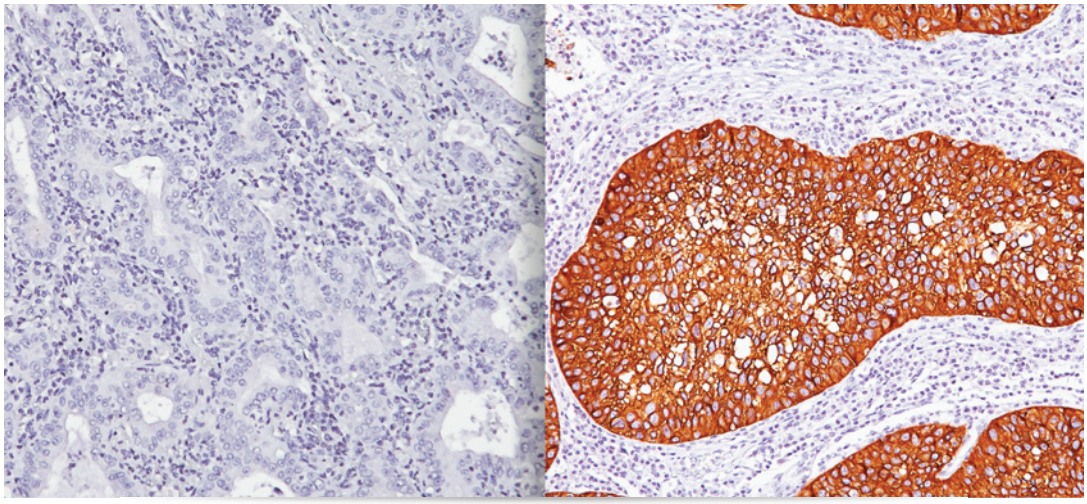


Multiplex IHC™

Biocare Medical's innovative range of Multiplex IHC products, including novel antibody combinations and highly sensitive multiplex detection technology, offer an expanding portfolio of integrated products to address the growing cancer, infectious disease diagnostics and research markets. The Multiplex IHC™ product line allows for simultaneous testing for morphologically distinct markers; solving complex clinical problems and simplifying interpretation. By their innate ability to rapidly exclude or diagnose disease states, Multiplex IHC supplies superior diagnostic data, increases the predictive value of the test and as it can replace up to four single antibody stains, can significantly reduce labor and reagent costs and more importantly conserve precious patient tissue. With key products such as PIN-4™ and ERG-2™ for prostate, ADH-5™ and the new LC/DC Breast Cocktail™ for breast disease diagnosis, we can offer the pathologists and clinical IHC laboratory a set of precise diagnostic tools which provide a critical aid in cancer diagnosis and detection.

- Simultaneous testing to supply superior diagnostic data
- Allows for rapid exclusion or diagnosis of disease states
- Rapid 4-step automated procedure
- Convenient, ready to use reagents
- The most advanced multiplex technology available for IHC

Desmoglein 3 + CK5



(Left) Desmoglein 3 + CK5 staining adenocarcinoma (-); (Right) Desmoglein 3 + CK5 staining squamous cell carcinoma (+)

Studies have shown that Desmoglein 3 (DSG3) had a sensitivity and specificity of 83% and 100% respectively, in detecting SqCC vs. adenocarcinomas. DSG3 expression in lung SqCC indicated a poor prognosis resulting in a more aggressive clinical outcome. CK5 is expressed in active basal layers of most stratified squamous epithelia including basal cells in prostate glands and myoepithelial cells in mammary glands. CK5 has been shown to be extremely specific for lung SqCC and negative in lung adenocarcinomas.

Co-expression of DSG3 + CK5 is observed in most lung SqCCs. One study showed that DSG3 used in combination with CK5, provided 93.7% sensitivity with 100% specificity for lung SqCC. DSG3 + CK5 were 100% negative for all adenocarcinomas. This single color antibody cocktail should become the premier screener for most squamous cell carcinomas. Note: Potential use for doublestain with Napsin A.

Clinical Relevance

- DSG3 + CK5 should be considered a mainline screener for squamous cell carcinomas
- Demonstrated superiority over p63 and 34βE12 as a result of its 100% specificity for lung SqCC

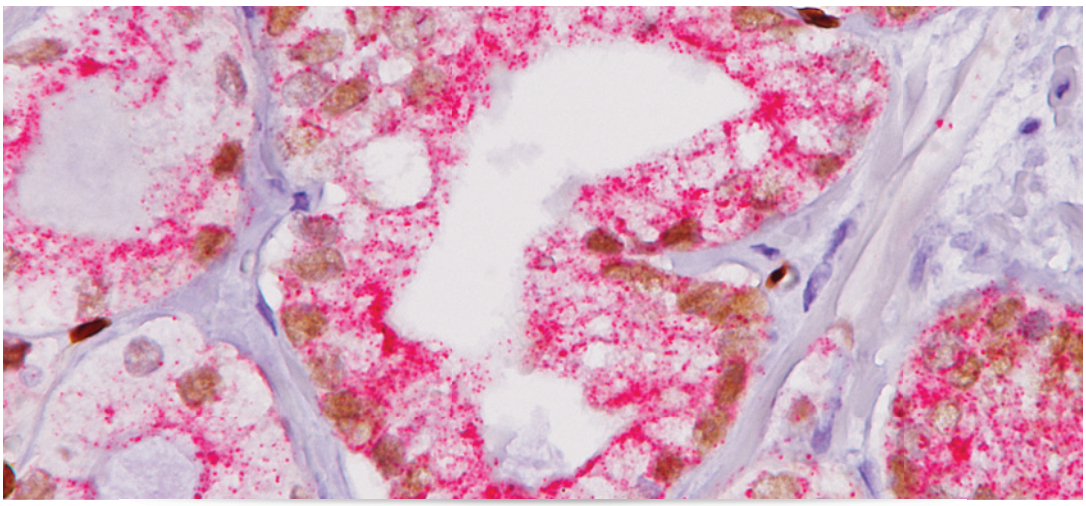
Ordering Information

Concentrate	ACI 3018 A, C	**Predilute**	API 3018 AA

Specifications

Clone	BC11 + XM26
Isotype	IgG1 + IgG1/Kappa
Reactivity	
Control	Lung Squamous Cell Carcinoma

ERG + AMACR RUO FFPE



ERG (DAB) + AMACR (FR) in prostate cancer

There is a 96.5% concordance between the TMPRSS2:ERG rearrangement and ERG-positive prostatic intraepithelial neoplasia (PIN) and ERG positive carcinoma in prostatectomy specimens. Therefore, ERG expression offers a rare, but definitive marker of adenocarcinoma of prostatic origin. AMACR (P504S) protein is expressed in prostatic adenocarcinoma, but not in benign prostatic tissue. It has also been found to be expressed in some premalignant lesions of the prostate: HGPIN and atypical adenomatous hyperplasia. AMACR can be used as a positive marker for prostate cancer and may be useful to confirm small foci of prostate carcinoma in needle biopsies. AMACR stains the majority of prostate cancer; however, AMACR has been shown to stain many other types of carcinomas such as hepatomas, breast carcinomas, pancreatic and islet tumors. *Note: ERG [9FY] was developed by the Center for Prostate Disease Research in association with the Henry M. Jackson Foundation, Rockville, Maryland. Patent Pending.*

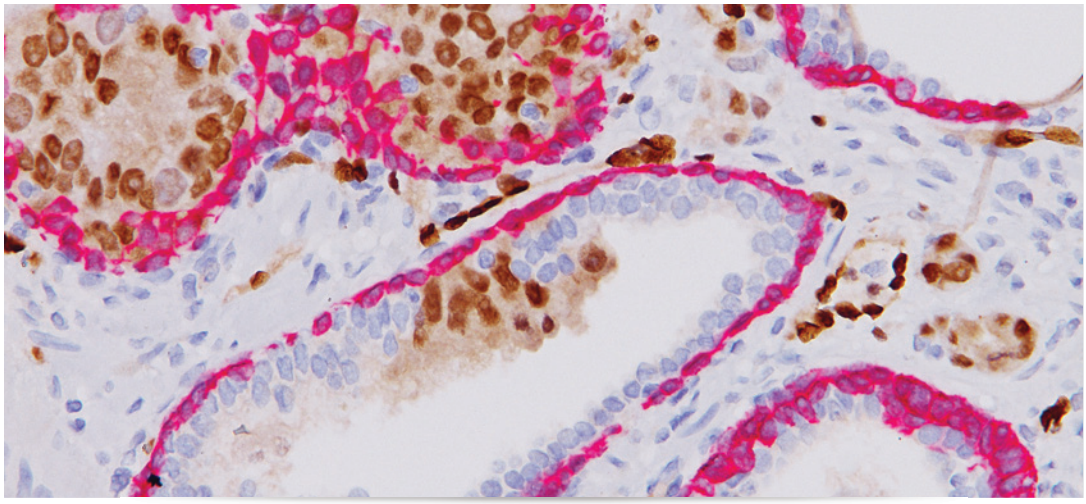
Ordering Information

Predilute	APR 3013DS AA

Specifications

Clone	9FY + 13H4
Isotype	IgG1 + Rabbit IgG
Reactivity	
Control	ERG+ Prostate Cancer with Normal and / or PIN glands

ERG-2™ (ERG + CK5) IVD FFPE + 



ERG (DAB) + CK5 (FR) in prostate cancer and PIN

A mouse monoclonal anti-ERG antibody was developed with 99.9% specificity for detecting prostatic adenocarcinomas. There is a 96.5% concordance between the TMPRSS2:ERG rearrangement and ERG-positive prostatic intraepithelial neoplasia (PIN) and ERG positive carcinoma in prostatectomy specimens. ERG expression offers a rare, but definitive marker of adenocarcinomas of prostatic origin. CK5 is expressed in basal layers of most epithelia including normal prostate and normal breast tissues. CK5 stains normal basal cell layers in prostate, benign prostate hyperplasia (BPH) and PIN. The combination of ERG + CK5 provides a unique stain that identifies the TMPRSS2:ERG chromosomal translocation in prostate cancer (brown); but also highlights PIN (red): thus helping to visualize ERG positive PINs. *Note: ERG [9FY] was developed by the Center for Prostate Disease Research in association with the Henry M. Jackson Foundation, Rockville, Maryland. Patent Pending.*

Clinical Relevance

- Clearly identify ERG in prostatic intraepithelial neoplasia (PIN)
- CK5 identifies PIN, while ERG identifies the chromosomal translocation

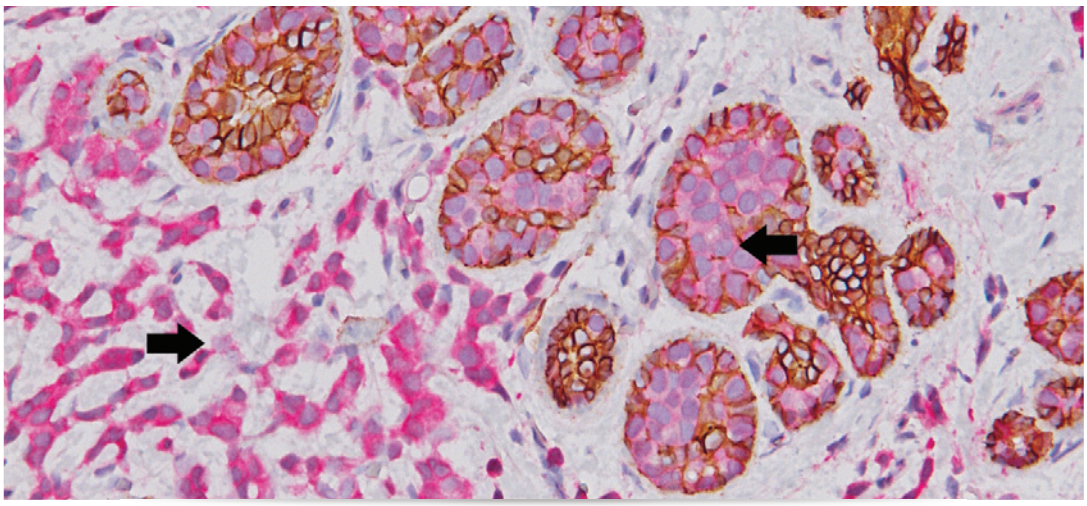
Ordering Information

Predilute	API 437DS AA	**Ventana**	AVI 437DS KG

Specifications

Clone	9FY + EP1601Y
Isotype	IgG1 + N/A
Reactivity	
Control	ERG+ Prostate Cancer with Normal and/or PIN glands

LC/DC Breast Cocktail™ (p120 + E-cadherin) IVD FFPE



(Left) Invasive lobular carcinoma; (Right) Lobular hyperplasia with stained with LC/DC Breast Cocktail

Diagnostic reproducibility of lobular vs. ductal lesions, based on histology alone, is challenging. Proper distinction between atypical lobular hyperplasia, lobular carcinoma *in situ* and low-grade ductal carcinoma *in situ* is critical. E-cadherin, a negative membrane marker for lobular neoplasia, is useful in the distinction of ductal neoplasia vs. lobular; however as a negative marker for lobular carcinoma, it can be difficult to interpret. Studies have shown accurate categorization of ductal vs. lobular neoplasia in the breast with p120 + E-cadherin and helped give further clarification in the separation of low-grade ductal carcinoma *in situ* from lobular neoplasia. This Multiplex IHC enables the identification of the extent of the lobular lesions due to its bright pink color in lobular lesions, and therefore may provide a more accurate diagnosis.

Clinical Relevance

- Differentiate lobular from ductal carcinoma in breast
- Distinguish lobular hyperplasia vs. lobular carcinoma *in situ* (CIS) vs. invasive lobular carcinoma

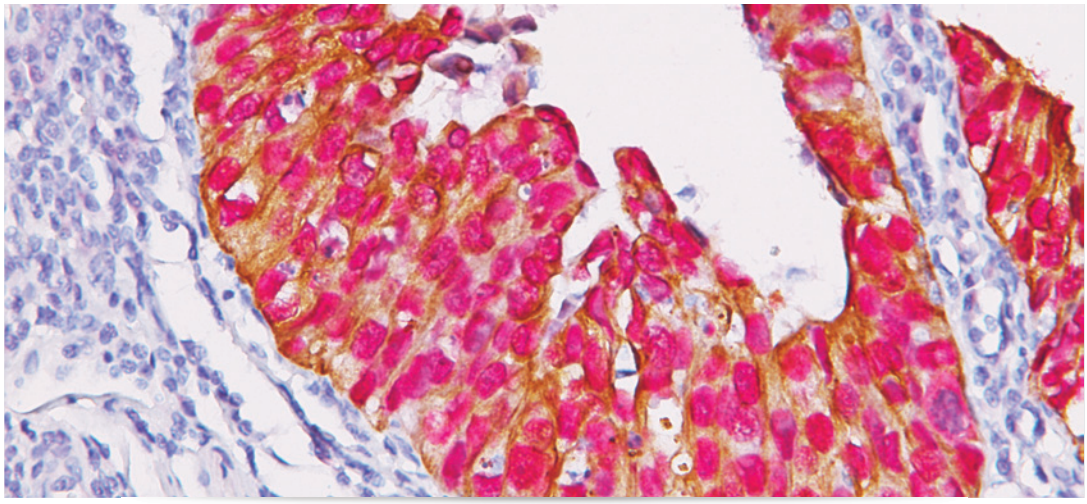
Ordering Information

Predilute	API 3011DS AA

Specifications

Clone	98/pp120 + EP700Y
Isotype	IgG1 + Rabbit IgG
Reactivity	
Control	Breast Cancer

Uro-2™ (CK20 + p53) IVD FFPE +



Bladder CIS stained with Uro-2™ (CK20 + p53)

Description

Uro-2™ (CK20 + p53) can be used to differentiate urothelial reactive atypia from CIS (carcinoma *in situ*) in bladders. In normal urothelium, the superficial umbrella cell layer shows reactivity for CK20 only; whereas p53 nuclear staining is absent to focal. For urothelium with reactive atypia, particularly in cases with marked atypia, CK20 and p53 staining remain identical to those seen in normal urothelium. In cases of CIS, diffuse, strong cytoplasmic reactivity for CK20 and diffuse nuclear reactivity for p53 is observed throughout the urothelium. Most high-grade dysplasia stains with p53 when compared to low-grade dysplasia, which may aid the pathologist in differentiating between high and low grade dysplasia in bladder urothelium.

Clinical Relevance

- Distinguish reactive atypia from CIS
- May aid in differentiating between low and high grade dysplasia

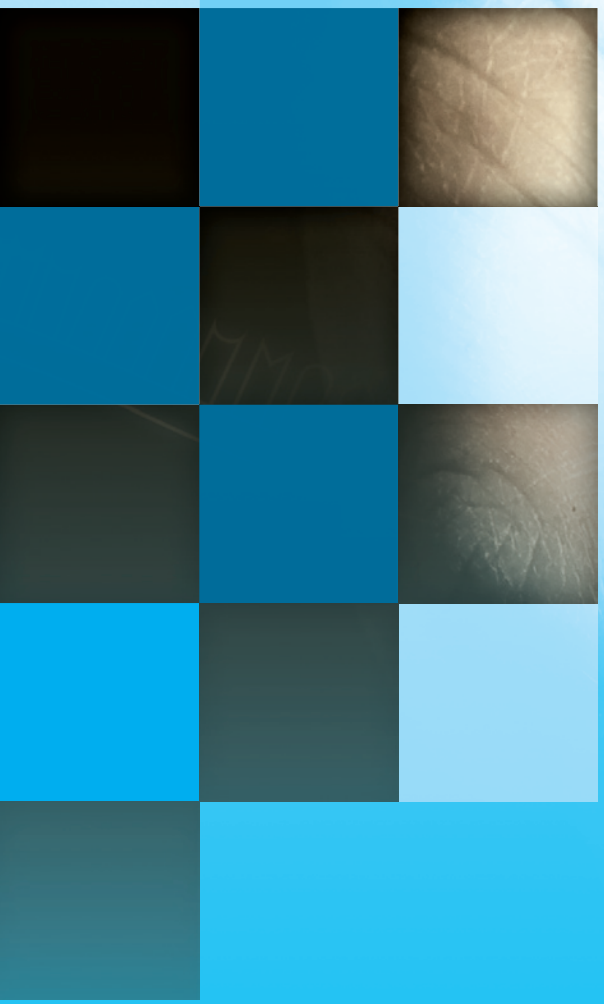
Ordering Information

Predilute	API 3001DS AA

Specifications

Clone	Ks20.8 + Y5
Isotype	IgG2a + IgG
Reactivity	
Control	p53 positive Bladder or Colon Cancers

Molecular

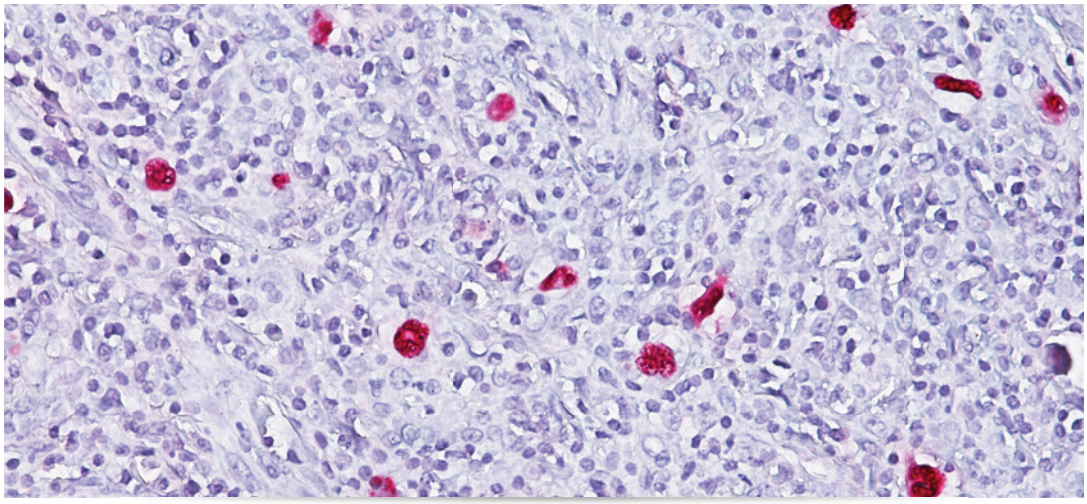


Bring molecular pathology into your laboratory with our chromogenic *in situ* hybridization (CISH) products designed to solve difficult clinical problems. Have confidence in using our advanced DNA probe technology to enhance specificity and accuracy of your slides. The crisp chromogenic signal is easily visualized under brightfield microscopy, along with the tissue morphology on a single slide. Our molecular product line includes the simplified *in situ* hybridization RISH™ and the FDA-approved SPOT-Light® HER2 CISH kit.

The RISH™ technology combines the accuracy and objectivity of *in situ* hybridization with the ease of immunohistochemistry (IHC). It can be completed by virtually any histology or pathology laboratory, with results in about 2.5 hours. The protocol has been simplified by removal of the overnight hybridization, harsh stringent wash conditions, and requirement for RNase-free solutions. The result is clear, with virtually no background.

SPOT-Light® HER2 CISH kit is the FDA approved CISH product to quantify HER2 gene amplification. It is indicated as an aid in the assessment of breast cancer patients for whom Herceptin® (trastuzumab) treatment is being considered. This CISH technology allows for a simplified interpretation scheme compared to both IHC and FISH (fluorescent *in situ* hybridization) methods. The HER2 CISH kit is 99% concordant with an FDA approved HER2 FISH test.

RISH™ AP Detection Kit IVD



RISH Epstein-Barr Encoded RNA (EBER) Probe staining Hodgkin's Lymphoma

The RISH™ AP Detection Kit is specifically designed for rapid visualization of *in situ* hybridization (ISH) staining. This kit is optimized to react with Biocare RISH™ probes and other digoxigenin (DIG) labeled probes that react with mRNA targets in formalin fixed paraffin embedded (FFPE) tissues. This two-step micro-polymer detection system is formulated to produce highly accurate and specific results. The vivid red chromogenic signal is easily visualized under a brightfield microscope. Clear ISH results are achieved in approximately 2.5 hours with virtually no background.

- Rapid: Results in 2.5 hours
- Accurate: High specificity and reactivity with RISH™ or other DIG-labeled probes
- Archivable: Vivid red chromogenic signal is stable for extended storage
- RISH™ probes available: EBER, CMV, Kappa & Lambda Light Chains and Dual Kappa /Lambda

Ordering Information	Cat. No.
RISH™ AP Detection Kit	RIO213 KG

RISH™ AP Detection Kit Components	Volume / Quantity
RISHzyme™	6 ml
RISHzyme™ Buffer	6 ml
RISH™ Secondary Reagent	6 ml
RISH™ AP Tertiary Reagent	6 ml
Warp Red™ Chromogen	0.7 ml
Warp Red™ Substrate Buffer	25 ml
Mixing Vial	1

Instrumentation

Biocare Medical offers the most advanced instruments to support your anatomic pathology, immunohistochemistry (IHC), and scientific research needs. Our manual and semi-automated instrumentation, including the intelliPATH™, Decloaking Chamber™ and IQ Kinetic Slide Stainer™, simplify laboratory procedures and deliver robust slide stains.

The intelliPATH™ is the most flexible automated IHC stainer for research laboratories today, allowing the use of reagents from any source. This fully open system also features continuous random access to work with the user schedule to add any slide, with any protocol, at any time during an ongoing run.

The Decloaking Chamber™ NxGen ensures optimal antigen retrieval with superior and consistent results. It offers a combination of complete walk-away and quality control capabilities.

The IQ Kinetic Slide Stainer™ minimizes manual slide handling for IHC, immunofluorescence (IF), *in situ* hybridization (ISH), or special stains. The combination of heat and agitation allows tissues to be evenly and optimally stained while accelerating enzymatic reactions and increasing probe or antibody binding specificity.

Take advantage of our technologies to boost productivity and simplify your entire laboratory workflow, with superior results.

Decloaking Chamber™ NxGen

The Decloaking Chamber™ NxGen has been designed for heat-induced epitope retrieval (HIER) and ease of use. It has 5 discrete temperature settings ranging between 60ºC and 110ºC with user programmable times. The 110ºC antigen retrieval protocol can be completed from start to finish in under an hour. With a 72 total slide capacity and only minutes of hands-on time per run, the NxGen offers a walk-away capability similar to fully automated staining instruments.

The Decloaking Chamber NxGen transfers run data to a USB drive for export to a user's computer. The run data recorded includes the date and time per run with temperature and pressure readings throughout. With the Decloaking Chamber NxGen recalling the settings from the last run, a quick start of the same protocol is possible.

The Decloaking Chamber is an excellent tool for HIER. The proper use of heat and pressure in conjunction with the appropriate buffer solutions is of the utmost importance for consistent immunohistochemistry (IHC) staining. The Decloaking Chamber is designed to optimize and standardize antibody staining procedures and has been engineered to pass strict laboratory safety and quality control requirements. Temperature, pressure and time can be monitored and recorded with the Decloaking Chamber to produce consistent staining.

Specifications	
Dimensions (W x H x D)	14.2" x 13.5" x 13" / 36.1 cm x 34.3 cm x 33.0 cm
Weight	13 lbs / 6.91 kg
Temperature range	60ºC - 110ºC (+/- 5ºC)
Slide capacity	72 total slides (3 slide canisters of 24 slides each)
Power requirements	115V, 60Hz, 1000W

Ordering Information	**Cat. No.**
Decloaking Chamber NxGen (For use in 110V markets)	DC2012

Ancillaries	**Cat. No.**
Metal Slide Canister, single	DCA004
Pressure Limit Valve	DCA068
Pot	DCA069
Sealing Gasket Kit	DCA061
Condensation Collector	DCA070

IQ Kinetic Slide Stainer™

2 Digital Hot Bars™, 1 Waste Basin, 1 Orbital Shaker

The IQ Kinetic Slide Stainer™ offers the flexibility and reliable performance that both clinical and research investigators need for today's complex assays. This open system staining platform can be adapted for immunohistochemistry (IHC), *in situ* hybridization (ISH), immunofluorescence, or special stains.

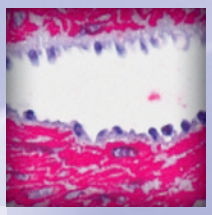
It features an innovative 45-degree tilt-action rack that eliminates individual slide handling and prevents cross-contamination. The programmable Digital Hot Bar™ enables the user to elevate the temperature up to 95°C, and with the slide rack lids on, create a humidity chamber.

The orbital shaker provides smooth agitation action for the reagents on the slides. The combination of heat and agitation allows tissues to be evenly and intensely stained while accelerating enzymatic or hybridization reactions and increasing reagent specificity.

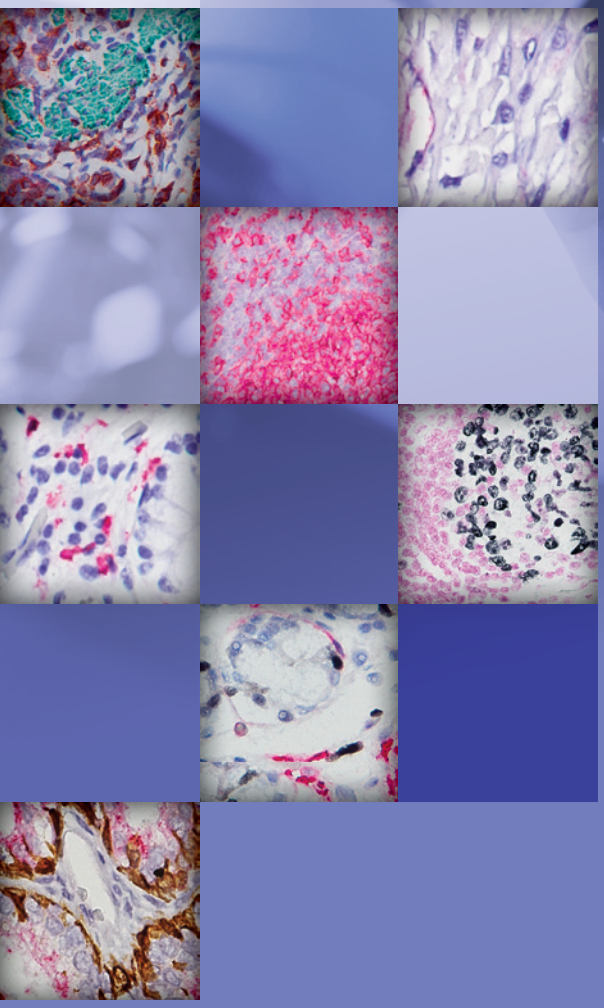
The IQ2000 is supplied as 2 Digital Hot Bars™ with the three space waste basin and an orbital shaker. This provides the lab with the option to expand to 3 Digital Hot Bars™ should there be an increase in daily slide quantity.

Specifications		
Dimensions (W x H x D)	23" x 15" x 19" / 58 cm x 38 cm x 48 cm	
Weight	69 lbs / 31 kg	
Temperature range	20ºC - 95ºC (+/- 4ºC)	
Slide capacity	Up to 24 slides (1" x 3")	
Power requirements	100-200/ 200-240 VAC; 50/60 Hz	
Ordering Information	**Description**	**Cat. No.**
IQ2000 (For use in 110V markets)	2 Digital Hot Bars™, 1 Waste Basin, 1 Orbital Shaker	IQ2000US
IQ2000 (For use in 220V markets)	2 Digital Hot Bars™, 1 Waste Basin, 1 Orbital Shaker	IQ2000INTL
Ancillaries	**Volume**	**Cat. No.**
IQ Aqua Sponge	3-pack	IQ030
Thermal Test Strips	(30-65ºC, 49-71ºC, 77-120ºC) 1 box (10 tests)	TS002 A, TS001 A, TS003 A
Digital Hot Bar™	1 each	IQ105

Instrumentation



Detection

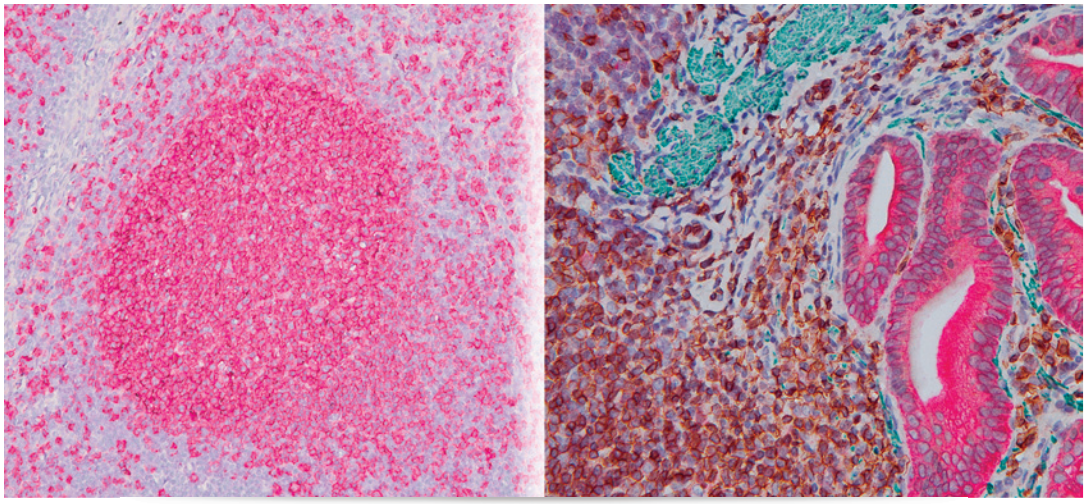


Select from Biocare Medical's collection of micro-polymer detections and chromogens for utmost sensitivity, specificity and reliability. With formulations designed for both human and animal tissues, Biocare's detection systems are the most specific, sensitive, clean, and reproducible biotin-free detection technology. Our innovative micro-polymer detection technology enables superior antigen access, giving unsurpassed specificity and sensitivity. The ability to further dilute primary antibodies provides reagent and cost savings as well as higher specificity, potentially eliminating false positives.

The micro-polymer detection systems were developed to avoid problems inherent in the use of biotin-streptavidin systems – specifically, non-specific background staining that results from endogenous biotin, present in nearly all tissues. Unlike enzyme-labeled streptavidin reagents, micro-polymer systems do not have a natural affinity for endogenous biotin, resulting in minimum background staining. The micro-polymer technology gives significantly sharper and cleaner results with a simplified work flow compared to conventional methods.

To complement our Horseradish Peroxidase (HRP) and Alkaline Phosphatase (AP) enzyme labels, Biocare Medical offers a large variety of IHC-specific permanent chromogens. With five HRP and two AP colors available, the IHC end-results can be tailored to best suit the assay. Biocare's large selection of chromogen colors are vivid and clear under bright-field microscopy.

Canine AP-Polymer Detection RUO



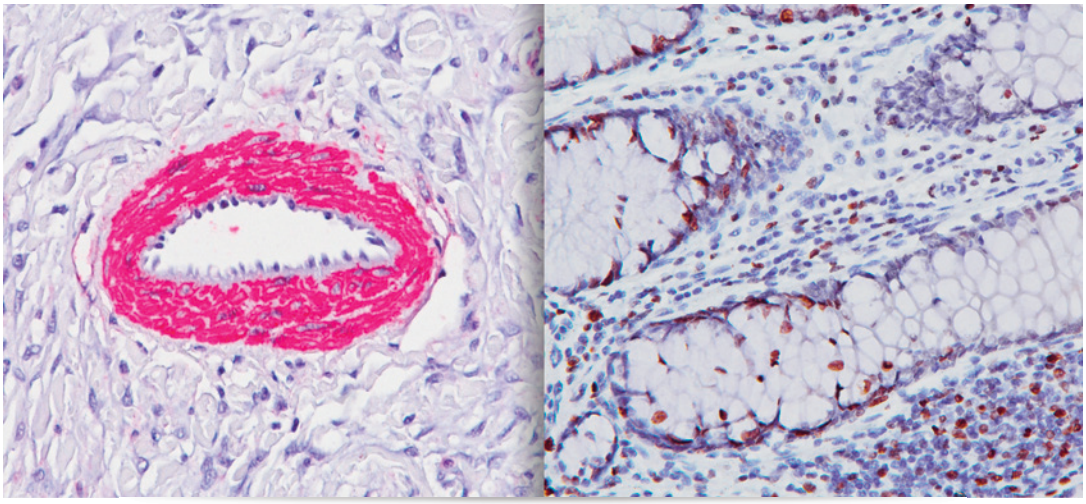
(Left) Dog tonsil stained with CD20 (P) antibody; (Right) CD20 (DAB) + Muscle Specific Actin (WR) + CK8 (VG) on Feline Colon

All PromARK™ micro-polymer detection systems are designed specifically for use on animal tissues. The Mouse-on-Canine AP-Polymer and the Rabbit-on-Canine AP-Polymer are specially intended for detection of mouse or rabbit primary antibodies, respectively, on canine and feline tissues. The advanced one-step polymer technology virtually eliminates cross-reactivity to endogenous canine and feline IgGs, increases sensitivity and reduces IHC steps (no Avidin/Biotin block or Link/Probe). Proprietary blockers included in the detection reagents permit the use of any of Biocare Medical's retrieval solutions (Reveal/Diva/Borg) or enzyme digestion. These polymer detections can be used with paraffin-embedded tissues, floating sections and frozen sections. The canine polymer detections are suitable for both manual and automated systems such as the intelliPATH™.

For Multiplex IHC™ detection the Mouse-on-Canine AP-Polymer may be combined in equal volumes with the Rabbit-on-Canine HRP-Polymer to prepare a solution that will label the mouse antibody with AP and the rabbit antibody with HRP. The Rabbit-on-Canine AP-Polymer may be combined in equal volumes with the Mouse-on-Canine HRP-Polymer to prepare a solution that will label the rabbit antibody with AP and the mouse antibody with HRP. These new additions to Biocare's PromARK™ series expand IHC detection applications to a broader range of animal tissues, resulting in increased research capability.

Ordering Information	Cat. No.
Mouse-on-Canine AP-Polymer	BRR4003 G, H, L
Rabbit-on-Canine AP-Polymer	BRR4004 G, H, L

Mouse-on-Farma Polymer Detection RUO



(Left) Muscle Specific Actin on Equine Artery; (Right) Ki-67 on Porcine Colon

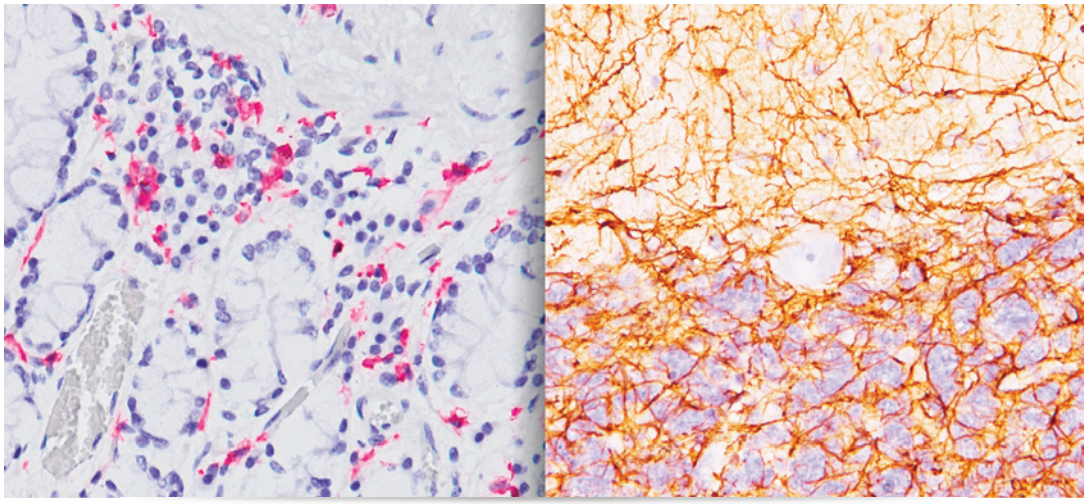
All PromARK™ micro-polymer detection systems are designed specifically for use on animal tissues. The Mouse-on-Farma HRP-Polymer and the Mouse-on-Farma AP-Polymer are specially intended for detection of mouse primary antibodies on bovine, equine, porcine and ovine tissues. The advanced one-step polymer technology virtually eliminates cross-reactivity to endogenous bovine, equine, porcine, and ovine IgGs, increases sensitivity and reduces IHC steps (no Avidin/Biotin block or Link/Probe). In most cases, tissues do not require a protein block. These polymer detections are suitable with any of Biocare Medical's retrieval solutions (Reveal/Diva/Borg) or enzyme digestion. The Farma polymer detections can be used with paraffin-embedded tissues and are suitable for both manual and automated systems such as the intelliPATH™.

The Mouse-on-Farma HRP-Polymer may be combined in equal volumes with the Rabbit-on-Farma HRP-Polymer to prepare a universal Multiplex HRP-Polymer detection that will label both mouse and rabbit antibodies with HRP.

For Multiplex IHC™ detection the Mouse-on-Farma HRP-Polymer may be combined in equal volumes with the Rabbit-on-Farma AP-Polymer to prepare a solution that will label the mouse antibody with HRP and the rabbit antibody with AP. The Mouse-on-Farma AP-Polymer may be combined in equal volumes with the Rabbit-on-Farma HRP-Polymer to prepare a solution that will label the mouse antibody with AP and the rabbit antibody with HRP. These new additions to Biocare's PromARK™ series expand IHC detection applications to a broader range of animal tissues, resulting in increased research capability.

Ordering Information	Cat. No.
Mouse-on-Farma HRP-Polymer	BRR4002 G, H
Mouse-on-Farma AP-Polymer	BRR4010 G, H

Rabbit-on-Farma Polymer Detection RUO



(Left) Microglia on Ovine Colon (macrophages); (Right) Dog brain stained with GFAP

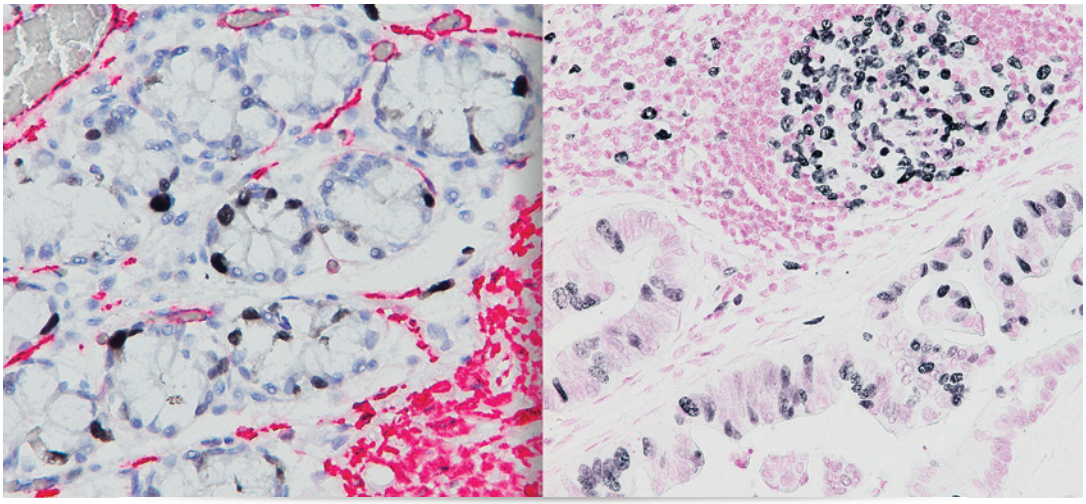
PromARK™ micro-polymer detection systems are designed specifically for use on animal tissues. The Rabbit-on-Farma HRP-Polymer and the Rabbit-on-Farma AP-Polymer are specially intended for detection of rabbit primary antibodies on bovine, equine, porcine and ovine tissues. The advanced one-step polymer technology virtually eliminates cross-reactivity to endogenous bovine, equine, porcine, and ovine IgGs, increases sensitivity and reduces IHC steps (no Avidin/Biotin block or Link/Probe). In most cases, tissues do not require a protein block. These polymer detections are suitable for use with any of Biocare Medical's retrieval solutions (Reveal/Diva/Borg) or enzyme digestion. The Farma polymer detections can be used with paraffin-embedded tissues and are suitable for both manual and automated systems such as the intelliPATH™.

The Rabbit-on-Farma HRP-Polymer may be combined in equal volumes with the Mouse-on-Farma HRP-Polymer to prepare a universal Multiplex HRP-Polymer detection that will label both mouse and rabbit antibodies with HRP.

For Multiplex IHC™ detection the Rabbit-on-Farma HRP-Polymer may be combined in equal volumes with the Mouse-on-Farma AP-Polymer to prepare a solution that will label the rabbit antibody with HRP and the mouse antibody with AP. The Rabbit-on-Farma AP-Polymer may be combined in equal volumes with the Mouse-on-Farma HRP-Polymer to prepare a solution that will label the rabbit antibody with AP and the mouse antibody with HRP. These new additions to Biocare's PromARK™ series expand IHC detection applications to a broader range of animal tissues, resulting in increased research capability.

Ordering Information	Cat. No.
Rabbit-on-Farma HRP-Polymer	BRR4009 G, H
Rabbit-on-Farma AP-Polymer	BRR4011 G, H

Deep Space Black™ Chromogen Kit IVD

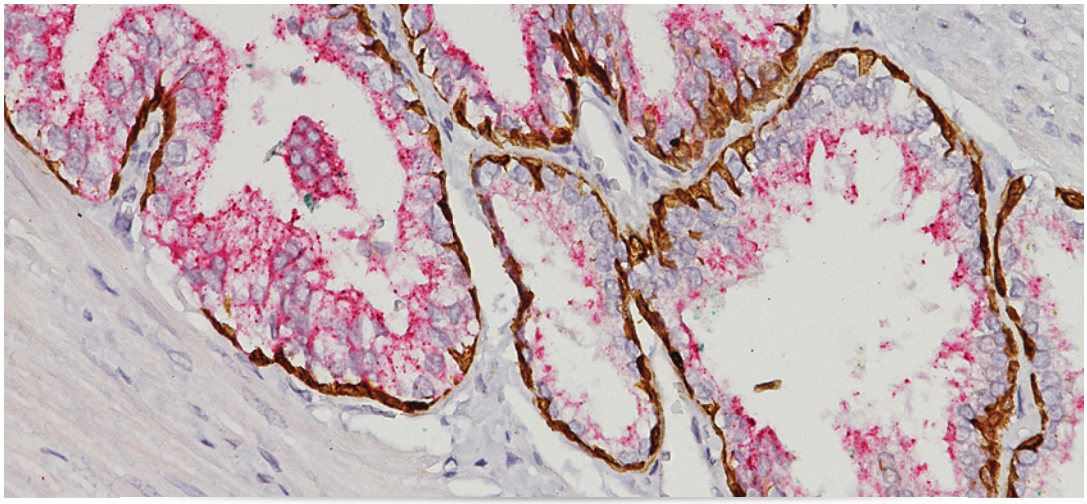


(Left) SMA (red) & Ki-67 (black) on Ovine Colon; (Right) Ki-67 on Human Colon Cancer counter-stained with Feulgen's

Deep Space Black™ is a novel permanent chromogen that produces a dark grey to black stain in the presence of horseradish peroxidase (HRP). The kit consists of liquid Deep Space Black chromogen and buffer that is stable for 8 hours at room temperature once mixed. Deep Space Black is clearly distinguishable from Warp Red™, DAB, Vina Green™ and Ferangi Blue™ on a single slide, enabling high flexibility for Multiplex IHC™ applications. Developed for both manual and automated platforms, Deep Space Black is suitable for both immunohistochemistry (IHC) and *in situ* hybridization (ISH) applications including HPV, CMV, EBV, Kappa, Lambda, p63, HMWCK, TTF-1, Ki-67, and other targets/antigens such as cytokeratins, melanoma, and basal and myoepithelial cells.

Ordering Information	Cat. No.
Deep Space Black™ Chromogen Kit	BRI4015 H, L

intelliPATH™ Multiplex Secondary Reagent 2 IVD



High-grade prostatic intraepithelial neoplasia (HGPIN) with PIN-4: CK5/14 (DAB), p63 (DAB), P504S (FR)

The intelliPATH™ Multiplex Secondary Reagent 2 is specifically designed for use on the intelliPATH™ automated stainer, in conjunction with a cocktail consisting of a mouse monoclonal antibody and a rabbit polyclonal/monoclonal antibody. The innovative goat anti-mouse HRP (Horseradish Peroxidase) and goat anti-rabbit AP (Alkaline Phosphatase) polymer technology provides a significant increase in staining sensitivity when compared to conventional HRP- or AP-conjugated secondary antibodies. This superior detection system increases reimbursement per slide, simplifies workflow, and reduces turnaround time. In fact, this method provides a rapid, 4-step staining procedure that can be completed in as little as two hours.

Note: Optimized for use with intelliPATH antibodies.

Ordering Information	Cat. No.
intelliPATH™ Multiplex Secondary Reagent 2	IPSC5004 G20, G80

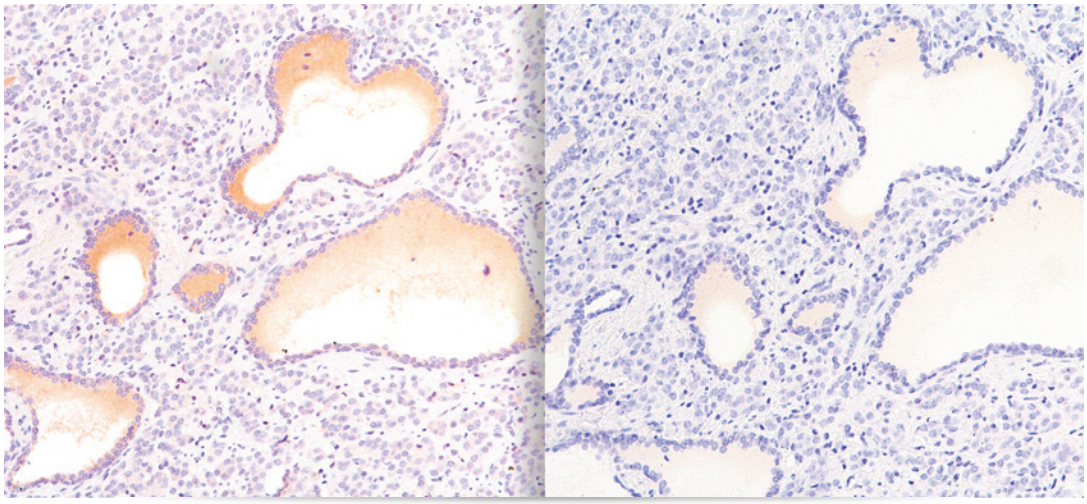
Ancillaries

Biocare Medical supports the entire IHC workflow by providing ancillary products. This includes Heat-Induced Epitope Retrieval (HIER) buffers, antibody diluents, blocking reagents, enzymes, buffers, dewaxing and deparaffinization reagents, mounting media and Hematoxylin. With a wide selection of reagents available, Biocare Medical has the selection of products a laboratory needs for successful IHC.

HIER buffers are specially formulated for superior pH stability at high temperatures with Assure™ color-coded pH indicator technology and are sodium azide and thimerosal free. Citrate-based, tris-based and EDTA-based solutions are available, as well as Biocare Medical's proprietary solutions which eliminate the need for multiple buffers. Antibody diluents have optimized formulations for improving antibody titers and are extremely stable for long-term storage. Blocking reagents reduce non-specific background staining and are available in casein, serum and serum-free formulations. In addition, rodent tissue specialty blocking solutions are available, helping to eliminate endogenous mouse and rat IgG staining. Endogenous peroxidase and avidin-biotin blockers reduce background staining and provide superior results. Enzymes have been designed for optimum digestion and ease of use. Biocare's dewaxing, deparaffinization and mounting medias are non-flammable and non-toxic alternatives to hazardous reagents such as xylene. Hematoxylin is available for manual and automated IHC and provides a high contrast to Biocare's chromogens.

V-Blocker IVD

VP Echelon™ Series*



(Left) Prostate Cancer Negative Control with no V-Blocker; (Right) Prostate Cancer Negative Control with V-Blocker

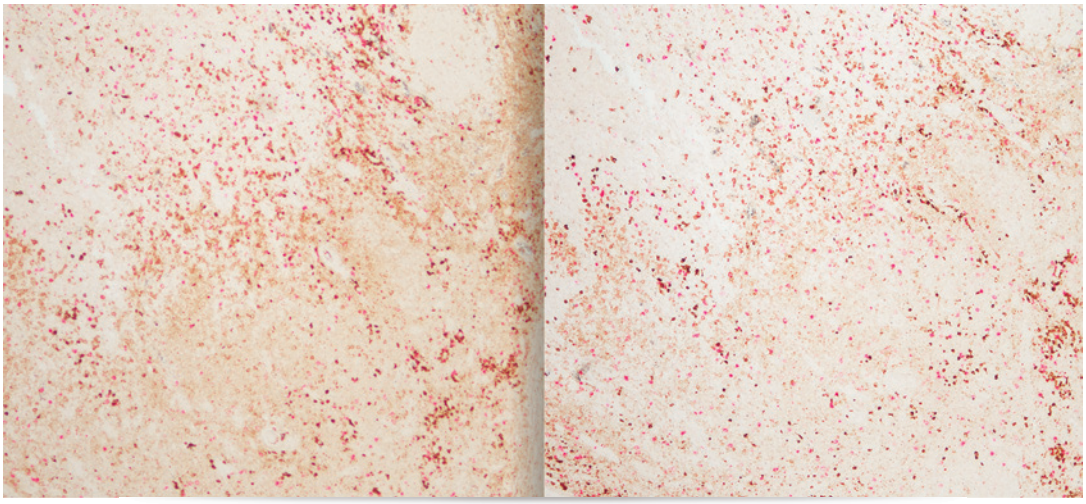
V-Blocker is a universal blocking reagent used for reducing nonspecific background staining often observed with immunohistochemistry on BenchMark® automated staining systems. This formulation has been proven to be the most effective blocking reagent for automated IHC systems. It can be used in the conventional manner by applying before the primary antibody; however, using V-Blocker after the primary antibody and before detection has shown to be much more effective, especially when using Multiplex IHC™ applications. V-Blocker is specifically formulated for superior pH stability and is sodium azide and thimerosal free.

Biocare's VP Echelon™ Series products have been developed for use with Ventana® Medical Systems BenchMark® XT Immunohistochemistry Staining System in combination with Ventana® Detection Kits and Ventana® Prep Kit Dispensers.

Ordering Information	Cat. No.
V-Blocker	BRI4001 G

*VP Echelon Series products are developed solely by Biocare Medical LLC and do not imply approval or endorsement of Biocare's products by Ventana Medical Systems, Inc. Biocare and Ventana are not affiliated, associated or related in any way. Ventana®, BenchMark®, iVIEW™ and ultraView™ are trademarks of Ventana Medical Systems, Inc.

intelliPATH™ Background Punisher IVD



Tonsil stained with Kappa (DAB) and Lambda (FR): (Left) Without intelliPATH Background Punisher and (Right) With

Biocare's intelliPATH™ Background Punisher is a universal blocking reagent used for reducing non-specific background staining. Background Punisher utilizes casein, which has been shown to be a superior blocking reagent compared to serum proteins. It is specifically designed and optimized for use on the intelliPATH™ automated stainer. The intelliPATH Background Punisher is formulated for superior pH stability, while being sodium azide and thimerosal free.

Ordering Information	Cat. No.
intelliPATH™ Background Punisher	IP974 G20

BIOCARE MEDICAL
800.799.9499
4040 Pike Lane
Concord CA 94520

www.biocare.net