Bond™ Ready-to-Use Primary Antibody CD20 (L26)

Catalog No: PA0359

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EN FR IT DE ES PT
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Instructions for Use
Please read before using this product.

Mode d'emploi
Á lire avant d'utiliser ce produit.

Istruzioni per l'uso
Si prega di leggere, prima di usare il prodotto.

Gebrauchsanweisung
Bitte vor der Verwendung dieses Produkts lesen.

Instrucciones de uso
Por favor, leer antes de utilizar este producto.

Instruções de Utilização
Leia estas instruções antes de utilizar este produto.

Bruksanvisning
Var god läs innan ni använder produkten.

Οδηγίες Χρήσης
Παρακαλούμε διαβάστε τις οδηγίες πριν χρησιμοποιήσετε το προϊόν αυτό.

Brugsanvisning
Læs venligst før produktet tages i brug.

Gebruiksinstructies
Lezen vóór gebruik van dit product.

Bruksanvisning
Vennligst les denne før du bruker produktet.

Kullanım Talimatları
Lütfen bu ürünü kullanmadan önce okuyunuz.

Check the integrity of the packaging before use.
Vérifier que le conditionnement est en bon état avant l'emploi.
Prima dell'uso, controllare l'integrità della confezione.
Vor dem Gebrauch die Verpackung auf Unversehrtheit überprüfen.
Comprobar la integridad del envase, antes de usarlo.
Verifique a integridade da embalagem antes de utilizar o produto.
Kontrollera att paketet är obrutet innan användning.
Ελέγξτε την ακεραιότητα της συσκευασίας πριν από τη χρήση.
Kontroller, at pakken er ubeskadiget før brug.
Controleer de verpakking vóór gebruik.
Sjekk at pakningen er intakt før bruk.
Kullanmadan önce ambalajın bozulmamış olmasını kontrol edin.

www.LeicaBiosystems.com

Bond™ Ready-To-Use Primary Antibody CD20 (L26) Catalog No: PA0359

Intended Use

This reagent is for *in vitro* diagnostic use.

CD20 (L26) monoclonal antibody is intended to be used for the qualitative identification by light microscopy of human CD20 protein in formalin-fixed, paraffin-embedded tissue by immunohistochemical staining using the automated BOND system (includes Leica BOND-MAX system and Leica BOND-III system).

The clinical interpretation of any staining or its absence should be complemented by morphological studies and proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

Summary and Explanation

Immunohistochemical techniques can be used to demonstrate the presence of antigens in tissue and cells (see "Using BOND Reagents" in your BOND user documentation). CD20 (L26) primary antibody is a ready to use product that has been specifically optimized for use with Bond Polymer Refine Detection. The demonstration of human CD20 protein is achieved by first allowing the binding of CD20 (L26) to the section, and then visualizing this binding using the reagents provided in the detection system. The use of these products, in combination with the automated BOND system (includes Leica BOND-MAX system and Leica BOND-III system), reduces the possibility of human error and inherent variability resulting from individual reagent dilution, manual pipetting and reagent application.

Reagents Provided

CD20 (L26) is a mouse anti-human monoclonal antibody produced as a tissue culture supernatant, and supplied in Tris buffered saline with carrier protein, containing 0.35 % ProClin™ 950 as a preservative.

Total volume = 30 mL.

Clone

L26

Immunogen

Human tonsil B cells.

Specificity

An intracytoplasmic epitope localized on the human CD20 molecule. Reacts predominantly with a 33 kD polypeptide, but also with a minor component of 30 kD.

Ig Class

IgG2a, Kappa

Total Protein Concentration

Approx 10 mg/mL.

Antibody Concentration

Greater than or equal to 0.93 mg/L as determined by ELISA.

Dilution and Mixing

CD20 (L26) primary antibody is optimally diluted for use on the BOND system (includes Leica BOND-MAX system and Leica BOND-III system). Reconstitution, mixing, dilution or titration of this reagent is not required.

Materials Required But Not Provided

Refer to "Using BOND Reagents" in your BOND user documentation for a complete list of materials required for specimen treatment and immunohistochemical staining using the BOND system (includes Leica BOND-MAX system and Leica BOND-III system).

Storage and Stability

Store at 2–8 °C. Do not use after the expiration date indicated on the container label.

The signs indicating contamination and/or instability of CD20 (L26) are: turbidity of the solution, odor development, and presence of precipitate.

Return to 2–8 °C immediately after use.

Storage conditions other than those specified above must be verified by the user[1].

Precautions

- This product is intended for *in vitro* diagnostic use.
- The concentration of ProClin™ 950 is 0.35 %. It contains the active ingredient 2-methyl-4-isothiazolin-3-one, and may cause irritation to the skin, eyes, mucous membranes and upper respiratory tract. Wear disposable gloves when handling reagents.
- To obtain a copy of the Material Safety Data Sheet contact your local distributor or regional office of Leica Biosystems, or alternatively, visit the Leica Biosystems' Web site, www.LeicaBiosystems.com

- Specimens, before and after fixation, and all materials exposed to them, should be handled as if capable of transmitting infection and disposed of with proper precautions[2]. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents or specimens. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water. Seek medical advice.
- Consult Federal, State or local regulations for disposal of any potentially toxic components.
- Minimize microbial contamination of reagents or an increase in non-specific staining may occur.
- Retrieval, incubation times or temperatures other than those specified may give erroneous results. Any such change must be validated by the user.

Instructions for Use

CD20 (L26) primary antibody was developed for use on the automated BOND system (includes Leica BOND-MAX system and Leica BOND-III system) in combination with Bond Polymer Refine Detection. The recommended staining protocol for CD20 (L26) primary antibody is IHC Protocol F. Heat induced epitope retrieval is recommended using Bond Epitope Retrieval Solution 1 for 20 minutes.

Results Expected

Normal Tissues

Clone L26 detects the CD20 antigen on the cell surface of the cells of the B cell lineage, except plasma cells. (Total number of normal cases evaluated = 53).

Tumor Tissues

Clone L26 stained 11/11 diffuse large B cell lymphomas, 6/6 follicular lymphomas, 2/2 MALTomas, 1/5 Hodgkin's disease, 1/1 Burkitt's lymphoma and 1/1 mantle cell lymphoma. No staining was observed in peripheral T-cell lymphomas (0/6), anaplastic large cell lymphomas (0/2), a malignant lymphoblastic lymphoma (0/1), an angioimmunoblastic T cell lymphoma (0/1), or a NK/T cell lymphoma (0/1), thyroid tumors (0/4), lung tumors (0/4, including a non small cell carcinoma (0/1), an adenocarcinoma (0/1), a squamous cell carcinoma (0/1) and a large cell carcinoma (0/1)), liver tumors (0/4, including cholangiocarcinomas (0/2) and hepatocellular carcinomas (0/2)), ovarian tumors (0/4, including a malignant germ cell tumor (0/1), a serous cystadenocarcinoma (0/1), a clear cell carcinoma (0/1) and a mucinous cystadenocarcinoma (0/1)), squamous cell carcinomas of the cervix (0/2), seminomas (0/2), colon adenocarcinomas (0/2), adenocarcinomas of the rectum (0/2), adenocarcinomas of the stomach (0/2), renal cell carcinomas (0/2), ductal carcinomas of the breast (0/2), soft tissue tumors (0/2), squamous cell carcinomas if the tongue (0/2), squamous cell carcinomas of the esophagus (0/2), metastatic carcinomas of unknown origin (0/2), skin tumors (0/2, including a dermatofibrosarcoma (0/1) and a squamous cell carcinoma (0/1)), brain tumors (0/2, including an anaplastic astrocytoma (0/1) and a choroid plexus papilloma (0/1)), an atypical carcinoid of the thymus (0/1) and a squamous cell carcinoma of the larynx (0/1). (Total number of tumor cases evaluated = 81).

CD20 (L26) is recommended for use as part of an antibody panel to aid in the characterization of B cell disorders.

Product Specific Limitations

CD20 (L26) has been optimized at Leica Biosystems for use with Bond Polymer Refine Detection and BOND ancillary reagents. Users who deviate from recommended test procedures must accept responsibility for interpretation of patient results under these circumstances. The protocol times may vary, due to variation in tissue fixation and the effectiveness of antigen enhancement, and must be determined empirically. Negative reagent controls should be used when optimizing retrieval conditions and protocol times.

Troubleshooting

Refer to reference 3 for remedial action.

Contact your local distributor or the regional office of Leica Biosystems to report unusual staining.

Further Information

Further information on immunostaining with BOND reagents, under the headings Principle of the Procedure, Materials Required, Specimen Preparation, Quality Control, Assay Verification, Interpretation of Staining, Key to Symbols on Labels, and General Limitations can be found in "Using BOND Reagents" in your BOND user documentation.

Bibliography

1. Clinical Laboratory Improvement Amendments of 1988, Final Rule 57 FR 7163 February 28, 1992.
2. Villanova PA. National Committee for Clinical Laboratory Standards (NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. 1991; 7(9). Order code M29-P.
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4. Chen CC, Raikow RB, Sonmez-Alpan E et al. Classification of small B-cell lymphoid neoplasms using a paraffin section immunohistochemical panel. Applied Immunohistochemistry Molecular Morphology. 2000; 8(1):1–11.
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10. Ishii Y, Takami T, Yuasa H et al. Two distinct antigen systems in human B lymphocytes: identification of cell surface and intracellular antigens using monoclonal antibodies. Clinical Experimental Immunology. 1984; 58:183–192.

Date of Issue

27 May 2014

Anticorps Primaire Prêt À L'emploi Bond™ CD20 (L26)

Référence: PA0359

Utilisation Prévue

Ce réactif est destiné au diagnostic *in vitro*.

CD20 (L26) est un anticorps monoclonal destiné à l'identification qualitative par microscopie optique de la protéine CD20 humaine dans les tissus fixés au formol et enrobés de paraffine par coloration immunohistochimique en utilisant le système automatisé BOND (comprenant les systèmes Leica BOND-MAX et Leica BOND-III).

L'interprétation clinique de tout marquage ou de son absence doit être complétée par des études morphologiques utilisant des contrôles appropriés et évaluée dans le contexte des antécédents cliniques du patient et des autres tests diagnostiques par un pathologiste qualifié.

Résumé et Explications

Les techniques immunohistochimiques peuvent être utilisées pour la mise en évidence d'antigènes sur tissus ou cellules (voir « Utilisation des réactifs BOND » dans votre manuel d'utilisation BOND). L'anticorps primaire CD20 (L26) est prêt à l'emploi et a été spécialement optimisé pour Bond Polymer Refine Detection. La démonstration de la protéine CD20 humaine s'effectue d'abord par la liaison de CD20 (L26) à la coupe, puis par la visualisation de cette liaison au moyen des réactifs fournis dans le système de détection. L'utilisation de ces produits, en combinaison avec le système BOND automatisé (qui comprend les systèmes Leica BOND-MAX et Leica BOND-III), réduit le risque d'erreurs humaines et la variabilité inhérente résultant de la dilution des réactifs individuels, du pipetage manuel et de l'application des réactifs.

Réactifs Fournis

CD20 (L26) est un anticorps monoclonal anti-humain de souris, produit par surnageant de culture de tissu et conditionné dans du tampon salin Tris avec une protéine de transport, contenant 0,35 % de ProClin™ 950 comme conservateur.

Volume total = 30 mL.

Clone

L26

Immunogène

Lymphocytes B d'amygdale humaine.

Spécificité

Un épitope intracytoplasmique situé sur la molécule CD20 humaine. Réagit principalement avec un polypeptide de 33 kD, mais également avec un composant mineur de 30 kD.

Classe d'Ig

IgG2a, Kappa

Concentration Totale en Protéine

Environ 10 mg/ml.

Concentration en Anticorps

Supérieure ou égale à 0,93 mg/l déterminée par ELISA.

Dilution et Mélange

L'anticorps primaire CD20 (L26) est dilué de manière optimale pour une utilisation sur le système BOND (qui comprend les systèmes Leica BOND-MAX et Leica BOND-III). Reconstitution, mélange, dilution et titration de ce réactif non nécessaires.

Matériel Nécessaire Mais Non Fournis

Veuillez vous référer à la section "Utilisation des réactifs BOND" dans votre mode d'emploi BOND pour obtenir une liste détaillée des matériaux requis pour le traitement des échantillons et la coloration immunohistochimique via le système BOND (qui comprend les systèmes Leica BOND-MAX et Leica BOND-III).

Conservation et Stabilité

Conserver entre 2 et 8 °C. Ne pas utiliser après la date de péremption indiquée sur l'étiquette du récipient.

Une turbidité de la solution, une présence d'odeurs ou de précipité sont des signes indicateurs d'une contamination et/ou d'une instabilité de CD20 (L26).

Remettre à 2–8 °C immédiatement après usage.

Des conditions de stockage différentes de celles ci-dessus doivent être contrôlées par l'utilisateur[1].

Précautions

- Ce produit est conçu pour le diagnostic *in vitro*.
- La concentration de ProClin™ 950 est de 0,35 %. Contient du 2-méthyl-4-isothiazoline-3-one (principe actif) et peut entraîner des irritations de la peau, des yeux, des muqueuses et des voies aériennes supérieures. Porter des gants jetables lors de la manipulation des réactifs.
- Pour obtenir une copie de la fiche technique des substances dangereuses, contactez votre distributeur local ou le bureau régional de Leica Biosystems, ou allez sur le site Web de Leica Biosystems, www.LeicaBiosystems.com

- Les échantillons, avant et après fixation, et tous les matériels ayant été en contact avec eux, devraient être manipulés comme s'ils étaient à risque infectieux et éliminés avec les précautions adéquates [2]. Ne jamais pipeter les réactifs à la bouche et éviter le contact de la peau et des muqueuses avec les réactifs ou les échantillons. Si des réactifs ou des échantillons entrent en contact avec des zones sensibles, rincer abondamment à l'eau. Consultez un médecin.
- Renseignez-vous sur les règlements fédéraux, nationaux et locaux pour l'élimination des composés potentiellement toxiques.
- Éviter une contamination microbienne des réactifs qui peut entraîner un marquage non spécifique.
- Des durées ou températures de démasquage ou d'incubation autres que celles spécifiées peuvent donner des résultats erronés. Tout changement doit être validé par l'utilisateur.

Mode d'emploi

L'anticorps primaire CD20 (L26) a été développé pour être utilisé sur le système BOND automatisé (qui comprend les systèmes Leica BOND-MAX et Leica BOND-III) en combinaison avec le Bond Polymer Refine Detection. Le protocole de marquage recommandé pour l'anticorps primaire CD20 (L26) est IHC Protocol F. Un démasquage d'épitope par la chaleur est recommandé avec Bond Epitope Retrieval Solution 1 durant 20 minutes.

Résultats Attendus

Tissus sains

Le clone L26 détecte l'antigène CD20 présent à la surface des cellules de la lignée des lymphocytes B, à l'exception des plasmocytes. (Nombre total de cas normaux évalués = 53).

Tissus tumoraux

Le clone L26 a marqué 11/11 lymphomes diffus à larges cellules B, 6/6 lymphomes folliculaires, 2/2 lymphomes de MALT, 1/5 maladies de Hodgkins, 1/1 lymphome de Burkitt et 1/1 lymphome des cellules du manteau. Aucune coloration n'a été observée dans des lymphomes T périphériques (0/6), des lymphomes anaplasiques à grandes cellules (0/2), un lymphome lymphoblastique malin (0/1), un lymphome T angioimmunoblastique (0/1), ou un lymphome à cellules NK/T (0/1), des tumeurs de la thyroïde (0/4), des tumeurs du poumon (0/4, dont un carcinome non à petites cellules (0/1), un adénocarcinome (0/1), un carcinome à cellules squameuses (0/1) et un carcinome à grandes cellules (0/1)), des tumeurs du foie (0/4, dont des cholangiocarcinomes (0/2) et des carcinomes hépatocellulaires (0/2)), des tumeurs ovariennes (0/4, dont une tumeur maligne des cellules germinales (0/1), un cystadénocarcinome séreux (0/1), un carcinome à cellules claires (0/1) et un cystadénocarcinome mucineux (0/1)), des carcinomes à cellules squameuses du col de l'utérus (0/2), des séminomes (0/2), des adénocarcinomes du côlon (0/2), des adénocarcinomes du rectum (0/2), des adénocarcinomes de l'estomac (0/2), des carcinomes à cellules rénales (0/2), des carcinomes canalaires du sein (0/2), des tumeurs des tissus mous (0/2), des carcinomes à cellules squameuses de la langue (0/2), des carcinomes à cellules squameuses de l'œsophage (0/2), des carcinomes métastatiques d'origine inconnue (0/2), des tumeurs de la peau (0/2, dont un dermatofibrosarcome (0/1) et un carcinome à cellules squameuses (0/1)), des tumeurs du cerveau (0/2, dont un astrocytome anaplasique (0/1) et un papillome des plexus choroïdes (0/1)), un carcinoïde du thymus atypique (0/1) et un carcinome à cellules squameuses du larynx (0/1). (Nombre total de cas de tumeurs évalués = 81).

CD20 (L26) est recommandé pour utilisation au sein d'un panel d'anticorps pour l'aide à la caractérisation des pathologies des cellules B.

Limites Spécifiques du Produit

CD20 (L26) a été optimisé chez Leica Biosystems pour une utilisation avec Bond Polymer Refine Detection et les réactifs auxiliaires BOND. Les utilisateurs qui ne respectent pas les procédures de test recommandées prennent la responsabilité de l'interprétation des résultats des patients dans ces conditions. Les durées du protocole doivent être déterminées empiriquement, à cause des variations de fixation des tissus et d'efficacité du renforcement antigénique. Des contrôles négatifs des réactifs devraient être réalisés lors de l'optimisation des conditions de démasquage et des durées du protocole.

Identification des Problèmes

Voir la référence 3 pour connaître les actions correctrices.

Prenez contact avec votre distributeur local ou avec le bureau régional de Leica Biosystems pour signaler tout marquage inattendu.

Informations Complémentaires

Des informations complémentaires sur l'immunomarquage avec les réactifs BOND, les principes de la méthode, le matériel nécessaire, la préparation des échantillons, le contrôle qualité, les vérifications d'analyse, l'interprétation du marquage, les légendes et symboles sur les étiquettes et les limites générales, peuvent être obtenues dans « Utilisation des réactifs BOND » dans votre manuel d'utilisation BOND.

Bibliographie

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2. Villanova PA. National Committee for Clinical Laboratory Standards (NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. 1991; 7(9). Order code : M9-P.
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Date de Publication

27 mai 2014

Anticorpo Primario Pronto All'uso Bond™ CD20 (L26)

N. catalogo: PA0359

Uso Previsto

Reagente per uso diagnostico *in vitro*.

L'anticorpo monoclonale CD20 (L26) è stato progettato per l'utilizzo nell'identificazione qualitativa in microscopia ottica della proteina CD20 umana in tessuti fissati in formalina e inclusi in paraffina con colorazione immunoistochimica con sistema automatizzato BOND (include i sistemi Leica BOND-MAX e Leica BOND-III).

L'interpretazione clinica di un'eventuale colorazione, o della sua assenza, deve avvalersi di studi morfologici e di opportuni controlli ed essere effettuata da patologi qualificati, nel contesto dell'anamnesi clinica del paziente e di altri test diagnostici.

Sommario e Speigazione

Grazie alle tecniche di immunoistochimica è possibile dimostrare la presenza di antigeni nel tessuto e nelle cellule (vedere "Uso dei reagenti BOND" nella documentazione per l'utente BOND). L'anticorpo primario CD20 (L26) è un prodotto pronto per l'uso che è stato ottimizzato in modo specifico per l'impiego con il Bond Polymer Refine Detection. La dimostrazione della proteina CD20 umana si ottiene in primo luogo consentendo il legame di CD20 (L26) alla sezione, quindi visualizzando tale legame per mezzo dei reagenti forniti nel sistema di rilevazione. L'uso di questi prodotti in combinazione con il sistema automatizzato BOND (include il sistema Leica BOND-MAX e il sistema Leica BOND-III), riduce la possibilità di errori umani e la variabilità inerente derivante dalla diluizione dei reagenti, dal pipettaggio manuale e dall'applicazione dei reagenti.

Reagenti Forniti

Il CD20 (L26) è un anticorpo monoclonale murino anti-umano prodotto come surnatante di coltura tissutale e fornito in soluzione salina tamponata Tris con proteina carrier, contenente 0,35 % di ProClin™ 950 come conservante.

Volume totale = 30 mL.

Clone

L26

Immunogeno

Cellule B di tonsilla umana.

Specificità

Un epitopo intracitoplasmatico localizzato su molecola CD20 umana. Reagisce prevalentemente con un polipeptide di 33 kD, ma anche con un componente minore di 30 kD.

Classe Ig

IgG2a, Kappa.

Concentrazione Proteica Totale

Circa 10 mg/ml.

Concentrazione Dell'anticorpo

Uguale o superiore a 0,93 mg/l, determinata mediante ELISA.

Diluizione e Miscelazione

L'anticorpo primario CD20 (L26) è diluito in modo ottimale per essere usato con il sistema BOND (include il sistema Leica BOND-MAX e il sistema Leica BOND-III). Non è necessario ricostituire, miscelare, diluire o titolare il reagente.

Materiale Necessario Non Fornito

Per una lista completa dei materiali necessari al trattamento dei campioni e alla colorazione immunoistochimica usando il sistema BOND (include il sistema Leica BOND-MAX e il sistema Leica BOND-III), consultare "L'uso dei reagenti BOND" nel proprio manuale utente BOND.

Conservazione e Stabilità

Conservare a 2–8 °C. Non utilizzare dopo la data di scadenza indicata sull'etichetta del contenitore.

I segni di contaminazione e/o instabilità del CD20 (L26) sono: torbidità della soluzione, formazione di odori e presenza di un precipitato.

Riportare a 2–8 °C immediatamente dopo l'uso.

L'utente deve verificare eventuali condizioni di conservazione diverse da quelle specificate[1].

Precauzioni

- Il prodotto è destinato all'uso diagnostico *in vitro*.
- La concentrazione del ProClin™ 950 è 0,35 %. Esso contiene il principio attivo 2-metil-4-isotiazolin-3-one e può causare irritazione alla cute, agli occhi, alle membrane mucose e alle alte vie respiratorie. Per la manipolazione dei reagenti usare guanti monouso.
- Una copia della Scheda di sicurezza può essere richiesta al distributore locale o all'ufficio di zona di Leica Biosystems o, in alternativa, visitando il sito di Leica Biosystems www.LeicaBiosystems.com
- I campioni, prima e dopo la fissazione, e tutti i materiali esposti ad essi devono essere manipolati come potenziali vettori di infezione e smaltiti con le opportune precauzioni[2]. Non pipettare mai i reagenti con la bocca ed evitare il contatto dei reagenti o dei campioni con la pelle e le membrane mucose. Se un reagente o un campione viene a contatto con zone sensibili, lavare abbondantemente con acqua. Consultare un medico.

- Consultare la normativa nazionale, regionale o locale vigente per lo smaltimento dei componenti potenzialmente tossici.
- Ridurre al minimo la contaminazione microbica dei reagenti per evitare il rischio di una colorazione non specifica.
- Tempi o temperature di incubazione diversi da quelli specificati possono fornire risultati erronei. Ogni eventuale modifica deve essere validata dall'utente.

Istruzioni per L'uso

L'anticorpo primario CD20 (L26) è stato sviluppato per l'uso nei sistemi automatizzati BOND (include il sistema Leica BOND-MAX e il sistema Leica BOND-III) in combinazione con il Bond Polymer Refine Detection. Il protocollo di colorazione consigliato per l'anticorpo primario CD20 (L26) è l'IHC Protocol F. Un démasquage d'épitope par la chaleur est recommandé avec Bond Epitope Retrieval Solution 1 durant 20 minutes.

Risultati Attesi

Tessuti normali

Il clone L26 rileva l'antigene CD20 sulla superficie cellulare delle cellule della linea cellulare B, eccetto le cellule plasmatiche. (Numero totale di casi normali esaminati = 53).

Tessuti neoplastici

Il clone L26 ha colorato 11/11 linfomi diffusi a grandi cellule B, 6/6 linfomi follicolari, 2/2 MALToma, 1/5 linfoma di Hodgkin, 1/1 linfoma di Burkitt e 1/1 linfoma mantellare. Non è stata osservata colorazione nei linfomi a cellule T periferiche (0/6), nei linfomi anaplastici a grandi cellule (0/2), in un linfoma linfoblastico maligno (0/1), in un linfoma angioimmunoblastico a cellule T (0/1) o in un linfoma a cellule NK/T (0/1), nei tumori alla tiroide (0/4), nei tumori ai polmoni (0/4, incluso un carcinoma non a cellule piccole (0/1), in un adenocarcinoma (0/1), in un carcinoma a cellule squamose (0/1) e in un carcinoma a grandi cellule (0/1)), nei tumori al fegato (0/4, inclusi colangiocarcinomi (0/2) e nei carcinomi epatocellulari (0/2)), nei tumori alle ovaie (0/4, incluso un tumore a cellule germinali maligne (0/1), in un cistadenocarcinoma sieroso (0/1), in un carcinoma a cellule chiare (0/1) e in un cistadenocarcinoma mucinoso (0/1)), nei carcinomi a cellule squamose della cervice (0/2), nei seminomi (0/2), negli adenocarcinomi del colon (0/2), negli adenocarcinomi del retto (0/2), negli adenocarcinomi dello stomaco (0/2) nei carcinomi delle cellule renali (0/2), nei carcinomi duttali del seno (0/2), nei tumori dei tessuti molli (0/2), nei carcinomi a cellule squamose della lingua (0/2), nei carcinomi a cellule squamose dell'esofago (0/2), nei carcinomi metastatici di origine sconosciuta (0/2), nei tumori della pelle (0/2, inclusi un dermatofibrosarcoma (0/1) e un carcinoma a cellule squamose (0/1)), nei tumori cerebrali (0/2, inclusi un astrocitoma anaplastico (0/1) e un papilloma del plesso corioideo (0/1)), in un carcinoide atipico del timo (0/1) e in un carcinoma a cellule squamose della laringe (0/1). (Numero totale di casi di tumore valutati = 81).

Si raccomanda l'utilizzo di CD20 (L26) come parte di un pannello di anticorpi per assistere nella caratterizzazione di disturbi a carico delle cellule B.

Limitazioni Specifiche del Prodotto

Il CD20 (L26) è stato ottimizzato da Leica Biosystems per l'uso con il Bond Polymer Refine Detection e con i reagenti ausiliari BOND. Gli utenti che modificano le procedure raccomandate devono assumersi la responsabilità dell'interpretazione dei risultati relativi ai pazienti in tali circostanze. I tempi del protocollo possono variare in base alle variazioni nella fissazione del tessuto e nell'efficienza del potenziamento dell'antigene e devono essere definiti in modo empirico. Nell'ottimizzazione delle condizioni di riconoscimento e dei tempi del protocollo si devono impiegare dei controlli negativi del reagente.

Soluzione Problemi

Per le azioni di rimedio consultare il riferimento bibliografico n. 3.

Per riferire una colorazione inusuale rivolgersi al distributore locale o all'ufficio di zona di Leica Biosystems.

Ulteriori Informazioni

Altre informazioni sull'immunocolorazione con i reagenti BOND si trovano in "Uso dei reagenti BOND" nella documentazione per l'utente BOND, ai titoli Principio della procedura, Materiali necessari, Preparazione del campione, Controllo di qualità, Verifica del saggio, Interpretazione della colorazione, Leggenda dei simboli delle etichette e Limitazioni generali.

Bibliografia

1. Clinical Laboratory Improvement Amendments of 1988, Final Rule 57 FR 7163 February 28, 1992.
2. Villanova PA. National Committee for Clinical Laboratory Standards (NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. 1991; 7(9). Order code : M9-P.
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4. Chen CC, Raikow RB, Sonmez-Alpan E et al. Classification of small B-cell lymphoid neoplasms using a paraffin section immunohistochemical panel. Applied Immunohistochemistry Molecular Morphology. 2000; 8(1):1–11.
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9. Norton AJ and Isaacson PG. Monoclonal antibody L26: an antibody that is reactive with normal and neoplastic B lymphocytes in routinely fixed and paraffin wax embedded tissues. Journal of Clinical Pathology. 1987; 40:1405–1412.
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Data di Pubblicazione

27 maggio 2014

Gebrauchsfertiger Bond™ -Primärantikörper CD20 (L26)

Bestellnr.: PA0359

Verwendungszweck

Dieses Reagenz ist für die *In-vitro*-Diagnostik bestimmt.

Der monoklonale Antikörper CD20 (L26) wurde zur Verwendung bei der lichtmikroskopischen qualitativen Detektion des Humanproteins CD20 in Formalin fixiertem, in Paraffin eingebettetem Gewebe mittels immunhistochemischer Färbung auf einem automatisierten BOND System (Leica BOND-MAX System und Leica BOND-III System) entwickelt.

Die klinische Auswertung der An- oder Abwesenheit einer Färbung sollte durch morphologische Untersuchungen und geeignete Kontrollen ergänzt werden und sollte im Zusammenhang mit der Krankengeschichte eines Patienten und anderen diagnostischen Tests von einem qualifizierten Pathologen vorgenommen werden.

Zusammenfassung und Erläuterung

Immunhistochemische Methoden können dazu verwendet werden, die Anwesenheit von Antigenen in Geweben und Zellen zu demonstrieren (sehen Sie dazu “Das Arbeiten mit BOND-Reagenzien” in Ihrem BOND-Benutzerhandbuch). Der Primärantikörper CD20 (L26) ist ein gebrauchsfertiges Produkt, das speziell für den Gebrauch mit dem Bond Polymer Refine Detection optimiert wurde. Die Darstellung des Humanproteins CD20 wird dadurch erreicht, dass man zunächst die Bindung von CD20 (L26) an den Abschnitt ermöglicht und anschließend die entstandene Bindung mittels der im Detektionssystem verfügbaren Reagenzien sichtbar macht. Die Verwendung dieser Produkte in Kombination mit dem automatisierten BOND-system (bestehend aus dem Leica BOND-MAX-System und dem Leica BOND-III-System) reduziert die Wahrscheinlichkeit von menschlichem Versagen sowie die inhärente Variabilität, die aus der Verdünnung der einzelnen Reagenzien, der manuellen Pipettierung und der Anwendung der Reagenzien resultieren.

Mitgelieferte Reagenzien

CD20 (L26) ist ein monoklonaler Maus-anti-Human Antikörper, der aus Zellkulturüberstand hergestellt wurde, in Tris-gepufferter Salzlösung mit einem Trägerprotein geliefert wird und 0,35 % ProClin™ 950 als Konservierungsmittel enthält.

Gesamtvolumen = 30 mL.

Klon

L26

Immunogen

Humantonsillen-B-Zellen.

Spezifität

Ein auf dem humanen CD20 Molekül vorliegendes zytoplasmatisches Epitop. Bindet vorrangig an ein 33-kD-Polypeptid, aber auch an eine kleinere 30-kD-Komponente.

Ig-Klasse

IgG2a, Kappa.

Gesamtproteinkonzentration

Ca.10 mg/ml.

Antikörperkonzentration

Größer oder gleich 0,93 mg/l, bestimmt mit ELISA.

Verdünnung und Mischung

Der primäre Antikörper CD20 (L26) weist eine optimale Verdünnung für die Verwendung mit dem BOND-system (bestehend aus dem Leica BOND-MAX-System und dem Leica BOND-III-System) auf. Rekonstitution, Mischen, Verdünnen oder Titrieren dieses Reagenzes ist nicht erforderlich.

Erforderliche, Aber Nicht Mitgelieferte Materialien

In Ihrer BOND-Benutzerdokumentation finden Sie unter “Verwendung von BOND-Reagenzien” eine vollständige Liste der Materialien, die für die Probenvorbereitung und die immunhistochemische Färbung mit dem BOND-system (bestehend aus dem Leica BOND-MAX-System und dem Leica BOND-III-System) benötigt werden.

Lagerung und Stabilität

Bei 2–8 °C lagern. Nach Ablauf des auf dem Behälteretikett angegebenen Verfallsdatums nicht mehr verwenden.

Zeichen, die auf eine Kontamination und/oder Instabilität von CD20 (L26) hinweisen, sind eine Trübung der Lösung, Geruchsentwicklung, und das Vorhandensein von Präzipitat.

Unmittelbar nach Gebrauch wieder bei 2–8 °C aufbewahren.

Andere als die oben angegebenen Lagerungsbedingungen müssen vom Anwender selbst getestet werden[1].

Vorsichtsmaßnahmen

- Dieses Produkt ist für die *In-vitro*-Diagnostik bestimmt.
- Die Konzentration von ProClin™ 950 beträgt 0,35 %. Es enthält 2-Methyl-4-isothiazolin-3-on als aktiven Bestandteil und kann Reizungen der Haut, Augen, Schleimhäute und oberen Atemwege verursachen. Tragen Sie beim Umgang mit Reagenzien Einweghandschuhe.

- Ein Exemplar des Sicherheitsdatenblattes erhalten Sie von Ihrer örtlichen Vertriebsfirma, von der Regionalniederlassung von Leica Biosystems oder über die Webseite von Leica Biosystems unter www.LeicaBiosystems.com
- Behandeln Sie Präparate vor und nach der Fixierung sowie sämtliche damit in Berührung kommenden Materialien so, als ob sie Infektionen übertragen könnten und entsorgen Sie sie unter Beachtung der entsprechenden Vorsichtsmaßnahmen[2]. Pipettieren Sie Reagenzien niemals mit dem Mund und vermeiden Sie den Kontakt von Haut oder Schleimhäuten mit Reagenzien oder Präparaten. Falls Reagenzien oder Präparate mit empfindlichen Bereichen in Kontakt kommen, spülen Sie diese mit reichlich Wasser. Holen Sie anschließend ärztlichen Rat ein.
- Beachten Sie bei der Entsorgung potentiell toxischer Bestandteile die behördlichen und örtlichen Vorschriften.
- Mikrobielle Kontaminationen sollten minimiert werden, da es sonst zu einer Zunahme unspezifischer Färbungen kommen kann.
- Die Verwendung anderer als die angegebenen Retrievals, Inkubationszeiten oder Temperaturen kann zu fehlerhaften Ergebnissen führen. Diesbezügliche Änderungen müssen vom Anwender selbst getestet werden.

Gebrauchsanleitung

Der primäre Antikörper CD20 (L26) wurde für die Verwendung in dem automatisierten BOND-system (bestehend aus dem Leica BOND-MAX-System und dem Leica BOND-III-System) in Kombination mit Bond Polymer Refine Detection entwickelt. Das empfohlene Färbeverfahren für den Primärantikörper CD20 (L26) ist das IHC Protocol F. Das hitzeinduzierte Epitop-Retrieval wird unter Verwendung der Bond Epitope Retrieval Solution 1 für 20 Minuten empfohlen.

Erwartete Ergebnisse

Normale Gewebe

Klon L26 detektiert das CD20-Antigen auf der Zelloberfläche von Zellen der B-Zelllinie, mit Ausnahme von Plasmazellen. (Gesamtzahl der bewerteten Normalfälle = 53).

Tumorgewebe

Mit Klon L26 erfolgte Anfärbung von 11/11 diffusen großen B-Zell-Lymphomen, 6/6 follikulären Lymphomen, 2/2 MALTomen, 1/5 Morbus Hodgkin, 1/1 Burkitt-Lymphomen und 1/1 Mantelzelllymphomen. Keine Anfärbung wurde beobachtet bei peripheren T-Zell-Lymphomen (0/6), anaplastischen großzelligen Lymphomen (0/2), einem malignen lymphoblastischen Lymphom (0/1), einem angioimmunoblastischen T-Zell-Lymphom (0/1), oder einem NK/T-Zell-Lymphom (0/1), Schilddrüsentumoren (0/4), Lungentumoren (0/4, einschließlich einem nicht-kleinzelligen Karzinom (0/1), einem Adenokarzinom (0/1), einem Plattenepithelkarzinom (0/1) und einem großzelligen Karzinom (0/1)), Lebertumoren (0/4, einschließlich Cholangiokarzinomen (0/2) und hepatozellulären Karzinomen (0/2)), Ovarialtumoren (0/4, einschließlich einem malignen Keimzellentumor (0/1), einem serösen Zystadenokarzinom (0/1), einem klarzelligen Karzinom (0/1) und einem muzinösen Zystadenom (0/1)), Plattenepithelkarzinomen der Zervix (0/2), Seminomen (0/2), Adenokarzinomen des Dickdarms (0/2), Adenokarzinomen des Rektums (0/2), Adenokarzinomen des Magens (0/2), Nierenzellkarzinomen (0/2), duktales Mammakarzinom (0/2), Weichteiltumore (0/2), Plattenepithelkarzinomen der Zunge (0/2), Plattenepithelkarzinomen des Oesophagus (0/2), metastasierten Karzinomen unbekannten Ursprungs (0/2), Hauttumoren (0/2, einschließlich eines Dermatofibrosarkoms (0/1) und ein Plattenepithelkarzinom (0/1)), Hirntumoren (0/2, einschließlich eines anaplastischen Astrozytoms (0/1) und eines Papilloms des Choroidplexus (0/1) und eines Plattenepithelkarzinoms des Kehlkopfes (0/1). (Gesamtzahl der bewerteten Tumorfälle = 81).

CD20 (L26) wird zur Verwendung bei der Charakterisierung von B-Zell-Störungen als Teil eines Antikörperpanels empfohlen.

Produktspezifische Einschränkungen

CD20 (L26) wurde von Leica Biosystems zur Verwendung mit dem Bond Polymer Refine Detection und BOND-Zusatzreagenzien optimiert. Anwender, die andere als die empfohlenen Testverfahren verwenden, müssen unter diesen Umständen die Verantwortung für die Auswertung der Patientenergebnisse übernehmen. Die Verfahrenszeiten können aufgrund von Unterschieden in der Gewebefixierung und der Wirksamkeit der Antigenverstärkung variieren und müssen empirisch bestimmt werden. Bei der Optimierung der Retrieval-Bedingungen und Verfahrenszeiten sollten negative Reagenzkontrollen verwendet werden.

Fehlersuche

Maßnahmen zur Abhilfe beim Auftreten von Fehlern finden Sie in Referenz 3.

Falls Sie ungewöhnliche Färbeergebnisse beobachten, wenden Sie sich an Ihre örtliche Vertriebsfirma oder an die Regionalniederlassung von Leica Biosystems.

Weitere Informationen

Weitere Informationen zur Immunfärbung mit BOND-Reagenzien finden Sie in den Abschnitten Grundlegende Vorgehensweise, Erforderliches Material, Probenvorbereitung, Qualitätskontrolle, Assay-Verifizierung, Deutung der Färbung, Schlüssel der Symbole auf den Etiketten und Allgemeine Einschränkungen in “Das Arbeiten mit BOND-Reagenzien” in Ihrem BOND-Benutzerhandbuch.

Bibliografie

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2. Villanova PA. National Committee for Clinical Laboratory Standards (NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. 1991; 7(9). Order code : M9-P.
3. Bancroft JD and Stevens A. Theory and Practice of Histological Techniques. 4th Edition. Churchill Livingstone, New York. 1996.
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Ausgabedatum

27 Mai 2014

Anticuerpo Primario Listo Para Usar Bond™ CD20 (L26)

Catálogo Nº.: PA0359

Indicaciones de Uso

Este reactivo es para uso diagnóstico *in vitro*.

El anticuerpo monoclonal CD20 (L26) está diseñado para la identificación cualitativa mediante microscopía óptica de la proteína CD20 humana en tejidos fijados en formol e incluidos en parafina mediante tinción inmunohistoquímica con el sistema automatizado BOND (incluye los sistemas Leica BOND-MAX y Leica BOND-III).

La interpretación clínica de cualquier tinción o de la ausencia de ésta debe complementarse con estudios morfológicos y controles adecuados, y debe evaluarla un patólogo cualificado junto con el historial clínico del paciente y con otras pruebas diagnósticas.

Resumen y Explicación

Las técnicas inmunohistoquímicas pueden ser utilizadas para detectar la presencia de antígenos en tejidos y células (véase “Uso de reactivos BOND” en la documentación de usuario suministrada por BOND). El anticuerpo primario CD20 (L26) es un producto listo para usar que se ha optimizado específicamente para su uso con Bond Polymer Refine Detection. La demostración de la proteína CD20 humana se consigue al permitir, en primer lugar, la fijación de CD20 (L26) al corte y, a continuación, visualizar esta fijación por medio de los reactivos que se incluyen en el sistema de detección. La utilización de estos productos, en combinación con el sistema BOND automatizado (incluye el sistema Leica BOND-MAX y el sistema Leica BOND-III), reduce las posibilidades de que se produzca un error humano y la variabilidad inherente que resulta de la dilución de un reactivo individual, del pipeteo manual y de la aplicación de un reactivo.

Reactivos Suminstrados

CD20 (L26) es un anticuerpo monoclonal antihumano de ratón que se produce como sobrenadante en cultivos de tejido, y se suministra en solución salina tamponada de Tris con proteína portadora, que contiene el 0,35 % de ProClin™ 950 como conservante.

Volumen total = 30 mL.

Clon

L26

Inmunógeno

Células B humanas de las amígdalas.

Especificidad

Un epítopo intracitoplasmático localizado en la molécula CD20 humana. Reacciona principalmente con un polipéptido de 33 kD, pero también con un componente menor de 30 kD.

Clase de Ig

IgG2a, Kappa.

Concentración Total de Proteína

Aprox. 10 mg/mL.

Concentración de Anticuerpos

Mayor o igual a 0,93 mg/L según lo determinado por ELISA.

Dilución y Mezcla

El anticuerpo primario CD20 (L26) se diluye óptimamente para usarse en el sistema BOND (incluye el sistema Leica BOND-MAX y el sistema Leica BOND-III). No es necesaria la reconstitución, mezcla, dilución o titulación de este reactivo.

Material Necesario Pero No Suministrado

Consulte el apartado “Utilización de reactivos BOND” de la documentación de usuario BOND para leer una lista completa de los materiales requeridos en el tratamiento de muestras y en la tinción inmunohistoquímica con el sistema BOND (incluye el sistema Leica BOND-MAX y el sistema Leica BOND-III).

Conservación y Estabilidad

Debe conservarse a 2–8 °C. No utilizar después de la fecha de caducidad que aparece en la etiqueta.

Los signos de contaminación y/o inestabilidad de CD20 (L26) son turbidez de la solución, aparición de olor y presencia de precipitado.

Volver a guardar a 2–8 °C inmediatamente después de su uso.

Si las condiciones de conservación son diferentes de las especificadas, el usuario debe realizar las comprobaciones necesarias[1].

Precauciones

- Este producto es para uso diagnóstico *in vitro*.
- La concentración de ProClin™ 950 es de 0,35 %. Contiene el principio activo 2-metil-4-isotiazolin-3-ona, que puede producir irritación en la piel, ojos, mucosas y tracto respiratorio superior. Lleve siempre guantes desechables cuando manipule los reactivos.
- Si desea obtener un ejemplar de la Hoja de datos de seguridad de los materiales, póngase en contacto con su distribuidor o con la oficina regional de Leica Biosystems, o visite la página Web de Leica Biosystems en www.LeicaBiosystems.com

- Las muestras, antes y después de ser fijadas, y cualquier material en contacto con ellas, deben ser tratados como sustancias capaces de transmitir infecciones y deben ser eliminadas con las precauciones correspondientes[2]. No pipetee nunca los reactivos con la boca, y evite el contacto de la piel y las mucosas con reactivos o muestras. Si algún reactivo o alguna muestra entra en contacto con zonas sensibles, lávelas con agua abundante. Consulte a un médico.
- Consulte la normativa federal, nacional o local referente a la eliminación de sustancias potencialmente tóxicas.
- Minimice la contaminación microbiana de los reactivos, ya que puede producir un aumento de las tinciones inespecíficas.
- Los tiempos de exposición e incubación, y las temperaturas diferentes de las especificadas pueden dar resultados erróneos. Cualquier cambio que se produzca deberá ser validado por el usuario.

Instrucciones de Uso

El anticuerpo primario CD20 (L26) se ha desarrollado para usarse en el sistema BOND automatizado (incluye el sistema Leica BOND-MAX y el sistema Leica BOND-III) en combinación con la Bond Polymer Refine Detection. El protocolo de tinción recomendado para el anticuerpo primario CD20 (L26) es IHC Protocol F. Se recomienda la exposición de epítopos inducida por calor usando Bond Epitope Retrieval Solution 1 durante 20 minutos.

Resultados Esperados

Tejidos normales

El clon L26 detecta el antígeno CD20 en la superficie de las células del linaje de células B, excepto en las células del plasma. (Número total de casos normales evaluados = 53).

Tejidos tumorales

El clon L26 produjo la tinción en 11/11 linfomas B difusos de células grandes, 6/6 linfomas foliculares, 2/2 maltolinfomas, 1/5 linfomas de Hodgkin, 1/1 linfoma de Burkitt y 1/1 linfoma del manto. No se observó tinción en los linfomas de linfocitos T periféricos (0/6), los linfomas anaplásicos de células grandes (0/2), el linfoma linfoblástico maligno (0/1), el linfoma T angioinmunoblástico (0/1), el linfoma de células T/NK (0/1), los cánceres tiroideos (0/4), los cánceres de pulmón (0/4, que incluyen un carcinoma amicrocítico [0/1], un adenocarcinoma [0/1], un carcinoma escamoso [0/1] y un carcinoma de células grandes [0/1]), los cánceres hepáticos (0/4, que incluyen colangiocarcinomas [0/2] y carcinomas hepatocelulares [0/2]), tumores ováricos (0/4, que incluyen un tumor maligno de células reproductoras [0/1], un quistoadenoma seroso [0/1], un carcinoma de células claras [0/1] y un quistoadenoma mucinoso [0/1]), los carcinomas escamosos del cuello uterino (0/2), los seminomas (0/2), los adenocarcinomas de colon (0/2), los adenocarcinomas de recto (0/2), los adenocarcinomas de estómago (0/2), los adenocarcinomas renales (0/2), los carcinomas ductales de la mama (0/2), los tumores de partes blandas (0/2), los carcinomas escamosos de lengua (0/2), los carcinomas escamosos de esófago (0/2), los carcinomas metastásicos de origen desconocido (0/2), los cánceres de piel (0/2, que incluyen un dermatofibrosarcoma [0/1] y un carcinoma espinocelular [0/1]), los tumores cerebrales (0/2, que incluyen un astrocitoma anaplásico [0/1] y un papiloma de los plexos coroideos [0/1]), el tumor carcinoide atípico de timo (0/1) y el carcinoma escamoso de laringe (0/1). (Número total de casos de tumor evaluados = 81).

Se recomienda el uso de CD20 (L26) como parte de un panel de anticuerpos que ayude en la caracterización de trastornos de células B.

Limitaciones Específicas del Producto

CD20 (L26) se ha optimizado en Leica Biosystems para su uso con Bond Polymer Refine Detection y reactivos auxiliares BOND. Los usuarios que se aparten de los procedimientos de análisis recomendados deben asumir la responsabilidad de interpretar los resultados del paciente tomando en cuenta estas circunstancias. Los tiempos de protocolo pueden diferir debido a la variación en la fijación de los tejidos y a la eficacia en la preservación del antígeno, y deben determinarse empíricamente. Se debe utilizar reactivos de control negativos a la hora de optimizar las condiciones de detección y los tiempos de protocolo.

Resolución de Problemas

Consulte la referencia 3 para ver las acciones correctoras.

Contacte con su distribuidor local o la oficina regional de Leica Biosystems para informar de cualquier tinción anómala.

Más Información

Para obtener más información sobre inmunotinciones con reactivos BOND, consulte los apartados Principio del procedimiento, Material necesario, Preparación de las muestras, Control de calidad, Verificación del análisis, Interpretación de la tinción, Clave de símbolos en las etiquetas y Limitaciones generales de la sección “Utilización de reactivos BOND” de la documentación de usuario suministrada por BOND.

Bibliografía

1. Clinical Laboratory Improvement Amendments of 1988, Final Rule 57 FR 7163 February 28, 1992.
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Fecha de Publicación

27 de mayo de 2014

Anticorpo Primário Pronto a Usar Bond™ CD20 (L26)

Nº de catálogo: PA0359

Utilização Prevista

Este reagente destina-se a utilização diagnóstica *in vitro*.

O anticorpo monoclonal CD20 (L26) destina-se a ser utilizado na identificação qualitativa por microscopia ótica da proteína CD20 humana em tecidos embebidos em parafina e fixados em formalina por coloração imuno-histoquímica usando o sistema BOND automatizado (inclui o sistema Leica BOND-MAX e o sistema Leica BOND-III).

A interpretação clínica de qualquer coloração ou da sua ausência deve ser complementada por estudos morfológicos utilizando controlos adequados, e deve ser avaliada no contexto da história clínica do doente e de outros testes complementares de diagnóstico por um anátomo-patologista qualificado.

Resumo e Explicação

As técnicas de imunohistoquímica podem ser usadas para demonstrar a presença de antigénios em tecidos e células (ver “Usar os Reagentes BOND” na sua documentação do utilizador BOND). O anticorpo primário CD20 (L26) consiste num produto pronto usar que foi especificamente optimizado para utilização com Bond Polymer Refine Detection. A demonstração da proteína CD20 humana é alcançada ao permitir primeiro a ligação do CD20 (L26) à secção e, em seguida, observar esta ligação usando os reagentes fornecidos no sistema de deteção. O uso destes produtos, combinado com o sistema BOND automatizado (inclui o sistema Leica BOND-MAX e o sistema Leica BOND-III), reduz a possibilidade de erro humano e de variação inerente devido à diluição do reagente individual, pipetagem manual e aplicação do reagente.

Reagentes Fornecidos

CD20 (L26) é um anticorpo monoclonal anti-humano de ratinho produzido como sobrenadante de cultura tecidular e fornecido em solução salina com tampão Tris com proteína transportadora, contendo 0,35 % de ProClin™ 950 como conservante.

Volume total = 30 mL.

Clone

L26

Imunogénio

Células B de amígdalas humanas.

Especificidade

Um epítopo intracitoplásmico situado na molécula CD20 humana. Reage predominantemente com um polipéptido 33 kD, mas também com um componente menor de 30 kD.

Classe De Ig

IgG2a, Kappa.

Concentração de Proteínas Totais

Aproximadamente 10 mg/mL.

Concentração de Anticorpos

Maior ou igual a 0,93 mg/L conforme determinado por ELISA.

Diluição e Mistura

O anticorpo primário Product name é devidamente diluído para uso no sistema BOND (inclui o sistema Leica BOND-MAX e o sistema Leica BOND-III). Não é necessária reconstituição, mistura, diluição ou titulação deste reagente.

Materias Necessários Mas Não Fornecidos

Consulte “Uso de reagentes BOND” em sua documentação de usuário BOND para ter uma lista completa de materiais necessário para coloração imuni-histoquímica e tratamento da amostra usando o sistema BOND (inclui o sistema Leica BOND-MAX e o sistema Leica BOND-III).

Armazenamento e Estabilidade

Armazene a uma temperatura de 2 a 8 °C. Não utilize após o fim do prazo de validade referido no rótulo do recipiente.

Os sinais que indicam contaminação e/ou instabilidade de CD20 (L26) são: turvação da solução, desenvolvimento de odor e presença de precipitado.

Coloque entre 2 e 8 °C imediatamente depois de utilizar.

Condições de armazenamento diferentes das acima especificadas devem ser confirmadas pelo utilizador [1].

Precauções

- Este produto destina-se a utilização diagnóstica *in vitro*.
- A concentração de ProClin™ 950 é de 0,35 %. Contém o ingrediente activo 2-metil-4-isotiazolina-3-a e pode provocar irritação da pele, olhos, membranas mucosas e vias aéreas superiores. Use luvas descartáveis quando manipular os reagentes. Use luvas descartáveis quando manipular os reagentes.

- Para obter uma cópia da Ficha de Dados de Segurança do Material, entre em contacto com o seu distribuidor local ou sucursal regional da Leica Biosystems ou, em alternativa, visite o site da Leica Biosystems na internet, www.LeicaBiosystems.com
- As amostras, antes e depois da fixação, e todo o material que a elas seja exposto, devem ser manipulados como se fossem capazes de transmitir infecção e eliminados usando as precauções adequadas[2]. Nunca pipete reagentes com a boca e evite o contacto entre a pele e membranas mucosas com reagentes ou amostras. Se reagentes ou amostras entrarem em contacto com os olhos, lave-os com uma quantidade abundante de água. Consultar um médico.
- Consulte os regulamentos federais, estatais e locais relativamente à eliminação de quaisquer componentes potencialmente tóxicos.
- Minimize a contaminação microbiana dos reagentes ou poderá ocorrer um aumento da coloração inespecífica.
- A utilização de tempos e temperaturas de recuperação e incubação diferentes dos especificados pode produzir resultados erróneos. Qualquer alteração deste tipo deve ser validada pelo utilizador.

Instruções de Utilização

O anticorpo primário Product name foi desenvolvido para uso no sistema BOND automatizado (inclui o sistema Leica BOND-MAX e o sistema Leica BOND-III) em combinação com a Bond Polymer Refine Detection. O protocolo de coloração indicado para o anticorpo primário CD20 (L26) é o IHC Protocol F. Recomenda-se a recuperação de epítopos induzida por calor utilizando a Bond Epitope Retrieval Solution 1 durante 20 minutos.

Resultados Esperados

Tecidos normais

O clone L26 deteta o antígeno CD20 na superfície das células da linhagem B, exceto nas células do plasma. (Número total de casos normais avaliados = 53).

Tecidos tumorais

O clone L26 corou 11/11 linfomas de células B grandes difusas, 6/6 linfomas foliculares, 2/2 linfomas MALT, 1/5 doença de Hodgkin, 1/1 linfoma de Burkitt e 1/1 linfoma das células do manto. Não foi observada coloração em linfomas das células T periféricas (0/6), linfomas anaplásicos das células T grandes (0/2), um linfoma linfoblástico maligno (0/1), linfomas angioimunoblásticos das células T (0/1), ou um linfoma das células NK/T (0/1), tumores da tiroide (0/4), tumores pulmonares (0/4, incluindo um carcinoma de células não pequenas (0/1), um adenocarcinoma (0/1), um carcinoma de células escamosas (0/1) e um carcinoma das células grandes (0/1)), tumores hepáticos (0/4, incluindo colangiocarcinomas (0/2) e carcinomas hepatocelulares (0/2)), tumores ováricos (0/4, incluindo um tumor maligno de células germinativas (0/1), um cistoadenocarcinoma seroso (0/1), um carcinoma das células claras (0/1) e um cistoadenocarcinoma mucinoso (0/1)), carcinomas de células escamosas do colo do útero (0/2), seminomas (0/2), adenocarcinomas do cólon (0/2), adenocarcinomas do reto (0/2), adenocarcinomas do estômago (0/2), carcinomas das células renais (0/2), carcinomas ductais da mama (0/2), tumores dos tecidos moles (0/2), carcinomas de células escamosas da língua (0/2), carcinomas de células escamosas do esófago (0/2), carcinomas metastáticos de origem desconhecida (0/2), tumores de pele (0/2, incluindo um dermatofibrosarcoma (0/1) carcinoma das células escamosas (0/1)), tumores cerebrais (0/2, incluindo um astrocitoma anaplásico (0/1) e um papiloma do plexo coroide (0/1)), um tumor carcinoide atípico do timo (0/1) carcinoma das células escamosas da laringe (0/1). (Número total de casos de tumores avaliados = 81).

CD20 (L26) é recomendado para utilizar como parte de um painel de anticorpos para ajudar na caracterização de desordens das células B.

Informações Específicas do Produto

CD20 (L26) foi optimizada na Leica Biosystems para utilização com a Bond Polymer Refine Detection e reagentes auxiliares BOND. Utilizadores que se desviem dos procedimentos de teste recokmendados devem assumir a responsabilidade pela interpretação dos resultados dos doentes nestas circunstâncias. Os tempos de protocolo podem variar, devido a variações na fixação tecidular e na eficácia de valorização com antigénios, devendo ser determinados de forma empírica. Os controlos de reagente negativos devem ser usados quando se optimizam as condições de recuperação e os tempos do protocolo.

Resolução de Problemas

Consulte a referência 3 para acções de resolução.

Entre em contacto com o seu distribuidor local ou com a sucursal regional da Leica Biosystems para notificar qualquer coloração pouco habitual.

Informações Adicionais

Poderá encontrar informações adicionais sobre imunocoloração com reagentes BOND nas secções de Princípios do Procedimento, Material Necessário, Preparação da Amostra, Controlo de Qualidade, Verificação do Ensaio, Interpretação da Coloração, Significado dos Símbolos nos Rótulos e Limitações Gerais em “Utilizar os Reagentes BOND” na documentação do utilizador BOND.

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1. Clinical Laboratory Improvement Amendments of 1988, Final Rule 57 FR 7163 February 28, 1992.
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Data de Emissão

27 de Maio de 2014

Bond™ Primär Antikropp - Färdig Att Användas
CD20 (L26)
Artikelnummer: PA0359

Användningsområde
Reagenset är avsett för *in vitro*-diagnostik.

CD20 (L26) monoklonal antikropp är avsedd att användas för kvalitativ identifiering av humant CD20-protein i formalinfixerad, paraffininbäddad vävnad med ljusmikroskopi och immunhistokemisk färgning med användning av det automatiserade BOND-systemet (inkluderar Leica BOND-MAX-systemet och Leica BOND-III-systemet).

Den kliniska tolkningen av varje infärgning, eller utebliven infärgning, måste alltid kompletteras med morfologiska studier och lämpliga kontroller. Utvärderingen bör göras av kvalificerad patolog och inkludera patientens anamnes och övriga diagnostiktester.

Förklaring och Sammanfattning
Immunhistokemiska tekniker kan användas för att påvisa antigener i vävnader och celler (se "Använda BOND-reagens" i Bondanvändar-dokumentationen). CD20 (L26) primär antikropp är en produkt, färdig att användas, som har optimerats specifikt för att användas med Bond Polymer Refine Detection. Påvisande av humant CD20-protein uppnås genom att man först möjliggör bindning av CD20 (L26) till snittet och sedan visualiserar denna bindning med hjälp av de reagenser som ingår i detektionssystemet. Om du använder dessa produkter i kombination med det automatiska BOND-systemet (som innefattar systemen Leica BOND-MAX och Leica BOND-III) minskar du risken för mänskliga misstag och de oundvikliga variationer som blir resultatet av individuell reagensutspädning och manuell pipettering och reagensanvändning.

Ingående Reagenser
CD20 (L26) är en mus anti-human monoklonal antikropp, producerad som supernatant från cellkultur. Den levereras i trisbuffrad koksaltlösning med bärarprotein. Lösningen innehåller 0,35 % ProClin™ 950 som konserveringsmedel.

Total volym = 30 mL.

Klon
L26

Immunogen
Humana B-celler från tonsill.

Specificitet
En intracytoplasmisk epitop, som lokaliseras på den humana CD20-molekylen. Reagerar huvudsakligen med en polypeptid på 33 kD, men även med en mindre komponent på 30 kD.

Ig-klass
IgG2a, Kappa.

Total Proteinkoncentration
Omkring 10 mg/ml.

Antikroppskoncentration
Större än eller lika med 0,93 mg/l enligt bestämning med ELISA.

Spädning och Blandning
CD20 (L26) primär antikropp är optimalt utspädd för att användas på BOND-systemet (som innefattar systemen Leica BOND-MAX och Leica BOND-III). Denna reagens behöver inte rekonstitueras, blandas, spädas eller titreras.

Nödvändig Materiel Som Ej Medföljer
I avsnittet "Att använda Bondreagenser" i din användardokumentation för BOND hittar du en komplett lista över de material som krävs för preparatbehandling och immunohistokemisk infärgning i BOND-systemet (som innefattar systemen Leica BOND-MAX och Leica BOND-III).

Förvaring och Stabilitet
Förvara vid 2–8 °C. Använd ej efter det utgångsdatum som står på förpackningen.

Tecken på kontaminering och/eller instabilitet hos CD20 (L26) är grumling i lösningen, luktutveckling och förekomst av fällning.

Ställ tillbaka i 2–8 °C omedelbart efter användning.

Andra förvaringsbetingelser än de ovan angivna måste verifieras av användaren[1].

Säkerhetsföreskrifter
- Produkten är avsedd för *in vitro*-diagnostik.
- Koncentrationen av ProClin™ 950 är på 0,35 %. Det innehåller den aktiva beståndsdelen 2-metyl-4-isotiazolin-3-on som kan verka irriterande på hud, ögon, slemhinnor och övre luftvägar. Använd engångshandskar när reagenserna hanteras.
- Du kan få tillgång till säkerhetsdatablad genom att kontakta en lokal distributör eller Leica Biosystems regionkontor. En annan möjlighet är Leica Biosystems webbsajt på www.LeicaBiosystems.com

- Prover, både före och efter fixeringen, och allt material som använts tillsammans med dem ska hanteras som infektiöst avfall enligt gängse praxis [2]. Pipettera aldrig reagenser med munnen och undvik att reagenser eller prover kommer i kontakt med hud och slemhinnor. Om reagenser eller prover kommer i kontakt med känsliga områden, skölj med stora mängder vatten. Sök läkarvård.
- Angående avfallshantering av potentiellt toxiska material hänvisar vi till gällande europeiska, nationella och lokala bestämmelser och förordningar.
- Minimera mikrobiologisk kontamination av reagens, annars kan en ökad icke-specifik infärgning bli resultatet.
- Återvinnande och andra inkubationstider eller temperaturer än de angivna kan ge felaktiga resultat. Sådana förändringar ska valideras av användaren.

Instruktioner vid Användning

CD20 (L26) primär antikropp har utvecklats för att användas på det automatiska BOND-systemet (som innefattar systemen Leica BOND-MAX och Leica BOND-III) i kombination med Bond Polymer Refine Detection. Rekommenderat färgningsprotokoll för CD20 (L26) primär antikropp är IHC Protocol F. Värmeinducerat epitop-retrieval rekommenderas med användande av Bond Epitope Retrieval Solution 1 i 20 minuter.

Förväntade Resultat

Normala vävnader

Klonen L26 detekterar CD20-antigen på cellytan hos celler med B-cellsursprung, förutom plasmaceller. (Totalt antal utvärderade normalfall = 53).

Tumörvävnader

Klonen L26 färgade 11/11 diffusa, stora B-cellslymfom, 6/6 follikulära lymfom, 2/2 MALTom, 1/5 Hodgkins lymfom, 1/1 Burkitts lymfom och 1/1 mantelcellslymfom. Ingen färgning observerades i perifera T-cellslymfom (0/6), anaplastiska storcelliga lymfom (0/2), ett malignt lymfoblastiskt lymfom (0/1), ett angioimmunoblastiskt T-cellslymfom (0/1), eller ett NK/T-cellslymfom (0/1), sköldkörteltumörer (0/4), lungtumörer (0/4, inklusive ett icke-småcelligt carcinom (0/1), ett adenocarcinom (0/1), ett skivepitelcarcinom (0/1) och ett storcelligt carcinom (0/1)), levertumörer (0/4, inklusive kolangiocarcinom (0/2) och hepatocellulära carcinom (0/2)), ovarialtumörer (0/4, inklusive en malign könscellstumör (0/1), ett seröst cystadenocarcinom (0/1), ett klarcellscarcinom (0/1) och ett mucinöst cystadenocarcinom (0/1)), skivepitelcarcinom i cervix (0/2), seminom (0/2), kolonadenocarcinom (0/2), adenocarcinom i rektum (0/2), adenocarcinom i mage (0/2), renalcellscarcinom (0/2), duktalcarcinom i bröst (0/2), mjukvävnadstumörer (0/2), skivepitelcarcinom i tunga (0/2), skivepitelcarcinom i matstrupen (0/2), metastatiskt carcinom av okänt ursprung (0/2), hudtumörer (0/2, inklusive ett dermatofibrosarkom (0/1) och ett skivepitelcarcinom (0/1)), hjärntumörer (0/2, inklusive ett anaplastiskt astrocytom (0/1) och ett choroid plexus-papillom (0/1)), en atypisk carcinoid i tymus (0/1) och ett skivepitelcarcinom i struphuvud (0/1). (Totalt antal utvärderade tumörfall = 81).

CD20 (L26) rekommenderas för användning som en del av en antikroppspanel för att underlätta karakteriseringen av B-cellssjukdomar.

Specifika Begränsningar För Produkten

CD20 (L26) har optimerats vid Leica Biosystems för att användas med Bond Polymer Refine Detection och BOND hjälpreagenser. Användare som avviker från rekommenderat testförfarande måste vid ändrade förhållanden ta ansvar för tolkningen av patientresultaten. Protokolltiderna kan variera på grund av variationer i vävnadsfixering och hur effektivt antigenet intensifieras, och ska fastställas empiriskt. Negativa reagenskontroller ska användas då förhållanden för återvinnande och protokolltider optimeras.

Felsökning

Se referens 3 för förslag till åtgärder.

Kontakta en lokal distributör eller Leica Biosystems regionkontor för att rapportera onormal infärgning.

Mer information

Mer information om immunfärgning med BOND-reagens finns under rubrikerna Bakgrund till metoden, Nödvändig materiel, Förbereda provet, Kvalitetskontroll, Verifiering av assayer, Tolka infärgningsresultat, Symbolförklaring för etiketter och Allmänna begränsningar i ”Använda BOND-reagens” i Bonds användardokumentation.

Litteraturförteckning

1. Clinical Laboratory Improvement Amendments of 1988, Final Rule 57 FR 7163 February 28, 1992.
2. Villanova PA. National Committee for Clinical Laboratory Standards (NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. 1991; 7(9). Order code : M9-P.
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10. Ishii Y, Takami T, Yuasa H et al. Two distinct antigen systems in human B lymphocytes: identification of cell surface and intracellular antigens using monoclonal antibodies. Clinical Experimental Immunology. 1984; 58:183–192.

Utgivningsdatum

27 maj 2014

Έτοιμο Για Χρήση Πρωτογενές Αντίσωμα Bond™ CD20 (L26)

Αρ. καταλόγου: PA0359

Σκοπός Χρήσης

Αυτό το αντιδραστήριο προορίζεται για διαγνωστική χρήση *in vitro*.

Το μονοκλωνικό αντίσωμα CD20 (L26) προορίζεται για την ποιοτική ταυτοποίηση με μικροσκοπία φωτός της ανθρώπινης πρωτεΐνης CD20 σε ιστό μονιμοποιημένο με φορμαλίνη και ενσωματωμένο σε παραφίνη μέσω ανοσοϊστοχημικής χρώσης, χρησιμοποιώντας το αυτοματοποιημένο σύστημα BOND (περιλαμβάνει το σύστημα Leica BOND-MAX και το σύστημα Leica BOND-III).

Η κλινική ερμηνεία οποιασδήποτε χρώσης ή της απουσίας της θα πρέπει να συμπληρώνεται με μορφολογικές μελέτες και σωστούς μάρτυρες και θα πρέπει να αξιολογείται στα πλαίσια του κλινικού ιστορικού του ασθενούς και άλλων διαγνωστικών εξετάσεων από ειδικευμένο παθολογοανατόμο.

Περίληψη Και Επεξήγηση

Για την κατάδειξη της παρουσίας αντιγόνων στον ιστό και στα κύτταρα μπορούν να χρησιμοποιηθούν ανοσοϊστοχημικές τεχνικές (δείτε την ενότητα "Χρήση αντιδραστηρίων BOND" στο υλικό τεκμηρίωσης χρήσης της BOND). Το πρωτογενές αντίσωμα CD20 (L26) είναι ένα έτοιμο για χρήση προϊόν που έχει βελτιστοποιηθεί ειδικά για χρήση με το Bond Polymer Refine Detection. Η κατάδειξη της ανθρώπινης πρωτεΐνης CD20 επιτυγχάνεται επιτρέποντας πρώτα τη δέσμευση του CD20 (L26) στην τομή και, κατόπιν, οπτικοποιώντας αυτήν τη δέσμευση με χρήση των αντιδραστηρίων που παρέχονται στο σύστημα ανίχνευσης. Η χρήση αυτών των προϊόντων, σε συνδυασμό με το αυτοματοποιημένο σύστημα BOND (περιλαμβάνει το σύστημα Leica BOND-MAX και το σύστημα Leica BOND-III), μειώνει τις πιθανότητες ανθρώπινου λάθους και την εγγενή μεταβλητότητα που προκαλούνται από τις αραιώσεις των επιμέρους αντιδραστηρίων, τη χειροκίνητη διανομή με πιπέτα και την εφαρμογή των αντιδραστηρίων.

Αντιδραστήρια Που Παρέχονται

Η CD20 (L26) είναι ένα μονοκλωνικό αντι-ανθρώπινο αντίσωμα ποντικού που παράγεται ως υπερκείμενο ιστοκαλλιέργειας και παρέχεται σε αλατούχο ρυθμιστικό διάλυμα Tris με πρωτεΐνη φορέα που περιέχει 0,35 % ProClin™ 950 ως συντηρητικό.

Συνολικός όγκος = 30 mL.

Κλώνος

L26

Ανοσογόνο

Β κύτταρα ανθρώπινης αμυγδαλής.

Ειδικότητα

Ένας ενδοκυτταροπλασματικός επίτοπος που εντοπίζεται στο ανθρώπινο μόριο CD20. Αντιδρά κυρίως με ένα πολυπεπτίδιο 33 kD, αλλά επίσης με ένα ελάσσον τμήμα 30 kD.

Τάξη Ig

IgG2a, Kappa.

Συνολική Συγκέντρωση Πρωτεΐνης

Περίπου 10 mg/mL.

Συγκέντρωση Αντισώματος

Μεγαλύτερη ή ίση με 0,93 mg/L όπως προσδιορίζεται με ELISA.

Αραίωση Και Ανάμειξη

Το πρωτογενές αντίσωμα CD20 (L26) έχει αραιωθεί ιδανικά για χρήση στο σύστημα BOND (περιλαμβάνει το σύστημα Leica BOND-MAX και το σύστημα Leica BOND-III). Δεν απαιτείται ανασύσταση, ανάμειξη, αραίωση ή τιτλοδότηση του αντιδραστηρίου αυτού.

Υλικά Που Απαιτούνται Αλλά Δεν Παρέχονται

Ανατρέξτε στην ενότητα "Using BOND Reagents" (Χρήση αντιδραστηρίων BOND) στην τεκμηρίωση χρήστη του συστήματος BOND για τον πλήρη κατάλογο των υλικών που απαιτούνται για την επεξεργασία των δειγμάτων και την ανοσοϊστοχημική χρώση με χρήση του συστήματος BOND (περιλαμβάνει το σύστημα Leica BOND-MAX και το σύστημα Leica BOND-III).

Φύλαξη Και Σταθερότητα

Φυλάσσεται στους 2–8 °C. Μη χρησιμοποιείτε μετά την ημερομηνία λήξης που αναγράφεται στην ετικέτα του περιέκτη.

Οι ενδείξεις που υποδηλώνουν μόλυνση ή/και αστάθεια της CD20 (L26) είναι: θολερότητα του διαλύματος, ανάπτυξη οσμής και παρουσία ιζήματος.

Επαναφέρετε το προϊόν στους 2–8 °C αμέσως μετά τη χρήση.

Συνθήκες φύλαξης εκτός από αυτές που καθορίζονται παραπάνω πρέπει να επαληθεύονται από τον χρήστη[1].

Προφυλάξεις

- Το προϊόν αυτό προορίζεται για *in vitro* διαγνωστική χρήση.
- Η συγκέντρωση του ProClin™ 950 είναι 0,35 %. Περιέχει το δραστικό συστατικό 2-μεθυλ-4-ισοθειαζολιν-3-όνη και ενδέχεται να προκαλέσει ερεθισμό στο δέρμα, τους οφθαλμούς, τους βλεννογόνους και την άνω αναπνευστική οδό. Φοράτε αναλώσιμα γάντια κατά το χειρισμό των αντιδραστηρίων.
- Για να λάβετε ένα αντίτυπο του δελτίου δεδομένων ασφαλείας υλικού, επικοινωνήστε με τον τοπικό σας διανομέα ή τα περιφερειακά γραφεία της Leica Biosystems ή, εναλλακτικά, επισκεφθείτε τον ιστότοπο της Leica Biosystems, www.LeicaBiosystems.com Τα δείγματα, πριν και μετά τη μονιμοποίηση, καθώς και όλα τα υλικά που εκτίθενται σε αυτά, πρέπει να υποβάλλονται σε χειρισμό ως δυνητικά μετάδοσης λοίμωξης και να απορρίπτονται με κατάλληλες προφυλάξεις2. Μην αναρροφάτε ποτέ με πιπέτα τα αντιδραστήρια με το στόμα και αποφεύγετε την επαφή του δέρματος και των βλεννογόνων με αντιδραστήρια ή δείγματα. Εάν τα αντιδραστήρια ή τα δείγματα έλθουν σε επαφή με ευαίσθητες περιοχές, πλύνετε με άφθονες ποσότητες νερού. Ζητήστε τη συμβουλή ιατρού.

- Συμβουλευτείτε τους ομοσπονδιακούς, πολιτειακούς ή τοπικούς κανονισμούς για απόρριψη τυχόν δυνητικώς τοξικών συστατικών.
- Ελαχιστοποιήστε τη μικροβιακή μόλυνση των αντιδραστηρίων, διότι διαφορετικά ενδέχεται να αυξηθεί η μη ειδική χρώση.
- Ανάκτηση, χρόνοι ή θερμοκρασίες επώασης διαφορετικές από εκείνες που καθορίζονται ενδέχεται να δώσουν εσφαλμένα αποτελέσματα. Τυχόν τέτοια μεταβολή πρέπει να επικυρώνεται από το χρήστη.

Οδηγίες Χρήσης

Το πρωτογενές αντίσωμα CD20 (L26) αναπτύχθηκε για χρήση στο αυτοματοποιημένο σύστημα BOND (περιλαμβάνει το σύστημα Leica BOND-MAX και το σύστημα Leica BOND-III) σε συνδυασμό με το σύστημα ανίχνευσης Bond Polymer Refine Detection. Το συνιστώμενο πρωτόκολλο χρώσης για το πρωτογενές αντίσωμα CD20 (L26) είναι το IHC Protocol F. Συνιστάται ανάκτηση επιτόπου επαγόμενη με θερμότητα χρησιμοποιώντας το Bond Epitope Retrieval Solution 1 για 20 λεπτά.

Αναμενόμενα Αποτελέσματα

Φυσιολογικοί ιστοί

Ο κλώνος L26 ανιχνεύει το αντιγόνο CD20 στην επιφάνεια των κυττάρων της γενεαλογίας των Β κυττάρων, εκτός από τα πλασματοκύτταρα. (Συνολικός αριθμός φυσιολογικών περιστατικών που αξιολογήθηκαν = 53).

Νεοπλασματικοί ιστοί

Με τον κλώνο L26 χρωματίστηκαν 11/11 διάχυτα μεγαλοκυτταρικά λεμφώματα Β κυττάρων, 6/6 θυλακιώδη λεμφώματα, 2/2 λεμφώματα MALT, 1/5 νόσος του Hodgkin, 1/1 λύμφωμα του Burkitt και 1/1 λέμφωμα μανδύα. Δεν παρατηρήθηκε χρώση σε περιφερικά λεμφώματα Τ κυττάρων (0/6), αναπλαστικά μεγαλοκυτταρικά λεμφώματα (0/2), ένα κακοήθες λεμφοβλαστικό λέμφωμα (0/1), ένα αγγειοανοσοβλαστικό λέμφωμα Τ κυττάρων (0/1) ή ένα λέμφωμα Τ/ΝΚ κυττάρων (0/1), όγκοι του θυρεοειδούς (0/4), όγκοι του πνεύμονα (0/4, μεταξύ τω οποίων ένα μη μικροκυτταρικό καρκίνωμα (0/1) ένα αδενοκαρκίνωμα (0/1), ένα ακανθοκυτταρικό καρκίνωμα (0/1) και ένα μεγαλοκυτταρικό καρκίνωμα (0/1)), όγκους του ήπατος (0/4, συμπεριλαμβανομένων χολαγγειοκαρκινωμάτων (0/2) και ηπατοκυτταρικά καρκινώματα (0/2)), όγκους των ωοθηκών (0/4, μεταξύ των οποίων έναν κακοήθη όγκο γεννητικών κυττάρων (0/1), ένα ορώδες κυσταδενοκαρκίνωμα (0/1), ένα διαυγοκυτταρικό καρκίνωμα (0/1) και ένα βλεννώδες κυσταδενοκαρκίνωμα (0/1)), ακανθοκυτταρικά καρκινώματα του τραχήλου (0/2), σεμινώματα (0/2), αδενοκαρκινώματα του κόλου (0/2), αδενοκαρκινώματα του ορθού (0/2), αδενοκαρκινώματα του στομάχου (0/2), νεφροκυτταρικά καρκινώματα (0/2), πορογενή καρκινώματα του μαστού (0/2), όγκοι μαλακών ιστών (0/2), ακανθοκυτταρικά καρκινώματα της γλώσσας (0/2), ακανθοκυτταρικά καρκινώματα του οισοφάγου (0/2), μεταστατικά καρκινώματα αγνώστου προέλευσης (0/2), όγκοι του δέρματος (0/2, μεταξύ των οποίων ένα δερματοϊνοσάρκωμα (0/1) και ένα ακανθοκυτταρικό καρκίνωμα (0/1)), όγκοι του εγκεφάλου (0/2, μεταξύ των οποίων ένα αναπλαστικό αστροκύτωμα (0/1) και ένα θήλωμα χοριοειδούς πλέγματος (0/1)), άτυπος καρκινοειδής όγκος του θύμου αδένα (0/1) και ένα ακανθοκυτταρικό καρκίνωμα του λάρυγγα (0/1). (Συνολικός αριθμός περιστατικών με νεοπλασματικούς ιστούς που αξιολογήθηκαν = 81).

Το CD20 (L26) συνιστάται για χρήση ως μέρος μιας σειράς αντισωμάτων για τον χαρακτηρισμό διαταραχών των Β κυττάρων.

Ειδικοί Περιορισμοί Του Προϊόντος

CD20 (L26) έχει βελτιστοποιηθεί στην Leica Biosystems για χρήση με το Bond Polymer Refine Detection και τα βοηθητικά αντιδραστήρια BOND. Χρήστες που αποκλίνουν από τις συνιστώμενες διαδικασίες εξέτασης πρέπει να αποδέχονται την ευθύνη για ερμηνεία των αποτελεσμάτων ασθενών υπό τις συνθήκες αυτές. Οι χρόνοι του πρωτοκόλλου ενδέχεται να διαφέρουν, λόγω της μεταβλητότητας της μονιμοποίησης του ιστού και της αποτελεσματικότητας ενίσχυσης των αντιγόνων και πρέπει να προσδιορίζονται εμπειρικά. Κατά τη βελτιστοποίηση των συνθηκών ανάκτησης και των χρόνων πρωτοκόλλου, πρέπει να χρησιμοποιούνται αρνητικοί μάρτυρες αντιδραστηρίων.

Αντιμετώπιση Προβλημάτων

Σχετικά με τις διορθωτικές ενέργειες, ανατρέξτε στην παραπομπή 3.

Για να αναφέρετε περιπτώσεις ασυνήθιστης χρώσης, επικοινωνήστε με τον τοπικό σας διανομέα ή τα περιφερειακά γραφεία της Leica Biosystems.

Πρόσθετες Πληροφορίες

Μπορείτε να βρείτε περισσότερες πληροφορίες σχετικά με την ανοσοχρώση με αντιδραστήρια BOND, υπό τους τίτλους Αρχή της διαδικασίας, Απαιτούμενα υλικά, Προετοιμασία δείγματος, Ποιοτικός έλεγχος", "Επαλήθευση προσδιορισμού, Ερμηνεία της χρώσης, Υπόμνημα για τα σύμβολα στις ετικέτες και Γενικοί περιορισμοί στην ενότητα "Χρήση αντιδραστηρίων BOND" στο υλικό τεκμηρίωσης χρήσης της BOND.

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Ημερομηνία Έκδοσης

27 Μαΐου 2014

Bond™ Brugsklart Primaert Antistof CD20 (L26)

Katalognummer.: PA0359

Tilsigtet Anvendelse

Dette reagens er beregnet til brug i *in vitro*-diagnostik.

CD20 (L26) monoklonalt antistof er beregnet til brug til kvalitativ identifikation ved hjælp af lysmikroskopi af det humane CD20 proteinet i formalinfikseret, paraffinindstøbt væv ved immunhistokemisk farvning ved anvendelse af det automatiske BOND-system (bestående af Leica BOND-MAX system og Leica BOND-III system).

Den kliniske fortolkning af enhver farvning eller fravær af samme skal ledsages af morfologiske undersøgelser og egnede kontroller og skal evalueres af en uddannet patolog i konteksten af patientens anamnese samt andre diagnostiske prøver.

Resumé og Forklaring

Immunhistokemiske teknikker kan anvendes til at påvise tilstedeværelse af antigener i væv og celler (se "Anvendelse af BOND-reagenser" i BOND-brugerdokumentationen). CD20 (L26) primært antistof er et brugsklart produkt, som er blevet optimeret specielt til brug sammen med Bond Polymer Refine Detection. Påvisningen af det humane CD20 proteinet sker ved først at muliggøre, at CD20 (L26) binder til snittet, og efterfølgende visualisere denne binding ved hjælp af de reagenser, der følger med detektionssystemet. Brugen af disse produkter sammen med det automatiske BOND-system (bestående af Leica BOND-MAX-systemet og Leica BOND-III-systemet) reducerer risikoen for menneskelige fejl og de indbyggede variationer, som opstår ved individuel reagensfortynding, manual pipettering og reagensapplicering.

Leverede Reagenser

CD20 (L26) er et murint antihumant monoklonalt antistof produceret som en vævskultursupernatant og leveret i Tris-bufferjusteret saltvandsopløsning med bæreprotein indeholdende 0.35 % ProClin™ 950 som konserveringsmiddel.

Totalt volumen = 30 mL.

Klon

L26

Immunogen

Humane tonsillære B-celler.

Specificitet

En intracytoplasmatisk epitop lokaliseret på det humane CD20-molekyle. Reagerer hovedsageligt med et polypeptid på 33 kD, men også med en mindre komponent på 30 kD.

Ig-klasse

IgG2a, Kappa.

Total Proteinkoncentration

Ca. 10 mg/ml.

Antistofkoncentration

Større end eller lig med 0,93 mg/l som bestemt med ELISA.

Fortynding og Blanding

CD20 (L26) primært antistof er fortyndet optimalt med henblik på brug i BOND-systemet (bestående af Leica BOND-MAX-systemet og Leica BOND-III-systemet). Rekonstitution, blanding, fortynding eller titrering af dette reagens er ikke påkrævet.

Nødvendige Materialer, der ikke Medfølger

Se under "Brug af BOND-reagenser" i BOND-brugsanvisningen for at se en komplet liste over de materialer, der skal bruges i forbindelse med behandling og immunohistokemisk staining af prøver ved hjælp af BOND-systemet (bestående af Leica BOND-MAX-systemet og Leica BOND-III-systemet).

Opbevaring og Stabilitet

Opbevares ved 2–8 °C. Må ikke anvendes efter udløbsdatoen, der er angivet på beholderens etiket.

De tegn, der indikerer, at CD20 (L26) er kontamineret og/eller ustabilt, omfatter turbiditet af opløsningen, lugtudvikling og tilstedeværelse af præcipitat.

Sættes tilbage til opbevaring ved 2–8 °C umiddelbart efter brug.

Opbevaringsbetingelser, der adskiller sig fra de oven for specificerede, skal verificeres af brugeren[1].

Forholdsregler

- Dette produkt er beregnet til brug i *in vitro*-diagnostik.
- Koncentrationen af ProClin™ 950 er 0,35 %. Det indeholder det aktive indholdsstof 2-methyl-4-isothiazolin-3-one og kan forårsage irritation af hud, øjne, slimhinder og øvre luftveje. Der skal anvendes handsker ved håndtering af reagenser.
- En kopi af sikkerhedsdatabladet (MSDS) kan fås ved henvendelse til den lokale distributør eller til Leica Biosystems' regionale kontor. Det kan tillige hentes på Leica Biosystems' hjemmeside www.LeicaBiosystems.com

- Præparater, både før og efter fiksering, samt alle øvrige materialer, der eksponeres for disse, skal håndteres som værende i stand til at overføre infektion og skal bortskaffes under iagttagelse af passende forholdsregler[2]. Afpipettér ikke reagenser med munden, og undgå at reagenser og præparater kommer i kontakt med hud og slimhinder. Hvis reagenser eller præparater kommer i kontakt med følsomme områder, skal disse vaskes med rigelige mængder vand. Søg læge.
- Bortskaffelse af potentielt toksiske komponenter skal ske i overensstemmelse med gældende statslig eller lokal lovgivning.
- Mikrobiel kontamination af reagenser skal minimeres for at undgå en øget ikke-specifik farvning.
- Genfinding, inkubationstider eller -temperaturer ud over de specificerede kan give fejlagtige resultater. Enhver ændring af denne art skal valideres af brugeren.

Brugsanvisning

CD20 (L26) primært antistof er udviklet med henblik på brug i det automatiske BOND-system (bestående af Leica BOND-MAX-systemet og Leica BOND-III-systemet) kombineret med Bond Polymer Refine Detection. Den anbefalede farvningsprotokol for CD20 (L26) primært antistof er IHC Protocol F. Varmeinduceret epitopgenfinding anbefales ved hjælp af Bond Epitope Retrieval Solution 1 i 20 minutter.

Forventede Resultater

Normala væv

Klon L26 detekterer CD20-antigen på celleoverfladen på celler af B-celle-afstamning, undtagen plasmaceller. (Samlet antal evaluerede, normale tilfælde = 53).

Tumorvæv

Klon L26 farvede 11/11 diffuse storcellede B-cellelymfomer, 6/6 follikulære lymfomer, 2/2 MALTomer, 1/5 Hodgkins sygdom, 1/1 Burkitts lymfom og 1/1 mantlecelle-lymfom. Der sås ingen farvning af perifere T-cellelymfomer (0/6), anaplastiske storcellede lymfomer (0/2), et malignt lymfoblastisk lymfom (0/1), et angioimmunoblastisk T-cellelymfom (0/1) eller et NK/T-cellelymfom (0/1), thyreoideatumorer (0/4), lungetumorer (0/4, herunder et ikke-småcellet karcinom (0/1), et adenokarcinom (0/1), et pladecellekarcinom (0/1) og et storcellet karcinom (0/1)), levertumorer (0/4, herunder kolangiokarcinomer (0/2) og hepatocellulære karcinomer (0/2)), ovarietumorer (0/4, herunder en malign kimcelletumor (0/1), et serøst cystadenokarcinom (0/1), et clear cell-karcinom (0/1) og et mucinøst cystadenokarcinom (0/1)), pladecellekarcinomer i cervix (0/2), seminomer (0/2), adenokarcinomer i colon (0/2), adenokarcinomer i rectum (0/2), adenokarcinomer i maven (0/2), renalcellekarcinomer (0/2), duktale karcinomer i brystet (0/2), bløddelstumorer (0/2), pladecellekarcinomer i tungen (0/2), pladecellekarcinomer i esophagus (0/2), metastatiske karcinomer af ukendt oprindelse (0/2), hudtumorer (0/2, herunder et dermatofibrosarkom (0/1) og et pladecellekarcinom (0/1)), hjernetumorer (0/2, herunder et anaplastisk astrocytom (0/1) og et plexus choroideus-papillom (0/1)), et atypisk karcinoid i thymus (0/1) og et pladecellekarcinom i larynx (0/1). (Samlet antal evaluerede tumortilfælde = 81).

CD20 (L26) anbefales til anvendelse som en del af et antistofpanel til hjælp ved karakterisering af B-celle-forstyrrelser.

Produktspecifikke Begrænsninger

CD20 (L26) er blevet optimeret hos Leica Biosystems til brug sammen med Bond Polymer Refine Detection og BOND-hjælpereagenser. Brugere, som afviger fra anbefalede test procedurer, må selv tage ansvaret for tolkningen af patientresultater under disse betingelser. Protokoltiderne kan variere på grund af variationer i vævsfiksering og effektiviteten af antigenforbedring og skal bestemmes empirisk. Der skal anvendes negative reagenskontroller ved optimering af genfindingsbetingelser og protokoltider.

Fejlfinding

Der henvises til reference 3 for afhjælpende foranstaltninger.

Kontakt den lokale distributør eller Leica Biosystems' regionale kontor for at rapportere usædvanlig farvning.

Yderligere Oplysninger

Yderligere oplysninger om immunfarvning med BOND-reagenser kan findes i "Anvendelse af BOND-reagenser" i BOND-brugerdokumentationen under overskrifterne Proceduremæssige principper, Nødvendige materialer, Præparatklargøring, Kvalitetskontrol, Analyseverifikation, Fortolkning af farvning, Nøgle til symboler på etiketter og Generelle begrænsninger.

Bibliografi

1. Clinical Laboratory Improvement Amendments of 1988, Final Rule 57 FR 7163 February 28, 1992.
2. Villanova PA. National Committee for Clinical Laboratory Standards (NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. 1991; 7(9). Order code : M9-P.
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9. Norton AJ and Isaacson PG. Monoclonal antibody L26: an antibody that is reactive with normal and neoplastic B lymphocytes in routinely fixed and paraffin wax embedded tissues. Journal of Clinical Pathology. 1987; 40:1405–1412.
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Udgivelsesdato

27 maj 2014

Bond™ Klaar Voor Primaire Antilichaam te Gebruiken CD20 (L26)

Catalogusnummer.: PA0359

Beoogd Gebruik

Deze reagens wordt gebruikt voor *in-vitro* -diagnostiek.

CD20 (L26) monoklonaal antilichaam is bedoeld voor gebruik bij de kwalitatieve identificatie door middel van lichtmicroscopie van humaan CD20-eiwit in met formaline gefixeerd, in paraffine ingebed weefsel, door immunohistochemische kleuring met gebruik van het automatische BOND-systeem (het Leica BOND-MAX-systeem en het Leica BOND-III-systeem).

De klinische interpretatie van iedere kleuring of de afwezigheid ervan moet worden aangevuld met morfologisch onderzoek en goede controles. De interpretatie moet worden geëvalueerd door een vakkundige patholoog binnen de context van de klinische geschiedenis van de patiënt en eventueel ander diagnostisch onderzoek.

Samenvatting en Uitleg

Immunohistochemische technieken kunnen gebruikt worden om de aanwezigheid van antilichamen in weefsel en cellen aan te tonen (zie “BOND-reagentie gebruiken” in de gebruikersdocumentatie van BOND). CD20 (L26) primaire antilichaam is een klaar voor gebruik product dat speciaal geoptimaliseerd is voor het gebruik met Bond Polymer Refine Detection. Humaan CD20-eiwit wordt aangetoond door eerst CD20 (L26) aan de coupe te laten binden en daarna die binding te visualiseren met behulp van de reagentia die in het detectiesysteem worden geleverd. Door deze producten te gebruiken in combinatie met het geautomatiseerde BOND-systeem (waaronder het Leica BOND-MAX-systeem en het Leica BOND-III-systeem) neemt de kans op menselijke fouten af en zijn er ook minder afwijkingen voortvloeiende uit de individuele reagensverdunning, het handmatig pipetteren en de reagenstoepassing.

Meegeleverde Reagentia

CD20 (L26) is een anti-monoklonaal muisantilichaam geproduceerd als een supernatant van de weefselkweek, en wordt geleverd in Tris gebufferde saline met draagproteïne, en bevat 0,35 % ProClin™ 950 als conserveringsmiddel.

Totale volume = 30 mL.

Kloon

L26

Immunogeen

B-cellen uit menselijke amandelen.

Specificiteit

Een epitoop op een cytoplasmatisch domein van het humane CD20-molecuul. Reageert voornamelijk met een polypeptide van 33 kD, maar ook met een kleinere component van 30 kD.

Ig-klasse

IgG2a, Kappa.

Totale Proteïneconcentratie

Ca. 10 mg/ml.

Antilichaamconcentratie

Groter of gelijk aan 0,93 mg/L zoals bepaald door ELISA.

Verdunning en Menging

CD20 (L26) primair antilichaam is optimaal verdund voor gebruik op het BOND-systeem (waaronder het Leica BOND-MAX-systeem en het Leica BOND-III-systeem). Reconstitutie, menging, verdunning of titratie van deze reagens is niet vereist.

Niet Meegeleverde Vereiste Materialen

Zie “BOND-reagentia gebruiken” in uw BOND-gebruikershandleiding voor een compleet overzicht van materialen die nodig zijn voor het verwerken van monsters en het uitvoeren van immunohistochemische kleuringen met het BOND-systeem (waaronder het Leica BOND-MAX-systeem en het Leica BOND-III-systeem).

Opslag en Stabiliteit

Opslaan bij temperaturen van 2–8 °C. Niet gebruiken na de expiratiedatum die op het etiket van de container staat.

Tekenen die contaminatie en/of instabiliteit van CD20 (L26) aangeven zijn: vertroebeling van de oplossing, geurontwikkeling en de aanwezigheid van neerslag.

Laat het systeem direct na gebruik terugkeren naar een temperatuur van 2–8 °C.

Opslagcondities andere dan degene die hierboven gespecificeerd zijn, dienen door de gebruiker geverifieerd te worden[1].

Voorzorgsmaatregelen

- Dit product is bedoeld voor in-vitro -diagnostiek.
- De concentratie van ProClin™ 950 is 0,35 %. Het bevat het actieve ingrediënt 2-methyl-4-isothiazoline-3-one, en kan irritatie veroorzaken aan de huid, ogen, slijmvlies en het bovenste deel van de luchtwegen. Draag wegwerphandschoenen bij het werken met reagentia.
- Om een kopie van het materiaalveiligheidsblad te verkrijgen, dient u contact op te nemen met uw lokale distributeur of het regionale kantoor van Leica Biosystems, of de website van Leica Biosystems te bezoeken: www.LeicaBiosystems.com

- Monsters moeten voor en na fixatie worden behandeld als potentiële overdragers van infecties en volgens de juiste voorzorgsmaatregelen worden afgedankt. Dit geldt tevens voor alle materialen die aan de monsters zijn blootgesteld[2]. Reagentia mogen nooit met de mond worden gepipetteerd. Daarnaast moet contact tussen de huid/het slijmvlies en reagentia en monsters worden vermeden. Als reagentia of monsters in contact komen met gevoelige gebieden, moet u deze gebieden wassen met een ruime hoeveelheid water. Neem contact op met een arts.
- Raadpleeg de richtlijnen van de lokale of nationale overheid voor het afdanken van potentieel giftige componenten.
- Minimaliseer de kans van microbacteriële contaminatie van reagentia. Als u dit niet doet, kan er een toename van niet-specifieke kleuring optreden.
- Terugwinning, incubatietijden of temperaturen die afwijken van degenen die gespecificeerd zijn, kunnen tot onjuiste resultaten leiden. Iedere dergelijke verandering moet door de gebruiker gevalideerd worden.

Instructies Voor Gebruik

CD20 (L26) primair antilichaam is ontwikkeld voor gebruik op het geautomatiseerde BOND-systeem (waaronder het Leica BOND-MAX-systeem en het Leica BOND-III-systeem) in combinatie met Bond Polymer Refine Detection. Het aanbevolen kleuringsprotocol voor CD20 (L26) primaire antilichaam is IHC Protocol F. Door warmte geïnduceerde terugwinning van epitoop is aanbevolen met gebruik van Bond Epitope Retrieval Solution 1 gedurende 20 minuten.

Verwachte Resultaten

Normale weefsels

Met kloon L26 werd het CD20-antigeen gedetecteerd op het oppervlak van cellen van B-cellijnen, behalve plasmacellen. (Totaal aantal beoordeelde tumorgevallen = 53).

Tumorweefsels

Kloon L26 kleurde 11/11 diffuse grootcellige B-cellymfomen, 6/6 folliculaire lymfomen, 2/2 MALTomen, 1/5 ziekte van Hodgkin, 1/1 Burkitt-lymfoom en 1/1 mantelcellymfoom. Er werd geen kleuring waargenomen van perifere T-cellymfomen (0/6), grootcellige anaplastische lymfomen (0/2), een maligne lymfoblastair lymfoom (0/1), een angioimmunoblastisch T-cellymfoom (0/1), of een NK-T-cellymfoom (0/1), tumoren van de schildklier (0/4), longtumoren (0/4, waaronder een niet-kleincellig carcinoom (0/1), een adenocarcinoom (0/1), een plaveiselcelcarcinoom (0/1) en een grootcellig carcinoom (0/1)), levertumoren (0/4, waaronder cholangiocarcinomen (0/2) en hepatocellulaire carcinomen (0/2)), ovariumtumoren (0/4, waaronder een maligne kiemceltumor (0/1), een sereus cystadenocarcinoom (0/1), een ‘clear cell’-carcinoom (0/1) en een mucineus cystadenocarcinoom (0/1)), plaveiselcelcarcinomen van de baarmoederhals (0/2), seminomen (0/2), adenocarcinoom van het colon (0/2), adenocarcinomen van het rectum (0/2), adenocarcinomen van de maag (0/2), niercelcarcinomen (0/2), ductale carcinomen van de borst (0/2), wekedelentumoren (0/2), plaveiselcelcarcinomen van de tong (0/2), plaveiselcelcarcinomen van de slokdarm (0/2), gemetastaseerde carcinomen van onbekende oorsprong (0/2), huidtumoren (0/2, waaronder een dermatofibrosarcoom (0/1) en een plaveiselcelcarcinoom (0/1)), hersentumoren (0/2, waaronder een anaplastisch astrocytoom (0/1) en een papilloom van de plexus choroideus (0/1)), een atypisch carcinoïd van de thymus (0/1) en een plaveiselcelcarcinoom van de larynx (0/1). (Totaal aantal beoordeelde tumorgevallen = 81).

CD20 (L26) wordt aanbevolen voor gebruik als onderdeel van een panel antilichamen als hulpmiddel bij het karakteriseren van B-celaandoeningen.

Productspecifieke Beperkingen

CD20 (L26) is geoptimaliseerd door Leica Biosystems voor het gebruik met Bond Polymer Refine Detection en BOND-hulpreagentia. Gebruikers die afwijken van de aanbevolen testprocedures moeten de verantwoordelijkheid accepteren voor de interpretatie van de patiëntresultaten onder deze omstandigheden. De protocoltijden kunnen variëren door de variatie in weefselfixatie en de effectiviteit van antigeenversterking, en moet empirisch worden bepaald. Negatieve reagenscontroles dienen gebruikt te worden voor het optimaliseren van terugwinningscondities en protocoltijden.

Probleemoplossing

Raadpleeg referentie 3 voor herstelactie.

Neem contact op met uw lokale distributeur of het regionale kantoor van Leica Biosystems om een ongebruikelijke kleuring te melden.

Overige Informatie

Meer informatie over immunokleuring met BOND-reagentie, onder de titels Uitgangspunten, Vereiste materialen, Voorbereiding monsters, Kwaliteitscontrole, Verificatie van de analyse, Interpretatie van de kleuring, Legenda van symbolen op etiketten, en Algemene beperkingen kunt u vinden in “BOND-reagentia gebruiken” in de gebruikersdocumentatie van BOND.

Literatuurlijst

1. Clinical Laboratory Improvement Amendments of 1988, Final Rule 57 FR 7163 February 28, 1992.
2. Villanova PA. National Committee for Clinical Laboratory Standards (NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. 1991; 7(9). Order code : M9-P.
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4. Chen CC, Raikow RB, Sonmez-Alpan E et al. Classification of small B-cell lymphoid neoplasms using a paraffin section immunohistochemical panel. Applied Immunohistochemistry Molecular Morphology. 2000; 8(1):1–11.
5. Hsi ED, Eisbruch A, Greenson JK et al. Classification of primary gastric lymphomas according to histologic features. American Journal of Surgical Pathology. 1998; 22(1):17–27.
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10. Ishii Y, Takami T, Yuasa H et al. Two distinct antigen systems in human B lymphocytes: identification of cell surface and intracellular antigens using monoclonal antibodies. Clinical Experimental Immunology. 1984; 58:183–192.

Publicatiedatum

27 mei 2014

Bond™ Primært Antistoff Klart til Bruk
CD20 (L26)
Katalognummer: PA0359

Tiltenkt Bruk
Denne reagensen er til *in vitro* -diagnostisk bruk.

CD20 (L26) er beregnet på kvalitativ identifisering ved lysmikroskopi av det humane CD20-Protein i formalinfiksert, parafininnstøpt vev ved hjelp av immunhistokjemisk farging med det automatiserte BOND-systemet (herunder Leica BOND-MAX-systemet og Leica BOND-III-systemet).

Den kliniske tolkningen av farging eller manglende farging skal være i tillegg til morfologiske undersøkelser og egnede kontroller, og skal evalueres av en kvalifisert patolog i lys av pasientens kliniske historie og eventuelle andre diagnostiske tester.

Oppsummering og Forklaring
Immunhistokjemiske teknikker kan brukes til å vise tilstedeværelse av antigener i vev og celler (se "Bruk av BOND-reagenser" i brukerdokumentasjonen for BOND-systemet). Det primære antistoffet CD20 (L26) er et produkt som er klart for bruk og spesielt optimalisert for bruk sammen med Bond Polymer Refine Detection. Påvisningen av det humane CD20 proteinet oppnås ved først å la CD20 (L26) binde seg til preparatet, for deretter å visualisere bindingsprosessen ved hjelp av reagensene som brukes i deteksjonssystemet. Ved bruk av disse produktene kombinert med det automatiserte BOND-systemet (herunder Leica BOND-MAX-systemet og Leica BOND-III-systemet) reduseres risikoen for menneskelige feil og den iboende variasjon som skylles individuell reagensfortynning, manuell pipettering og reagensapplikasjon.

Reagenser Som Følger Med
CD20 (L26) er et anti-humant, monoklonalt antistoff fra mus laget som en vevskultursupernatant, og den leveres i en Tris-bufret saltløsning med bærerprotein, og inneholder 0,35 % ProClin™ 950 som konserveringsmiddel.

Totalt volum = 30 mL.

Klon
L26

Immunogen
Humane B-celler i tonsill.

Spesifisitet
En intracytoplasmatisk epitop som finnes på det humane CD20-molekylet. Reagerer hovedsaklig med et polypeptid på 33 kD, men også med en mindre komponent på 30 kD.

Ig-klasse
IgG2a, Kappa.

Totalproteinkonsentrasjon
Cirka 10 mg/mL.

Antistoffkonsentrasjon
Større enn eller tilsvarende 0,93 mg/l i henhold til ELISA.

Fortynning og Blanding
Det primære antistoffet CD20 (L26) er optimalt fortynnet for bruk med BOND-systemet (herunder Leica BOND-MAX-systemet og Leica BOND-III-systemet). Rekonstituering, blanding, fortynning eller titrering av denne reagensen er ikke nødvendig.

Materiell Som Kreves, Men Som Ikke Medfølger
Under avsnittet "Bruk av BOND-reagenser" i brukerveiledningen for BOND finner du en komplett liste over de materialer som trengs til prøvebehandling og immunhistokjemisk farging med BOND-systemet (herunder Leica BOND-MAX-systemet og Leica BOND-III-systemet).

Oppbevaring og Stabilitet
Oppbevares ved 2–8 °C. Må ikke brukes etter utløpsdatoen angitt på produktetiketten.

Tegn på kontaminering og/eller ustabilitet for Product name er: blakket løsning, endret lukt og bunnfall.

Returneres til 2–8 °C umiddelbart etter bruk.

Andre oppbevaringsbetingelser må valideres av brukeren[1].

Forholdsregler
- Dette produktet skal brukes til in vitro-diagnostikk.
- Konsentrasjonen av ProClin™ 950 er 0,35 %. Den inneholder virkestoffet 2-metyl-4-isotiasolin-3-on, og kan skape irritasjoner på hud, øyne, slimhinner og øvre luftveier. Bruk engangshansker ved håndtering av reagenser.
- Dataark om materialsikkerhet (MSDS) er tilgjengelig hos den lokale forhandleren eller regionkontoret til Leica Biosystems. Det kan også lastes ned fra nettsidene til Leica Biosystems: www.LeicaBiosystems.com
- Preparater (før og etter fiksering) og alt materiale som eksponeres for dem, skal behandles som potensielt smittefarlig og kasseres i samsvar med gjeldende forholdsregler[2]. Hold aldri pipetter med reagens i munnen, og unngå at hud og slimhinner kommer i kontakt med reagenser og prøver. Hvis reagenser eller prøver kommer i kontakt med følsomme områder, skal de skylles med rikelig vann. Kontakt lege.

- Følg nasjonale og lokale forskrifter for kassering av komponenter som kan være giftige.
- Reduser mikrobiell kontaminering av reagensene til et minimum, ellers kan det forekomme økt uspesifisert farging.
- Gjenfinning, inkubasjonstider eller temperaturer som er annerledes enn det som er angitt, kan gi unøyaktige resultater. Slike endringer må valideres av brukeren.

Bruksanvisning

Det primære antistoffet CD20 (L26) er blitt utviklet for bruk med det automatiserte BOND-systemet (herunder Leica BOND-MAX-systemet og Leica BOND-III-systemet) i kombinasjon med Bond Polymer Refine Detection. Anbefalt fargeprotokoll for Product name primært antistoff er IHC Protocol F. Varmeindusert epitop gjenvinning er anbefalt ved bruk av Bond Epitope Retrieval Solution 1 i 20 minutter.

Forventede resultater

Normalt vev

Klon L26 detekterer antigenet CD20 på celleoverflaten av celler i B-cellelinjen, bortsett fra plasmaceller. (Totalt antall evaluerte normale tilfeller = 53).

Tumorvev

Klon L26 farget 11/11 diffuse storcellede B-cellelymfomer, 6/6 follikulære lymfomer, 2/2 MALTomas, 1/5 Hodgkins sykdom, 1/1 Burkitts lymfom og 1/1 mantelcellelymfomer. Ingen flekker ble observert i perifere T -cellelymfomer (0/6) , anaplastic brede cellelymfomer (0/2) , en ondartet lymfatisk lymfom (0/1) , en Angioimmunoblastic T-cellelymfom (0 /1) , eller en NK/T-cellelymfom (0/1), skjoldbruskkjertelsvulster (0/4), lungesvulster (0/4), inkludert en ikke-småcellet karsinom (0/1), et adenokarsinom (0/1), en plateepitelcarcinom (0/1) og et bredt cellekarsinom (0/1), leversvulster (0/4), Inkludert cholangiocarcinom (0/ 2) og levercellekarsinom (0/2), eggstokksvulster (0/4), inkludert en ondartet bakteriecelletumor (0/1), en serøs cystadenocarcinoma (0/1), en klar cellcarcinoma (0/1) og en mucinous cystadenocarcinoma (0/1), plateepitelkreft karsinomer i livmorhalsen (0/2) seminomas (0/2), tykktarmadenokarsinomer (0/2), adenocarcinomer i rektum (0/2), adenocarcinomer i magesekken (0/2), nyrecellekarsinomer (0/2), duktalt karsinom fra bryst (0/2), bløtvevssvulster (0/2), plateepitelkreft karsinomer på tungen (0/2), plateepitelkarsinom i spiserøret (0/2), metastatisk karsinom av ukjent opprinnelse (0/2), hudsvulster (0/2) inkludert en dermatofibrosarcoma (0/1) og plateepitelkarsinom (0/1), hjernesvulster (0/2) Inkludert en anaplastisk astrocytom (0/1) og årehinnen plexus papilloma (0/1), en atypisk karsinoid av thymus (0/1) og plateepitelkarsinom i strupehodet (0/1) . (Totalt antall evaluerte tumortilfeller = 81).

CD20 (L26) anbefales til bruk som en del av et antistoffpanel for å avhjelpe karakterisering av B-cellelidelser.

Produktspesifikke Begrensninger

CD20 (L26) er optimalisert av Leica Biosystems til bruk sammen med Bond Polymer Refine Detection og BOND tilleggsreagenser. Brukere som avviker fra de anbefalte testprosedyrene, må selv ta ansvar for tolkningen av pasientresultater i slike situasjoner. Protokolltidene kan variere grunnet variasjon i vevsfiksering og effektiviteten til antigenforsterkningen, og må dermed bestemmes empirisk. Negative reagenskontroller bør brukes ved optimalisering av gjenvinningsforhold og protokolltider.

Feilsøking

Se referanse nr. 3 for opprettingstiltak.

Ta kontakt med den lokale forhandleren eller regionkontoret til Leica Biosystems for å rapportere om unormal farging.

Ytterligere opplysninger

Du finner mer informasjon om immunfarging med BOND-reagenser i “Bruk av BOND-reagenser” i brukerdokumentasjonen for BOND-systemet under overskriftene Testprinsipper, Materiell som kreves, Preparering av prøver, Kvalitetskontroll, Analysekontroll, Tolkning av farging, Oversikt over symboler og Generelle begrensninger.

Bibliografi

1. Clinical Laboratory Improvement Amendments of 1988, Final Rule 57 FR 7163 February 28, 1992.
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Utgivelsesdato

27 mai 2014

Bond™ Kullanıma Hazır Primer Antikor CD20 (L26)

Katalog No: PA0359

Kullanım Amacı

Bu reagent, *in vitro* diagnostik kullanımı içindir.

CD20 (L26) monoklonal antikor otomatik BOND sistemini (Leica BOND-MAX sistemi ve Leica BOND-III sistemi dahil) kullanarak immünohistokimyasal boyama yoluyla, formalinle fikse edilmiş, parafine gömülü dokudaki insan CD20 proteininin ışık mikroskopisi ile nitel tanımlanmasında kullanım için tasarlanmıştır.

Herhangi bir boyamanın mevcut olması veya olmaması ile ilgili klinik yorumlama, morfolojik çalışmalarla ve uygun kontrollerle tamamlanmalıdır ve hastanın klinik geçmişi ve diğer diagnostik testler kapsamında kalifiye bir patolojist tarafından değerlendirilmelidir.

Özet ve Açıklama

İmmünohistokimyasal teknikler, doku ve hücrelerde antijen olduğunu göstermek amacıyla kullanılabilir (BOND kullanıcı dokümantasyonunuzdaki "BOND Reagent'larının Kullanılması" bölümüne bakınız). Product name primer antikor, özellikle Bond Polymer Refine Detection ile kullanılmak üzere optimize edilmiş kullanıma hazır bir üründür. İnsan CD20 proteininin gösterimi, öncelikle kesite CD20 (L26) bağlanmasının sağlanması ve ardından tespit sisteminde verilen ayıraçlar kullanılarak bu bağlanmanın görüntülenmesiyle elde edilir. Bu ürünlerin kullanımı, otomatikleştirilmiş BOND Sistemi ile kombinasyonlu olarak (Leica BOND-MAX sistemi ve Leica BOND-III sistemi de dahildir), insan hatalarının veya bireysel reagent seyrelmenin, elle pipetlemenin ve reaktif uygulamaların sonucu olarak ortaya çıkan doğal değişkenliklerin olasılığını azaltır.

Sağlanan Reagent'lar

CD20 (L26), bir supernatant doku kültürü olarak oluşturulan bir mouse anti-human monoklonal antikordur ve prezervatif olarak % 0,35 ProClin™ 950 içeren taşıyıcı proteine sahip Tris buffer salin içerisinde verilir.

Toplam hacim = 30 mL.

Clone

L26

İmmünojen

İnsan bademcik B hücreleri.

Spesifite

İnsan CD20 molekülünde bulunan bir intrasitoplazmik epitop. Ağırlıklı olarak 33 kD polipeptid ile tepki gösterir, ancak minör bir 30 kD bileşiğiyle de tepki gösterebilir.

Ig Sınıfı

IgG2a, Kappa.

Toplam Protein Konsantrasyonu

Yaklaşık 10 mg/mL.

Antikor Konsantrasyonu

ELISA tarafından belirlendiği gibi 0,93 mg/L'ye eşit veya bu değerden yüksek.

Dilüsyon ve Karışım

CD20 (L26) birincil antikor BOND Sistemi'nde (Leica BOND-MAX sistemini ve Leica BOND-III sistemini de içermektedir) kullanılmak üzere en uygun biçimde seyreltilmiştir. Bu reagent için sulandırma, karıştırma, dilüsyon veya titraj işlemlerinin yapılması gerekli değildir.

Sağlanmayan Ancak Gerekli Olan Materyaller

BOND Sistemi'ni (Leica BOND-MAX sistemini ve Leica BOND-III sistemini de içermektedir) kullanarak örnek tedavi ve immünohistokimyasal boyamada gerekli materyallerin toplu bir listesini görebilmek için BOND kullanıcı belgelerinizdeki "BOND reagent'lerini Kullanma" bölümüne bakın.

Saklama ve Dayanıklılık

2–8 °C'de saklayın. Konteyner etiketinin üzerinde belirtilen son kullanım tarihinden sonra kullanmayın.

CD20 (L26) kontaminasyonunu ve/veya instabilitesini belirten işaretler: solüsyonun türbiditesi, koku gelişimi ve presipitatın mevcut olması.

Kullanımdan hemen sonra 2–8 °C'ye dönün.

Yukarıda belirtilenlerin dışındaki saklama koşullarının, kullanıcı[1] tarafından kontrol edilmesi gerekir.

Önlemler

- Bu ürün, in vitro diagnostik kullanımı içindir.
- ProClin™ 950 konsantrasyonu % 0,35'dir. 2-metil-4-izotiyazolin-3-tek etken maddesini içerir ve ciltte, gözlerde, muköz membranlarda ve üst solunum yolunda iritasyona neden olabilir. Reagent'larla işlem yaparken tek kullanımlık eldiven takın.
- Bir Material Safety Data Sheet (Malzeme Güvenlik Veri Sayfası) kopyası elde etmek için yerel distribütörünüze veya bölgesel Leica Biosystems ofisine başvurun veya alternatif olarak www.LeicaBiosystems.com Leica Biosystems internet sitesini ziyaret edin
- Fikse etme işleminden önce ve sonra numuneler ve bunlara maruz kalan tüm materyaller, enfeksiyon yayabilecek gibi ele alınmalı ve doğru önlemler alınarak atığa çıkartılmalıdır.[2] Reagent'lar asla ağızla pipetlenmemeli ve cildin ve muköz membranların reagent ve

numunelerle temasından kaçınılmalıdır. Reagent veya numunelerin hassas alanlarla temas etmesi durumunda bu alanları bol su ile yıkayın. Doktora başvurun.

- Potansiyel tüm toksik komponentlerin imhası için federal, ulusal veya lokal düzenlemelere başvurun.
- Reagent'ların mikrobiyal kontaminasyonunu minimize edin, aksi durumda nonspesifik boyamada bir artış ortaya çıkabilir.
- Belirtilenlerin dışında retrieval, inkübasyon süreleri veya sıcaklıkları, hatalı sonuçlara neden olabilir. Tüm değişiklikler, kullanıcı tarafından doğrulanmalıdır.

Kullanım Talimatları

CD20 (L26) birincil antikor, otomatikleştirilmiş BOND Sistemi'nde (Leica BOND-MAX sistemini ve Leica BOND-III sistemini de içermektedir) Bond Polymer Refine Detection (BOND Polimer Arındırma Algılama) ile kombinasyonlu olarak kullanılmak üzere geliştirilmiştir. CD20 (L26) primer antikor için önerilen boyama protokolü IHC Protocol F'dir. 20 dakika boyunca Bond Epitope Retrieval Solution 1 (Bond Epitop Geri Kazanım Solüsyonu) kullanılarak ısıyla indüklenen epitop geri kazanımı yapılması önerilir.

Öngörülen Sonuçlar

Normal Dokular

L26 Klonu, plazma hücreleri hariç olmak üzere B hücre kökeni hücrelerinin hücre yüzeyi üzerindeki CD20 antijenini saptar. (Değerlendirilen toplam normal vaka sayısı = 53).

Tümörlü Dokular

Klon L26, 11/11 diffüz büyük B hücresi lenfomalarını, 6/6 foliküler lenfomaları, 2/2 mukoza ile ilişkili lenfoid doku lenfomasını (MALTomas), 1/5 Hodgkin hastalığını, 1/1 Burkit lenfomasını ve 1/1 mantle hücre lenfomalarını boyamıştır. Periferal T hücreli lenfomalarda (0/6), anaplastik büyük hücreli lenfomalarda (0/2), malignan bir lenfoblastik lenfomada (0/1), bir anjiyoimmünoblastik T hücreli lenfomada (0/1) veya bir NK/T hücreli lenfomada (0/1), tiroid tümörlerinde (0/4), akciğer tümörlerinde (0/4, küçük hücreli olmayan bir karsinom (0/1), bir adenokarsinom (0/1), bir skuamöz hücreli karsinom (0/1) ve büyük hücreli bir karsinom dahil olmak üzere (0/1)), karaciğer tümörlerinde (0/4, kolanjiyokarsinom (0/2) ve hepatosellüler bir karsinom dahil olmak üzere (0/2)), ovaryen tümörlerinde (0/4, malignan bir germ hücreli tümör (0/1), seröz kistadenokarsinom (0/1), berrak hücreli bir karsinom (0/1) ve müsinöz kistadenokarsinom dahil olmak üzere (0/1)), serviks skuamöz hücreli karsinomlarda (0/2), seminomlarda (0/2), kolon adenokarsinomlarında (0/2), rektum adenokarsinomlarında (0/2), mide adenokarsinomlarında (0/2), renal hücre karsinomlarında (0/2), memenin duktal karsinomlarında (0/2), yumuşak doku tümörlerinde (0/2), dilin skuamöz hücreli karsinomlarında (0/2), özofagusun skuamöz hücreli karsinomlarında (0/2), nedeni bilinmeyen metastatik karsinomlarda (0/2), deri tümörlerinde (0/2, bir dermatofibrosarkom (0/1) ve bir skuamöz hücreli karsinom dahil olmak üzere (0/1)), beyin tümörlerinde (0/2, bir anaplastik astrositom (0/1) ve bir koroid pleksus papillom dahil olmak üzere (0/1)), timüsün atipik karsinoidinde (0/1) ve larenksin skuamöz hücreli karsinomunda (0/1) boyama gözlemlenmemiştir. (Değerlendirilen toplam tümör vakası sayısı = 81).

CD20 (L26), B hücre bozukluklarının karakterizasyonuna yardımcı olmak üzere antikor panelinin bir parçası olarak kullanım için tavsiye edilir.

Ürüne Özel Sınırlamalar

CD20 (L26), Leica Biosystems'da Bond Polymer Refine Detection ve BOND yardımcı reagent'ları ile birlikte kullanılmak üzere optimize edilmiştir. Önerilen test prosedürlerinin dışına çıkan kullanıcılar, bu şartlar altında hasta sonuçlarının yorumlanması için sorumluluğu kabul etmelidirler. Protokol süreleri, doku fiksasyonu ve antijen değerlendirme etkinliği nedeniyle değişiklik gösterebilir; bunlar ampirik olarak belirlenmelidir. Negatif reagent kontrolleri, retrieval koşulları ve protokol süreleri optimize edilirken kullanılmalıdır.

Arıza Giderme

Düzeltici işlem için 3 no'lu referansa başvurun.

Olağandışı boyamayı rapor etmek için yerel distribütörünüze veya bölgesel Leica Biosystems ofisine başvurun.

Daha Fazla Bilgi

Prosedür Prensibi, Gerekli Materyaller, Numune Hazırlığı, Kalite Kontrol, Test Doğrulaması, Boyamanın Yorumlanması, Etiketlerdeki Tuşlar ve Semboller ve Genel Sınırlamalar başlıkları altındaki BOND reagent'lar ile immünohistokimyasal boyama ile ilgili daha fazla bilgi, BOND kullanıcı dokümantasyonunuzun "BOND Reagent'larının Kullanılması" altında bulunabilir.

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