ADVANCED STAINING REAGENTS

CHROMOGENIC ISH PROBES FOR BOND

FULLY-AUTOMATED, CHROMOGENIC ISH PROBES FOR CLINICAL ANATOMICAL PATHOLOGY



Advancing Cancer Diagnostics Improving Lives



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ENHANCE YOUR WORKFLOW AND IMPROVE PATIENT CARE

Discover the benefits of BOND Chromogenic ISH, a range of fully-automated ISH probes for clinical anatomical pathology

This range of key clinical ISH probes complements the Novocastra HD antibody menu for IHC and demonstrates Leica Biosystems commitment to provide a complete solution for clinical pathology.

FOR THE PATHOLOGIST

SAME DAY RESULTS

With patients awaiting diagnosis, rapid turnaround time for each case is important.

- Rapid protocols for RNA and DNA ISH
- Reliable, high quality staining minimizes repeats
- Simultaneous staining of ISH and IHC slides on BOND, for rapid turnaround time of whole case

CONFIDENCE IN DIAGNOSIS

Accurate clinical diagnosis depends on the interpretation of reliable test results.

Achieve consistent high-quality staining of ISH slides on BOND.

IVD status reagents

Fully-automated and standardized protocols including on-board pre-treatment

Excellent clarity of staining, utilizing BOND Polymer Refine Detection

STRAIGHTFORWARD INTERPRETATION

The interpretation of stained FFPE slides is an important part of the workload of the anatomical pathologist. Results must be easy to interpret for efficient and accurate diagnosis.

Simplify interpretation with BOND Polymer Refine chromogenic detection for both ISH and IHC

Visualised by light microscopy, so no specialist facility is required

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FOR THE LABORATORY

LABORATORY EFFICIENCY

With increasing pressure on clinical pathology laboratories to deliver more with less, maximizing efficiency in the laboratory is key to success. Rapid protocols afford same day turnaround and high-throughput potential.

Simple to perform: free-up staff to work elsewhere with fully-automated protocols, including on-board pre-treatment. If you outsource CISH testing, consider bringing in-house, reducing turnaround time and cost.

Flexible workflow: one instrument for IHC and ISH. Simultaneously run up to 30 ISH and/ or IHC slides on BOND. Improve reliability by minimizing variability in testing:

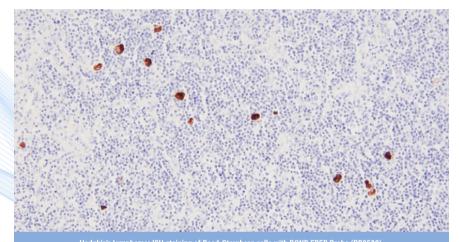
- · Fully-automated protocols
- · Ready-to-use reagents



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FLUORESCEIN-CONJUGATED OLIGONUCLEOTIDE RNA PROBES FOR THE QUALITATIVE DETECTION OF RNA TRANSCRIPTS

EBER PROBE PB0589

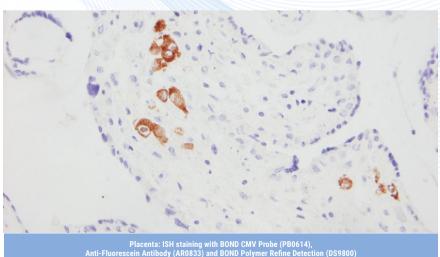


Anti-Eluorescein Antibody (AP0833) and BOND Polymer Patine Datection (DS0800)

Epstein-Barr Virus (EBV) is a member of the Gamma Herpes Virus family. Latent infection can be associated with many conditions, including infectious mononucleosis, Hodgkins Lymphoma, Burkitt's Lymphoma, and nasopharyngeal carcinoma. It is more common in immunocompromised patients.

Laboratory testing is useful in the confirmation of diagnosis and in monitoring disease burden after initiation of therapy. EBER transcripts are abundantly expressed in latent EBV infection and ISH is considered the gold standard technique in the determination of EBV infected lesions in biopsy tissue.

CMV PROBE PB0614



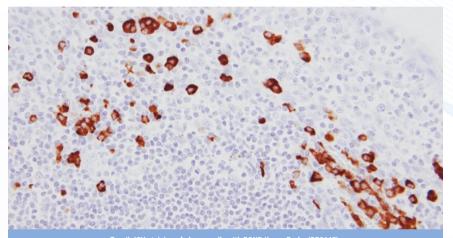
Cytomegalovirus is a herpes virus which can cause serious disease in immunocompromised patients such as transplant recipients and neonates.

CMV ISH is useful for detection of CMV infections in FFPE tissues. It has high a specificity (100%) and positive predictive value (92.6%)*. It is more sensitive than conventional diagnosis by H&E.

* Lu DY, Qian J, Easley KA, Waldrop SM, Cohen C. Appl Immunohistochem Mol Morphol. 2009 Mar;17(2):158-64. Automated in situ hybridization and immunohistochemistry for cytomegalovirus detection in paraffin-embedded tissue sections.

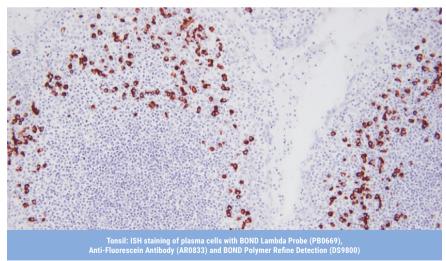
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KAPPA PROBE PB0645



Tonsil: ISH staining of plasma cells with BOND Kappa Probe (PB0645), nti-Fluorescein Antibody (AR0833) and BOND Polymer Refine Detection (DS9800)

LAMBDA PROBE PB0669



Immunoglobulins are glycoproteins produced in mature B-cells against a specific antigen. Each individual immunogloblin molecule is composed of one of five classes of heavy chains and either Kappa or Lambda light chains. In normal human lymphoid populations, the ratio of Kappa to Lambda light chains is approximately 2:1.

B-cell neoplasms are thought to arise from a single transformed cell (monoclonal). In contrast, reactive states result in proliferation of a number of B-cells (polyclonal). Since immunoglobulins from the same B-cell contain either Kappa or Lambda light chains, light chain restriction or monoclonality can be used to make the distinction between reactive and neoplastic B cell proliferations.

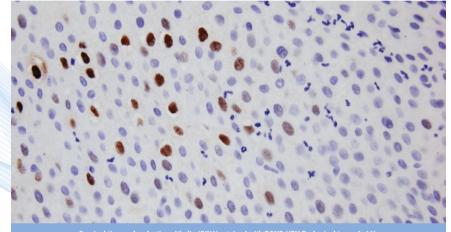
IHC for Kappa and Lambda can be associated with high levels of background staining due to tissue immunoglobulins which can lead to problems with interpretation of staining. ISH is more specific and may be useful in the identification of monoclonal plasma cell populations. It is particularly useful in bone marrow trephines where decalcification protocols can cause a loss of antigenicity and where serum immunoglobulins can lead to high levels of background with IHC.

Products in this flyer are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region. For more information on regulatory status and intended use, see the IHC & ISH Product Catalog or product IFUs.

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BIOTIN-CONJUGATED DNA PROBES FOR THE QUALITATIVE DETECTION OF DNA GENOTYPES

HPV (SUBTYPES 6, 11) PB0780



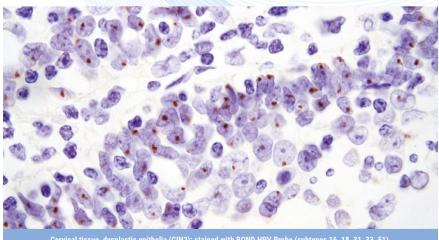
ervical tissue, dysplastic epithelia (CIN1): stained with BOND HPV Probe (subtypes 6, 11), Apti-Riotin antibody (AR0584) and ROND Polymor Polyno Detection (DS0800)

Human Papilloma Virus (HPV) infections have been associated with a number of malignant lesions, including anogenital and oropharyngeal cancers. HPV subtypes are associated with more than 95% of cervical cancer. As a result, HPV subtypes are broadly classified as high and low risk types, depending on the incidence to which they are associated with cervical malignant transformation (high risk) or benign lesion development (low risk).

BOND HPV ISH can be used to detect the low risk HPV subtypes 6 and 11 (PB0780) and the high risk subtypes 16, 18, 31, 33 and 51 (PB0829).

BOND HPV ISH facilitates the detection of HPV DNA within the context of tissue morphology.

HPV (SUBTYPES 16, 18, 31, 33, 51) PB0829



rvical tissue, dysplastic epithelia (CIN2): stained with BOND HPV Probe (subtypes 16, 18, 31, 33, 51), Anti-Biotin antibody (AR0584) and BOND Polymer Refine Detection (DS9800)

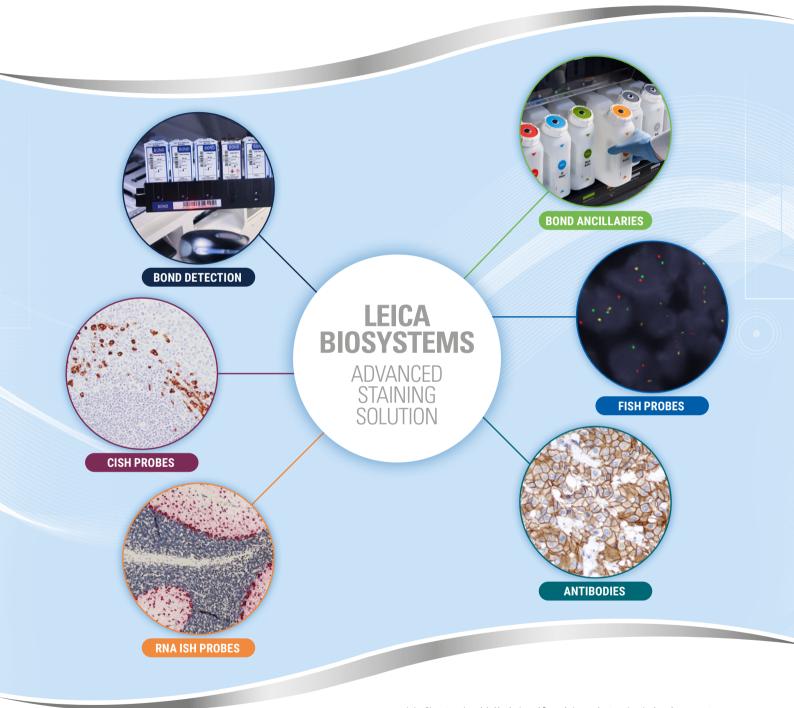
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CHROMOGENIC ISH PROBES

PRODUCT CODE	PRODUCT NAME	TESTS	STATUS
RNA PROBES (FLUC	RESCEIN-CONJUGATED)		
PB0614	CMV Probe	25	IVD
PB0589	EBER Probe	25	IVD
PB0645	Kappa Probe	25	IVD
PB0669	Lambda Probe	25	IVD
DNA PROBES (BIOT	IN-CONJUGATED)		
PB0780	HPV (subtypes 6, 11) Probe	25	IVD
PB0829	HPV (subtypes 16, 18, 31, 33, 51) Probe	25	IVD
BOND ISH CONTRO	L REAGENTS		
PB0785	RNA Positive Control	25	IVD
PB0809	RNA Negative Control	25	IVD
PB0682	DNA Positive Control	25	IVD
PB0731	DNA Negative Control	25	IVD
BOND ANCILLARY F	REAGENTS		
AR9551	Enzyme Pretreatment Kit	-	IVD
AR0833	Anti-Fluorescein Antibody	25	IVD
AR0222	Anti-Fluorescein Antibody	100	IVD
AR0584	Anti-Biotin Antibody	25	IVD
AR0633	Stringency Wash Solution	25	IVD
BOND COMPACT PO	DLYMER [™] DETECTION		
DS9800	Bond Polymer Refine Detection	200	IVD

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BOND Chromogenic ISH Probes are not available for sale in the USA.

*Independent analysis commissioned by Leica Biosystems and conducted by Nordi QC according to the manufacturer's instructions for use and on the corresponding staining platform.

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