Anexa nr. 7
la Documentația standard nr._____
din "____" _____ 20___

CERERE DE PARTICIPARE

Către: IP Universitatea de Stat de Medicină și Farmacie "Nicolae Testemițanu"

(mun.Chișinău, bd. Ștefan cel Mare 165)

Stimaţi domni,

Ca urmare a anunțului de participare apărut în Achiziții.MD nr. 21268805, din 13.08.2024, privind aplicarea procedurii pentru atribuirea contractului de achiziționare a ***reactivelor și consumabilelor de laborator pentru activitatea științifică***, noi Medist Grup SRL, am luat cunoștință de condițiile și de cerințele expuse în documentația de atribuire și exprimăm prin prezenta interesul de a participa, în calitate de ofertant/candidat, neavînd obiecții la documentația de atribuire.

Data completării 23.08.2024

Cu stimă

Digitally signed by Anghel Gabriela-Cristina
Date: 2024.08.23 11:04:19 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Ofertant/candidat

Gabriela-Cristina Anghel

MEDIST Grup S.R.L.
Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25
Oficiul 33, MD-2012 Chișinău, Rep. Moldova
Tel./Fax: +373 22 84 94 95
E-mail: office@medist.md
Web: www.medist.md

IDNO: 1018600004516
TVA: 0508191
BC Victoriabank SA, Filiala nr. 26 Chișinău
IBAN (MDL):MD57VI022242600000269MDL
SWIFT: VICBMD2X469

ORDIN DE PLATA NR.407 Tip.doc. 1

DATA EMITERII: 22 august 2024

PLATITI:336-60 LEI: Trei Sute Treizeci si Sase, 60

PLATITOR: (R)MEDIST GRUP SRL CODUL IBAN:MD57VI022242600000269MDL
CODUL FISCAL:1018600004516

PRESTATORUL PLATITOR
B.C VictoriaBank S.A. s.26 Chisinau

BENEFICIAR:(R)Universitatea de Stat de Me dicina si Farmacie N CODUL IBAN:MD19AG000000022512015544
CODUL FISCAL:1007600000794

PRESTATORUL BENEFICIAR
BC'MAIB'S.A.

DESTINATIA PLATII: Pentru garantia pentru oferta l a procedura de achizitie publica ID achitii MD 2126 8805 din 13.08.2024.

NORMAL/URGENT:NO

L.S.

CODUL TRANZACTIEI:001

DATA PRIMIRII: _____

DATA EXECUTARII: _____

SEMNATURILE EMITENTULUI

_____
SEMNATURA PRESTATORULUI

«VICTORIABANK»
DIRECȚIA OPERAȚIUNI
22. AUG. 2024

MOTIVUL REFUZULUI L.S.

12:18:37 22 AUG 2024
Semnatura electronica:

L35+KEckqD6gXTqsJcn5hOeCpSbj9Ot96n7BETmdn9Ts567S9LXJvo4UtCprJpyq0zFJ9LmS5qie
rCUdz3piEc0mvzDqNA6T1vL1qfUwaSmugCQI6dm28j6WDvQxCtAerDZdFsovE90fkwVs1tv9s7fI
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liMBfRjw+E0rRuRUrjVU0W6cD2y7nrSGIuel3A==

I.P. "AGENȚIA SERVICII PUBLICE"
Departamentul înregistrare și licențiere a unităților de drept

Extras
din Registrul de stat al persoanelor juridice
nr. **117493** din **15.09.2023**

Denumirea completă: **Societatea cu Răspundere Limitată "MEDIST GRUP"**
Denumirea prescurtată: **"MEDIST GRUP" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată**
Numărul de identificare de stat și codul fiscal: **1018600004516**
Data înregistrării de stat: **02.02.2018**
Sediu: **MD-2012, strada Mitropolit Gavriil Bănulescu-Bodoni 25, ap. 33, mun. Chişinău, Republica Moldova**
Genurile de activitate:

1. **Comerţ cu ridicata al produselor farmaceutice;**
2. **Comerţ cu ridicata nespecializat;**
3. **Repararea echipamentelor electronice şi optice;**
4. **Activităţi de testare şi analize tehnice;**
5. **Comerţ cu amănuntul al articolelor medicale şi ortopedice, în magazine specializate;**

Capitalul social: **373026 Lei**
Administrator: **ANGHEL GABRIELA-CRISTINA IDNP 2017803985939**
Asociați:

1. **MEDIST IMAGING & P.O.C. S.R.L., partea socială 6244 Euro, ce constituie 33.00%**
2. **MEDIST LIFE SCIENCE S.R.L., partea socială 6244 Euro, ce constituie 33.00%**
3. **MEDIST S.R.L., partea socială 6433 Euro, ce constituie 34.00%**

Beneficiari efectivi: **MANOLE IONEL, KLUMPNER CATALINA ANA, VLĂDESCU CARMEN, VLĂDESCU SEBASTIAN-ALEXANDRU**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr.220/2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de 15.09.2023

Specialist coordonator
Marina Franţuz
tel. 022-207837

AGENŢIA SERVICII PUBLICE A REPUBLICII MOLDOVA

Departamentul înregistrare şi licenţiere a unităţilor de drept

DECIZIE
privind înregistrarea persoanei juridice

02.02.2018 **Dosar Nr. 1018600004516** **Serviciul înregistrare a unităţilor de drept mun.Chişinău**

Prin cererea depusă la 31.01.2018 s-a solicitat înregistrarea
Societatea cu Răspundere Limitată "MEDIST GRUP"

Examinînd actele prezentate:

1. Proces-verbal al adunării de constituire din 31.01.2018
2. Actele de constituire MEDIST LIFE SCIENCE
3. Hotărârea Adunării Generale MEDIST LIFE SCIENCE nr. 1 din 15.01.2018
4. Actele de constituire MEDIST S.A.
5. Hotărârea Adunării Generale a acţionarilor Medist S.A. nr. 1 din 15.01.2018
6. PROCURĂ nr. 149 din 26.01.2018, CHIRICĂ OLESEA
7. Actele de constituire MEDIST IMAGING S.R.L.
8. Hotărârea Adunării Generale MEDIST IMAGING S.R.L. nr. 1 din 15.01.2018
9. Declaraţie nr. 32 din 22.01.2018
10. Certificat de verificare şi rezervare a denumirii nr. 375156 din 21.12.2017
11. Scrisoare de garanţie din 16.01.2018
12. Statut
13. Ordine de încasare din 31.01.2018
14. PROCURĂ nr. 117 din 22.01.2018, CHIRICĂ OLESEA
15. PROCURĂ nr. 148 din 26.01.2018, CHIRICĂ OLESEA

şi constatînd, că sînt respectate cerinţele legale ce ţin de constituirea şi înregistrarea persoanei juridice, în temeiul art. 11 al Legii nr. 220-XVI din 19.10.2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali, registratorul

DECIDE:

1. A admite cererea de înregistrare.
2. A înregistra persoana juridică şi a consemna în Registrul de stat al persoanelor juridice următoarele date:

Numărul de identificare de stat: **1018600004516** din 02.02.2018

Forma juridică de organizare: Societate cu răspundere limitată

Denumirea: Societatea cu Răspundere Limitată "MEDIST GRUP"

Sediul: MD-2012, str. Mitropolit Gavriil Bănulescu-Bodoni, 25, of. 33, mun. Chişinău, Republica Moldova

Administrator: ANGHEL GABRIELA-CRISTINA, anul naşterii 19.12.1967, cet. ROMÂNIA, PAŞAPORT NAŢIONAL AL CETĂŢEANULUI STRĂIN ROU 054481583 eliberat la data de 27.02.2017, domiciliu: str. bd. Timişoara, 41/P14, ap. 31, Bucureşti, România

Genurile principale de activitate:

1. Comerţ cu ridicata al produselor farmaceutice
2. Comerţ cu ridicata nespecializat
3. Repararea echipamentelor electronice şi optice
4. Activităţi de testare şi analize tehnice
5. Comerţ cu amănuntul al articolelor medicale şi ortopedice, în magazine specializate

Capitalul social: 20790,6 lei.

Fondator(i):

1. "MEDIST LIFE SCIENCE" S.R.L., înregistrat(ă) la 17.07.2008,
   numărul de înregistrare 24205119, sediul:
   str. Ion Urdăreanu, 34, et. 3, Bucureşti, România, parte socială în valoare de 330 EUR (33%)
2. "MEDIST IMAGING & P.O.C." S.R.L., înregistrat(ă) la 17.07.2008,
   numărul de înregistrare 24205100, sediul:
   str. Ion Urdăreanu, 34, et. 1, Bucureşti, România, parte socială în valoare de 330 EUR (33%)
3. "MEDIST" S.A., înregistrat(ă) la 05.01.1995,
   numărul de înregistrare 6705884, sediul:
   str. Ion Urdăreanu, 34A, Bucureşti, România, parte socială în valoare de 340 EUR (34%)

Termenul de activitate al întreprinderii este nelimitat.

3. Prezenta Decizie este întocmită în două exemplare, care au aceeaşi valoare juridică, dintre care un exemplar se păstrează la Agenţia Servicii Publice în dosarul de evidenţă al persoanei juridice, iar celălalt se eliberează solicitantului.

Registrator Dragomir Ala

GUVERNUL REPUBLICII MOLDOVA

SERVICIUL FISCAL DE STAT

MCabinet
PORTALUL GUVERNAMENTAL AL CETĂȚEANULUI ȘI AL UNITĂȚILOR DE DREPT

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr. № **1506516**

Din От **22.08.2024 15:06**

DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare
Фискальный код / Идентификационный номер

1018600004516

Denumirea
Наименование

Societatea cu Răspundere Limitată MEDIST GRUP

ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСВИЯ ИЛИ НАЛИЧИЯ ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie
На дату выдачи данной справки задолжность перед национальном публичным бюджетом составляет

0 MDL

VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО **06.09.2024 15:06**

Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответсвие со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предостоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la **22.08.2024 15:06**

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022
Сертификат подписан электронной попдписью в соответсвие с Законом № 124 от 19.05.2022

Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept (mcabinet.gov.md) și este semnat electronic de către posesorul acestui portal și are aceiași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

Сертификат скачен с Правительственного Портала Гражданина и Юридических Лиц (mcabinet.gov.md) и подписан электронной подписью владельца портала и имеет такаю же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлиности электронной подписи можно осуществить с помощью Государсвенной Службой Электронной Подписью (msign.gov.md)

VICTORIABANK
PRIMA BANCĂ DIN MOLDOVA
www.victoriabank.md
Fax: (+373 22) 78-47-30
SWIFT: VICBMD2X469
IDNO 1002600001338
Capital social – 250 000 910 lei
www.victoriabank.md

Nr. 26/466 din "19" iunie 2018

La Nr. 395 din "19" iunie 2018

Secret bancar
Confidențial

CERTIFICAT

Prin prezentul, BC "VICTORIABANK" SA Sucursala nr.26 Chişinău, codul băncii VICBMD2X469, cod fiscal 1002600001338, confirmă că MEDIST GRUP SRL, cod fiscal 1018600004516, deţine următoarele conturi curente în format IBAN:

MD57VI022242600000269MDL;
MD76VI022242600000105USD;
MD61VI022242600000116EUR;
MD83VI022242600000008RON.

Certificatul este eliberat la cererea clientului pentru a fi prezentat la destinaţie.

Cebanu Valentina
Director

REPUBLICA MOLDOVA, mun. CHIŞINĂU
SUCURSALA Nr.26 CHIŞINĂU
Nr. 1002600001338
BANCA COMERCIALĂ "VICTORIABANK" S.A.

Blanovscaia Anna
Contabil-şef

Ex: Scutaru Lilia
tel. 022 78-47-32

Anexe la SNC
"Prezentarea situatiilor financiare"
Aprobat de Ministerul Finantelor
al Republicii Moldova

SITUAŢIILE FINANCIARE

pentru perioada 01.01.2023 - 31.12.2023

Entitatea: MEDIST GRUP S.R.L.
Cod CUIÎO: 41247072
Cod IDNO: 1018600004516

Sediul:
MD:
Raionul(municipiul): 105, DDF BUIUCANI
Cod CUATM: 0120, SEC.BUIUCANI
Strada: Mitropolit Gavriil Banulescu-Bodoni nr.25 of.33

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice
Forma de proprietate: 23, Proprietatea statelor străine
Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:
Telefon: 06868147
WEB:
E-mail: natalia.mutu@medist.md
Numele și coordonatele al contabilului-șef: Dl (dna) Natalia Mutu Tel. 068681147

Numărul mediu al salariaților în perioada de gestiune: 5 **persoane.**

Persoanele responsabile de semnarea situațiilor financiare* Gabriela Anghel-Cristina

Unitatea de măsură: leu

BILANŢUL

Anexa 1

la 31.12.2023

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
A.	**ACTIVE IMOBILIZATE** **I. Imobilizări necorporale**			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020		
	din care: 2.1. concesiuni, licențe și mărci	021		
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		
	2.4. alte imobilizări necorporale	024		

3. Fond comercial	030		
4. Avansuri acordate pentru imobilizări necorporale	040		
Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050		
II. Imobilizări corporale			
1. Imobilizări corporale în curs de execuție	060		
2. Terenuri	070		
3. Mijloace fixe, total	080	3028298	3859991
din care: 3.1. clădiri	081		
3.2. construcții speciale	082		
3.3. mașini, utilaje și instalații tehnice	083	3018214	3854288
3.4. mijloace de transport	084		
3.5. inventar și mobilier	085		
3.6. alte mijloace fixe	086	10084	5703
4. Resurse minerale	090		
5. Active biologice imobilizate	100		
6. Investiții imobiliare	110		
7. Avansuri acordate pentru imobilizări corporale	120	141992	141992
Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	3170290	4001983
III. Investiții financiare pe termen lung			
1. Investiții financiare pe termen lung în părți neafiliate	140		
2. Investiții financiare pe termen lung în părți afiliate, total	150		
din care: 2.1. acțiuni și cote de participație deținute în părțile afiliate	151		
2.2 împrumuturi acordate părților afiliate	152		
2.3 împrumuturi acordate aferente intereselor de participare	153		
2.4 alte investiții financiare	154		
Total investiții financiare pe termen lung (rd.140 + rd.150)	160		
IV. Creanțe pe termen lung și alte active imobilizate			
1. Creanțe comerciale pe termen lung	170		
2. Creanțe ale părților afiliate pe termen lung	180		
inclusiv: creanțe aferente intereselor de participare	181		
3. Alte creanțe pe termen lung	190		
4. Cheltuieli anticipate pe termen lung	200		

	5. Alte active imobilizate	210		
	Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220		
	TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	3170290	4001983
B.	**ACTIVE CIRCULANTE** **I. Stocuri**			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	31649	63405
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	852838	765931
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	884487	829336
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	3969789	2559140
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	982652	991266
	4. Creanțele ale personalului	330	856	300
	5. Alte creanțe curente	340	1093188	1838152
	6. Cheltuieli anticipate curente	350	48056	10942
	7. Alte active circulante	360		27708
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	6094541	5427508
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți neafiliate	380		
	2. Investiții financiare curente în părți afiliate, total	390		
	din care: 2.1. acțiuni și cote de participație deținute în părțile afiliate	391		
	2.2. împrumuturi acordate părților afiliate	392		
	2.3. împrumuturi acordate aferente intereselor de participare	393		
	2.4. alte investiții financiare în părți afiliate	394		
	Total investiții financiare curente (rd.380 + rd.390)	400		
	IV. Numerar și documente bănești	410	4161583	3229017
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	11140611	9485861
	TOTAL ACTIVE	430	14310901	13487844

	(rd.230 + rd.420)			
	P A S I V			
C.	**CAPITAL PROPRIU** **I. Capital social și neînregistrat**			
	1. Capital social	440	373026	373026
	2. Capital nevărsat	450	( )	( )
	3. Capital neînregistrat	460		
	4. Capital retras	470	( )	( )
	5. Patrimoniul primit de la stat cu drept de proprietate	480		
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	373026	373026
	II. Prime de capital	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
	3. Alte rezerve	530		
	Total rezerve (rd.510 + rd.520 + rd.530)	540		
	IV. Profit (pierdere)			
	1. Corecții ale rezultatelor anilor precedenți	550	X	-103
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	5402413	5402413
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	318340
	4. Profit utilizat al perioadei de gestiune	580	X	( )
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	5402413	5720650
	V. Rezerve din reevaluare	600		
	VI. Alte elemente de capital propriu	610		
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	5775439	6093676
D.	**DATORII PE TERMEN LUNG**			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640	1579325	1307469
	din care: 2.1. împrumuturi din emisiunea de obligațiuni	641		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643	1579325	1307469
	3. Datorii comerciale pe termen lung	650		299803

	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700	1579325	1607272
E.	**DATORII CURENTE**			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720	1344767	951672
	din care: 2.1. împrumuturi din emisiunea de obligațiuni	721		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723	1344767	951672
	3. Datorii comerciale curente	730	2165195	100772
	4. Datorii față de părțile afiliate curente	740	3446175	4692920
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750		
	6. Datorii față de personal	760		
	7. Datorii privind asigurările sociale și medicale	770		28990
	8. Datorii față de buget	780		12542
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810		
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	6956137	5786896
F.	**PROVIZIOANE**			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clienților	840		
	3. Provizioane pentru impozite	850		
	4. Alte provizioane	860		
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870		
	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	14310901	13487844

SITUAŢIA DE PROFIT ŞI PIERDERE

de la 01.01.2023 pînă la 31.12.2023

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune

		precedenta	curenta
1	2	3	4
Venituri din vînzări, total	010	29021092	20271056
din care: venituri din vînzarea produselor și mărfurilor	011	28497093	19719964
venituri din prestarea serviciilor și executarea lucrărilor	012	126338	211868
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanţare	015		
alte venituri din vînzări	016	397661	339224
Costul vînzărilor, total	020	20867803	15060163
din care: valoarea contabilă a produselor și mărfurilor vîndute	021	20867803	15060163
costul serviciilor prestate și lucrărilor executate terților	022		
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanţare	025		
alte costuri aferente vînzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	8153289	5210893
Alte venituri din activitatea operațională	040	135089	66300
Cheltuieli de distribuire	050	118118	146520
Cheltuieli administrative	060	4920088	4367490
Alte cheltuieli din activitatea operațională	070	1931079	570712
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	1319093	192471
Venituri financiare, total	090	786797	991278
din care: venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobînzi	093		
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		
venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	786797	991278

Cheltuieli financiare, total	100	904528	804089
din care: cheltuieli privind dobînzile	101		
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	904528	804089
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	-117731	187189
Venituri cu active imobilizate și excepționale	120	5290	281416
Cheltuieli cu active imobilizate și excepționale	130		200390
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140	5290	81026
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	-112441	268215
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	1206652	460686
Cheltuieli privind impozitul pe venit	170	380423	142346
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	826229	318340

SITUAŢIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la 01.01.2023 pînă la 31.12.2023

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrșitul perioadei de gestiune
1	2	3	4	5	6	7
I.	**Capital social și neînregistrat**					
	1. Capital social	010	373026			373026
	2. Capital nevărsat	020	( )	( )	( )	( )
	3. Capital neînregistrat	030				
	4. Capital retras	040	( )	( )	( )	( )
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060	373026			373026
II.	**Prime de capital**	070				
III.	**Rezerve**					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				

	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
IV.	**Profit (pierdere)**					
	1. Corecții ale rezultatelor anilor precedenți	120	X		103	-103
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130	5402413	826229	826229	5402413
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X	318340		318340
	4. Profit utilizat al perioadei de gestiune	150	X	( )	( )	( )
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160	5402413	1144569	826332	5720650
V.	**Rezerve din reevaluare**	170				
VI.	**Alte elemente de capital propriu**	180				
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190	5775439	1144569	826332	6093676

SITUAŢIA FLUXURILOR DE NUMERAR

de la 01.01.2023 pînă la 31.12.2023

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vînzări	010	29053578	24793777
Plăți pentru stocuri și servicii procurate	020	20406745	19703580
Plăți către angajați și organe de asigurare socială și medicală	030	2732087	1905611
Dobînzi plătite	040		19210
Plata impozitului pe venit	050	1868681	169911
Alte încasări	060	5290	
Alte plăți	070	1588647	3499117
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080	2462708	-503652
Fluxuri de numerar din activitatea de investiții			
Încasări din vînzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
inclusiv: dividende încasate din străinătate	121		

Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150		800000
Plăți aferente rambursării creditelor și împrumuturilor	160	1457991	1375308
Dividende plătite	170		
inclusiv: dividende plătite nerezidenților	171		
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200	-1457991	-575308
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	1004717	-1078960
Diferențe de curs valutar favorabile (nefavorabile)	220	73028	146394
Sold de numerar la începutul perioadei de gestiune	230	3083838	4161583
Sold de numerar la sfîrşitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	4161583	3229017

Documente atașate - Notă explicativă (fișierul pdf)

Recipisa 2

Respondent
Codul fiscal: 1018600004516, denumire: MEDIST GRUP S.R.L.
A prezentat raportul: RSF1_21
Pentru perioada fiscala: A/2023
Data prezentarii: 28.05.2024
Marca temporală a raportului înregistrat în Sistemul Informațional al BNS
: 29.05.2024 13:37:56

Biroul Național de Statistică (BNS) a recepționat varianta electronică a raportului, expediat de DVs. Urmează verificarea și validarea raportului de către specialistul BNS pe domeniu.

DECLARAŢIE
privind valabilitatea ofertei

Către: IP Universitatea de Stat de Medicină și Farmacie ”Nicolae Testemițanu”
(mun.Chișinău, bd. Ștefan cel Mare 165)

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, privind achiziționarea prin procedura de achiziție a ***reactivelor și consumabilelor de laborator pentru activitatea științifică***, pentru o durată de **60 zile** (șasezeci zile), respectiv până la 15 Noiembrie 2024 și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării 23.08.2024

Cu stimă,

Ofertant/candidat

Gabriela-Cristina Anghel

MEDIST Grup S.R.L.
Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25
Oficiul 33, MD-2012 Chișinău, Rep. Moldova
Tel./Fax: +373 22 84 94 95
E-mail: office@medist.md
Web: www.medist.md

IDNO: 1018600004516
TVA: 0508191
BC Victoriabank SA, Filiala nr. 26 Chișinău
IBAN (MDL):MD57VI022242600000269MDL
SWIFT: VICBMD2X469

MEDIST Grup
Soluții pentru sănătate

DECLARAȚIE

Subsemnata Gabriela Anghel, reprezentant împuternicit al MEDIST GRUP S.R.L, cu sediul în mun. Chișinău, str. M.G. Bănulescu-Bodoni 25, oficiul 33, declar pe propria răspundere că:

- se va efectua asigurarea transportării la sediul indicat de către Cumpărător.
- termenul de garanție a bunurilor va constitui minim 12 luni pentru toate reactivele și consumabile, în afară de cele specificate de producător.
- deținem experiență specifică de minimum 3 ani în livrarea bunurilor similare.

Data: 23.08.2024

MEDIST GRUP S.R.L.
DIRECTOARE ADMINISTRATIVĂ
GABRIELA ANGHEL

MEDIST Grup S.R.L.
Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25
Oficiul 33, MD-2012 Chișinău, Rep. Moldova
Tel./Fax: +373 22 84 94 95
E-mail: office@medist.md
Web: www.medist.md

IDNO: 1018600004516
TVA: 0508191
BC Victoriabank SA, Filiala nr. 26 Chișinău
IBAN (MDL):MD57VI022242600000269MDL
SWIFT: VICBMD2X469

Anexa nr. 12
la Documentația standard

DECLARAȚIE
privind lista principalelor livrari efectuate în ultimii 3 ani de activitate

Nr d/o	Obiectul contractului	Denumirea/ numele beneficiarului/Adresa	Calitatea Furnizorului/ Prestatorului*)	Preţul contractului/ valoarea bunurilor livrate	Perioada de livrare/prestare (luni)
1	Achiziționarea articolelor parafarmaceutice și dispozitivelor medicale întru realizarea Programului Naţional de control al cancerului pentru anul 2022 (repetat)	IMSP Institutul Oncologic	Contract unic	3584784,00 MDL	Trimestrul II anul 2022 ***Contract nr. 20 de achiziționare a dipozitivelor medicale din 09.02.2022***
2	Achiziția de reactivi necesari realizării cercetărilor științifice	IP USMF „Nicolae Testemitanu” , mun. Chișinău, str. Ștefan cel Mare, 165	Contract unic	13532,40 MDL	45 zile de la semnarea contractului ***Contract nr.69 din 28.07.2023***
3	Achiziția de reactivi necesari realizării cercetărilor științifice	IP USMF „Nicolae Testemitanu” , mun. Chișinău, str. Ștefan cel Mare, 165	Contract unic	58246,80 MDL	45 zile de la semnarea contractului ***Contract nr.45 din 26.06.2023***

*) Se precizează calitatea în care a participat la îndeplinirea contractului, care poate fi de: contractant unic sau lider de asociaţie; contractant asociat; subcontractant.

Semnat: _____
Nume: Gabriela-Cristina Anghel
Funcţia în cadrul firmei: Directoarea administrativă
Denumirea firmei: Medist Grup SRL

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Leica Biosystems Newcastle Ltd
Balliol Business Park West
Benton Lane
Newcastle upon Tyne
NE12 8EW
United Kingdom

Holds Certificate Number: **MD 595830**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, and manufacture of in-vitro diagnostic reagents and their associated ancillaries, consumables, and test kits used in the diagnosis of cancer, disease status, endocrine disorders, genetic testing, protein metabolism, transmissible agents, and immunological typing.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2013-05-20
Effective Date: 2022-02-26
Latest Revision Date: 2023-03-30
Expiry Date: 2025-02-25

...making excellence a habit.™

Certificate No: **MD 595830**

Location	Registered Activities
Leica Biosystems Newcastle Ltd Balliol Business Park West Benton Lane Newcastle upon Tyne NE12 8EW United Kingdom	The design, development, and manufacture of in-vitro diagnostic reagents and their associated ancillaries, consumables, and test kits used in the diagnosis of cancer, disease status, endocrine disorders, genetic testing, protein metabolism, transmissible agents, and immunological typing.
Leica Biosystems Newcastle Ltd Second floor, Home Group Building 2 Gosforth Park Way Newcastle NE12 8ET United Kingdom	The design, development, and manufacture of in-vitro diagnostic reagents and their associated ancillaries, consumables, and test kits used in the diagnosis of cancer, disease status, endocrine disorders, genetic testing, protein metabolism, transmissible agents, and immunological typing.

Original Registration Date: 2013-05-20

Latest Revision Date: 2023-03-30

Effective Date: 2022-02-26

Expiry Date: 2025-02-25

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Leica Biosystems Nussloch GmbH
Heidelberger Strasse 17-19
Nussloch
69226
Germany

Holds Certificate No: **FM 543970**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The design & development, manufacturing and service for instruments and accessories for research and industrial specimen preparation.

For and on behalf of BSI:

Denelise L'Ecluse, Managing Director Assurance - Continental Europe

Original Registration Date: 2008-12-24
Effective Date: 2023-12-24
Latest Revision Date: 2023-12-18
Expiry Date: 2026-12-23

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CERTIFICATE

Reg. Number	11510 - M	Valid From	2023-07-31
First issue date	2011-08-01	Last change date	2023-07-31
Valid until	2026-07-31		

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

WALDEMAR KNITTEL GLASBEARBEITUNGS GMBH

Is in compliance with the standard UNI CEI EN ISO 13485:2021 for the following products/services:

Manufacturing and sale of microscope slides and coverslips for microscopy and analytic research. Production of slides and coverslips on behalf of third parties

President
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

The date of issuance of this certificate is the date of first issue by another accredited body
This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwa.it

WALDEMAR KNITTEL GLASBEARBEITUNGS GMBH
Registered Headquarters
- Varrentrapstrasse 5, 38114 Braunschweig - Deutschland Germania

Certified Sites
- Varrentrapstrasse 5, 38114 Braunschweig - Deutschland Germania

SGQ N° 007A

CERTIFICATE

Number	K-0211714
Issued on	23.06.2023
Valid from	01.08.2023
Valid until	31.07.2026

Kiwa International Cert GmbH

certifies that the company

Waldemar Knittel Glasbearbeitungs GmbH

Varrentrappstr. 5
38114 Braunschweig
Germany

for the scope

Manufacturing and distribution of microscope-slides and coverslips for microscopy and analytic research

has implemented and applies a Quality Management System, which is in compliance with the requirements of

ISO 9001:2015

Kiwa International Cert GmbH
Managing Director

Kiwa International Cert GmbH
Technical Manager

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16102-01-00

Kiwa International Cert GmbH
Grüner Deich 1
20097 Hamburg
Germany
Telefon +49 (0)40 30 39 49 60
Telefax +49 (0)40 30 39 49 79
e-mail: info@kiwa.de
www.kiwa.de

INSTRUCTION FOR USE
FOR MICROSCOPE SLIDES AND COVER GLASSES

IVD CE

For use by professional users

StarFrost® microscope slides and microscope slides for in vitro diagnostics are approx. 1 mm thick plates made of soda-lime glass for microscopic examinations of specimens derived from the human body. They are manufactured for single and professional use in accordance with the ISO 8037/1 standard and are intended to be used for the examination of cell suspensions and tissue sections as well as the preparation of slides and their archiving.
The refractive index of ne = 1.53 ± 0.02 at γe = 546.07 nm (green Hg line) describes the optical properties of soda-lime glass that are relevant for microscopy.

StarFrost® cover glasses and cover glasses for in-vitro diagnostics are approx. 0.16 mm thick plates made of borosilicate glass for microscopic examinations of samples derived from the human body. They are manufactured for single and professional use in accordance with the ISO 8255/1 standard and are intended to be used for covering specimens for archiving. The refractive index of ne = 1.525 5 ± 0.0015 and the Abbe number ve = 56 ± 2 at γe = 546.07 nm (green Hg line) describe the optical properties that are relevant for microscopy.

Indication:

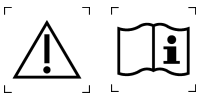
Microscope slides and cover slips may be used, for example, for routine diagnostics of cell suspensions and tissue sections. Since the possible applications are very diverse, handling the glassware requires trained specialist users in accordance with the national legal situation.

Contraindication:

Microscope slides and cover slips are for single use only. Reuse and/or improper surface treatment may lead to falsified results, destruction of the preparations/specimens and misdiagnosis.

General handling instructions:

Warning:


Before use, be sure to read all the information in the user instructions carefully.


The microscope slides and cover slips are intended for single use by qualified personnel only. They must never be used more than once and must be disposed of properly as potentially infectious waste after use or when archiving is complete.


If damage or signs of glass breakage are already visible on the packaging, the glassware must not be used because of the risk of injury from glass splinters.


Protect from moisture.


Storage at room temperature (15-30 °C).


Storage at a relative humidity of less than 60%.

Once the packaging has been opened, if stored properly, the product can be consumed until the expiry date. Protect opened packaging from light and moisture.

If the microscope slide box or the microscope slides are handled carelessly, the contents of the box may be damaged, or the slide may break.

Recommendation:
We recommend using slides with ground edges to reduce the risk of injury from sharp glass edges. It is recommended to apply coated products as soon as possible, as humidity and UV radiation can affect the functionality of the coating.

Preparation:
Microscope slides and cover slips are normally ready for use and can be used without further preparation after gradual adjustment to room temperature.
If the diagnostic procedures you are using require preparation of the microscope slides and cover glasses, they must be prepared according to the instructions for use of the respective system or reagent suppliers or according to your own validated procedure. Labelling fields on the slides are intended to provide clear identification of the preparations and should be written on with suitable, if necessary, solvent-resistant pens or diamond pens.
Further labelling options can be implemented using a suitable printer system.
This requires an in-house validation to be carried out in advance.

Application:
Microscope slides and cover glasses are only to be used by appropriately trained personnel. Since the glassware must not be used by non-specialists or for self-administration, we have refrained from describing the wide range of possible applications and would like to refer you to the relevant technical and training literature. In-house validation must be performed for coated slides to verify that the coating is suitable for the application.

Evaluation:
The evaluation of the preparations on the slides is carried out according to the instructions for use of the respective system or reagent suppliers or the specifications from our own validated procedures. When selecting the microscopic procedure, the instructions for use from the manufacturer of reagents and systems or the instructions of the validated in-house procedures must be followed. It is important to ensure that microscopes with suitable light sources or wavelengths are used. The preparation of a diagnosis on the basis of the preparations may only be carried out by a trained physician or a person with comparable qualifications. Any instructions from the reagent suppliers' manufacturers must be considered during the diagnostic procedure.
In the diagnosing physician's own interest, the diagnosis must be backed up by other diagnostic measures. If the identification or quality of the sample is poor, no diagnosis may be made.

Archiving
If necessary, the preparations are archived in accordance with the instructions for use of the respective reagent suppliers. Special attention must be paid to the specified environmental storage conditions, and the respective national legislation must also be considered with regard to the archiving period. Please observe the storage instructions when archiving.

Disposal:
Used slides must be disposed of as infectious waste. The reagents used may also contain substances that must be disposed of as hazardous waste. In this case, the respective regional legislation must be considered.

Warnings:

The diagnostic use of the microscope slides and cover glasses and the evaluation of the preparations shall be carried out by a physician or an appropriately qualified personnel under the responsibility of the laboratory physician.
The respective international, national, and regional legal situation must be complied with. For the Federal Republic of Germany, these are, for example, the Medical Devices Act, the Distribution Channels Ordinance, the Medical Devices Operator Ordinance, the Biological Substances Ordinance, GLP, GLDP, GMP and the guidelines of the German Medical Association. Accident prevention and hygiene regulations must also be observed.

Therefore, make sure to use appropriate personal protective equipment when handling potentially infectious sample materials. Compliance with room air quality in accordance with national regulations (e.g., guidelines for hospital hygiene and infection prevention, RKI) must also be ensured to ensure safe diagnostics in the laboratory.

Always use appropriate personal protective equipment (e.g., safety goggles) when handling microscope slides and cover slips.

The operating instructions for the diagnostic equipment used must always be followed.
The laboratory shall ensure the traceability of the patient sample, and appropriate labelling and archiving methods must be established.

Microscope slides or cover glasses must not be used for diagnostic purposes once the expiry date has been reached.

The adhesion of coated slides may weaken towards the end of the expiry date.

Delivery form:

Microscope slides are packed in boxes of 50, 72 or 100 ±2 pieces and sold in sales units of 1,000, 1,440, 1,500, 2,500 and 5,000 pieces. Cover glasses are packed in boxes of 100, 200 or 1 ounce. For cover glasses, the smallest sales unit consists of a carton containing ten individual boxes. The products are usually shipped on pallets. In the case of smaller unit purchases, the products must additionally be suitably protected for the corresponding shipment.

Storage instructions:

- These products should be stored and opened in their original packaging in a dry (relative humidity not exceeding 60%) and clean environment, preferably protected from light.
- The glass must adjust to room temperature (15-30 °C) for 24 hours before opening.
- Fluctuations in temperature and humidity should be kept to a minimum, both during storage and use.
- Rapid cooling of the product can lead to condensation processes and consequently to moisture between the individual slides or cover slips.
- Protect the glass from ground moisture by not storing the boxes on the ground.
- Always use the oldest product in stock according to the "first in first out" principle.
- Avoid strong vibrations even during internal transport.

Incident reporting notice:

All serious incidents related to the product shall be reported to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is established.

Manufacturer:

Waldemar Knittel Glasbearbeitungs GmbH, Varrentrappstrasse 5, D-38114 Braunschweig, Germany
Tel +49 (0) 531 - 59000 – 0 Fax +49 (0) 531 - 59000 – 36 Internet: www.knittel-glaeser.de

Date of publication or revision
Rev.: 5
28/07/2022

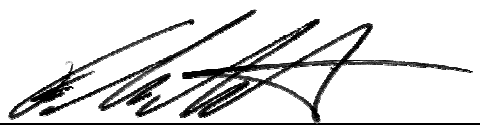
CE Declaration of Conformity

Manufacturer code	DE/0000041767 at DIMDI
Manufacturer	Waldemar Knittel Glasbearbeitungs GmbH Varrentrappstr. 5, 38114 Braunschweig Germany
Product	**Coverglass** in accordance with **ISO 8255/1** **Microscope slides** in accordance with **ISO 8037/1**
Nomenclature	27-02 by using EDMS classifaction
Classifacation	Other Devices

We herewith declare that the products are in conformity with the provisions of the following EC Directive:

European Guideline 98/79 EG for in vitro diagnostics
dated 27th October 1998

Notified Body	DE/CA08 Bezirksregierung Braunschweig Bohlweg 38, D-38100 Braunschweig, Germany
Certificates	**ISO 9001:2015** valid until 31.07.2026 **ISO 13485:2016** valid until 31.07.2026

Place & date of issue	Braunschweig, 31.07.2023
Signature Legal representative: Fabio Insalata Chief Operating Officer	

Waldemar Knittel Glasbearbeitungs GmbH
Varrentrappstraße 5
D-38114 Braunschweig
Telefon ++49 (0)531 / 59000-0
Telefax ++49 (0)531 / 59000-36
www.knittel-glaeser.de
info@knittel-glaeser.de

Geschäftsführer: Waldemar Knittel
Sitz Braunschweig
Handelsreg. Amtsgericht
Braunschweig, HRB 2471
V.A.T. Reg. Nr.: DE 114883519
Steuer-Nr.: 14/202/45519

Commerzbank
BLZ 270 400 80, Konto 530 395 300
IBAN DE11 2704 0080 0530 3953 00
SWIFT-BIC COBA DE FF
Nord/LB Braunschweig
BLZ 250 500 00, Konto 1 548 700
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Dresdner Bank
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SWIFT-BIC DRES DE FF
Postbank Hannover
BLZ 250 100 30, Konto 5589 30-309
IBAN DE 37 2501 0030 0558 9303 09
SWIFT-BIC PBNK DE FF

1 Manufacturer and / or Authorised Representative details.

Manufacturer:	**Authorised Representative:**
Leica Biosystems Newcastle Ltd Balliol Business Park West Benton Lane Newcastle upon Tyne NE12 8EW United Kingdom Tel: +44 (0)191 215 0567 Fax: +44 (0)191 215 1152 Single Registration Number (SRN): GB-MF-000020595	CEpartner4U BV Esdoornlaan 13 3951 DB Maarn The Netherlands Tel: +31 343 442 524 Fax: +31 343 442 162 E-mail: office@cepartner4u.com Single Registration Number (SRN): NL-AR-000000111

2 Manufacturer Responsibility Statement.

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer, detailed in Section 1 of this declaration.

3 Basic UDI-DI.

Refer to Appendix 1.

4 Product name and catalogue code.

Class A Consumables. For product details refer to Appendix 1.

5 Risk Classification in accordance with Annex VIII.

The devices covered by this declaration, listed in Appendix 1, have been assigned the risk classification of A in accordance with Rule 5(a) of Annex VIII:
"Rule 5: The following devices are classified as class A: (a) products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for in vitro diagnostic procedures relating to a specific examination;"
For classifications details of individual products, refer to Appendix 1.

6 Conformity Statement.

The devices covered by this declaration, listed in Appendix 1, are in conformity with the relevant provisions of Regulation (EU) 2017/746 and are CE marked in accordance with Annex V.

7 Common Specifications.

There are currently no common specifications applicable for our devices. There are currently no standards harmonised with IVDR which LBN can utilise to demonstrate conformity. LBN prefer the use of harmonised standards to demonstrate conformity to the current essential requirements checklist per IVDD. LBN shall ensure the IVDs will conform to the IVDR and propose the solution for conformity as:

1) Using state of the art versions of standards which are harmonised under the current IVDD. This approach will not allow LBN to state conformity by using these standards alone, but it allows demonstration of part conformity to the IVDR.
2) Other published standards identified as candidates for harmonisation under the respective regulation, and
3) Utilise appropriate International and European consensus standards given that harmonised standards mostly originated from them.

For applicable standards refer to Appendix 2

8	**Notified Body, Conformity Assessment Procedure & Certificate Details.**	
	Name of notified body: Identification number of notified body:	In accordance with Annex VIII, Rule 5(a) of the IVDR the devices listed in Appendix 1 have been assigned the risk classification of A. Conformity assessment by a notified body is therefore not applicable.
	Conformity assessment procedure:	Self Declaration of Conformity based on Annex II: Technical Documentation and Annex III: Technical Documentation on Post-Market Surveillance.
	Certificates issued:	N/A
9	**Additional information.**	
	N/A	
10	**Issuing and Signing of Declaration.**	
	Signed on behalf of the manufacturer by:	
	Signature:	DocuSigned by: Laura Tracy Signer Name: Laura Tracy Signing Reason: I approve this document Signing Time: 21 March 2022 | 12:31:07 AM PDT C4B2D6F558A342E1B5DDD387086C4006
	Name:	Laura Tracy
	Position:	Director, Global Regulatory Affairs - Advanced Staining
	Date of issue:	21 March 2022
	Place of issue:	Leica Biosystems Newcastle Ltd

Appendix 1
Device Details

Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
OP79193, 7mL	OP79193	BOND Open Containers (7mL)	Rule 5(a)	50553313OP791900005SW
	Intended Purpose:	BOND Open Containers 7 mL is an accessory product specifically intended to be used for *in vitro* diagnostic examinations performed on the BOND System. The device is an empty container for holding a user-supplied reagent.		
OP309700, 30mL	OP309700	BOND Open Containers (30mL)	Rule 5(a)	50553313OP309700005N5
	Intended Purpose:	BOND Open Containers 30 mL is an accessory product specifically intended to be used for *in vitro* diagnostic examinations performed on the BOND System. The device is an empty container for holding a user-supplied reagent.		
OPT9049	OPT9049	BOND Open Titration Kit (10 Pack)	Rule 5(a)	50553313OPT90400005CK
	Intended Purpose:	BOND Titration Kit is an accessory product specifically intended to be used for *in vitro* diagnostic examinations performed on the BOND System. The kit consists of empty containers and inserts that supports user optimization of primary antibody concentrates on the BOND system.		
OPT9719	OPT9719	BOND Open Titration Container Insert (50 Pack)	Rule 5(a)	50553313OPT97100005F3
	Intended Purpose:	BOND Titration Container Inserts are an accessory product specifically intended to be used for *in vitro* diagnostic examinations performed on the BOND System. The inserts support user optimization of primary antibody concentrates on the BOND system.		

Appendix 2
Applicable Standards

Regulatory Authority/Group	Standard/Guidance Title and Revision
EU IVDD Harmonised Standards	• EN ISO 18113-1:2011 In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements (British Standard) • EN ISO 18113-2:2011 In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for professional use (British Standard) • EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents • EN ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. • EN 13975:2003 Sampling procedures used for acceptance testing of in vitro diagnostic medical devices. Statistical aspects
EU IVDR Harmonised Standards	• EN ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
Other ISO Standards	• EN ISO 14971:2019 Medical devices — Application of risk management to medical devices

BOND Polymer Refine Detection

FORMAT	CODE	USAGE	STATUS
200-300 Tests	DS9800	-	IVD

APPLICATION

Immunohistochemistry (IHC)

Primary antibody binding to tissue sections can be visualized using BOND Polymer Refine Detection, where it provides intense, high resolution staining. A range of BOND Ready-to-Use primary antibodies are available, or alternatively, use antibody concentrates diluted with BOND Primary Antibody Diluent (AR9352).

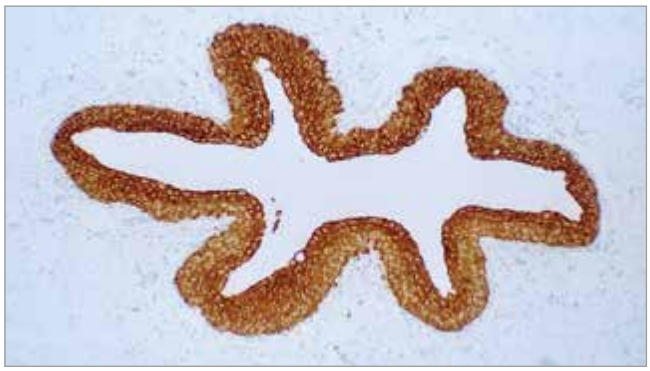
Chromogenic *in situ* Hybridization (ISH)

BOND Polymer Refine Detection produces highly specific, sensitive and reproducible demonstration of nucleic acid sequences through controlled hybridization reactions.

COMPONENTS

A state-of-the-art Compact Polymer detection system HRP horseradish peroxidase (HRP) polymer for use in both immunohistochemistry and chromogenic *in situ* hybridization. Small multifunctional linkers enhance tissue penetration, producing unsurpassed sensitivity. The system is biotin-free.

BOND Polymer Refine Detection contains a peroxide block, post primary, polymer reagent, DAB chromogen and hematoxylin counterstain. It is supplied ready-to-use for the automated BOND system.



Colon mucosa: immunohistochemical staining with BOND Ready-to-Use Cytokeratin 8/18 (5D3) (PA0067) using BOND Polymer Refine Detection.

BOND Polymer Refine Detection.

BOND Polymer Refine Red Detection

FORMAT	CODE	USAGE	STATUS
100 Tests	DS9390	-	IVD

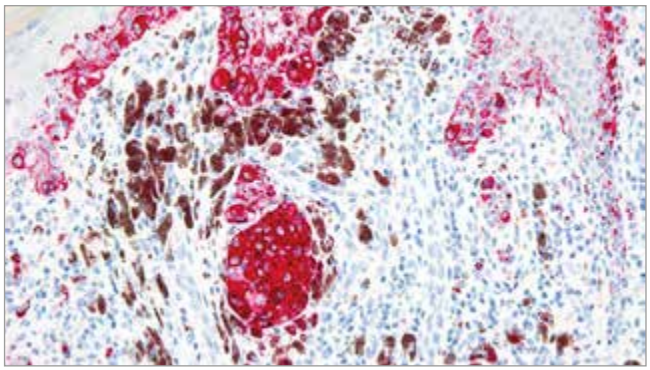
APPLICATION

Immunohistochemistry (IHC)

Primary antibody binding to tissue sections can be visualized using the BOND Polymer Refine Red Detection, providing an intense and high resolution stain.

COMPONENTS

BOND Polymer Refine Red Detection is an IVD labeled red detection system for the automated BOND system. BOND Polymer Refine Red Detection is biotin-free, utilizing alkaline phosphatase (AP)-linked compact polymer to provide enhanced tissue penetration and unsurpassed reagent sensitivity. It contains post primary, polymer reagent, Fast Red chromogen, and hematoxylin counterstain and is supplied in a convenient, Ready-to-Use format.



Human skin stained for melanoma marker HMB45 using BOND Polymer Refine Red Detection. Note intense cytoplasmic staining of melanocytes in contrast to the brown endogenous melanin.

BOND Polymer Refine Red Detection.

BOND Dewax Solution

FORMAT	CODE	USAGE	STATUS
1 L	AR9222	P	IVD

APPLICATION

The use of BOND Dewax Solution allows paraffin wax to be removed from tissue sections before rehydration and staining on BOND. It is specially formulated to be compatible with the automated BOND system, and efficiently removes wax from slides while retaining the integrity of tissue antigens and probe binding sites. BOND Dewax Solution is less harmful than alternative deparaffinization solutions such as xylene.

COMPONENTS

BOND Dewax Solution is a deparaffinization solution specifically designed for use on the automated BOND system. It is provided ready-to-use in 1 L bottles and can be poured directly into the appropriate bulk reagent container on the instrument.

BOND Dewax Solution.

BOND Wash Solution 10X Concentrate

FORMAT	CODE	USAGE	STATUS
1 L	AR9590	P	IVD

APPLICATION

BOND Wash Solution is the only wash buffer that should be used in BOND automated staining procedures. It is formulated for optimal reagent flow under the BOND Covertile to help ensure that excess reagent is removed from the tissue section before new reagent is added.

COMPONENTS

BOND Wash Solution 10X Concentrate is a concentrated buffer solution specifically for use on the automated BOND system. It is available in 1 L quantities, and when diluted will make up 10 L of working solution.

BOND Wash Solution 10X Concentrate.

BOND Epitope Retrieval Solution 1

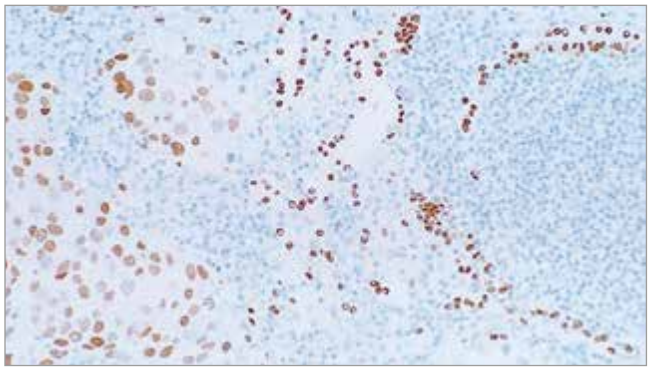
FORMAT	CODE	USAGE	STATUS
1 L	AR9961	P	IVD

APPLICATION

BOND Epitope Retrieval Solution 1 is for use on formalin-fixed, paraffin-embedded tissue sections to expose epitopes within tissue that have been masked during fixation. The solution is gentle on sections as it has a reduced boiling temperature and utilizes BOND Covertile technology to prevent reagent evaporation.

COMPONENTS

BOND Epitope Retrieval Solution 1 is a 1 L ready-to-use, citrate-based pH 6.0 solution. It is specifically for heat-induced epitope retrieval (HIER) on the automated BOND system.



Human lung stained for TTF-1 with BOND Ready-to-Use Thyroid Transcription Factor-1 (SPT24, PA0364), using BOND Polymer Refine Detection and BOND Epitope Retrieval Solution 1.

BOND Epitope Retrieval Solution 1.

BOND Epitope Retrieval Solution 2

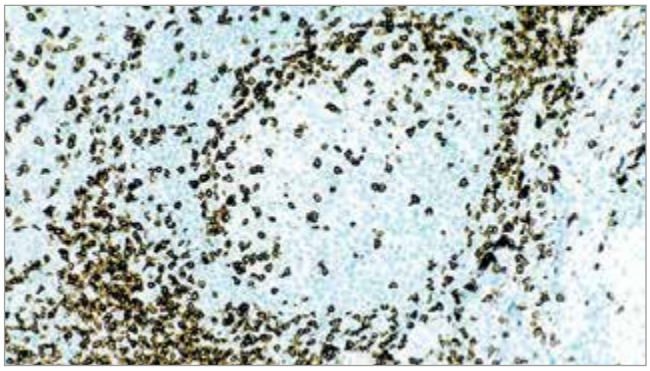
FORMAT	CODE	USAGE	STATUS
1 L	AR9640	P	IVD

APPLICATION

BOND Epitope Retrieval Solution 2 is for use on formalin-fixed, paraffin-embedded tissue sections to expose epitopes within tissue that have been masked during fixation. The solution is gentle on sections as it has a reduced boiling temperature and utilizes BOND Covertile technology to prevent reagent evaporation.

COMPONENTS

BOND Epitope Retrieval Solution 2 is a 1 L ready-to-use, EDTA-based pH 9.0 solution. It is specifically for heat-induced epitope retrieval (HIER) on the BOND system.



Human tonsil stained for CD3 with BOND Ready-to-Use CD3 (LN10, PA0533), using BOND Polymer Refine Detection and BOND Epitope Retrieval Solution 2.

BOND Epitope Retrieval Solution 2.

BOND Universal Covertile

FORMAT	CODE	USAGE	STATUS
160 Pack	S21.4611	P	IVD

APPLICATION

The BOND Universal Covertile is a patented technology that facilitates gentle, even reagent flow over tissue. It prevents reagent evaporation and minimizes waste generation. The Covertile is re-usable and can also be recycled once its staining life is over.

BOND Universal Covertile.

BOND Primary Antibody Diluent

FORMAT	CODE	USAGE	STATUS
500 mL	AR9352	P	IVD

APPLICATION

BOND Primary Antibody Diluent is specifically for diluting concentrated primary antibodies for use on the automated BOND system. It is not intended for the reconstitution of lyophilized reagents.

COMPONENTS

BOND Primary Antibody Diluent is ready-to-use and available in a quantity of 500 mL.

BOND Primary Antibody Diluent.

BOND Enzyme Pretreatment Kit

FORMAT	CODE	USAGE	STATUS
1 Kit	AR9551	P	IVD

APPLICATION

Immunohistochemistry (IHC)

The BOND Enzyme Pretreatment Kit can be used for enzymatic digestion on formalin-fixed, paraffin-embedded tissue sections to assist in epitope exposure. Enzymatic pretreatment improves the staining of some antibodies by exposing epitopes within tissue that have been masked during fixation.

In situ Hybridization (ISH)

The diluted enzyme solution can also be used for ISH. Enzymatic digestion of tissue assists in the penetration of probes and facilitates binding.

COMPONENTS

- BOND Enzyme Concentrate, 1 mL
- BOND Enzyme Diluent, 200 mL
- 3 x BOND Open Containers, 7 mL

The enzyme is diluted before use in the BOND Open Containers supplied. The diluted enzyme solution is used for enzymatic digestion on the automated BOND system.

BOND Enzyme Pretreatment Kit.

BOND DAB Enhancer

FORMAT	CODE	USAGE	STATUS
30 mL	AR9432	P	IVD

APPLICATION

BOND DAB Enhancer changes the color of the DAB reaction deposit from golden to dark brown, providing an increase in contrast between chromogen-specific staining and the slide back drop. This can assist in qualitative identification of antigens.

COMPONENTS

BOND DAB Enhancer is a heavy metal solution for use on the automated BOND system. The no-mix, ready-to-use format simplifies laboratory workflow.

BOND DAB Enhancer.

BOND Anti-Fluorescein Antibody

FORMAT	CODE	USAGE	STATUS
3.75 mL	AR0833	P	IVD
15 mL	AR0222	P	IVD

APPLICATION

In situ hybridization (ISH) allows the detection and visualization of specific nucleic acids in tissues sections. ISH probes used for the detection of mRNA or DNA on BOND contain a fluorescein label. The BOND Anti-Fluorescein Antibody allows linking of the oligonucleotide probe with the detection reagents, and consequently, visualization of a chromogenic product by light microscopy.

COMPONENTS

BOND Anti-Fluorescein Antibody is a purified IgG fraction of a mouse monoclonal antibody. It is supplied ready-to-use.

BOND Hybridization Solution

FORMAT	CODE	USAGE	STATUS
100 mL	AR9037	-	IVD
100 mL	AR9013	-	RUO

APPLICATION

BOND Hybridization Solution is intended to be used for the dilution of individual *In situ* hybridization (ISH) probes for use on the automated BOND system.

BOND Anti-Biotin Antibody

FORMAT	CODE	USAGE	STATUS
7.5 mL	AR0584	P	IVD

APPLICATION

In situ hybridization (ISH) allows the detection and visualization of specific nucleic acids in tissue sections. Some ISH probes used for detection of DNA on the BOND system contain a biotin label. The Anti-Biotin Antibody allows the linking of the probe with the detection reagents and consequently visualization of a chromogenic product by light microscopy.

COMPONENTS

Anti-Biotin Antibody is a purified anti-biotin, IgG1 isotype. It is supplied ready-to-use.

Anti-Biotin Antibody

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

BOND Aspirating Probe Cleaning System

FORMAT	CODE	USAGE	STATUS
15 Cleaning Cycles	CS9100	-	-

PRODUCT DESCRIPTION

The BOND Aspirating Probe Cleaning System contains reagents optimized to clean the aspirating probe of residual DAB. Sold in a standard reagent tray, the system is loaded onto BOND where a predefined cleaning protocol ensures maximum wash efficiency.

BOND Mixing Stations

FORMAT	CODE	USAGE	STATUS
5 Pack	S21.1971	-	IVD

PRODUCT DESCRIPTION

BOND Mixing Stations are reusable inserts with six vials for mixing and catalyzing chromogens prior to slide application. Fresh chromogen promotes high quality staining. Replacing the mixing stations at recommended intervals ensures that the mixed chromogen does not become contaminated.

BOND Mixing Stations.

BOND Open Containers 7 mL

FORMAT	CODE	USAGE	STATUS
10 Pack, Minimum 200 Tests/Container	OP79193	-	IVD

PRODUCT DESCRIPTION

BOND Open 7 mL Containers allow the use of reagents from any source on the BOND system. Each container can be refilled until a total of 40 mL has been dispensed from it. They are ideal for reagents that are consumed intermittently and have a short shelf life.

BOND Open Containers 7 mL.

BOND Open Containers 30 mL

FORMAT	CODE	USAGE	STATUS
10 Pack, Minimum 200 Tests/Container	OP309700	-	IVD

PRODUCT DESCRIPTION

BOND Open 30 mL Containers allow the use of reagents from any source on the BOND system. Each container holds 30 mL and can be refilled until a total of 40 mL has been dispensed from it. They are ideal for high throughput reagents that are consumed on a daily basis and their use can minimize reagent preparation time.

BOND Open Containers 30 mL.

BOND Titration Kit

FORMAT	CODE	USAGE	STATUS
10 Titration Containers and 50 Titration Container Inserts	OPT9049	-	IVD

PRODUCT DESCRIPTION

The BOND Titration Kit contains BOND Titration Container Inserts and BOND Titration Containers. The kit allows users to optimize primary antibody concentrates on the BOND system. The kits can be re-used for different antibodies and are designed with minimal dead volume to preserve reagent.

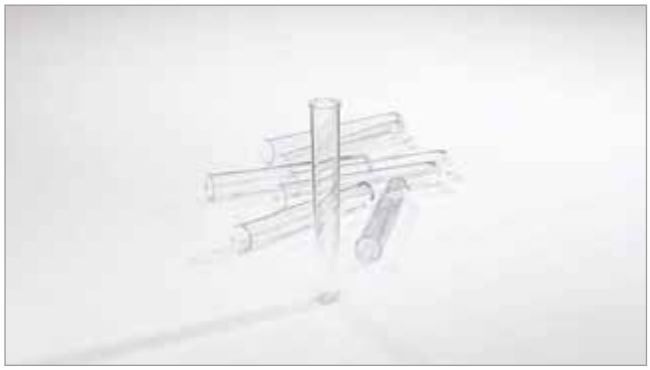
BOND Titration Kit.

BOND Titration Container Inserts

FORMAT	CODE	USAGE	STATUS
50 Pack	OPT9719	-	IVD

PRODUCT DESCRIPTION

BOND Titration Container Inserts are tubes that fit directly into the BOND Titration Containers. They enable use of up to 40 mL of reagent per titration container.



BOND Titration Container Inserts.

BOND Slide Label and Print Ribbon Kit

FORMAT	CODE	USAGE	STATUS
1 Pack, 3000 Labels	S21.4564	Zebra	IVD
1 Pack, 3000 Labels	S21.4604	Cognitive	IVD
6 Pack, 18000 Labels	S21.4610	Cognitive	IVD

PRODUCT DESCRIPTION

The BOND Slide Label and Print Ribbon Kit produces high-quality, solvent-resistant slide labels for use on the BOND system. This assists in preserving the integrity of slide identification and patient data records on BOND slides. The BOND Universal Slide labels adhere to slides for easy and secure identification.

BOND Slide Label and Print Ribbon Kit.

BOND Reagent Tray

FORMAT	CODE	USAGE	STATUS
1 Tray	S21.1003	-	-

PRODUCT DESCRIPTION

Additional BOND Reagent Trays let laboratories setup reagents for upcoming runs while other reagent trays are in use. This reduces setup delays and improves laboratory workflow.

BOND Reagent Tray.

BOND Slide Tray

FORMAT	CODE	USAGE	STATUS
1 Tray	S21.4586	-	-

PRODUCT DESCRIPTION

The BOND slide tray offers keying cues to improve usability and Covertile placement. Additional BOND Slide Trays to allow laboratories to prepare slides while other trays are running. This reduces setup delays and improves laboratory workflow. This tray can be used with all BOND Covertiles.

BOND Slide Tray.

BOND Syringe (for 9-Port Pump)

FORMAT	CODE	USAGE	STATUS
1 Syringe	S21.2131	-	-
4 Syringes	S21.4565	P	-

PRODUCT DESCRIPTION

The BOND Syringe precisely measures reagent volumes to be dispensed onto the slides. The syringe must be replaced at regular intervals as prompted by the software or if problems are found during scheduled fluidics checks. This part is for BOND-MAX instruments with a 9-Port valve.

BOND Syringe.

BOND Plus Slides

FORMAT	CODE	USAGE	STATUS
20 Boxes x 72 Slides/Box	S21.2113	P	IVD

PRODUCT DESCRIPTION

BOND Plus Slides are positively charged glass microscopic slides designed for use on the BOND system. They include defined margins to enable the accurate placement of tissue for staining in the 100 µL and the 150 µL dispense modes, which helps in maintaining the integrity of staining quality.

BOND Plus Slides.

BOND Covertile Cleaning Rack

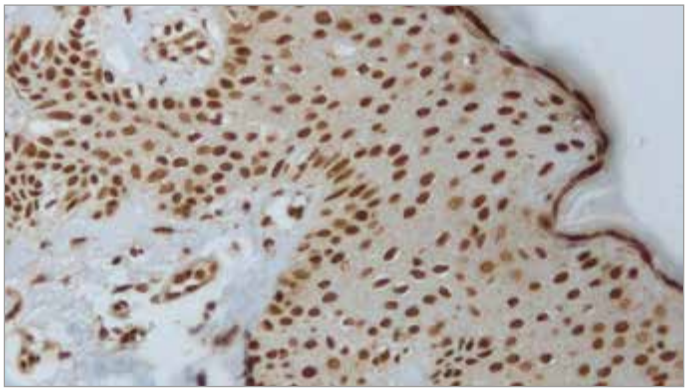
FORMAT	CODE	USAGE	STATUS
1 Rack	S21.4588	-	-

PRODUCT DESCRIPTION

The BOND Covertile Cleaning Rack makes Covertile cleaning even easier. It is easy to load, securely locks the Covertiles in place, and sits either vertically or horizontally.

BOND Covertile Cleaning Rack.

Akt (Phosphorylated)



Human skin: immunohistochemical staining for Phosphorylated Akt.
Akt (Phosphorylated): clone LP18

LP18

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-Akt-Phos	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

SPECIALIZED

ANTIGEN BACKGROUND

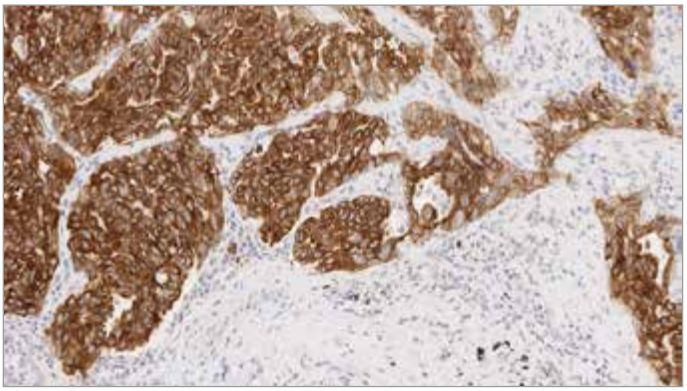
Akt-1, also referred to as protein kinase B (PKB) or Rac alpha is a member of the Akt serin/threonine protein kinase family. It plays an important role in many biological responses including metabolism, cell survival and growth by phosphorylation and inactivating several targets including GSK 3 beta, caspase 9, BAD and the forkhead transcription factor.

Akt (Phosphorylated) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Akt-Phos is not recommended for use with PBS, since the use of PBS-based wash buffers and possibly PBS-based antibody diluents gives increased background staining and decreased staining intensity. Proprietary reagents from Leica Biosystems or TBS-based wash buffer and diluents are recommended.

ALK



Non-small cell lung cancer: immunohistochemical staining for ALK. ALK: clone 5A4

5A4

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0831	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

LUNG PATHOLOGY

5A4

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0306	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-ALK	P(HIER)	IVD	IVD/RUO	IVD/RUO

PATHOLOGY MENU

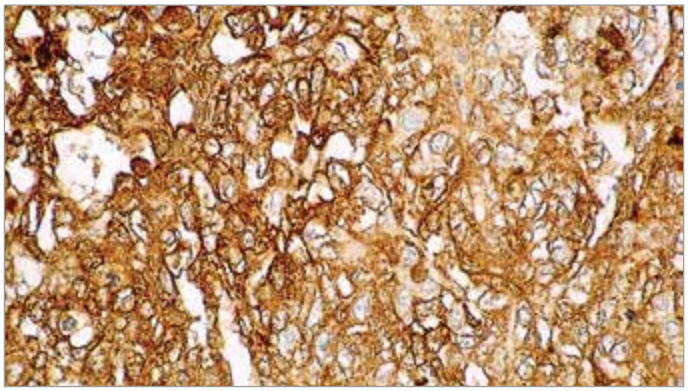
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Anaplastic large cell lymphoma (ALCL) is usually composed of large pleomorphic cells which are reported to express CD30 antigen and epithelial membrane antigen (EMA). These tumor cells tend to occur in younger individuals and may be associated with cutaneous and extranodal involvement. A proportion of these cases contain a chromosomal translocation t(2;5) (p23;q35). This results in a hybrid gene encoding part of the nucleophosmin (NPM) gene joined to the cytoplasmic domain of the anaplastic lymphoma kinase (ALK) gene, giving rise to the protein, p80. Large cell lymphomas account for approximately 25% of all non-Hodgkin's lymphomas in children and young adults, of which one third carry the NPM-ALK gene translocation.

ALK is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Alpha Fetoprotein



Human fetal liver: immunohistochemical staining for Alpha Fetoprotein.
Alpha Fetoprotein: clone C3

C3

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0963	P	IVD	IVD	IVD
Liquid 1 mL	NCL-L-AFP	P	IVD	IVD	IVD

PATHOLOGY MENU

GYNEPATHOLOGY

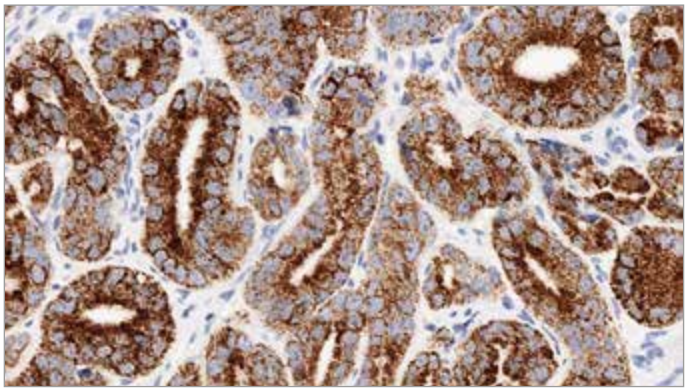
ANTIGEN BACKGROUND

Alpha fetoprotein (AFP) is an oncofetal antigen of 70 kD found in body fluids, which if detected in high concentrations has clinical implications.

AFP is expressed in fetal liver but is not present under normal circumstances in healthy adult tissues. It is reported to be expressed in a proportion of germ cell tumors, with high frequency in yolk sac tumors.

Alpha Fetoprotein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Alpha-Methylacyl-CoA Racemase (AMACR, p504s)



Human prostatic adenocarcinoma: immunohistochemical staining for AMACR.
AMACR: clone EPMU1

EPMU1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0210	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-AMACR	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

UROPATHOLOGY

ANTIGEN BACKGROUND

Alpha-methylacyl-CoA racemase (AMACR), also known as p504s, is a mitochondrial and peroxisomal enzyme that is involved in bile acid biosynthesis and beta-oxidation of branched-chain fatty acids. AMACR is essential in lipid metabolism, and is expressed in normal liver (hepatocytes), kidney (tubular epithelial cells) and gall bladder (epithelial cells). Expression has also been found in lung (bronchial epithelial cells) and colon (colonic surface epithelium). Expression is granular and cytoplasmic. AMACR expression can also be found in hepatocellular carcinoma and kidney carcinoma. Past studies have also shown that AMACR is expressed in various colon carcinomas (well, moderately and poorly differentiated) and over expressed in prostate carcinoma.

Alpha-Methylacyl-CoA Racemase (AMACR, p504s) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Alpha-Synuclein

Human brain, Lewy body dementia: immunohistochemical staining for alpha-synuclein. Note staining of alpha-synuclein-containing Lewy bodies. Alpha-Synuclein: clone KM51

KM51

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-ASYN	P(HIER)	RUO	RUO	RUO

PATHOLOGY MENU

NEUROPATHOLOGY

ANTIGEN BACKGROUND

Alpha-synuclein is a protein of 140 amino acids and a member of the synuclein family. It shares 61% sequence homology with beta-synuclein and is highly conserved between vertebrate species. It does not possess a signal sequence suggesting that it is an intracellular protein. All synucleins have an unusual organization based around the eleven residue repeating motif and an alpha-helical secondary structure resembling those found in the lipid-binding domain of exchangeable apolipoproteins, including Apo E. This homology suggests a direct interaction of alpha-synuclein with membranes consistent with its affinity for synaptosomes.

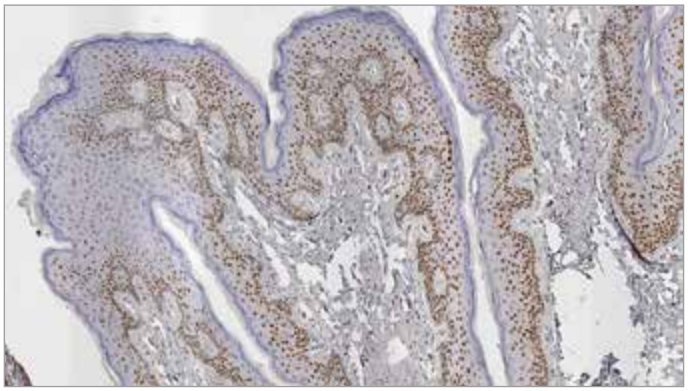
The function of alpha-synuclein may be to carry a target protein to the inner membrane of nerve terminals or to the outer surface of synaptic vesicles. Western Blot analyses of highly purified Lewy bodies from Lewy body dementia brain material has shown full-length, partially truncated and insoluble aggregates of alpha-synuclein.

Alpha-synuclein may be implicated in the formation of Lewy bodies and the selective degeneration of neurons in sporadic Parkinson's disease and Lewy body dementia.

PRODUCT SPECIFIC INFORMATION

Clone KM51 is specific for alpha-synuclein and is unreactive with beta-synuclein. Pretreatment of tissue sections with 98-100% formic acid is also recommended.

Androgen Receptor



Human skin: immunohistochemical staining for Androgen Receptor. Note the nuclear staining of the epithelial cells. Androgen Receptor: clone AR27

AR27

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-AR-318	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

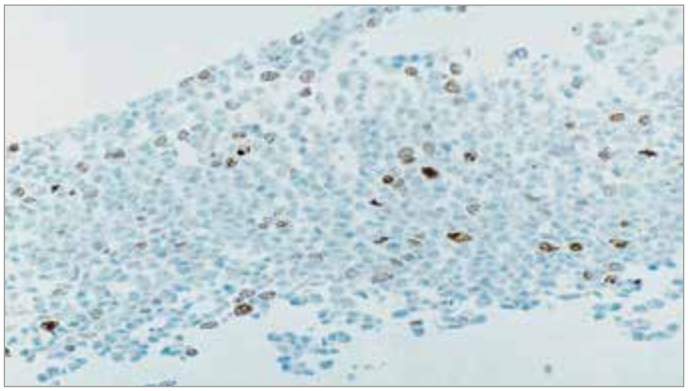
UROPATHOLOGY

ANTIGEN BACKGROUND

Androgen receptor is a member of the superfamily of ligand responsive transcription regulators. The androgen receptor functions in the nucleus where it is believed to act as a transcriptional regulator mediating the action of male sex hormones (androgens). The androgen receptor has wide distribution and can be demonstrated by immunohistochemistry in several tissues e.g. prostate, skin, and oral mucosa. Androgen receptor has been reported in a diverse range of human tumors eg osteosarcoma, and in prostatic carcinoma androgen receptor expression may be of clinical relevance. Furthermore, mutation of the gene encoding androgen receptor has been reported in prostatic carcinoma.

Androgen Receptor is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Aurora Kinase 2



HeLa cell line: immunohistochemical staining for Aurora Kinase. Note nuclear staining of a proportion of cells. Aurora Kinase 2: clone JLM28

JLM28

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-AK2	-	ASR	RUO	RUO

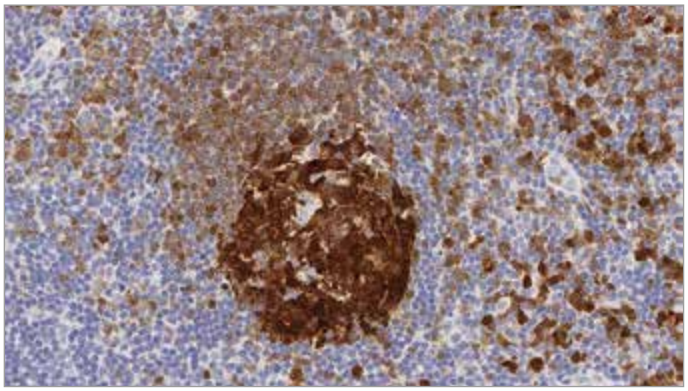
PATHOLOGY MENU

SPECIALIZED

ANALYTE SPECIFIC REAGENT

Analyte Specific Reagent. Analytical and performance characteristics are not established.

B Cell Specific Octamer Binding Protein-1 (BOB-1)



Human tonsil: Immunohistochemical staining for BOB-1. Note nuclear and cytoplasmic staining of B cells with BOB-1: clone TG14

TG14

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0558	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-BOB-1	-	ASR	RUO	RUO

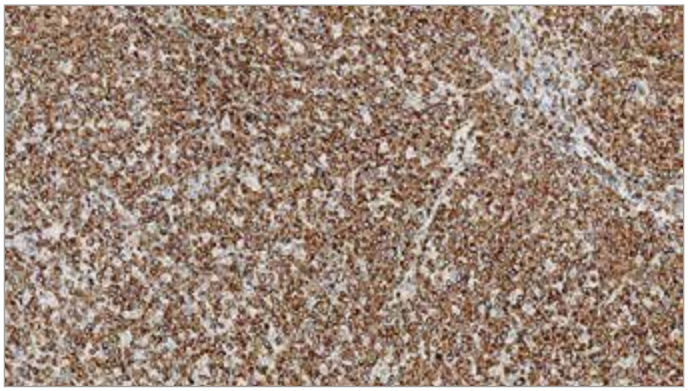
PATHOLOGY MENU

HEMATOPATHOLOGY

ANALYTE SPECIFIC REAGENT

Analyte Specific Reagent. Analytical and performance characteristics are not established.

Bcl-2 Oncoprotein



Human follicular lymphoma: immunohistochemical staining for Bcl-2. Bcl-2: clone bcl-2/100/D5

bcl-2/100/D5

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0117	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-bcl-2	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

HEMATOPATHOLOGY

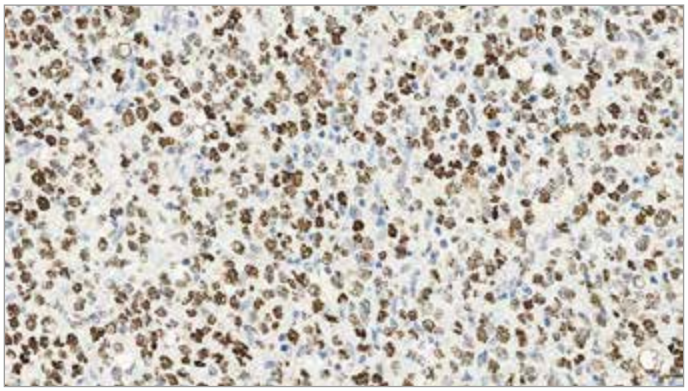
ANTIGEN BACKGROUND

Bcl-2 is a member of a family of proteins that are involved in apoptosis. Bcl-2 is an integral inner mitochondrial membrane protein of 25 kD and has a wide tissue distribution. It is considered to act as an inhibitor of apoptosis. For this reason, bcl-2 expression is inhibited in germinal centers where apoptosis forms part of the B cell production pathway.

In 90% of follicular lymphomas a translocation occurs which juxtaposes the bcl-2 gene at 18q21, to an immunoglobulin gene. This t(14;18) translocation can deregulate gene expression and bcl-2 over-expression can be demonstrated immunohistochemically in the vast majority of follicular lymphomas.

Bcl-2 Oncoprotein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Bcl-6 Oncoprotein



Human diffuse large B cell lymphoma: immunohistochemical staining for Bcl-6. Bcl-6: clone LN22

LN22

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0204	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-Bcl-6-564	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

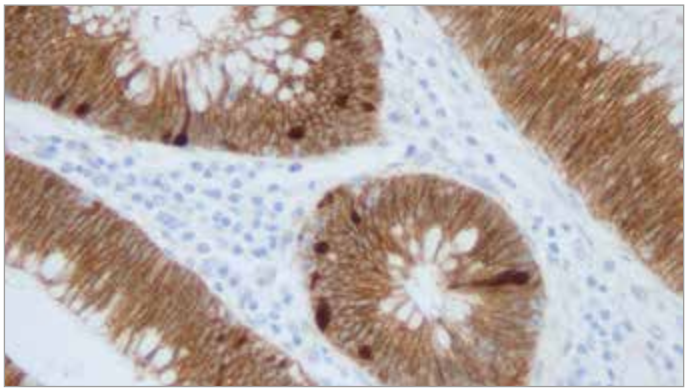
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Bcl-6 is a proto-oncogene that encodes a Kruppel-type zinc-finger protein of 95 kD and shares homology with other transcription factors. Bcl-6 protein is mainly expressed in normal germinal center B cells and related lymphomas. It has been shown that the Bcl-6 proto-oncogene is involved in chromosome rearrangements at 3q27 in non-Hodgkin's lymphomas and Bcl-6 rearrangements have also been detected in 33-45% of diffuse large B cell lymphomas. Immunohistochemistry has been reported to show the Bcl-6 gene product to be detectable in follicular lymphomas, diffuse large B cell lymphomas, Burkitt's lymphomas and in nodular, lymphocyte predominant Hodgkin's disease.

Bcl-6 Oncoprotein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Beta-Catenin



Human colon polyp: immunohistochemical staining for Beta-Catenin. Note the abnormal translocation of the protein to the nucleus. Beta-Catenin: clone 17C2

17C2

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0083	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-B-CAT	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

SOFT TISSUE PATHOLOGY

ANTIGEN BACKGROUND

The catenins, (alpha, beta and gamma) are cytoplasmic proteins which bind to the highly conserved tail of the E-cadherin molecule. Beta-catenin is a component of the adherens junction, a multiprotein complex which supports Ca^{2+} -dependent cell-to-cell contact, which in itself is critical for adhesion, signal transmission and for anchoring the actin cytoskeleton. Beta-catenin's role is as a transcription effector of the wnt-signaling pathway. Immunohistochemistry is the best way to demonstrate nuclear expression of beta-catenin and wnt-pathway activation. This aberrant expression is observed in human tumorigenesis, and especially in colorectal cancer.

Beta-Catenin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Beta-Dystroglycan

Human skeletal muscle: immunohistochemical staining on a frozen longitudinal section. Staining is localized in the sarcolemma of the fibers. Beta-Dystroglycan: clone 43DAG1/8D5

43DAG1/8D5

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-b-DG	F	IVD	IVD	IVD

PATHOLOGY MENU

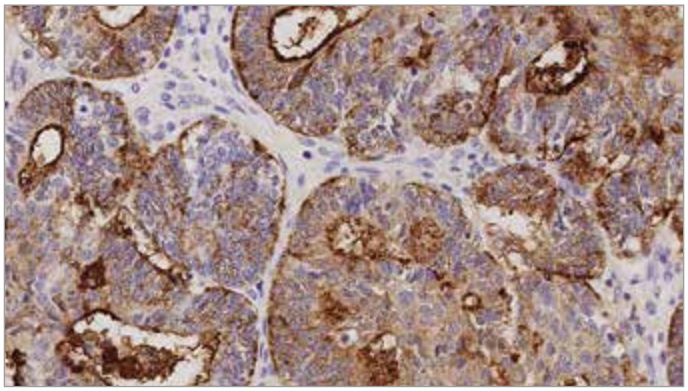
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Dystrophin associated glycoproteins (DAGs) are involved in the attachment of dystrophin to muscle membranes. The biological significance of this dystrophin/glycoprotein complex is not fully understood, but it appears to form an essential linkage between actin on the inside of the muscle fiber and muscle laminin in the basal lamina which surrounds the fiber. Beta-dystroglycan spans the sarcolemma and it has been suggested that it is the member of the complex which binds directly to dystrophin.

Beta-Dystroglycan is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CA125 (Ovarian Cancer Antigen)



Human adenocarcinoma of endometrium: immunohistochemical staining on CA125.
CA125: clone Ov185:1

Ov185:1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0539	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CA125	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

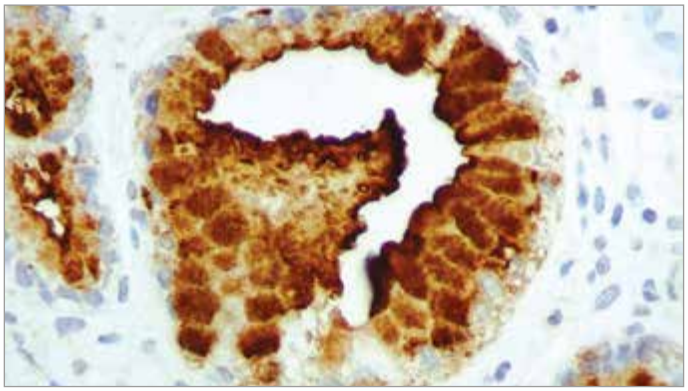
GYNEPATHOLOGY

ANTIGEN BACKGROUND

CA125 antigen is usually associated with ovarian epithelial malignancies. Serum assays are widely used to detect this protein in the monitoring of ovarian cancers. CA125 antigen may also be detected by immunohistochemistry and expression has been found in neoplasms such as seminal vesicle carcinoma and anaplastic lymphoma. CA125 antigen is not found exclusively in malignant tumors. CA125 is also known as MUC16.

CA125 (Ovarian Cancer Antigen) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CA19-9 (Sialyl Lewis [a])



Colonic adenocarcinoma: immunohistochemical staining for Sialyl Lewis [a] antigen.
CA19-9: clone C241:5:1:4

C241:5:1:4

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0424	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CA19-9	P(HIER)	RUO	RUO	RUO

PATHOLOGY MENU

GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

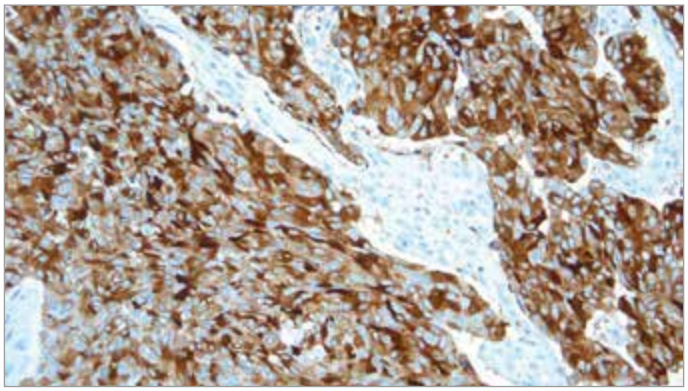
CA19-9 is an epitope on the sialylated Lewisa carbohydrate structure. Sialylated Lewisa plays a role in cell adhesion by acting as a functional ligand for the inducible adhesion molecule E-selectin. In carcinoma of the pancreas, it is reported that the immunohistochemical expression of both CA19-9 and CA50 correlates with tumor differentiation, where the strongest staining is observed in well-differentiated tumors. These two markers are also reported in a number of benign lesions such as chronic pancreatitis.

CA19-9 (Sialyl Lewis a) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone C241:5:1:4 reacts specifically with Sialyl Lewis a - containing glycolipids, showing no crossreaction with Lewis a, Lewis b, or other structurally related molecules. The epitope recognized by NCL-L-CA19-9 is designated CA19-9.

Calcitonin



Human medullary thyroid carcinoma: immunohistochemical staining for Calcitonin.
Calcitonin: clone CL1948

CL1948

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CALCITONIN	P(ENZYME)	IVD	IVD	IVD

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0406	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

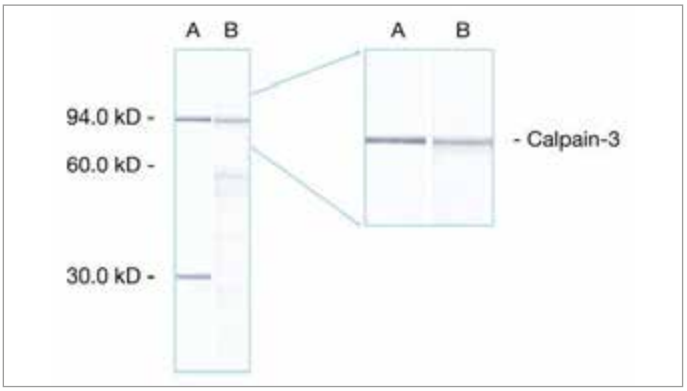
HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

Calcitonin (CT) is a 32 amino acid peptide synthesized by the parafollicular C cells of the thyroid. It acts through its receptors to inhibit osteoclast mediated bone resorption, decrease calcium resorption by the kidney and decrease calcium absorption by the intestines. The action of calcitonin is therefore to cause a reduction in serum calcium, an effect opposite to that of parathyroid hormone. The calcitonin gene transcript also encodes the calcitonin gene-related peptide (CGRP), which is thought to be a potent vasodilator. The tissue specificity of the transcript produced depends on alternative splicing of the CT/CGRP gene transcript. In the parafollicular cells of the thyroid 95% of the CT/CGRP is processed and translated to produce CT, however, in neuronal cells 99% of the CT/CGRP RNA is translated into CGRP. The C cells of the thyroid give rise to an endocrine tumor, medullary thyroid carcinoma (MTC), which occurs in a sporadic (75% of cases) and hereditary form (25% of cases). Familial MTC is associated with C cell hyperplasia (CCH), whereas sporadic MTC is thought not to be. However, in the general population CCH is present in 20-30% of thyroid glands, either with normal histology, thyroiditis or follicular tumors.

Calcitonin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Calpain Antibodies



Western Blot: analysis of human skeletal muscle showing detection of calpain 3 proteins. Lane A, calpain 3 bands at 94 and 30 kD detected with CALP-2C4. Lane B, Calpain 3 bands at 94 and approximately 60 kD detected with CALP-12A2. Calpain: clone Calc3d/2C4
Calpain: clone Calp3c/12A2

Calp3c/12A2

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 2.5 mL	NCL-CALP-12A2	W	RUO	RUO	RUO

Calp3d/2C4

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 2.5 mL	NCL-CALP-2C4	W	RUO	RUO	RUO

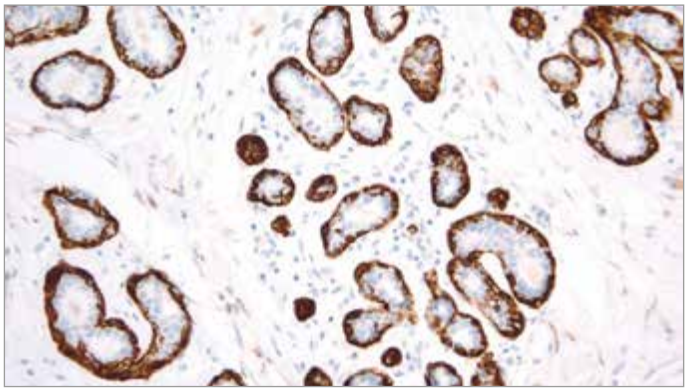
PATHOLOGY MENU

MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

The gene responsible for LGMD2A has been identified as the chromosome 15q15-encoded muscle-specific calcium-activated neutral protease, calpain 3. Calpain 3 enzyme is only stable in human muscle when homogenized in treatment buffer immediately after harvest (Anderson LVB et al. Am. J. of Pathol. 153(4), 1169-1179 (1998)), and in homogenates containing SDS and is therefore well suited for analysis by Western Blot. CALP-2C4 reacts with the full-size calpain 3 (94kD) and an additional fragment (30kD) in human skeletal muscle. CALP-12A2 reacts with full-size protein plus apparent degradation products at approximately 60kD.

Calponin (Basic)



Human prostate: immunohistochemical staining for Calponin (Basic). Note staining of basal cells. Calponin (Basic): clone 26A11

26A11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0416	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

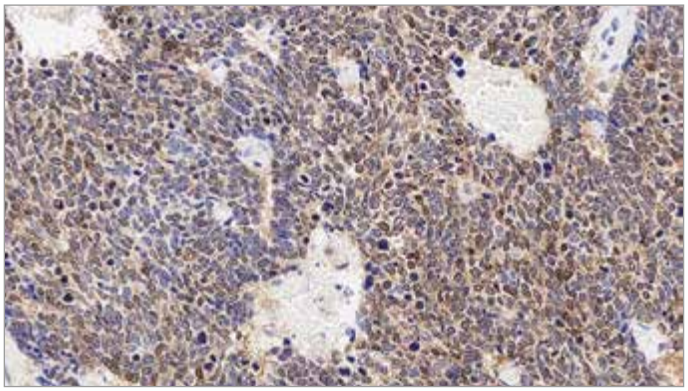
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Basic calponin (calponin-h1) is a 34 kD protein which exhibits a high degree of homology to acidic and neutral calponins at its N-terminal region. It is an actin, tropomyosin and calmodulin binding protein thought to be involved in the regulation of smooth muscle contraction. The expression of basic calponin is reported to be restricted to smooth muscle cells and is a marker of the differentiated contractile phenotype of developing smooth muscle. Vascular smooth muscle cells convert to a synthetic dedifferentiated phenotype when this protein is lost and this is a key stage in both atherosclerosis and restenosis of coronary arteries after balloon angioplasty. It is thought that basic calponin exerts its effect via the cortical actin cytoskeleton, and therefore influences proliferation, the transformed phenotype and the metastatic potential of tumor cells. Basic calponin mRNA is expressed in smooth muscle of prostate, bowel and aorta, whereas neutral and acidic calponin mRNAs are expressed in non-smooth muscle tissues such as heart, placenta, lung, kidney, pancreas, spleen, testis and ovary as well as in smooth muscle-containing tissues.

Calponin (Basic) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Calretinin



Human small cell lung carcinoma: immunohistochemical staining for Calretinin. Calretinin: clone CAL6

CAL6

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0346	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CALRET-566	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

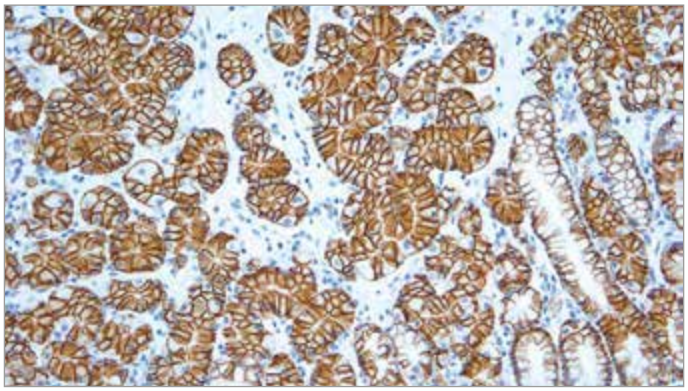
LUNG PATHOLOGY

ANTIGEN BACKGROUND

Calretinin is a calcium-binding protein of 29 kD that is a member of the family of so-called EF-hand proteins that also includes S-100 proteins. Calretinin is reported to be abundantly expressed in neurons. Outside the nervous system, calretinin is reported to be expressed in a range of cell types including mesothelial cells, steroid producing cells, (for example adrenal cortical cells, Leydig cells, ovarian theca interna cells, Sertoli cells, some neuroendocrine cells, eccrine sweat glands) and other cell types.

Calretinin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Carbonic Anhydrase IX



Human stomach: immunohistochemical staining for Carbonic Anhydrase IX. Note intense membrane and cytoplasmic staining of the deep glands. Carbonic Anhydrase IX: clone TH22

TH22

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CAIX	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

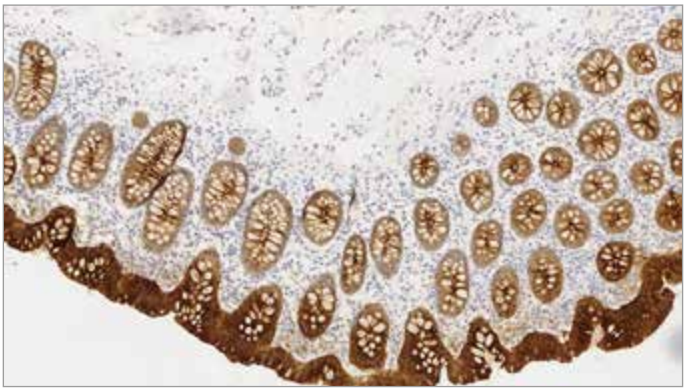
UROPATHOLOGY

ANTIGEN BACKGROUND

Carbonic anhydrase (CA) is an enzyme that assists rapid interconversion of carbon dioxide and water into carbonic acid, protons, and bicarbonate ions. Originally named MN/G250, carbonic anhydrase IX (CAIX) is a cell surface transmembrane protein, which is predominantly found in the gastrointestinal tract and gallbladder. The glandular regions of normal colon are reported to be negative, but in the case of adenocarcinoma, the glands are positive. CAIX is also reported to be expressed in common epithelial tumors such as carcinomas of the esophagus, lung, colon, kidney, cervix and non-small cell lung carcinoma.In breast carcinomas, CAIX expression has been reported to be associated with malignant tissue. Expression of CAIX is reported to be absent in normal kidney, chromophobe carcinomas or oncocytomas; however, it is specifically expressed in clear cell renal carcinomas.

Carbonic Anhydrase IX is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Carcinoembryonic Antigen (CD66e)



Human bowel: immunohistochemical staining for CD66e. Note cytoplasmic staining of epithelial cells. CD66e: clone 12-140-10

COL-1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0848	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CEA-609	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

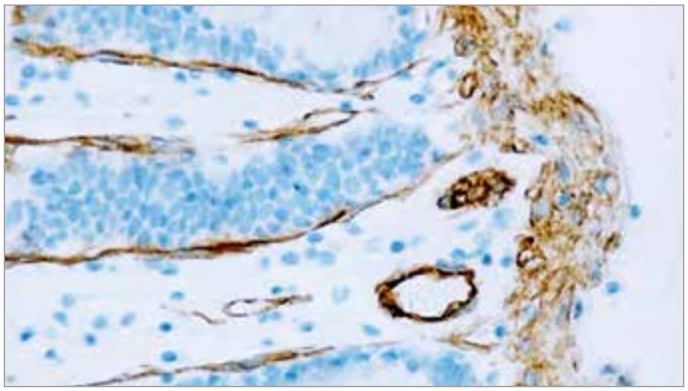
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Carcinoembryonic antigen (CEA) is a heterogeneous cell surface glycoprotein produced by cells of fetal colon. Low levels are also found on normal mucosal epithelia of the adult colon and a variety of other normal tissues. CEA is encoded by the CEA gene, which is located on chromosome 19. It is a member of the CEA gene family, which in turn is a subfamily of the immunoglobulin superfamily. Cell adhesion properties are now well recognized for CEA. It is believed that the expression of this glycoprotein in conjunction with other known adhesion molecules will influence the cell-cell interaction.

Carcinoembryonic Antigen (CD66e) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Caveolin-1



Normal human colon: immunohistochemical staining for Caveolin-1. Note cytoplasmic staining of smooth muscle and endothelium. Caveolin-1: clone 4D6

4D6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-Caveolin-1	P(HIER)	RUO	RUO	RUO

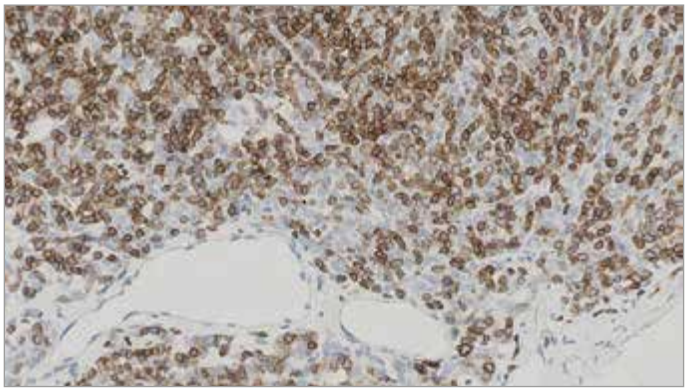
PATHOLOGY MENU

SPECIALIZED

ANTIGEN BACKGROUND

Caveolin-1 is a major structural component of caveolae, which are vesicular invaginations present on the plasma membrane of different cell types. It plays a regulatory role in several signaling pathways and is reported to be most abundantly expressed in terminally differentiated mesenchymal cells such as smooth muscle cells, adipocytes and endothelial cells. High levels are also reported in fibroblasts where a fine granular membranous and diffuse cytoplasmic staining pattern is described.

CD1a



Human thymoma: immunohistochemical staining for CD1a. CD1a: clone MTB1

MTB1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0235	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CD1a-235	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CD1a-235	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

DERMATOPATHOLOGY

ANTIGEN BACKGROUND

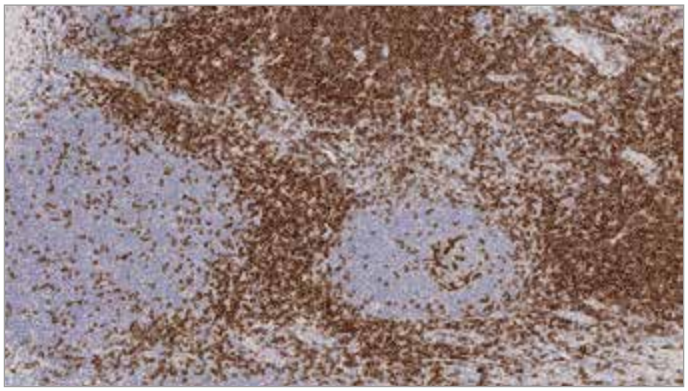
CD1a is a protein of 43 to 49 kD expressed on dendritic cells and cortical thymocytes. CD1a antigen expression has been shown to be useful in differentiating Langerhans cells, powerful antigen presenting cells present in skin and epithelia, from interdigitating cells. Immunohistochemical studies for CD1a antigen have reported a reduction in epidermal Langerhans cells in graft versus host disease and the participation of CD1a antigen-positive dendritic cells in atherosclerotic lesion formation and asthmatic inflammation.

CD1a is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone MTB1 detects cortical thymocytes, Langerhans cells in epidermis, interdigitating cells of dermis and interdigitating cells of stratified squamous epithelium of tonsil. Clone MTB1 may also detect small focal groups of lymphocytes outside the germinal centers of tonsil indicating a cross-reaction with CD1b antigen.

CD2 (LFA-2)



Human tonsil: immunohistochemical staining for CD2. Note membrane staining of T lymphocytes. CD2: clone 11F11

11F11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0271	P(HIER)	IVD	IVD	IVD

AB75

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD2-271	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

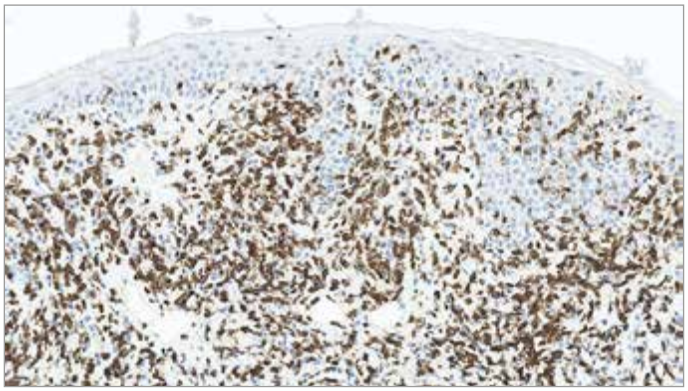
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD2 antigen (LFA-2) is a monomeric 45 to 58 kD glycoprotein. It is an accessory molecule important in mediating the adhesion of activated T cells and thymocytes with antigen-presenting cells and target cells.

CD2 (LFA-2) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD3



Human skin with mycosis fungoides: immunohistochemical staining for CD3. Note the extensively infiltrated positive cells. CD3: clone LN10

LN10

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0553	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0122	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD3-565	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

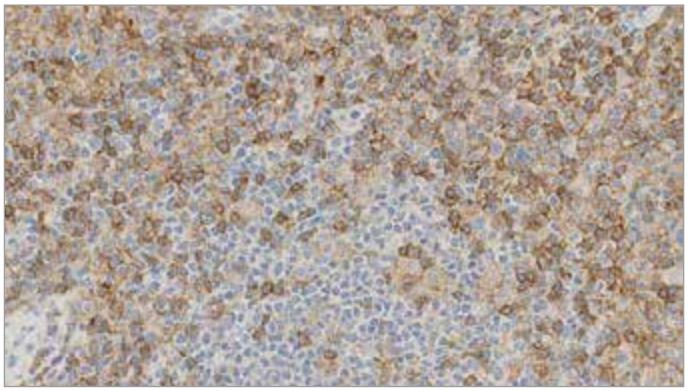
The CD3 molecule consists of five different polypeptide chains with molecular weights ranging from 16 to 28 kD. The CD3 antigen is first detected in early thymocytes and its appearance probably represents one of the earliest signs of commitment to the T cell lineage.

CD3 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone LN10 is specific for the non-glycosylated epsilon chain of the human CD3 molecule. Clone LN10 recognizes T cells in thymus, bone marrow, peripheral lymphoid tissue and blood and is a pan T cell marker.

CD4



T-Cell Lymphoma: immunohistochemical staining of CD4. CD4: clone 4B12

4B12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0427	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CD4-368	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CD4-368	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

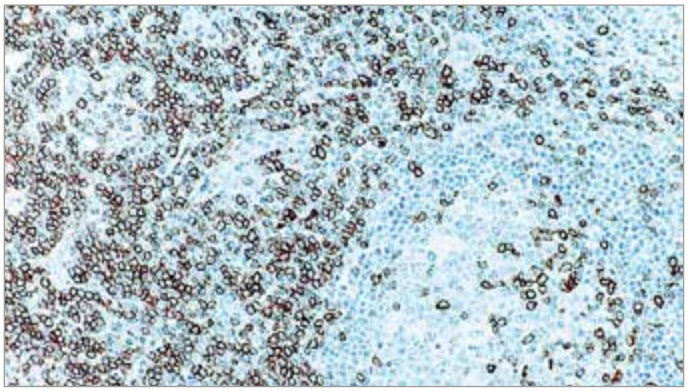
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD4 molecule (T4) is a single chain transmembrane glycoprotein with a molecular weight of 59 kD. The CD4 antigen is expressed on a T cell subset (helper/inducer) representing 45% of peripheral blood lymphocytes and at a lower level on monocytes and germinal center macrophages. Most cases of cutaneous T cell lymphoma, including mycosis fungoides, express the CD4 antigen and HTLV-1 associated adult T cell leukemia/lymphoma is also generally CD4 positive.

CD4 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD5



Human mantle cell lymphoma: immunohistochemical staining for CD5. CD5: clone 4C7

4C7

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0168	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CD5-4C7	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD5-4C7	P(HIER)	IVD	IVD/RUO	IVD/RUO

PATHOLOGY MENU

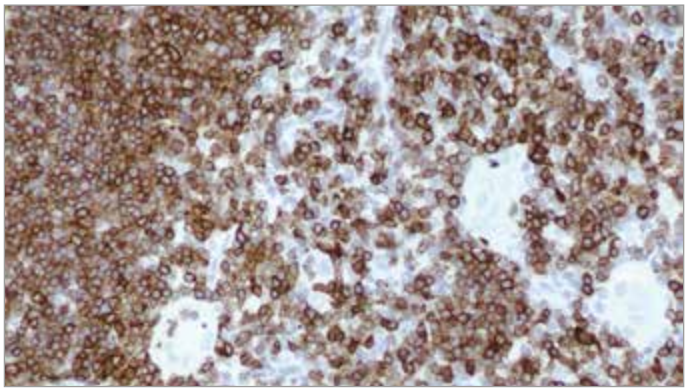
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD5 antigen is reported to be expressed on 95% of thymocytes and 72% of peripheral blood lymphocytes. In lymph nodes, the main reactivity is observed on T cells. CD5 antigen is also expressed by many T cell leukemias, lymphomas, activated T cells and on a subset of B cells located primarily in the mantle zones of normal lymph nodes. CD5 antigen expression is also reported in T cell acute lymphocytic leukemias (T-ALL), some B cell chronic lymphocytic leukemias (B-CLL) as well as B and T cell lymphomas.

CD5 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD7



T cell lymphoma: immunohistochemical staining for CD7. CD7: clone LP15

LP15

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0266	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD7-580	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

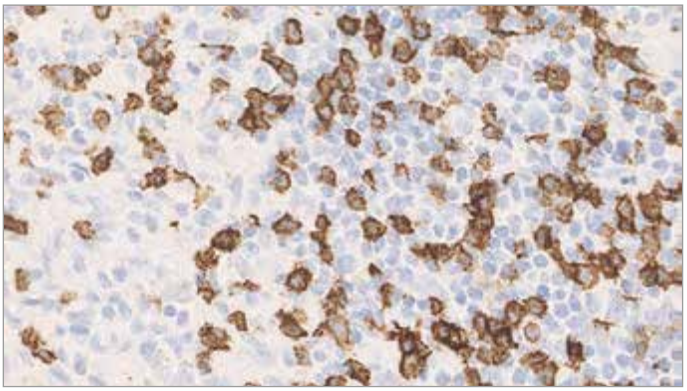
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD7 molecule is a membrane-bound glycoprotein of 40 kD and is the earliest T cell specific antigen to be expressed in lymphocytes. CD7 antigen is also the only early marker to persist throughout differentiation. The function and role of the CD7 molecule has not yet been fully identified, although the activation of T cells with gamma/delta receptors has been proposed based on mAb-induced activation. CD7 antigen is reported to be found on the majority of peripheral blood T cells, most natural killer cells and thymocytes.

CD7 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD8



Human lymph node, T cell lymphoma: immunohistochemical staining for CD8.
CD8: clone 4B11

4B11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0183	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CD8-4B11	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CD8-4B11	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

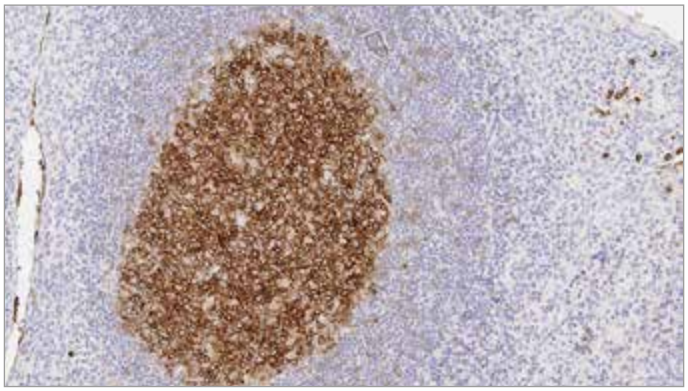
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD8 molecule is composed of two chains and has a molecular weight of 32 kD. It is found on a T cell subset of normal cytotoxic/suppressor cells which make up approximately 20-35% of human peripheral blood lymphocytes.The CD8 antigen is reported to be detected on natural killer cells, 80% of thymocytes, on a subpopulation of 30% of peripheral blood null cells and 15-30% of bone marrow cells.

CD8 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD10



Human tonsil: immunohistochemical staining for CD10. Note membrane staining of germinal centre B cells. CD10: clone 56C6

56C6

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0270	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0131	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD10-270	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

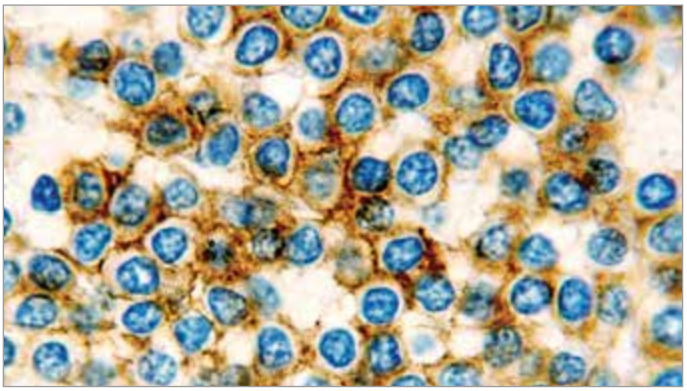
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD10 antigen, also called neprilysin, is a 100 kD cell surface metalloendopeptidase which inactivates a variety of biologically active peptides. It was initially identified as the common acute lymphoblastic leukemia antigen (CALLA) and was thought to be tumor-specific. Subsequent studies, however, have shown that CD10 antigen is expressed on the surface of a wide variety of normal and neoplastic cells. In other lymphoid malignancies, CD10 antigen is reported to be expressed on cells of lymphoblastic, Burkitt's and follicular lymphomas. CD10 antigen has been identified on the surface of normal early lymphoid progenitor cells, immature B cells within adult bone marrow and germinal center B cells within lymphoid tissue. It is also expressed in various non-lymphoid cells and tissues, such as breast myoepithelial cells, bile canaliculi, fibroblasts, with especially high expression on the brush border of kidney and gut epithelial cells. (G. McIntosh et al. American Journal of Pathology. 154(1): 77-82 (1999)).

CD10 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD11c



Human hairy cell leukemia: immunohistochemical staining for CD11c. CD11c: clone 5D11

5D11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0554	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD11c-563	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

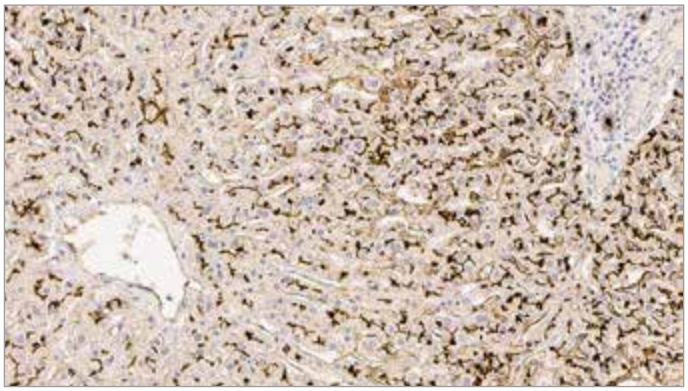
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD11c is a member of the leukocyte integrin family of adhesion proteins. It is reported to be expressed in normal tissues, mainly on myeloid cells, for example, in bone marrow myelocytes, premyelocytes, metamyelocytes, non-segmented and segmented neutrophils with high levels reported on tissue macrophages and monocytes and with lowest levels in granulocytes. It is also reported to be expressed on NK cells, activated T cells, lymphoid cell lines, including hairy cell leukemias and a proportion of interdigitating dendritic cells.

CD11c is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD13



Human liver: immunohistochemical staining for CD13. Note staining of the bile canaliculi.
CD13: clone 38C12

38C12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0304	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD13-304	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

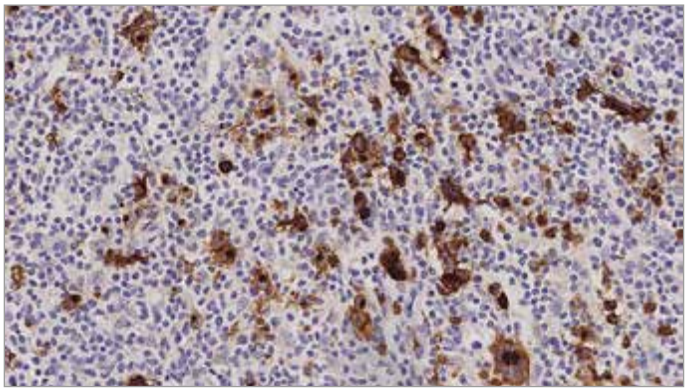
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD13 antigen, also known as aminopeptidase N, is a member of type II integral membrane metalloproteases, which also includes the leukocyte antigens CD10, CD26, CD73 and BP-1. CD13 antigen is a receptor for the coronaviruses which cause respiratory disease in humans and several animal species. The antigen functions as a zinc-binding metalloprotease which plays a role in cell surface antigen presentation by trimming the N-terminal amino acids from MHC class II-bound peptides. CD13 antigen is reported to be expressed on granulocytes, monocytes and their precursors, most acute myeloid leukemias and a smaller proportion of acute lymphoid leukemias. Non-hematopoietic cells which express CD13 antigen include epithelial cells, renal proximal tubules, intestinal brush border, endothelial cells, fibroblasts, brain cells, bone marrow, osteoclasts and cells lining the bile canaliculi.

CD13 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD15



Hodgkin's disease, mixed cellularity: immunohistochemical staining for CD15.
CD15: clone MMA

MMA

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0473	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD15-605	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

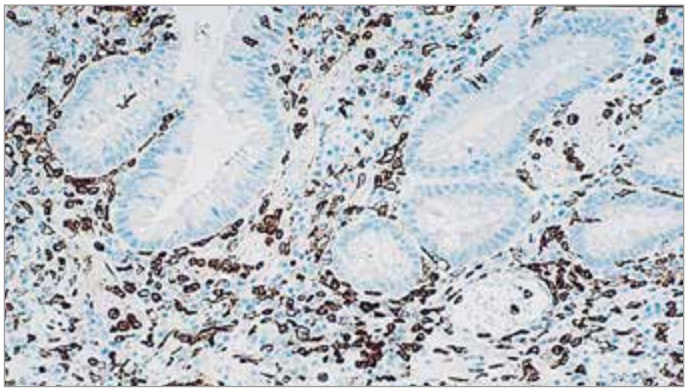
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD15 antigen, also known as X-hapten, is reported to be expressed on 90% of circulating human granulocytes, 30-60% of circulating monocytes and is absent from normal lymphocytes. The CD15 antigen is also expressed on Reed Sternberg cells of Hodgkin's disease and some leukemias.

CD15 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD16



Human colon, ulcerative colitis: immunohistochemical staining for CD16. CD16: clone 2H7

2H7

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD16	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

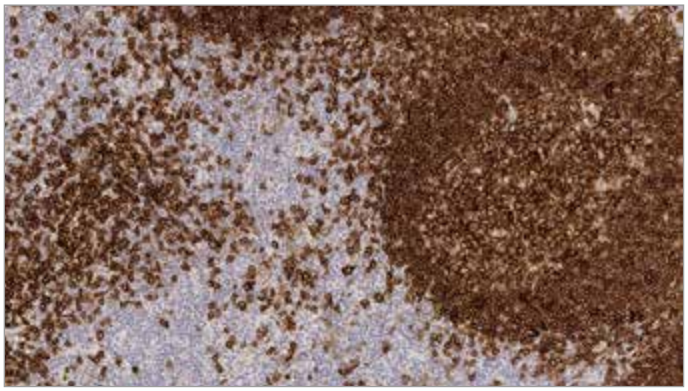
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD16 antigen has a molecular weight of 50 to 70 kD and is a low affinity Fc receptor for complexed IgG, Fc/gamma RIII, expressed on natural killer (NK) cells, granulocytes, activated macrophages and a subset of T cells expressing alpha-beta or gamma-delta T cell antigen receptors. The CD16 antigen exists both as a glycosyl-phosphatidylinositol (GPI)-anchored protein in polymorphonuclear cells and as a transmembrane protein in NK cells.

CD16 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD19



Human tonsil: immunohistochemical staining for CD19. Note membrane staining of B cells. CD19: clone BT51E

BT51E

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0843	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CD19-163	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CD19-163	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

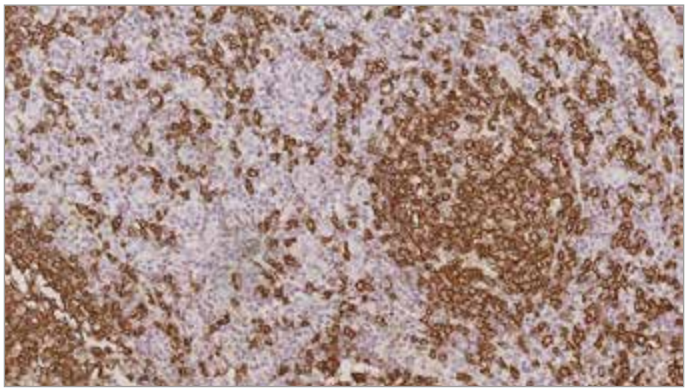
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD19 is a member of the immunoglobulin superfamily and has two Ig like domains. It is a single chain glycoprotein present on the surface of B lymphocytes and follicular dendritic cells of the hematopoietic system. CD19 is a crucial regulator in B cell development, activation and differentiation. On B cells, CD19 associates with CD21, CD81 and CD225 (Leu-13) forming a signal transduction complex. CD19 is expressed from the earliest recognizable B cell lineage stage, through development to B cell differentiation but is lost on maturation to plasma cells.

CD19 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD20



Follicular B cell lymphoma. immunohistochemical staining for CD20. CD20: Clone L26

L26

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0200	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0359	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CD20-L26	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CD20-L26	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

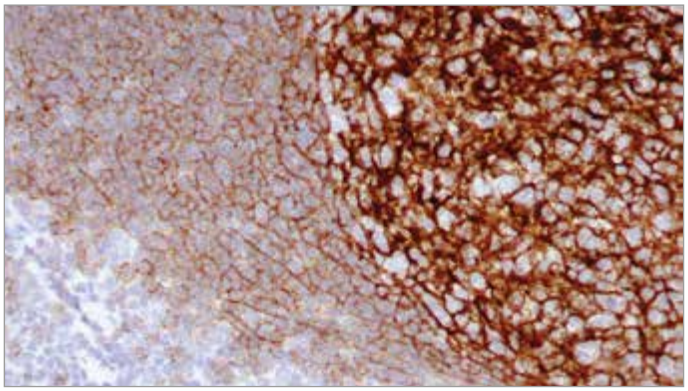
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD20 antigen is a non-glycosylated phosphoprotein of approximately 33kD which is expressed on normal and malignant human B cells and is thought to act as a receptor during B cell activation and differentiation. CD20 antigen has been reported to be expressed on normal B cells from peripheral blood, lymph node, spleen, tonsil, bone marrow, acute leukemias and chronic lymphocytic leukemias.

CD20 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD21



Human tonsil: immunohistochemical staining for CD21 antigen. Note intense membrane staining of follicular dendritic cells. CD21: clone 2G9

2G9

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0171	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD21-2G9	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

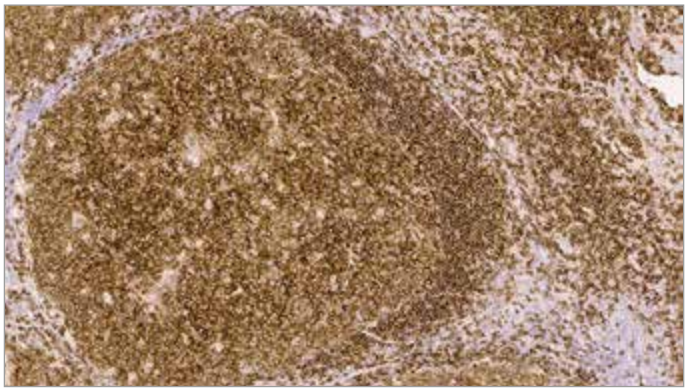
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD21 antigen is a type I integral membrane glycoprotein of molecular weight 140 kD, which functions as the receptor for the C3d fragment of the third complement component. The CD21 molecule, present on mature B cells, is involved in transmitting growth-promoting signals to the interior of the B cell and acts as a receptor for Epstein-Barr virus. CD21 antigen is reported to be found in B cell chronic lymphocytic leukemias and in a subset of T cell acute lymphocytic leukemias but is absent on T lymphocytes, monocytes and granulocytes. CD21 antigen is also reported to be expressed in follicular dendritic cells and in follicular and mantle cell lymphomas, mature leukemias and lymphomas.

CD21 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD22



Human tonsil: immunohistochemical staining for CD22. Note the mantle zone is staining stronger than the germinal center. CD22: clone FPC1

FPC1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0249	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

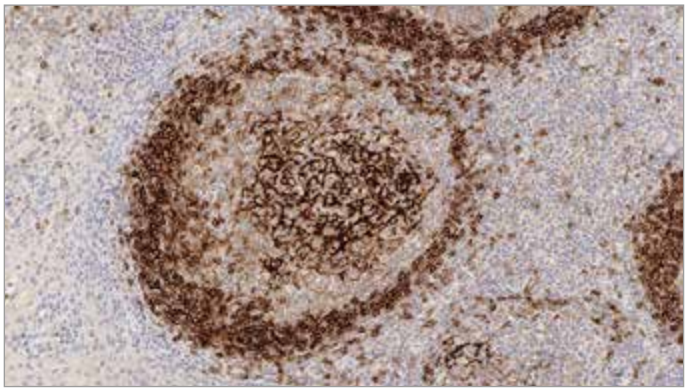
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD22 antigen (BL-CAM) is a type 1 integral membrane glycoprotein with a molecular weight of 130 to 140 kD. It is a heterodimer of two independently expressed glycoprotein chains present both on the membrane and in the cytoplasm of B lymphocytes. Expression of the CD22 antigen is reported to appear early in B cell lymphocyte differentiation at approximately the same stage as that of the CD19 antigen expression. Surface antigen expression is variable and may be lost upon differentiation. CD22 antigen is also reported to be weakly expressed on myeloid leukemias and non-T cell acute lymphoblastic leukemias and is strongly expressed on hairy cell leukemias. It is absent on peripheral blood T cells, T cell leukemias, granulocytes and monocytes.

CD22 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD23



Human tonsil: immunohistochemical staining for CD23. Note intense staining of follicular dendritic cell network and weaker staining of mantle zone cells. CD23: clone 1B12

1B12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0169	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CD23-1B12	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CD23-1B12	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

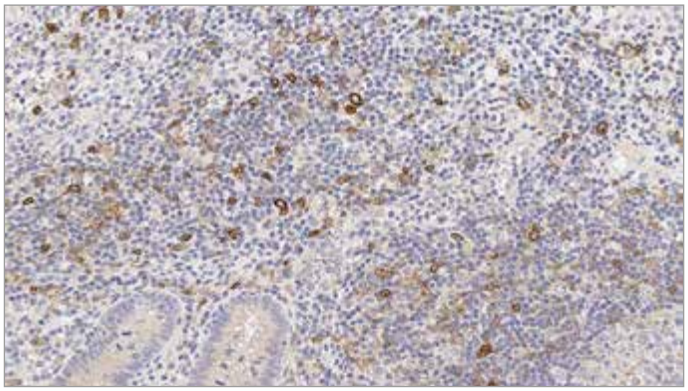
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD23 molecule is the low affinity IgE receptor found on B cells. It is a membrane glycoprotein of 45 kD and is reported to be found on a a sub-population of peripheral blood cells, B lymphocytes and on EBV-transformed B lymphoblastoid cell lines. Expression of CD23 antigen has been reported on monocytes and dendritic cells.

CD23 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD25



Human appendix: immunohistochemical staining for CD25. Note staining of activated lymphocytes. CD25: clone 4C9

4C9

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0305	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

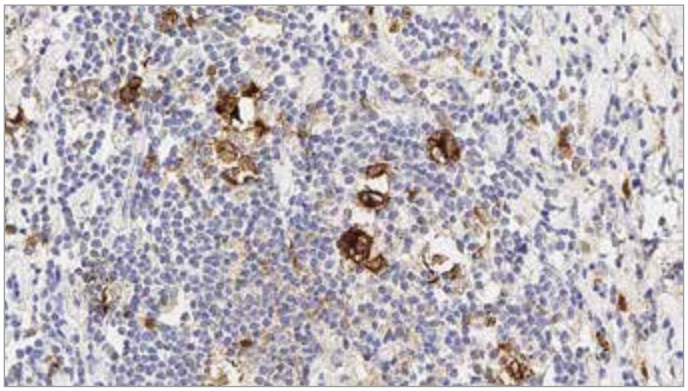
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD25 antigen, the alpha subunit of interleukin-2 receptor, is a single-chain glycoprotein with a molecular weight of 55 kD. Following the activation of T cells interleukin-2 (IL-2) is rapidly synthesized and secreted. In response to this a subpopulation of T cells expresses high affinity receptors for IL-2. These cells proliferate, expanding the T cell population which is capable of mediating helper, suppressor and cytotoxic functions. IL-2 receptor is not exclusively found on T cells, and is reported to be expressed on HTLV-transformed T and B cells, EBV-transformed B cells, myeloid precursors and oligodendrocytes. It is absent on thymocytes, resting T cells, non-activated B cells and null cells. IL-2 receptor expression is reported to be associated with inflammatory and malignant conditions, lymphoid neoplasia, auto-immune diseases and allograft rejection.

CD25 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD30



Human lymph node, nodular sclerosing Hodgkin's disease: immunohistochemical staining for CD30. CD30: clone JCM182

JCM182

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0790	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD30-591	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

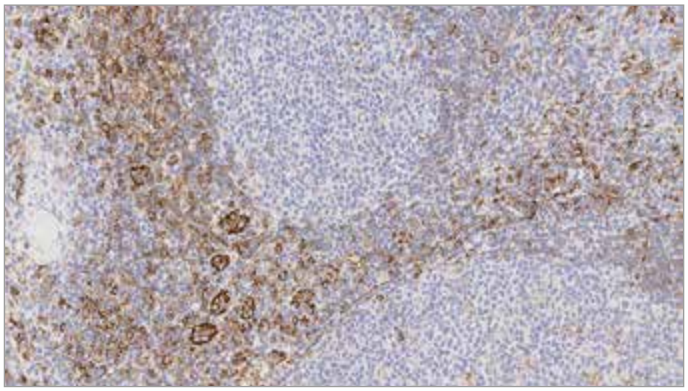
The CD30 antigen is a single chain glycoprotein with a molecular weight of 120 kD. CD30 antigen is known to act as a receptor for a cytokine ligand, CD30L, and may also play a role in the regulation of cellular growth and transformation. CD30 antigen is reported to be expressed on the surface of multinucleated Reed Sternberg cells, mononuclear Hodgkin's cells and in the majority of anaplastic large cell lymphomas. The CD30 antigen is expressed in non-Hodgkin's lymphoma and virally transformed cells, for example, EBV-transformed B cells.

CD30 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Using retrieval solutions other than that recommended for clone JCM182 in the datasheet may increase background reactivity.

CD31 (PECAM-1)



Human lymphoma: immunohistochemical staining for CD31. Note the membrane staining of endothelial cells. CD31: Clone JC70A

JC70A

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0414	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD31-607	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

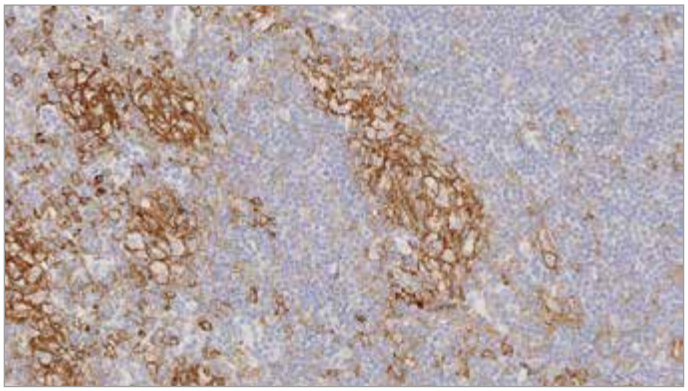
SOFT TISSUE PATHOLOGY

ANTIGEN BACKGROUND

CD31 antigen (PECAM-1) is a single chain transmembrane glycoprotein with a molecular weight of 130 to 140 kD. The CD31 molecule is expressed on the surface of platelets, monocytes, granulocytes, B cells and at the endothelial intracellular junction. The molecule has an extracellular domain that contains six Ig-like homology units of C2 subclass, typical of cell to cell adhesion molecules. This domain mediates endothelial cell to cell adhesion, plays a role in endothelial contact and may serve to stabilize the endothelial cell monolayer. The CD31 molecule also has a cytoplasmic domain with potential sites for phosphorylation after cellular activation. The properties of CD31 antigen suggest that it is involved in interactive events during angiogenesis, thrombosis and wound healing. Angiogenesis is essential for tumor growth and metastases.

CD31 (PECAM-1) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD33



Human lymph node, anaplastic lymphoma: immunohistochemical staining for CD33. CD33: clone PWS44

PWS44

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0555	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD33	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

HEMATOPATHOLOGY

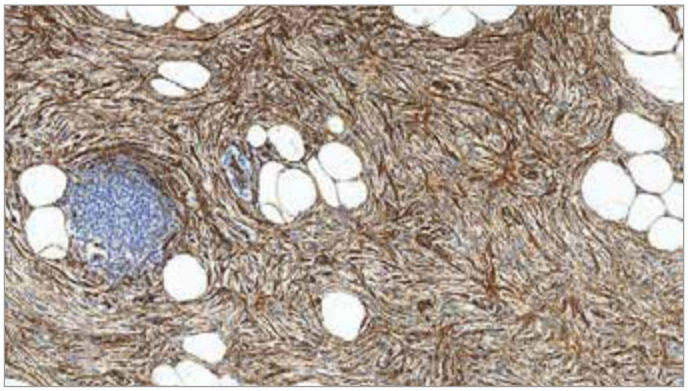
ANTIGEN BACKGROUND

CD33 antigen is reported to appear on myelomonocytic precursor cells after CD34 antigen expression. It then continues to be expressed on both the myeloid and monocyte lineages, although it is reported to be absent on granulocytes. It has been reported that expression of CD33 is restricted to monocytes, premyelocytes, myeloid blasts, some acute undifferentiated leukemias and acute lymphoblastic leukemias.

CD33 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent
F Frozen P Paraffin O Other Applications W Western blotting BOND BOND Ready-to-Use format Liquid Liquid Concentrate format

CD34 (Endothelial Cell Marker)



Dermatofibrosarcoma protuberans: immunohistochemical staining for CD34.
CD34: clone QBEnd/10

QBEnd/10

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0212	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0354	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-END	P(ENZYME)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

SOFT TISSUE PATHOLOGY

ANTIGEN BACKGROUND

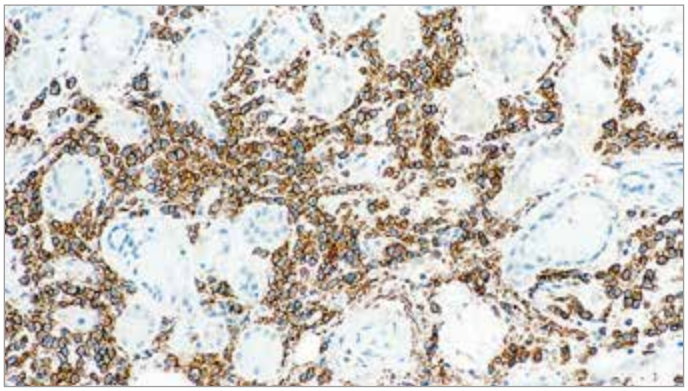
The CD34 antigen is a single chain transmembrane glycoprotein with a molecular weight of 110 kD. The CD34 protein is selectively expressed in human lymphoid and myeloid hematopoietic progenitor cells. The CD34 antigen is also expressed in vascular enothelium.

CD34 (Endothelial Cell Marker) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Enzyme digestion of paraffin sections is recommended with clone QBEnd/10 in perference to heat induced epitope retrieval as it produces stronger staining and reduces background elastin staining

CD38



Chronically inflamed human bronchus: immunohistochemical staining CD38.
CD38: clone SPC32

SPC32

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD38-290	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

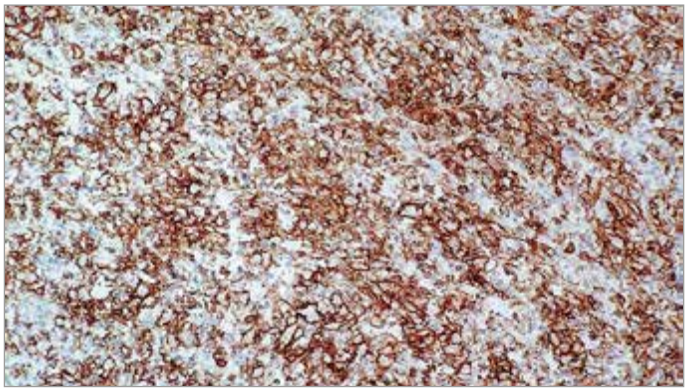
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD38 molecule is a type II single transmembrane glycoprotein with a molecular weight of 46 kD. It is an ectoenzyme with the activities of ADP-ribosyl cyclase, cyclic ADP-ribose hydrolase, NAD glycohydrolase and is involved in both the formation and hydrolysis of cADPR, a second messenger that regulates the mobilization of intracellular Ca^{2+} ions. Although the CD38 molecule was originally identified as a T lymphocyte differentiation antigen, it is reported to be expressed in a wide range of cells and tissues. CD38 antigen can deliver potent growth and differentiation signals to lymphoid and myeloid cells. It is found on immature cells of the B and T cell lineages but not on most mature resting peripheral lymphocytes. It is also present on thymocytes, pre-B cells, germinal center B cells, mitogen-activated T cells, Ig-secreting plasma cells, monocytes, NK cells, erythroid and myeloid progenitors in the bone marrow and brain cells. CD38 antigen has also been reported in neurofibrillary tangles, the pathological indicator of Alzheimer's disease that occurs in the neuronal perikarya and proximal dendrites.

CD38 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD43



Diffuse large B cell lymphoma: immunohistochemical staining for CD43. CD43: clone MT1

MT1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0938	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-MT1	P	IVD	RUO	RUO

PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

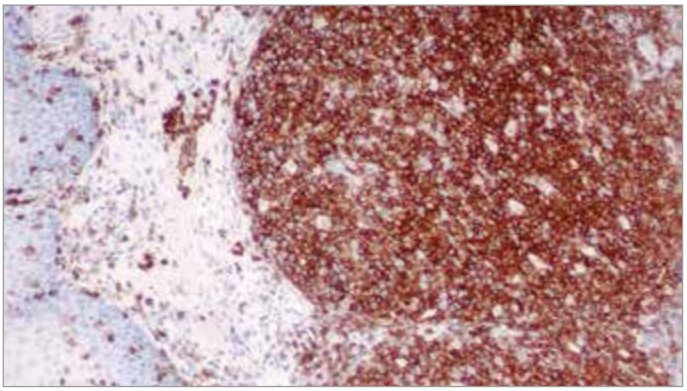
The CD43 antigen is expressed on the membrane and in the cytoplasm of T cells and cells of myeloid lineage. The molecule itself exhibits molecular weight heterogeneity with bands of 90 to 140 kD observed on SDS-PAGE between different cell lines. Cells expressing the CD43 antigen are reported to include normal and neoplastic T cells. A small proportion of B cell chronic leukemias and diffuse large B cell lymphomas are also reported to express CD43 antigen.

CD43 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

An enzyme pretreatment can be used to enhance staining in some cases.

CD45



Human tonsil: immunohistochemical staining of CD45 or leukocyte common antigen (LCA) in various hematolymphoid cells. CD45: clone X16/99

X16/99

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0042	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-LCA	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-LCA	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

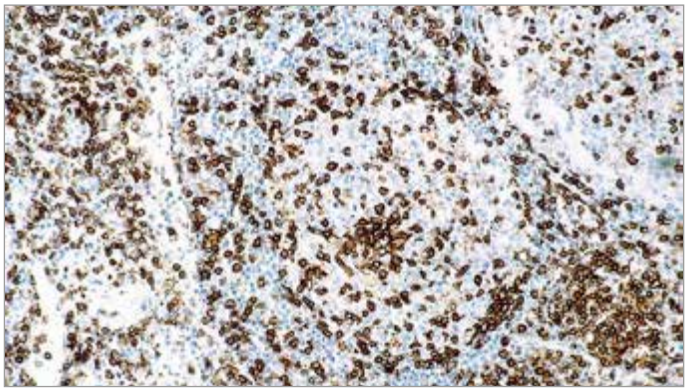
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD45 antigen (leukocyte common antigen) is a family of five or more high molecular weight glycoproteins present on the surface of the majority of the human leukocytes (including lymphocytes, monocytes and eosinophils) but absent from erythrocytes and platelets. Various isoforms of CD45 are generated by alternative splicing of three exons. Expression of CD45 is necessary for signaling through the T cell receptor.

CD45 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD45RO



Human tonsil: immunohistochemical staining with CD45RO: clone UCHL1

UCHL1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0146	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-UCHL1	P(HIER)	RUO	RUO	RUO

PATHOLOGY MENU

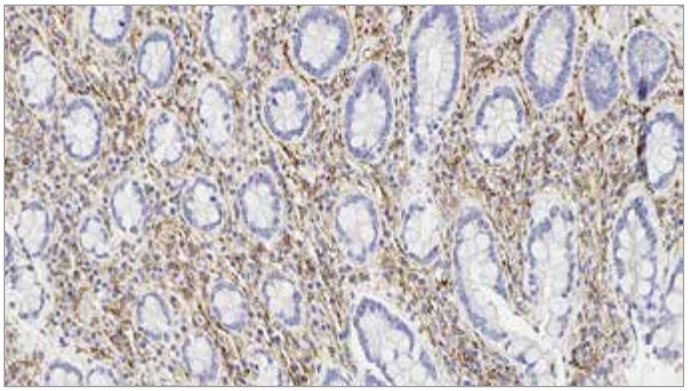
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD45RO molecule, a 180 kD isoform of CD45, is reported to be expressed on 48% of peripheral blood T lymphocytes, 37% of CD4 positive lymphocytes, 80% of thymocytes and on the majority of T cell malignancies. Monocytes and granulocytes show surface expression of the antigen whereas tissue macrophages exhibit cytoplasmic expression.

CD45RO is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD56 (NCAM)



Human tonsil: immunohistochemical staining for CD56. Note the NK cells and CD4/CD8 double positive T cells show a weak to moderate and distinct membrane staining reaction while the majority of lymphocytes are unstained. CD56: clone CD564

CD564

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0191	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD56-504	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

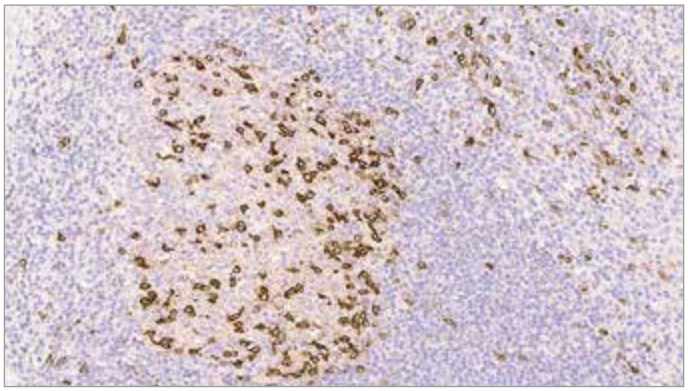
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The neural cell adhesion molecules are a family of closely-related cell surface glycoproteins thought to play a role in embryogenesis, development and contact-mediated interactions between neural cells. The CD56 antigen (NCAM) consists of four major isoforms generated by differential splicing of the RNA transcript from a single gene located on chromosome 5. The CD56 antigen is expressed on neurons, astrocytes, Schwann cells, NK cells and a subset of activated T lymphocytes.

CD56 (NCAM) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD57



Human tonsil: immunohistochemical staining of T lymphocytes. CD57: clone NK-1

NK-1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0443	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

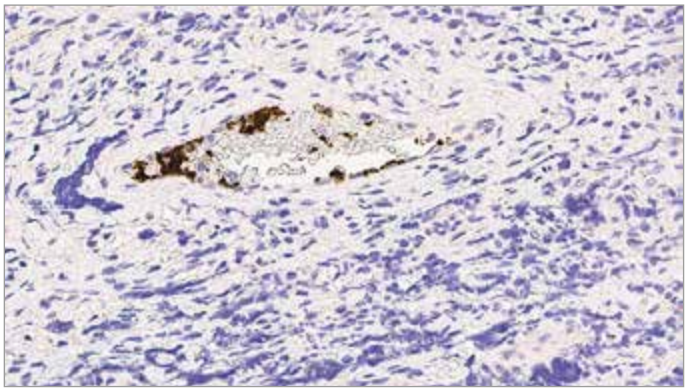
The CD57 glycoprotein, also known as HNK-1, has a molecular weight of 110 kD. It is found on a subset of mononuclear cells with natural killer activity and on neuroectodermal cells expressing myelin-associated glycoprotein. Many cells which co-express CD57 and CD8 proteins are a subset of suppressor/cytotoxic T cells. These cells play a role in the rejection of grafts in acute graft versus host disease. The CD57 molecule is not expressed on erythrocytes or platelets.

CD57 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

An enzyme pretreatment can be used to enhance staining in some cases.

CD61 (GPIIIa)



Human tonsil: immunohistochemical staining of CD61 antigen (GPIIIa) on platelets within the blood vessel. CD61 (GPIIIa): clone 2f2

2f2

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0308	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

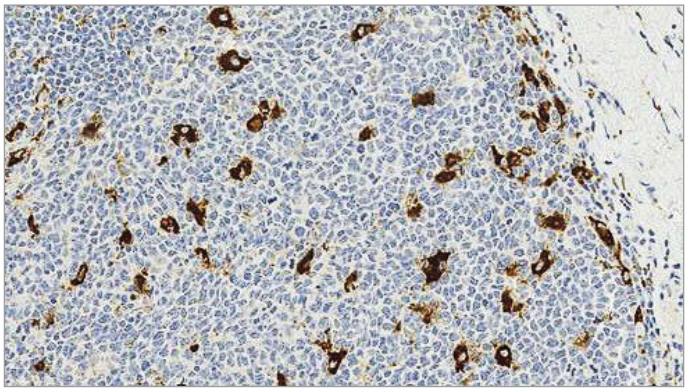
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD61 antigen, also known as GPIIIa, is a glycoprotein of 105 kD found on platelets, monocytes, endothelial cells, smooth muscle cells, B cells, macrophages, mast cells and fibroblasts. CD61 antigen plays a role in platelet aggregation and also as a receptor for fibrinogen, fibronectin, von Willebrand factor and vitronectin. Individuals with Glanzmann's thrombasthenia are reported to express little or no CD61 antigen. CD61 antigen is also reported to be expressed in most cases of megakaryocytic leukemias.

CD61 (GPIIIa) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD68



Human tonsil: immunohistochemical staining for CD68. Note the germinal centre macrophages show a strong cytoplasmic staining reaction, while the interfollicular macrophages show correct weak to moderate staining reaction. CD68: clone 514H12

514H12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0273	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD68	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

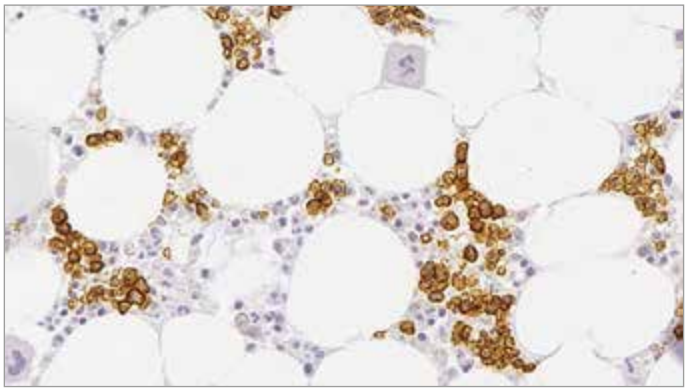
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD68 molecule is a 110 kD intracellular glycoprotein primarily reported to be associated with cytoplasmic granules and to a lesser extent the membranes of macrophages. Markers to CD68 antigen are the most frequently used for the identification of macrophages in immunohistochemistry; however, CD68 is also found in monocytes, neutrophils, basophils and large lymphocytes. The function of the CD68 molecule is not certain but these lysosomal membrane proteins are major components and may protect the membranes from attack by acid hydrolases. It is unclear if the surface-associated CD68 protein is functionally significant or due to leakage from the lysosomes. CD68 protein expression has been demonstrated in stimulated T cells and NK cells and non-hematopoietic tissues such as liver and renal tubules.

CD68 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD71



Human bone marrow: immunohistochemical staining for CD71. Note membrane staining of erythroid progenitor cells. CD71: clone 10F11

10F11

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD71-309	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

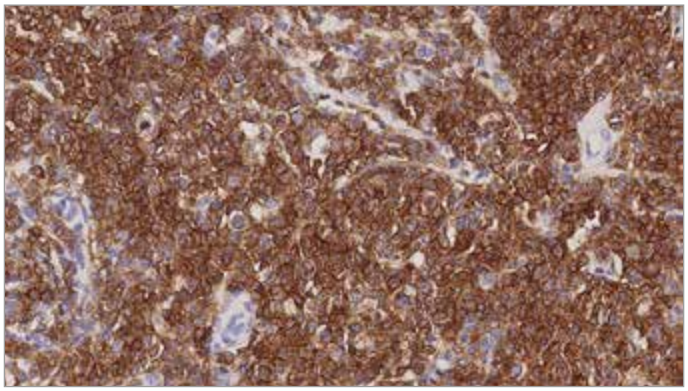
SPECIALIZED

ANTIGEN BACKGROUND

The CD71 molecule is a type II membrane glycoprotein with a molecular weight of approximately 180 kD. It is known as the transferrin receptor and is composed of two disulfide-BONDed 90 kD subunits. The CD71 molecule plays a critical role in cell proliferation by controlling the supply of iron, an essential component for many metabolic pathways, through the binding and endocytosis of transferrin, the major iron-carrying protein. CD71 protein is reported to be expressed on activated B and T cells, macrophages, proliferating cells and metabolically active cells, for example, neurons.

CD71 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD79a



Human diffuse large B cell lymphoma: immunohistochemical staining for CD79a. CD79a: clone JCB117

JCB117

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0599	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD79a-599	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

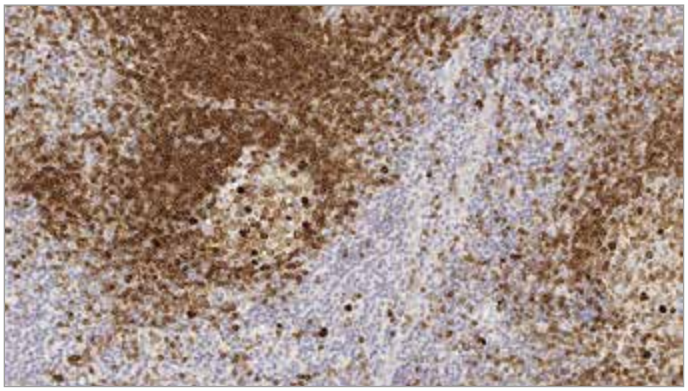
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD79 complex is a disulfide-linked heterodimer which is non-covalently associated with membrane-bound immunoglobulins on B cells. This complex of polypeptides and immunoglobulin constitute the B cell antigen receptor. The two components of this complex are designated CD79a and CD79b. The CD79a antigen is reported to first appear at the pre-B cell stage, early in maturation, and persist until the plasma cell stage where it is found as an intracellular component. It is not present in myeloid or T cell lines.

CD79a is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD79b



Human tonsil: immunohistochemical staining for CD79b. Note intense membrane staining of B cells. CD79b: clone JS01

JS01

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD79b	P(HIER)	RUO	RUO	RUO

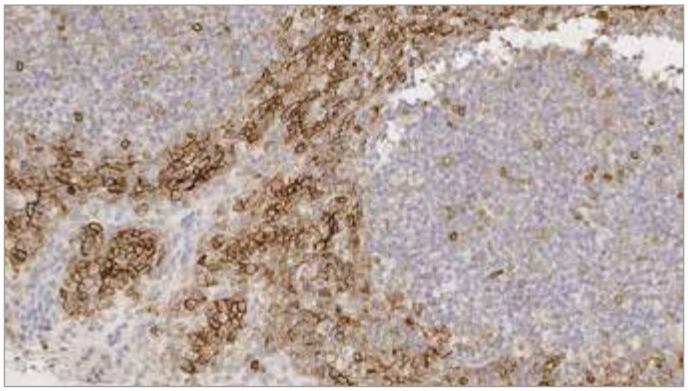
PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD79b, also known as B29 and Ig-beta is thought to function in the cellular activation and signaling that occurs when surface immunoglobulin (Ig) on B cells binds antigen or becomes cross-linked by anti-Ig antibody. This function occurs with the formation of a membrane signaling complex that is associated with Ig at the surface of B cells. CD79b, together with CD79a, forms the B cell antigen receptor (mIg) complex.

CD99



Human tonsil: immunohistochemical staining for CD99. Note membrane staining of vessel endothelium and a subpopulation of lymphocytes. CD99: clone PCB1

PCB1

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD99-187	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

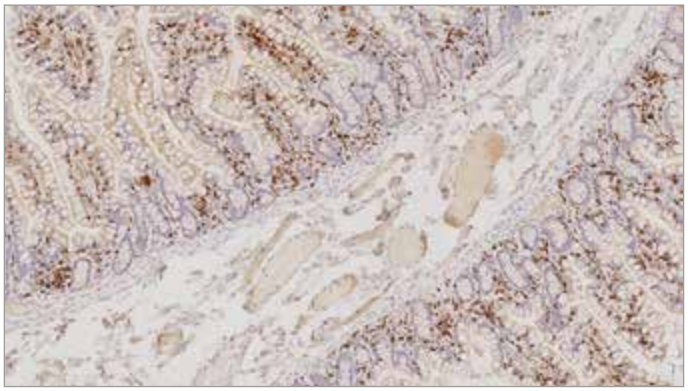
SOFT TISSUE PATHOLOGY

ANTIGEN BACKGROUND

CD99 is a 32 kDa transmembrane glycoprotein, encoded by the MIC2 gene, which is located in the pseudoautosomal region of the human X and Y chromosomes. Recently, the MIC2 gene has been shown to encode two distinct proteins which are produced by alternative splicing of the CD99 gene transcript and are identified as bands of 30 and 32 kDa (p30/32).

CD99 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD103



Human normal small bowel immunohistochemical staining of CD103. Note membrane and cytoplasmic staining of Intraepithelial T lymphocytes. CD103: clone EP206

EP206

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0374	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

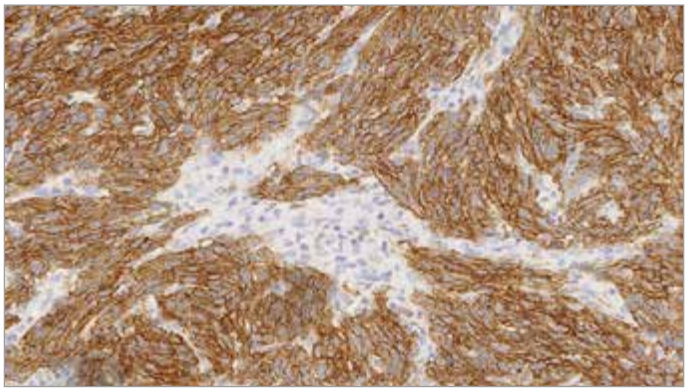
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD103, also known as alpha E integrin and human mucosal lymphocyte antigen 1, is an integrin protein with expression on intraepithelial T cells and some peripheral regulatory T cells. CD103 is expressed at high levels on tumor-infiltrating FOXP3-positive regulatory T cells in cancer. CD103-positive T cells are strongly associated with patient survival in high-grade serous ovarian cancer. CD103 expression has been suggested as a definitive marker of intraepithelial, tumor-specific infiltrating lymphocytes. In addition, CD103-positive cells have also been identified in a small proportion of breast cancers.

CD103 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD117



Human colon, gastrointestinal stromal tumor: immunohistochemical staining for CD117. CD117: clone EP10

EP10

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0007	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD117-032	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

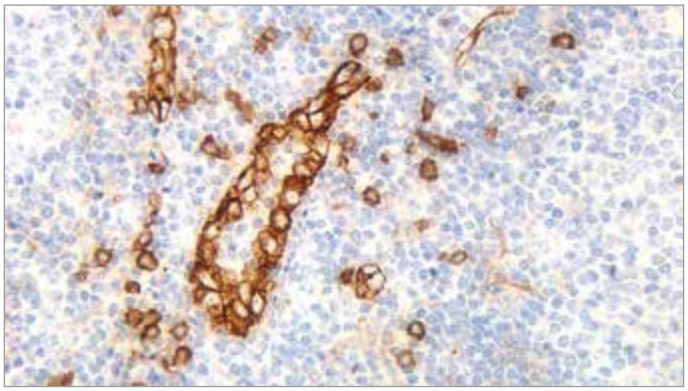
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

The c-kit proto-oncogene encodes a transmembrane receptor with tyrosine kinase activity, c-kit (CD117), which is closely-related to the platelet-derived growth factor receptor family. c-kit plays a role during hematopoiesis, gametogenesis and melanogenesis. The expression of CD117 antigen is of particular interest in the study of gastrointestinal stromal tumors (GIST), small lung cell carcinomas and in melanomas.

CD117 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD123



Human high walled venule endothelium and plasmacytoid dendritic cells: immunohistochemical staining for CD123: clone BR4MS

BR4MS

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD123	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

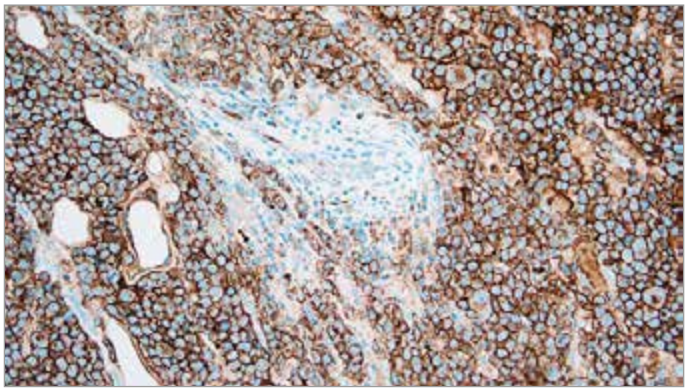
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD123 antigen is also known as the alpha subunit of the human interleukin-3 receptor. It is a type I transmembrane glycoprotein and is a member of the cytokine receptor superfamily. CD123 forms a heterodimer with CD131 (the beta subunit of the interleukin-3 receptor) to form the interleukin-3 receptor, where the cytokine specificity is provided by the alpha subunit and the signal transduction function is provided by the beta subunit. The interleukin-3 receptor is reported to be expressed on monocytes, neutrophils, basophils, eosinophils, megakaryocytes, erythroid precursors, mast cells, macrophages and a subpopulation of B cells, where it mediates proliferation and differentiation of these cells. Outside the hematopoietic system CD123 is reported to be expressed in Leydig cells of the testis, some endothelial cells, and cells of the placenta and brain.

CD123 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD138 (Syndecan 1)



Plasmacytoma: immunohistochemical staining for CD138. CD138: clone MI15

MI15

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0088	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

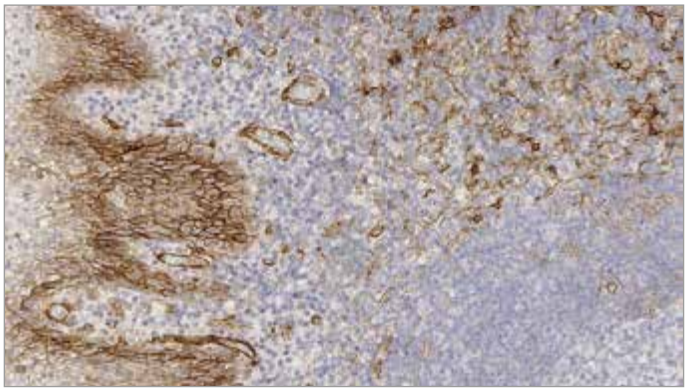
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD138 molecule is a transmembrane heparan sulphate glycoprotein expressed at distinct stages of differentiation in normal lymphoid cells such as pre-B cells, immature B cells and Ig-producing plasma cells as well as being expressed in stratified and simple epithelia. The loss of CD138 expression from atypical cells is reported to be an early event during cervical carcinogenesis whereas CD138 antigen expression shows a close association with preserved epithelial morphology and differentiation; however, the major utility of CD138 as a marker in immunohistochemistry is the quantification of plasma cells.

CD138 (Syndecan 1) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD141 (Thrombomodulin)



Human tonsil: immunohistochemical staining for CD141. Note membrane staining of the basal cells of the squamous mucosa, endothelium and a subset of dentritic cells. CD141: clone 15C8

15C8

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD141	P(HIER)	IVD	-	-

PATHOLOGY MENU

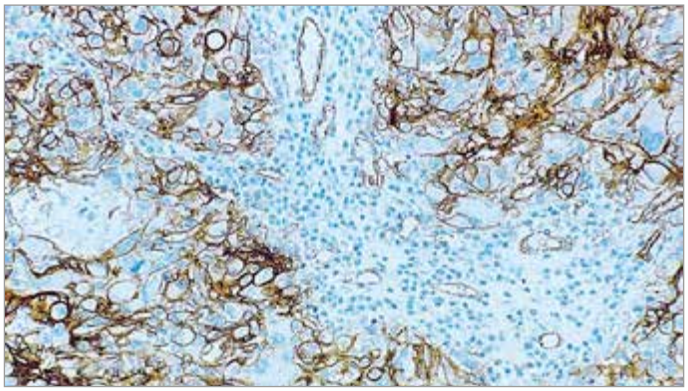
SPECIALIZED

ANTIGEN BACKGROUND

Thrombomodulin is a transmembrane glycoprotein of 75 kD which can accelerate the activation of protein C. Activated protein C functions as an anticoagulant by combining with protein S to inactivate factors Va and VIIIa of the blood coagulation pathway and by binding thrombin. Several factors regulate thrombomodulin expression. Downregulation of thrombomodulin may be induced by the cytokine interleukin-1, tumor necrosis factor and endotoxin. Agents which increase cyclic AMP such as forskolin may upregulate thrombomodulin activity in endothelial cells. Thrombomodulin has been identified within a number of normal tissues. These include the lining cells of arteries, veins, capillaries and the lymphatics as well as mesothelial cells, meningeal lining cells, synovial cells, syncytiotrophoblasts, megakaryocytes and platelets.

CD141 (Thrombomodulin) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD146 (MCAM)



Human malignant melanoma: immunohistochemical staining for CD146. CD146: clone N1238

N1238

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD146	P(HIER)	IVD	-	-

PATHOLOGY MENU

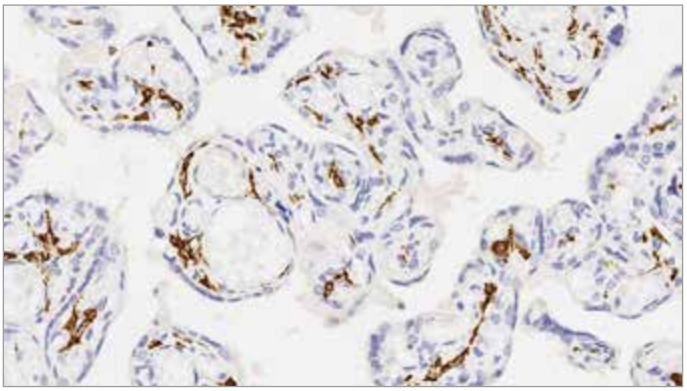
DERMATOPATHOLOGY

ANTIGEN BACKGROUND

CD146 protein is also known as the melanoma metastasis-associated surface molecule, MUC18, A32 antigen, S-Endo-1 and the melanoma cell adhesion molecule, MCAM or Mel-CAM. Originally, the CD146 molecule was defined as a marker of tumor progression and metastasis formation in human melanoma. More recently, it has been reported to be expressed on endothelial cells, smooth muscle and cerebellar cortex. Structurally, CD146 is an integral membrane glycoprotein of 113 kD with the characteristic V-V-C2-C2-C2 immunoglobulin-like domain structure. It shares considerable homology with chicken neural adhesion molecule, chicken gicerin, goldfish neurolin and is also closely related to the human blood group glycoprotein, lutheran. Although CD146 molecule functions as a cell adhesion molecule it interacts with an as yet uncharacterized ligand. CD146 can be induced on all T cells via PHA, recall antigen, superantigen and T cell receptor/CD3 stimulation. Furthermore reports suggest that the CD146 molecule is involved in the extravasation and homing of activated T cells. CD146 protein can promote tumor progression in human melanoma, possibly through enhanced interaction between melanoma cells and endothelial cells. In contrast, CD146 protein may act as a tumor suppressor in breast carcinoma with expression frequently lost in some cases.

CD146 (MCAM) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD163



Human placenta: immunohistochemical staining for CD163. Note cytoplasmic staining of Hofbauer cells. CD163: clone 10D6

10D6

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0090	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD163	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

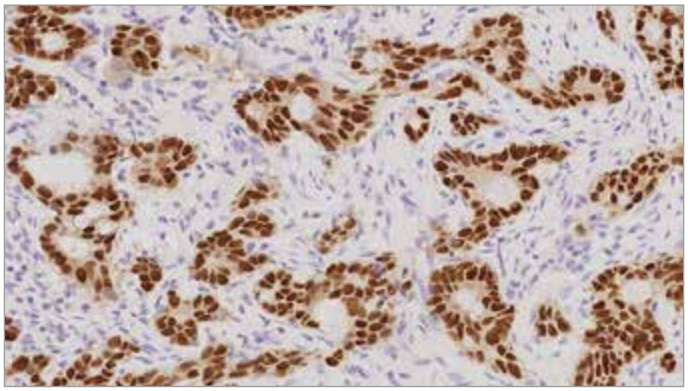
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD163 molecule is a type I membrane protein also known as M130 antigen, Ber-Mac3, Ki-M8 or SM4. CD163 protein is restricted in its expression to the monocytic/macrophage lineage. It is reported to be present on all circulating monocytes and most tissue macrophages except those found in the mantle zone and germinal centers of lymphoid follicles, interdigitating reticulum cells and Langerhans cells. In addition, multi-nucleated cells within inflammatory lesions are reported not to express CD163 protein. The protein is upregulated by glucocorticoids and downregulated by the immunosuppressant cyclosporin A and by phorbol esters, while lipopolysaccharide, an inflammatory mediator, has no influence on expression. It has been proposed that a specific release mechanism of soluble CD163 antigen by human monocytes may play an important role in modulating inflammatory processes.

CD163 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CDX2



Human colonic adenocarcinoma: immunohistochemical staining for CDX2. CDX2: clone EP25

EP25

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0375	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

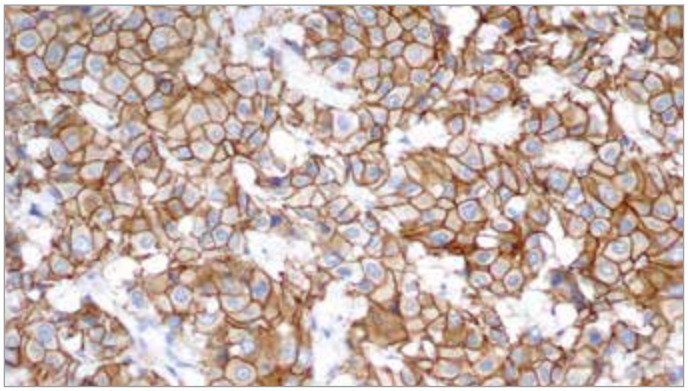
CDX2 is a caudal-type homeobox, intestine-specific transcription factor expressed early in intestinal development and may be involved in the regulation of proliferation and differentiation of intestinal epithelial cells. CDX2, as well as CDX1, is of particular interest as the intestine is the only organ that contains detectable levels of either gene product.

This pattern of restricted expression is unusual for homeobox genes. Phosphorylation of the CDX2 activation domain can modulate its function and different spatial expression patterns in the intestinal epithelium. CDX2 is primarily expressed on the surface of the villus and in the crypts. In contrast to CDX1, intense CDX2 expression is reported to occur in all but the distal portions of the developing intestine.

The loss of CDX2 has been reported to contribute towards the progression of some sporadic colorectal cancers. It has been reported that CDX2 may also be associated with carcinogenesis of the stomach as expression of CDX2 mRNA progressively decreases with the transition from well differentiated to poorly differentiated gastric cancer cell lines.

CDX2 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

c-erbB-2 Oncoprotein (HER-2) Antibodies



Human breast: invasive ductal carcinoma: immunohistochemical staining for c-erbB-2 Oncoprotein (HER-2): clone CB11

CB11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0983	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0571	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CB11	P	-	IVD	IVD

10A7

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CBE-356	P	-	IVD	IVD/RUO

PATHOLOGY MENU

BREAST PATHOLOGY

ANTIGEN BACKGROUND

The c-erbB-2 oncoprotein is closely related in structure to the epidermal growth factor receptor and is a member of a large family of cell surface growth factor receptors. c-erbB-2 oncoprotein is reported to be detectable in a proportion of breast and other adenocarcinomas as well as transitional cell carcinomas. c-erbB-2 oncoprotein is present in a wide variety of cell types in a range of normal human fetal and adult tissues, including breast, stomach and ovary. CB11 detects the internal domain of the c-erbB-2 oncoprotein. CBE-356 detects the external domain of the c-erbB-2 oncoprotein.

c-erbB-2 Oncoprotein (HER-2) Antibodies are recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

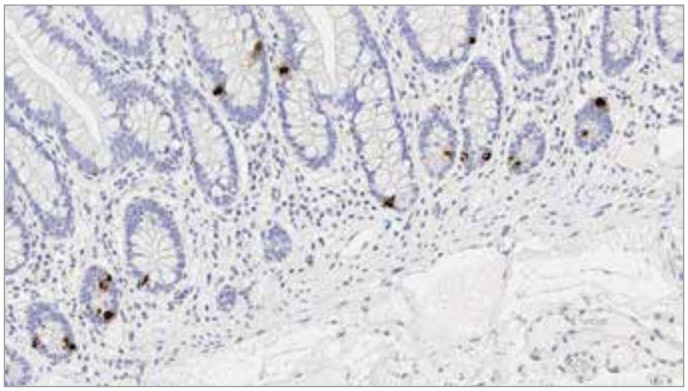
PRODUCT SPECIFIC INFORMATION

The use of the heat induced epitope retrieval (HIER) technique can enhance staining in some cases.

INTENDED USE

This reagent is for in vitro diagnostic use. The c-erbB-2 Oncoprotein (CB11) monoclonal antibody is intended to be used for the qualitative identification by light microscopy of c-erbB-2 oncoprotein in formalin-fixed, paraffin-embedded tissue by immunohistochemical staining.

Chromogranin A



Human small bowel: immunohistochemical staining for Chromogranin A. Note cytoplasmic staining of neuroedocrine cells. Chromogranin A: clone 5H7

5H7

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0515	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CHROM-430	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

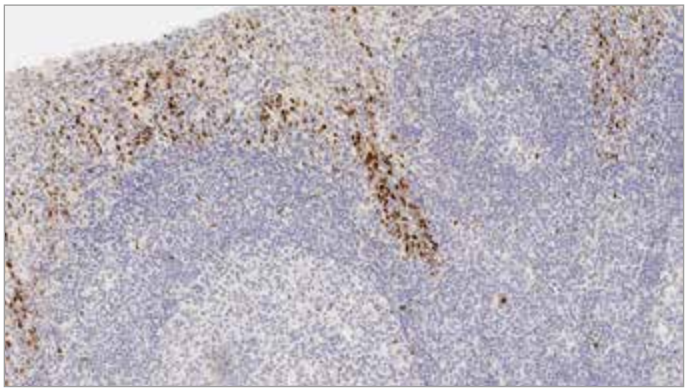
HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

Chromogranin A is a 68 kD acidic protein which is reported to be widely expressed in neural tissues and in secretory granules of human endocrine cells, for example, parathyroid gland, adrenal medulla, anterior pituitary gland, islet cells of the pancreas and C cells of the thyroid. Chromogranin A expression has been reported in neuroendocrine tumors such as pituitary adenomas, islet cell tumors, phaeochromocytomas, medullary thyroid carcinomas, Merkel cell tumors and carcinoids.

Chromogranin A is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Cyclin D1



Human mantle cell lymphoma: immunohistochemical staining for Cyclin D1.
Cyclin D1: clone EP12

EP12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0046	P(HIER)	IVD	IVD	IVD

P2D11F11

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CYCLIND1-GM	P(ENZYME/HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

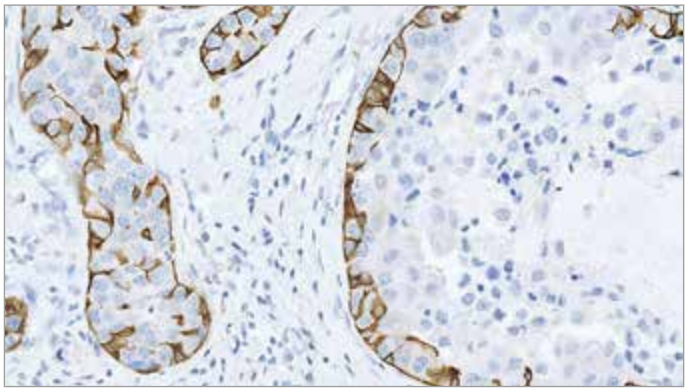
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The D-type cyclins are a family of proteins which function primarily by regulating the activity of cyclin dependent kinases in the G1 phase of the cell cycle. Cyclin D1, a protein of 36 kD, is also known as PRAD1 or bcl-1. Maximum expression of cyclin D1 occurs at a critical point in mid to late G1 phase of the cell cycle. The cyclin D1 gene, located on 11q13 has been reported to be overexpressed in mantle cell lymphomas due to the chromosomal translocation t(11;18).

Cyclin D1 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Cytokeratin 5



Human breast, ductal carcinoma in situ: immunohistochemical staining for Cytokeratin 5.
Cytokeratin 5: clone XM26

XM26

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0468	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CK5	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CK5	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

UROPATHOLOGY

ANTIGEN BACKGROUND

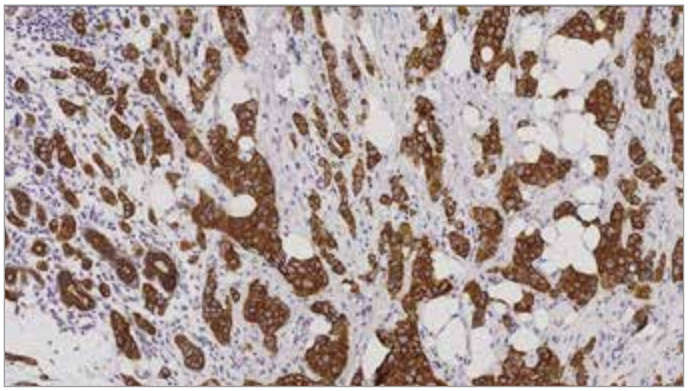
Cytokeratins are a large family of cytoskeletal proteins found in epithelial cells. They are co-ordinately synthesized in pairs so that at least one member of each family is expressed in each epithelial cell. Cytokeratins assemble into obligatory heteropolymers composed of type I (acidic) and type II (basic) polypeptides to form higher order tetramers and protofilaments. Basal cells of human epidermis express acidic keratin 14 and basic cytokeratin 5. Cytokeratin 5 is a 58 kD protein that is closely related to cytokeratin 6. They share similar tissue distribution and are found in various proportions in many non-keratinizing stratified squamous epithelia, for example, tongue mucosa, as well as in basal epithelia of trachea, basal cells of epidermis, hair follicles, sebaceous and sweat glands of skin, luminal cells of the mammary gland, basal cells of prostate, urothelium, vagina and endocervical mucosa. Cytokeratins 5 and 6 are also expressed in basal cell epitheliomas, squamous cell carcinomas of skin, tongue, epiglottis and of the rectal-anal region. Point mutations in the cytokeratin 5 gene at locus 12q11-q13 can cause various types of epidermolysis bullosa simplex. Cytokeratin 5 is also reported to be expressed in most epithelial and biphasic mesotheliomas.

Cytokeratin 5 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone XM26 is specific for the 58 kD intermediate filament protein known as cytokeratin 5. It is not cross-reactive with cytokeratin 6.

Cytokeratin 7



Invasive breast carcinoma: immunohistochemical staining for Cytokeratin 7.
Cytokeratin 7: clone RN7

RN7

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0942	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0138	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CK7-560	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

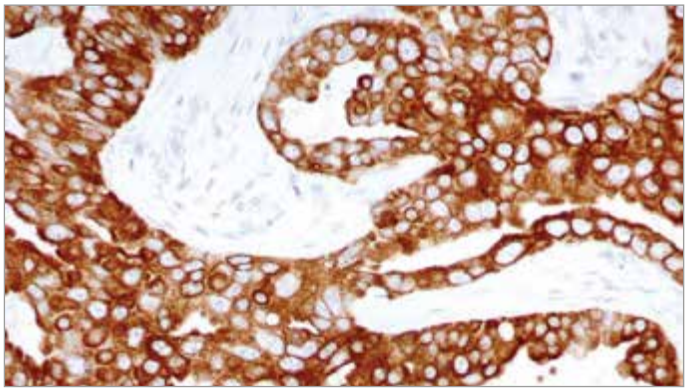
Cytokeratins are intermediate filament proteins present in epithelial cells. They are expressed in a tissue-specific manner in normal organs and the tumors that arise from them. Cytokeratin 7 belongs to the neutral basic type B subfamily of cytokeratins. Its distribution is confined to glandular and transitional epithelia. Cytokeratin 7 is reported to be expressed in abundance in cultured bronchial and mesothelial cells but only at lower levels in cultured epidermal cells. The predicted amino acid sequence of this keratin has revealed a striking difference between this keratin and the type II keratins expressed in epidermal cells. Cytokeratin 7 has been reported in adenocarcinomas of the lung, breast, endometrium, ovary, thyroid as well as in carcinomas of the bladder and chromophobe renal cell carcinoma. Cytokeratin 7 and Cytokeratin 20 expression have been reported to show characteristic patterns on primary and metastatic lung and colorectal adenocarcinomas.

Cytokeratin 7 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Where clone OV-TL 12/30 can produce unwanted staining of endothelial cells, clone RN7 does not stain these cell types. The choice of epitope retrieval, heat or enzyme, to provide the best result with clone OV-TL 12/30 should be determined and validated by the user. Clones RN7 and OV-TL 12/30 react with the human cytokeratin intermediate filament protein (54 kD) identified as cytokeratin 7.

Cytokeratin 8



Immunohistochemical staining for Cytokeratin 8: clone TS1

TS1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0567	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CK8-TS1	-	ASR	RUO	RUO

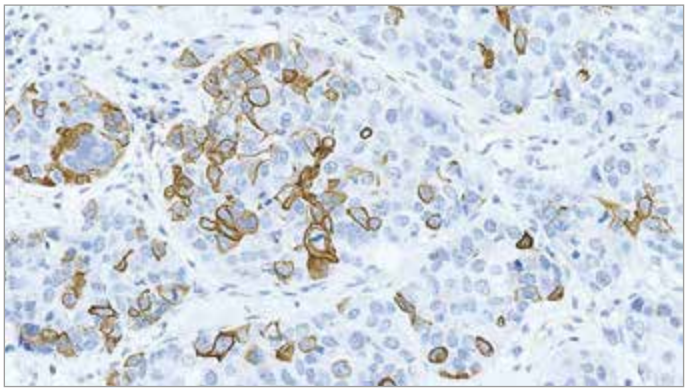
PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANALYTE SPECIFIC REAGENT

Analyte Specific Reagent. Analytical and performance characteristics are not established.

Cytokeratin 14



Invasive breast cancer: immunohistochemical staining for the Cytokeratin 14. Cytokeratin 14: clone LL002

LL002

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0074	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-LL002	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-LL002	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

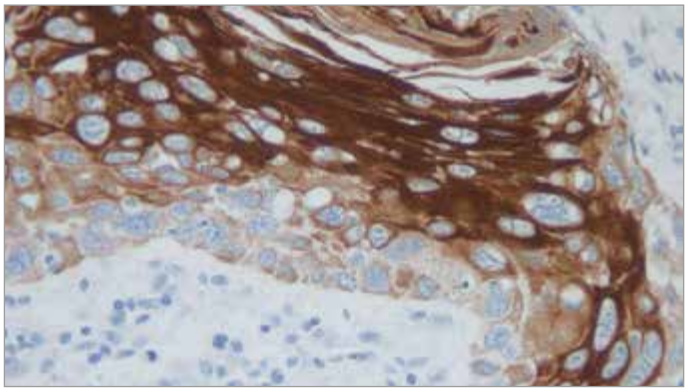
Cytokeratins 14 and 5 are useful to distinguish stratified epithelial cell types from simple epithelial cell types. Cytokeratin 14 has been reported to be expressed in neoplasms of squamous cell origin.

Cytokeratin 14 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone LL002 reacts with the human cytokeratin intermediate filament protein (50 kD) identified as cytokeratin 14.

Cytokeratin 17



Human squamous cell carcinoma, floor of the mouth: immunohistochemical staining for Cytokeratin 17. Cytokeratin 17: clone E3

E3

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0114	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CK17	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

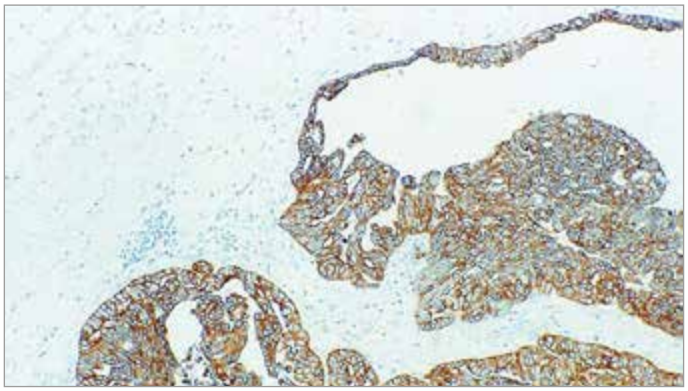
In normal tissues cytokeratin 17 is reported to be expressed in basal cells of complex epithelia, for example, basal cells of pseudostratified epithelium in the trachea, larynx, bronchi, myoepithelial cells in salivary glands and sweat glands. In neoplastic tissue, cytokeratin 17 is reported to be expressed in squamous cell carcinomas of the lung, cervix and oral cavity.

Cytokeratin 17 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

CK17 reacts with the human cytokeratin intermediate filament protein (46 kD) identified as cytokeratin 17.

Cytokeratin 18



Human colonic adenocarcinoma: immunohistochemical staining for Cytokeratin 18. Cytokeratin 18: clone DC-10

DC-10

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CK18	P(HIER)	IVD	-	-

PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

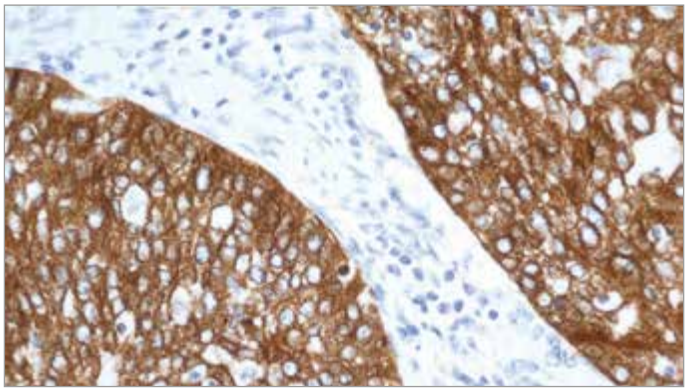
Cytokeratin 18 is normally co-expressed with cytokeratin 8 and is found in most simple ductal and glandular epithelia.

Cytokeratin 18 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

CK18 reacts with the acidic cytokeratin intermediate filament protein (45 kD) identified as cytokeratin 18. Cytokeratin 18 is reported not to be expressed in stratified squamous epithelium on most squamous cell carcinomas.

Cytokeratin 19



Human rectal adenocarcinoma: immunohistochemical staining for Cytokeratin 19. Cytokeratin 19: clone b170

b170

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0799	P(ENZYME)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CK19	P(HIER)	IVD	-	-

PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

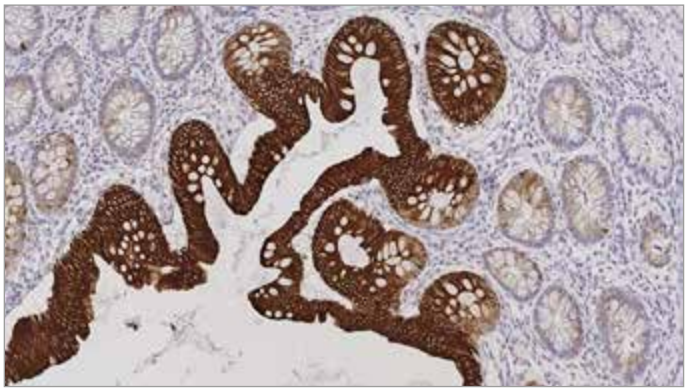
The smallest human cytokeratin filament protein (40 kD) has been identified as cytokeratin 19 and has been reported to be expressed in a large number of epithelial cell types, including many ductal and glandular epithelia.

Cytokeratin 19 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone b170 produces a complex heterogeneous staining pattern in non-keratinizing squamous epithelia and hair follicles, with strong staining of the basal layer observed.

Cytokeratin 20



Human colon: immunohistochemical staining for Cytokeratin 20. Note the intense staining of surface mucosa. Cytokeratin 20: clone Ks.20.8

Ks20.8

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0022	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0037	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CK20	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CK20	P(HIER)	IVD	IVD	IVD/RUO

PW31

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CK20-561	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

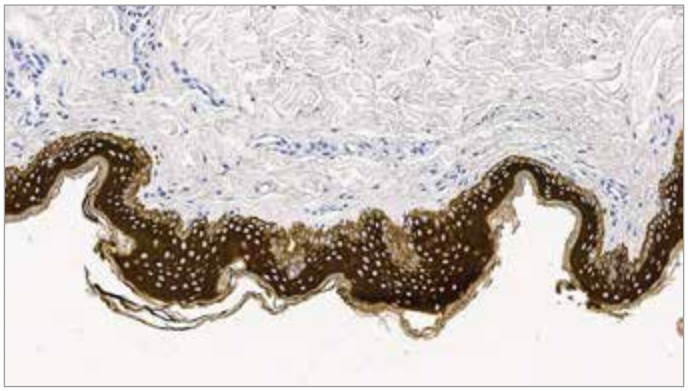
TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

Cytokeratin 20 has been demonstrated to be almost entirely confined to the gastric and intestinal epithelium, urothelium and Merkel cells of the skin. Cytokeratin 20 is less acidic than other type I cytokeratins and is of interest due to its restricted tissue expression. In normal tissue, cytokeratin 20 is expressed in intestinal epithelium, gastric foveolar epithelium, a number of endocrine cells in the upper portions of the pyloric glands, urothelium and Merkel cells in epidermis. In tumors it is reported, there is a marked difference in the expression of cytokeratin 20 within different carcinomas. Neoplasms expressing cytokeratin 20 are derived from normal epithelia which themselves expressed cytokeratin 20. Colorectal carcinomas consistently express cytokeratin 20, while gastric adenocarcinomas express cytokeratin 20 to a lesser degree. Adenocarcinomas of the gall bladder and bile duct, ductal cell adenocarcinomas of the pancreas, mucinous ovarian tumors, Merkel cell tumors and transitional cell carcinomas have also been reported to express cytokeratin 20.

Cytokeratin 20 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Cytokeratin (5/6/18)



Human skin: immunohistochemical staining of LP34 (cytokeratins 5/6/18) localized throughout the epidermis, with the strongest staining in the stratum spinosum. There is an absence of staining in the dermis. Cytokeratin (5/6/18): clone LP34

LP34

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-LP34	P(ENZYME)	IVD	RUO	RUO

PATHOLOGY MENU

UROPATHOLOGY

ANTIGEN BACKGROUND

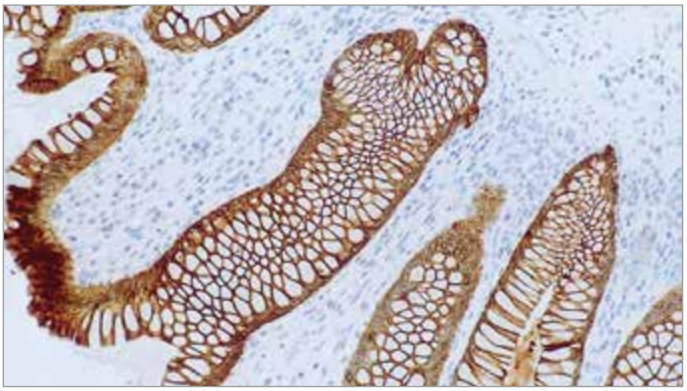
Cytokeratins 5, 6 and 18 are reported to be expressed in a broad range of human epithelial tissues, from simple glandular epithelia to stratified squamous epithelia. These include epithelial cells that are ectodermal, mesodermal, or endodermal in origin. These cytokeratins have been reported to be expressed in tumor cells of epithelial origin and less commonly of mesothelial origin. Non-epithelial tumors such as lymphomas do not express these cytokeratins.

Cytokeratin (5/6/18) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The recognition of cytokeratin 18 on formalin fixed paraffin embedded sections using clone LP34 may be variable.

Cytokeratin (8/18)



Colon mucosa: immunohistochemical staining for Cytokeratin 8/18: clone 5D3

5D3

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0067	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-5D3	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

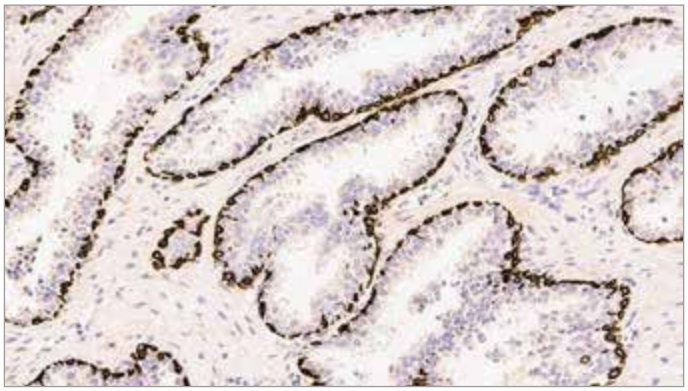
In normal tissues, cytokeratins 8 and 18 are reported to be expressed in all simple and glandular epithelium and in neoplastic tissues, they have been reported to be expressed in adenocarcinomas and most squamous cell carcinomas. These cytokeratins are absent from keratinizing squamous carcinomas.

Cytokeratin (8/18) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone 5D3 reacts with human cytokeratin intermediate filament proteins of 52.5 kD and 45 kD, identified as cytokeratins 8 and 18, respectively. Clone 5D3 shares similar specificities to clone CAM5.2 (Angus B et al. Journal of Pathology. 153: 377-384 (1987)).

Cytokeratin, Multi (1/5/10/14) (High Molecular Weight)



Human prostate: immunohistochemical staining of the basal cells of the prostate with anti-cytokeratin (high molecular weight) antibody. Cytokeratin, Multi (1/5/10/14): clone 34βE12

34βE12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0134	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

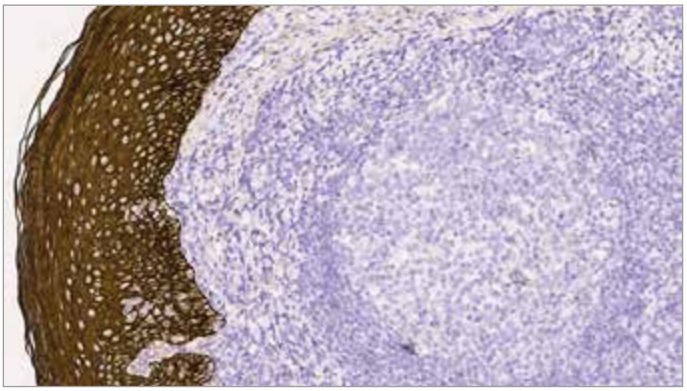
TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

34βE12 reacts with human cytokeratin intermediate filament proteins 1, 5, 10 and 14. The antibody is reported to react with squamous epithelium and sweat ducts in normal skin, some pneumocytes, bronchial epithelium and mesothelium in normal lung and bile ducts in normal liver. It also reacts with ductal cells of the normal pancreas, some acinar and ductal cells of normal breast, some follicular epithelia of normal thyroid and some epithelia and mesothelium of the normal small and large bowel.

Cytokeratin, Multi (1/5/10/14) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Cytokeratin, Multi (4/5/6/8/10/13/18)



Human tonsil: immunohistochemical staining for cytokeratin, Multi. Note the cytokeratins demonstrated in stratified squamous epithelium. The negative cells in the epithelium are infiltrating lymphocytes. Cytokeratin, Multi (4/5/6/8/10/13/18): clone C-11

C-11

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-C11	P(HIER)	IVD	-	-

PATHOLOGY MENU

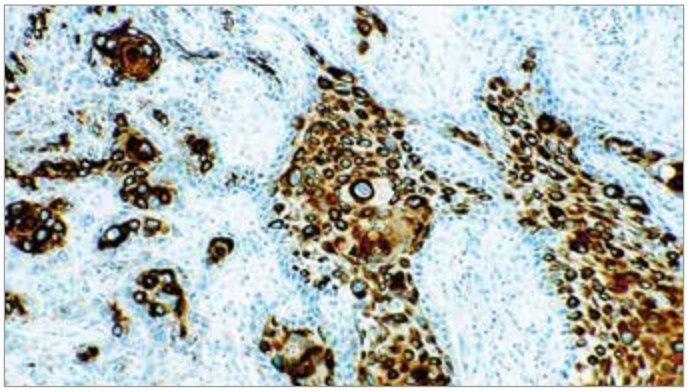
TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

Cytokeratins 4, 5, 6, 8, 10, 13 and 18 are differentially expressed between a variety of normal, reactive and neoplastic epithelia and also simple epithelium and both basal and suprabasal layers of cornifying and noncornifying squamous epithelium.

Cytokeratin, Multi (4/5/6/8/10/13/18) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Cytokeratin, Multi (5/6/8/18)



Human squamous cell carcinoma of the floor of the mouth: immunohistochemical staining for cytokeratins. Cytokeratin, Multi (5/6/8/18): clone 5D3/LP34

5D3/LP34

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CK5/6/8/18	P(ENZYME)	RUO	RUO	RUO

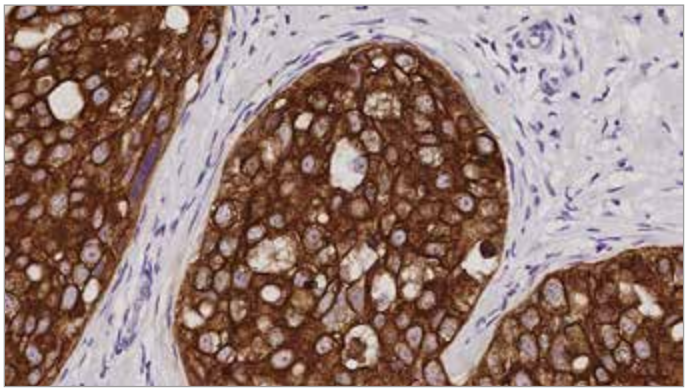
PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

CK5/6/8/18 reacts with human cytokeratins 5, 6, 8 and 18. These products are cocktails of monoclonal antibodies designed to recognize cytokeratins reported to be expressed in almost all epithelial tissues.

Cytokeratin, Multi (AE1/AE3)



Human invasive ductal carcinoma of breast: immunohistochemical staining for AE1/AE3. Multi-Cytokeratin: clone AE1/AE3

AE1/AE3

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0094	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-AE1/AE3-601	P(HIER)	IVD	IVD	IVD

AE1/AE3 (Previous Formulation)

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0909	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

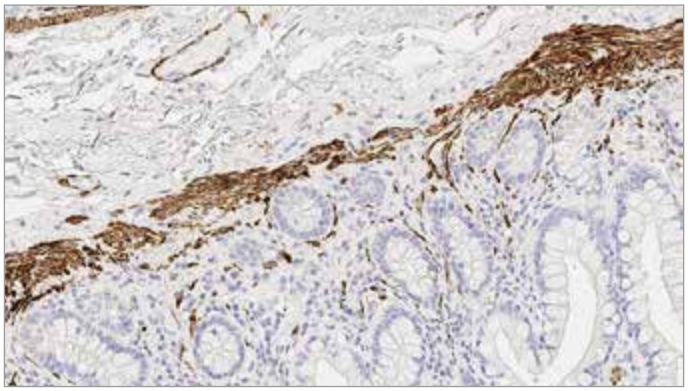
Keratins are a family of water insoluble proteins of 40 to 70 kD. These proteins form tonofilaments, a class of intermediate filament, in epidermis as well as in almost all other epithelia. The process of normal epidermal differentiation is characterized by a series of morphological and biochemical changes as cells progress from the germinative basal layer through the spinous and granular layers to the outer cornified layer. The 65 to 67 kD cytokeratins are reported to be present only above the basal layer, the 58 kD cytokeratin is reported to be expressed throughout the entire epidermis including the basal layer and the 56 kD cytokeratin is reported to be absent from the basal layer and is normally eliminated during stratum corneum formation. The 56 and 65 to 67 kD cytokeratins are reported to be characteristic of epidermal cells undergoing terminal differentiation and may be considered as molecular markers for keratinization.

Cytokeratin, Multi (AE1/AE3) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clones AE1 and AE3 are specific for the 56.5, 50, 50', 48 and 40 kD acidic cytokeratins as well as the 65 to 67, 64, 59, 58, 56 and 52 kD basic cytokeratins. The cocktail of clones AE1 and AE3 exhibit broad reactivity with two families of cytokeratin, acidic and basic.

Desmin



Human bowel: immunohistochemical staining for desmin. Note cytoplasmic staining of smooth muscle containing cells. Desmin: clone DE-R-11

DE-R-11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0032	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-DES-DERII	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

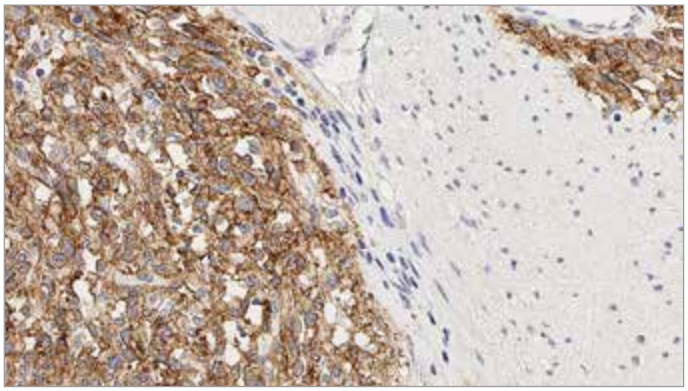
SOFT TISSUE PATHOLOGY

ANTIGEN BACKGROUND

DES-DERII reacts with an 18 kD rod piece of the intermediate filament protein desmin (53 kD) in muscle cells. The antibody does not appear to recognize other intermediate filament proteins. In normal tissues, Clone DE-R-11 reacts with both striated (skeletal and cardiac) and smooth muscle cells. The labeling is confined to the Z bands in skeletal and cardiac muscle giving a characteristic striated appearance.

Desmin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

DOG-1



Human colon, gastrointestinal stromal tumor: immunohistochemical staining for DOG-1. DOG-1: clone K9

K9

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0219	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-DOG-1	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

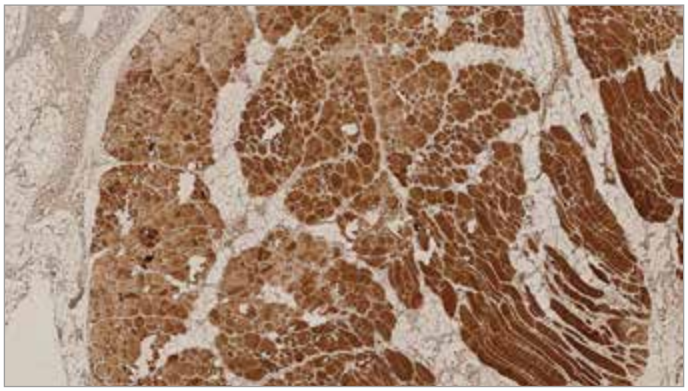
DOG-1, a 986 amino acid protein of unknown function, is expressed predominantly on the plasma membrane of gastrointestinal stromal tumors (GISTs) and is rarely expressed in other soft tissue tumors, which, due to appearance, can be confused with GISTs. Reactivity for DOG-1 has been suggested to aid in the identification of GISTs, including Platelet-Derived Growth Factor Receptor Alpha mutants that fail to express KIT antigen.

DOG-1 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of PBS-based diluents may result in increased background staining.

Dysferlin Antibodies



Human skeletal muscle: immunohistochemical staining of HAMLET: HAMLET: clone Ham1/7B6

Ham1/7B6

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-HAMLET	F;P(HIER)	IVD	IVD	IVD

Ham3/17B2

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-HAMLET-2	F;P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

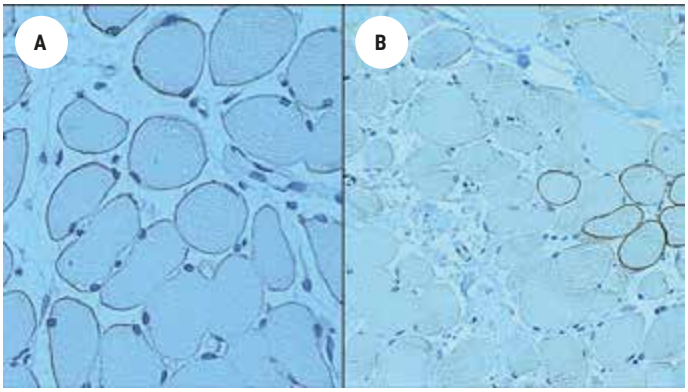
Dysferlin is the protein product of the 2p13 gene that is defective in patients with Limb-Girdle Muscular Dystrophy type 2B (LGMD2B) and Miyoshi Myopathy (MM). Dysferlin is normally localized to the muscle plasma membrane. In patients with LGMD2B and MM, immunoreactivity to dysferlin is severely reduced or lost. Patients with other neuromuscular conditions demonstrate normal labeling patterns.

Dysferlin Antibodies are recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of the heat induced epitope retrieval (HIER) technique can enhance staining in some cases.

Dystrophin Antibodies



Human skeletal muscle: immunohistochemical staining for Dystrophin. Note membrane staining of normal muscle fibers (A) and reduced and variable staining of revertant muscle fibers (B). Dystrophin: clone 13H6

DYSA (Rod Domain): clone 13H6

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-DYSA	P(HIER)	RUO	RUO	RUO

DYSB (N-terminus): clone 34C5

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-DYSB	P(HIER)	RUO	RUO	RUO

DYS1 (Rod Domain): clone Dy4/6D3

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 2.5 mL	NCL-DYS1	F	IVD	IVD	IVD

DYS2 (C-terminus) : clone Dy8/6C5

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 2.5 mL	NCL-DYS2	F	IVD	IVD	IVD

DYS3 (N-terminus) : clone Dy10/12B2

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 2.5 mL	NCL-DYS3	F	IVD	IVD	IVD

PATHOLOGY MENU

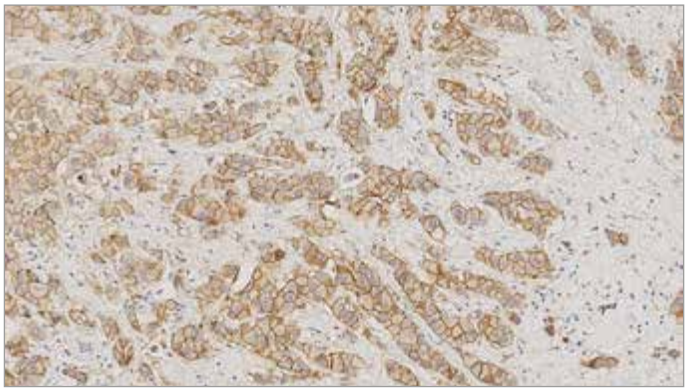
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Duchenne Muscular dystrophy (DMD) is the most common of the muscular dystrophies resulting in progressive muscular wasting and death. Dystrophin is the 427kD protein product of the DMD gene located on the X chromosome at position Xp21. Abnormalities in protein expression occur in patients with DMD/BMD and dystrophin analysis may be used to distinguish these conditions from other neuromuscular diseases. Severe Duchenne muscular dystrophy is associated with a marked dystrophin deficiency, whereas patients with the milder form of Becker muscular dystrophy show less pronounced abnormalities of protein expression. The immunolabeling patterns for DYS1, DYS2 and DYS3 are similar; however, the use of all three antibodies is recommended to avoid the possibility of occasional false negative results.

Dystrophin Antibodies are recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

E-Cadherin



Invasive breast carcinoma: immunohistochemical staining for E-Cadherin.
E-Cadherin: clone 36B5

36B5

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0387	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-E-Cad	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

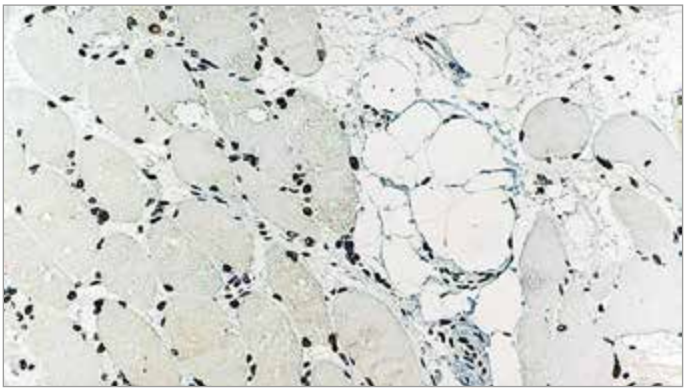
BREAST PATHOLOGY

ANTIGEN BACKGROUND

E-cadherin is a Ca^{2+}-dependent, transmembrane cell adhesion molecule. It plays an important role in the growth, development and the intercellular adhesion of epithelial cells. Most tumors have an abnormal architecture and any subsequent loss of adhesiveness is thought to be an important step in the development of local invasion. E-cadherin may have a role in neoplastic progression, particularly as a suppressor of invasion. In prostate cancers, for example, the expression of E-cadherin is reported to be reduced or absent in comparison with its expression in normal prostate which is uniformly strong. Reduced expression or absence of E-cadherin in addition to alpha, beta and gamma-catenin in primary breast carcinomas has also been reported and these four proteins are associated with the development of metastases.

E-Cadherin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Emerin



Human skeletal muscle: immunohistochemical staining for Emerin. Note perinuclear staining of all cell nuclei. Emerin: clone 4G5

4G5

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-EMERIN	F;P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

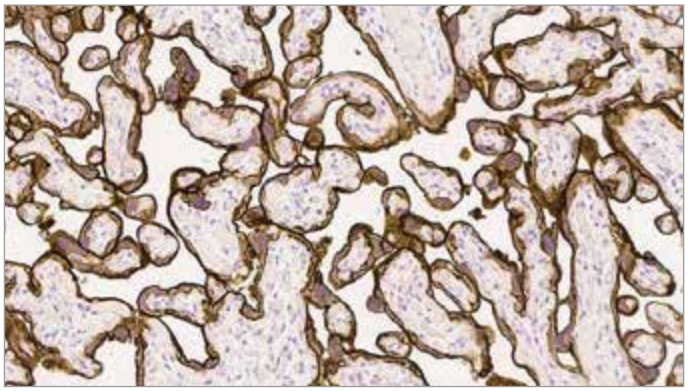
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Emery-Dreifuss muscular dystrophy (EDMD) is a late onset, X-linked, recessive disorder characterized by slowly progressing contractures, wasting of skeletal muscle and cardiomyopathy usually presented as heart block. Contractures are seen in the elbows, Achilles tendons and post cervical muscles with humero-peroneal distribution early in the course of the disease. The STA gene, at Xq28 locus, encodes a serine-rich 34kD protein, emerin, which is ubiquitous in tissues and is found in highest concentration in skeletal and cardiac muscle. Emerin is localized in the nuclear membrane of normal muscle cells and its deficiency plays a crucial part in the pathology of EDMD.

Emerin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Epidermal Growth Factor Receptor



Human Placenta: immunohistochemical staining for Epidermal Growth Factor Receptor. Epidermal Growth Factor Receptor: clone EGFR.113

EGFR.113

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-EGFR	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

LUNG PATHOLOGY

ANTIGEN BACKGROUND

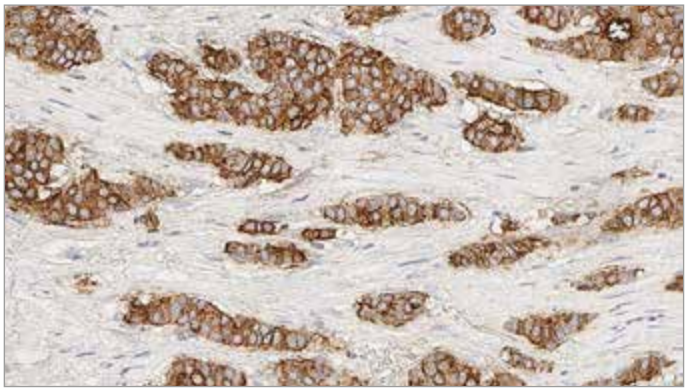
Epidermal growth factor receptor (EGFR) is a transmembrane protein receptor of 170 kD with tyrosine kinase activity. Increased levels of EGFR are reported to be linked with malignant transformation of squamous cells, for example, in squamous cell carcinoma of the lung, head, neck, skin, cervix and esophagus. EGFR may also play a role in the development and progression of hepatocellular carcinomas where recurrence rates are higher in EGFR-positive cases. This correlation has similarly been reported in colorectal cancers where EGFR, produced by tumor cells, plays an important role in the invasiveness and proliferation of colorectal cancers. The majority of published studies of EGFR expression in human breast cancer has similarly shown an association with EGFR expression where it is inversely related to estrogen receptor status.

Epidermal Growth Factor Receptor is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone EGFR.113 is raised to the extracellular domain of the EGFR molecule.

Epithelial Membrane Antigen



Human breast cancer: immunohistochemical staining for Epithelial Membrane Antigen. Epithelial Membrane Antigen: clone GP1.4

GP1.4

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0035	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-EMA	P	IVD	IVD	IVD/RUO

PATHOLOGY MENU

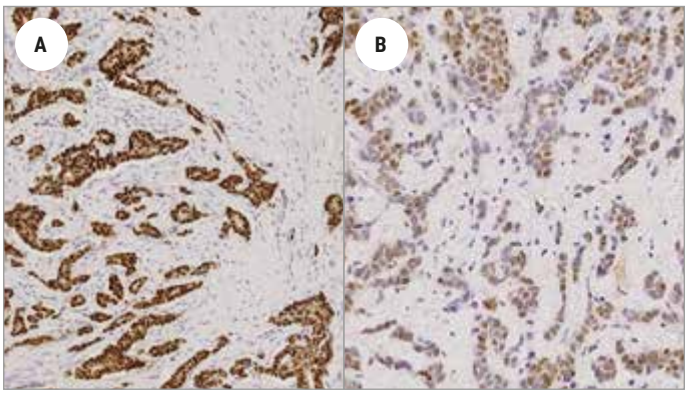
TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

Epithelial membrane antigen (EMA), also known as episialin, is reported to be expressed in a variety of normal and neoplastic epithelia. It has been reported that markers to CD45 (LCA) when used in conjunction with markers to EMA are useful in labeling cells of lymphoid origin, whereas the combination of anti-cytokeratin antibodies together with EMA is useful to characterize cells of epithelial origin. EMA is also notably described to be expressed in a subset of Hodgkin's lymphomas.

Epithelial Membrane Antigen is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Estrogen Receptor



Left: Invasive ductal carcinoma (high expressor): intense nuclear staining in nearly 100% of tumor cells. Right: Invasive ductal carcinoma (moderate expressor): immunohistochemical staining for estrogen receptor. Estrogen Receptor: clone 6F11

6F11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0151	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0009	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-ER-6F11	P(HIER)	IVD	IVD	IVD
Liquid 2 mL	NCL-L-ER-6F11/2	P(HIER)	-	IVD	IVD

PATHOLOGY MENU

BREAST PATHOLOGY

ANTIGEN BACKGROUND

Estrogen receptor (ER) content of breast cancer tissue is an important parameter in the prediction of prognosis and response to endocrine therapy. The introduction of highly specific monoclonal antibodies to ER has allowed the determination of receptor status of breast tumors to be carried out in routine histopathology laboratories.

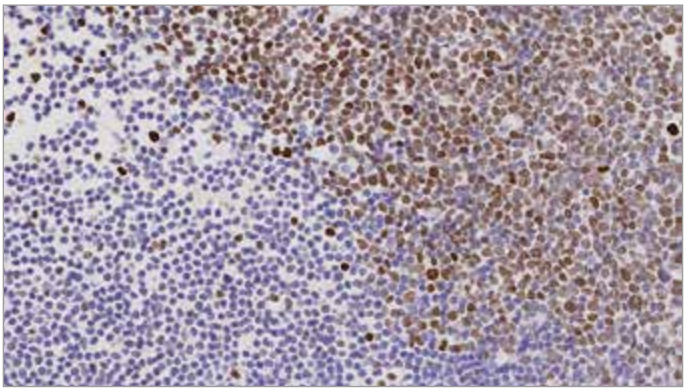
Estrogen Receptor is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone 6F11 is raised to the full length alpha form of the estrogen receptor molecule.

Refer to the IFU for appropriate use instructions.

EZH2 (Enhancer of Zeste Homolog 2 (Drosophila))



T-Cell Lymphoma: immunohistochemical staining for EZH2 antigen. EZH2 (Enhancer of Zeste Homolog 2 (Drosophila)): clone 6A10

6A10

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0575	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-EZH2	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

SPECIALIZED

ANTIGEN BACKGROUND

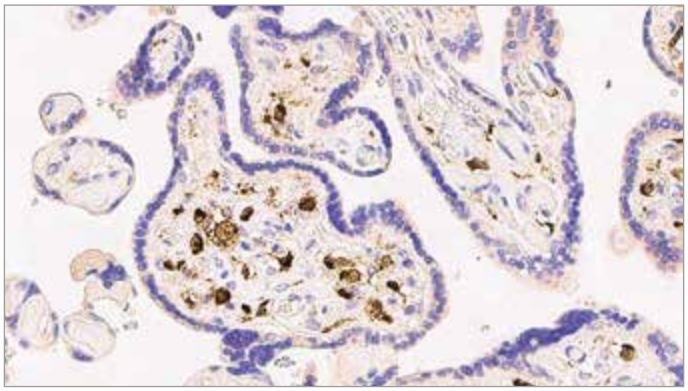
Polycomb-group proteins (PcG) such as EZH2 (Enhancer of Zeste Homolog 2 (Drosophila)) form multimeric gene repressing complexes involved in axial patterning, hematopoiesis and cell cycle regulation. PcG proteins ensure correct embryonic development by expressing homeobox genes as well as contributing to the regulation of lymphopoiesis.

EZH2 (Enhancer of Zeste Homolog 2 (Drosophila)) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

EZH2 stains optimally when used in TBS-based wash buffer and diluent systems.

Factor XIIIa (Blood Coagulation Factor XIIIa)



Human placenta: immunohistochemical staining of Factor XIIIa localized in the Hofbauer cells of the placental villi. Factor XIIIa (Blood Coagulation Factor XIIIa): clone E980.1

E980.1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0449	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-FXIIIa	P(HIER)	IVD	-	-

PATHOLOGY MENU

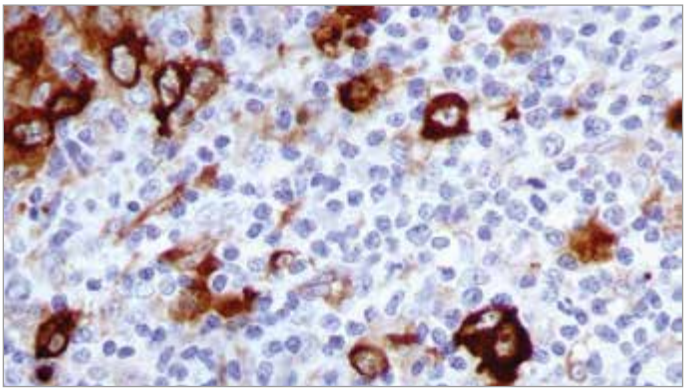
SPECIALIZED

ANTIGEN BACKGROUND

Factor XIIIa, also known as fibrinoligase and fibrin-stabilizing factor, is the last enzyme generated in the blood coagulation cascade. It is a Ca^{2+}-dependent transglutaminase or transamidating enzyme which forms intermolecular gamma-glutamyl-epsilon-lysine crosslinks between fibrin molecules resulting in the mechanical stabilization of the fibrin clot and its resistance to proteolysis. Factor XIIIa may also function to stabilize cell surface molecules and membranes. Ca^{2+}-dependent trans-glutaminases with thiol active centers are widespread in animal tissues and have been associated with cell proliferation, embryonic development and growth through the proliferation of mammary stroma and epithelial elements. Normal mammary stroma, like most collagenous connective tissue contains resident populations of CD34 positive dendritic interstitial cells and scattered Factor XIIIa positive collagen-associated dendrophages. Factor XIIIa has been examined to determine its expression in normal and inflamed skin. Factor XIIIa positive cells in human skin represent a specific population of bone marrow dermal dendritic cells, distinct from Langerhans cells which share some features common to mononuclear phagocytes. In benign skin conditions such as inflammatory dermatoses, for example, atopic eczema and psoriasis, an increased number of factor XIIIa positive cells in the upper dermis, closely associated with lymphocytes, has been described.

Factor XIIIa (Blood Coagulation Factor XIIIa) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Fascin



Hodgkin's lymphoma: immunohistochemical staining with Fascin: clone IM20

IM20

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0420	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-FASCIN	P(HIER); W	RUO	RUO	RUO

PATHOLOGY MENU

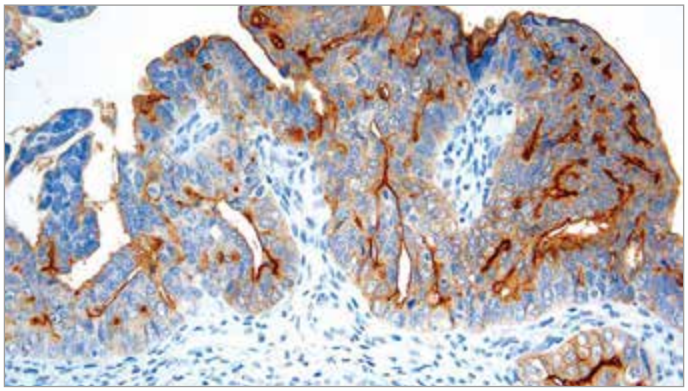
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Human fascin is a 55 to 58 kD actin-bundling protein, whose actin binding ability is regulated by phosphorylation. In normal tissues the detection of fascin is reported to be predominantly restricted to dendritic cells, and in the thymus has been observed only in medullary dendritic cells. In reactive nodes, interdigitating reticulum cells of T cell zones, cells in subcapsular areas, and cells of the reticular network express fascin. Variable expression is seen in follicular dendritic cells and endothelial cells. Lymphoid cells, myeloid cells and plasma cells do not express fascin; however, in cases of Hodgkin's disease, including nodular sclerosis, mixed cellularity lymphocyte depletion and unclassified cases, most or all Reed Sternberg cells are reported to be positive for fascin. Fascin expression may be induced by Epstein-Barr virus (EBV) infection of B cells with the possibility that viral induction of fascin in lymphoid or other cell types must also be considered in EBV-positive cases.

Fascin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Folate Receptor Alpha



Ovarian tumor: immunohistochemical staining for Folate Receptor Alpha.
Folate Receptor Alpha: clone BN3.2

BN3.2

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-FRalpha	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

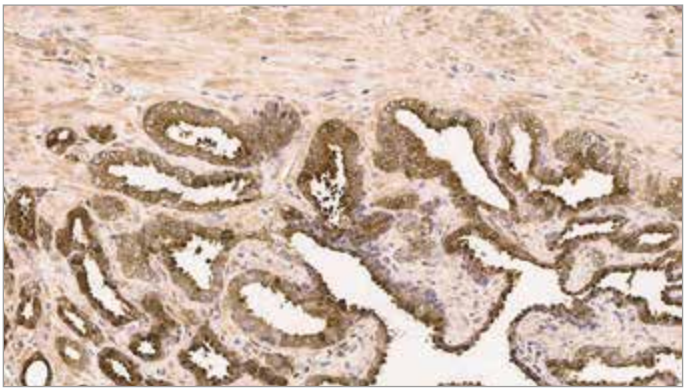
SPECIALIZED

ANTIGEN BACKGROUND

Folate is a basic component of cell metabolism and DNA synthesis and repair. It is involved in essential one-carbon transfer reactions and is a vitamin required by both normal and tumor cells. Folate entry into cells is facilitated via two different systems: the reduced folate carrier, which utilizes a bidirectional anion-exchange mechanism, and the folate receptor system. Folate receptor alpha is a membrane-bound member of the folate receptor family, facilitating folate transport via a mechanism termed potocytosis where the receptor is internalized and then recycled back to the cell membrane. Staining patterns are both membranous and cytoplasmic due to this mechanism. Members of the folate receptor family share highly conserved sequences in the open reading frames, but differ in amino acids in the 5' untranslated regions and as a consequence can differ in function and tissue expression. Folate receptor alpha expression is reported to be highly restricted in normal tissues and only selectively overexpressed in a limited number of epithelial malignancies.

Folate Receptor Alpha is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Galectin-3



Prostate carcinoma: immunohistochemical staining of Galectin-3. Galectin-3: clone 9C4

9C4

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0238	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

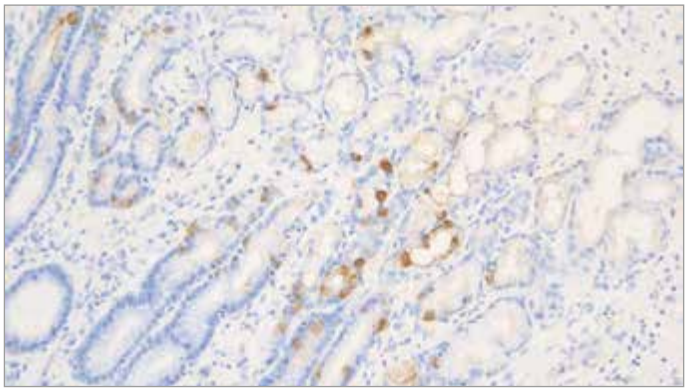
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Galectin-3 is a member of the beta-galactosidase-binding lectin family. It is involved in several biological events including binding to the basement membrane glycoprotein laminin. Cell surface galectin-3 may be involved in homotypical cell adhesion and is downregulated in colon cancer as the disease progresses. This downregulation has also been examined in breast carcinoma with a similar correlation of expression reported. Downregulation of galectin-3 could be one of the many events that enable cancer cells to interact with laminin to facilitate invasion and metastasis and may indicate activation of the invasive phenotype in various tumor types.

Galectin-3 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Gastrin



Normal human stomach: immunohistochemical staining for Gastrin. Note: intense cytoplasmic staining of neuroendocrine cells. Gastrin: Polyclonal

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0681	P	IVD	IVD	IVD

PATHOLOGY MENU

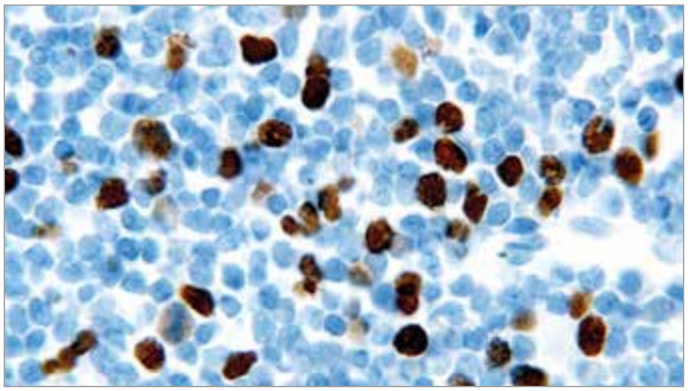
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Gastrin, a polypeptide hormone, occurs naturally in three forms: gastrin-14, gastrin-17 and gastrin-34. Both primary and secondary G cell hyperplasia are reported to be characterized by clustering of the immunoreactive cells which sometimes project buds from the mucous glands.

Gastrin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Geminin



Human chronic lymphocytic leukemia: immunohistochemical staining for Geminin. Geminin: clone EM6

EM6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-Geminin	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

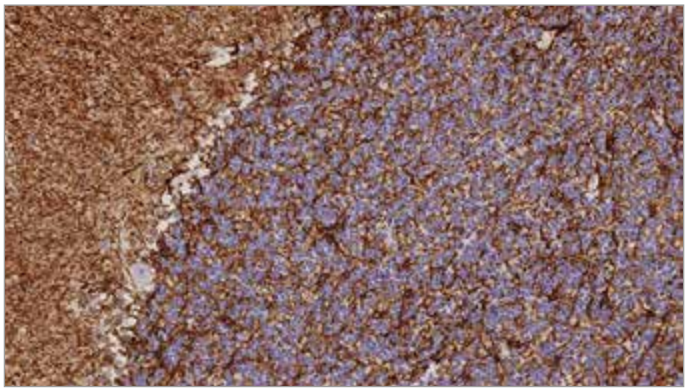
SPECIALIZED

ANTIGEN BACKGROUND

Geminin is a protein of 209 amino acids thought to be involved in the control of DNA replication via the interaction with Cdt1. Geminin is not found in the G1 phase of the cell cycle, but is first expressed in the G1 to S transition phase, with expression levels rising through the rest of the cell cycle and levels reaching a maximum during mitosis. It has been proposed that geminin may be a tumor suppressor protein. Geminin is reported to be expressed in proliferating lymphocytes and epithelial cells, for example, germinal centers in tonsil as well as in colon, spermatocytes, seminiferous tubules of the testes, within the basal layers of the squamous epithelium of the skin and breast. Geminin is reported to be upregulated in cancers such as non-Hodgkin's lymphoma, B cell lymphoma, breast carcinoma and colon carcinoma.

Geminin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Glial Fibrillary Acidic Protein



Normal brain: immunohistochemical staining for Glial Fibrillary Acidic Protein.
Glial Fibrillary Acidic Protein: clone GA5

GA5

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0026	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-GFAP-GA5	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

NEUROPATHOLOGY

ANTIGEN BACKGROUND

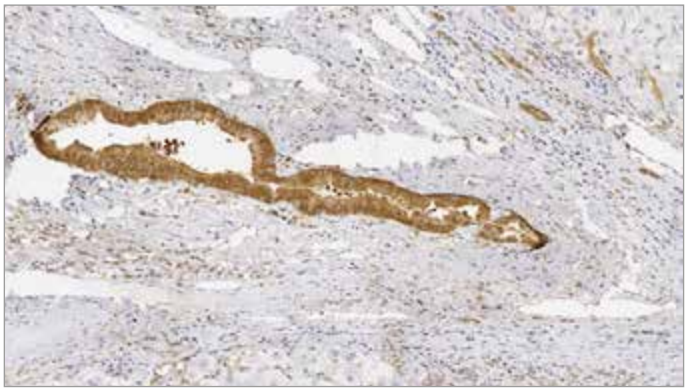
Glial fibrillary acidic protein (GFAP) is an intermediate filament protein of 52kD reported to be expressed in glial cells, for example, astrocytes and ependymal cells. In the peripheral nervous system, GFAP has been reported to be expressed in Schwann cells, enteric glial cells and satellite cells of human sensory ganglia and in neoplastic tissues GFAP has been reported to be expressed in astrocytomas and ependymomas.

Glial Fibrillary Acidic Protein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of the heat induced epitope retrieval (HIER) technique can enhance staining in some cases.

Glutathione S-Transferase (GST) Antibody



Human liver: immunohistochemical staining for GSTpi. Note staining of bile ducts.
Glutathione S-transferase pi: clone LW29

LW29

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-GSTpi-438	P	IVD	-	-

PATHOLOGY MENU

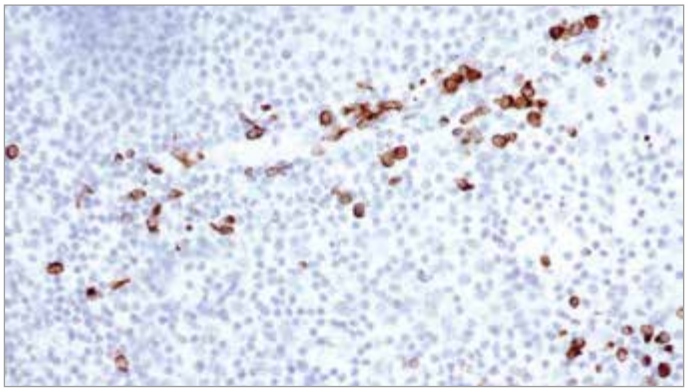
SPECIALIZED

ANTIGEN BACKGROUND

The glutathione S-transferases (GSTs) are a multigene family of isoenzymes which catalyze the conjugation of glutathione to electrophilic substrates. These enzymes are involved in the detoxification of both endogenous and exogenous electrophiles which can react with cellular components such as DNA. The modification of DNA by reactive compounds can initiate carcinogenesis and the GSTs are believed to play a role in neutralizing carcinogens. The cytosolic GST isoenzymes have been classified into four evolutionary classes; alpha, mu, pi and theta. These isoenzymes are reported to be singly or multi-expressed in a variety of normal tissues, including stomach, bowel, brain, heart, liver, pancreas, breast, kidney and skin at differing levels. In gastric cancers, the levels of GSTalpha and pi are reported to differ from normal gastric tissue with GSTalpha showing decreased levels and GSTpi increased levels.

Glutathione S-Transferase (GST) Antibody is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Granzyme B



Human tonsil: immunohistochemical staining for Granzyme B: clone 11F1

11F1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0291	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-GRAN-B	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

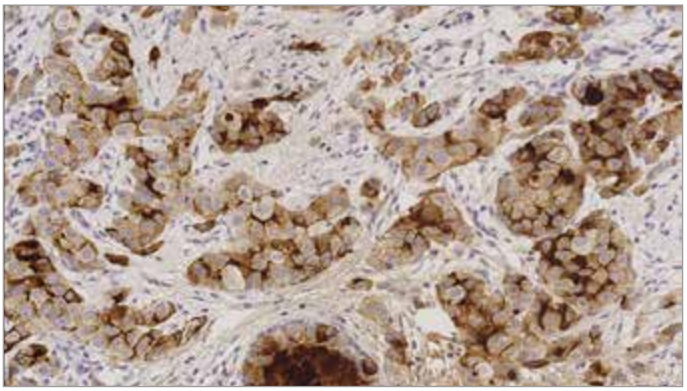
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Granzymes are neutral serine proteases which are stored in specialized lytic granules of cytotoxic T lymphocytes (CTL) and in natural killer (NK) cells. These CTL and NK cells are heavily involved in the elimination of neoplastic and virally infected cells. Secretory granules containing perforin and granzymes are instrumental in undertaking cytolytic activity. Granzyme B is understood to enter a target cell through a perforin pore-formed channel to induce DNA fragmentation and apoptosis. Granzyme B has also been described in neoplastic CTL and NK cells.

Granzyme B is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Gross Cystic Disease Fluid Protein-15



Invasive breast carcinoma: immunohistochemical staining for Gross Cystic Disease Fluid Protien-15. Gross Cystic Disease Fluid Protein-15: clone 23A3

23A3

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0708	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-GCDFP15	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

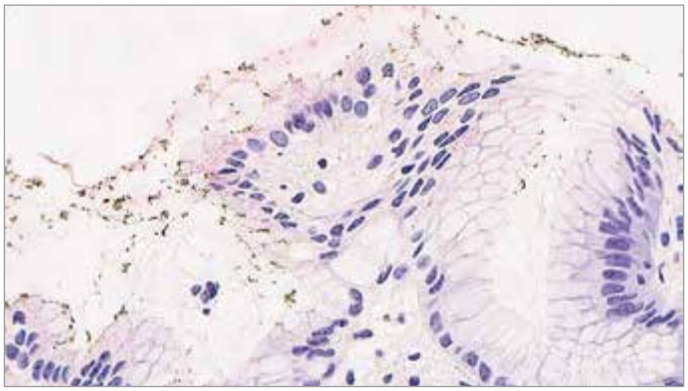
BREAST PATHOLOGY

ANTIGEN BACKGROUND

Gross cystic disease of the breast is a benign premenopausal disorder in which cysts are a predominant pathological lesion. These cysts appear to be formed from excessive apocrine cystic secretions. This fluid is composed of several glycoproteins including a unique 15 kD monomer protein, GCDFP15. It has been reported that cytosolic analysis of normal tissue from all major organs has demonstrated GCDFP15 in apocrine epithelia, lacrimal, ceruminous and Moll's glands and in numerous serous cells of the submandibular, tracheal, bronchial, sublingual and minor salivary glands. Cytosol from breast carcinoma lesions are reported to contain GCDFP15 at a wide range of concentrations. The concentration is reported to be highest in more differentiated carcinomas and GCDFP15 shows only a few positive individual epithelial cells within lobules and small ducts in normal breast. Expression has also been reported in fibroadenomas within areas of apocrine metaplasia.

Gross Cystic Disease Fluid Protein-15 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Helicobacter pylori



Immunohistochemical staining for Helicobacter pylori: clone ULC3R

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 7 mL	IHC5994-A	-	ASR	-	-

ULC3R

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-Hpylori	-	ASR	IVD	IVD

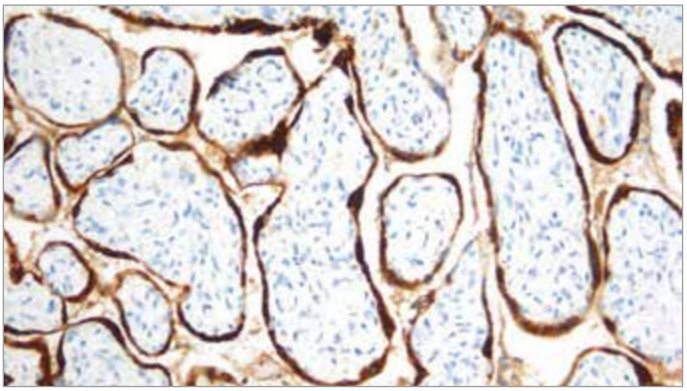
PATHOLOGY MENU

GASTROINTESTINAL PATHOLOGY

ANALYTE SPECIFIC REAGENT

Analyte Specific Reagent. Analytical and performance characteristics are not established.

Human Chorionic Gonadotrophin (beta)



Human placenta: immunohistochemical staining with Human Chorionic Gonadotrophin (beta): Polyclonal

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0014	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

GYNEPATHOLOGY

ANTIGEN BACKGROUND

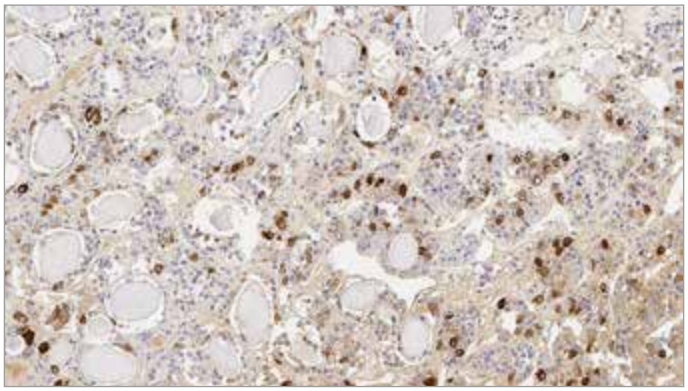
Human chorionic gonadotrophin (hCG) is a glycoprotein hormone produced by trophoblastic cells of the placenta beginning 10 to 12 days after conception. Maintenance of the fetus in the first trimester of pregnancy requires the production of hCG, which binds to the corpus luteum of the ovary which is stimulated to produce progesterone which in turn maintains the secretory endometrium. hCG is composed of two subunits, alpha and beta. The alpha subunit of hCG is identical to the subunit of luteinising hormone, thyroid stimulating hormone and follicle stimulating hormone. The common alpha chain and the hormone-specific beta chains have molecular weights of 14 kD and 17 kD, respectively. The hCG beta-subunit is unique in the family of beta-containing glycoprotein hormones in that it contains an extension of 29 amino acids at its COOH end. It is believed that the C-terminal region of the HCG-beta subunit plays a role in the intracellular behavior of the heterodimer.

Human Chorionic Gonadotrophin (beta) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

HCGp was raised to the isolated beta-chain of human chorionic gonadotrophin and reacts with placental trophoblasts. HCGp shows a slight cross-reaction with luteinising hormone and may, therefore, stain basophil cells in the pituitary.

Human Follicle Stimulating Hormone (beta 2) (HFSH)



Human pituitary: immunohistochemical staining for HFSH. Note cytoplasmic staining of gonadotrophic cells. Human Follicle Stimulating Hormone (beta 2): clone INN-hFSH-60

INN-hFSH-60

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0693	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

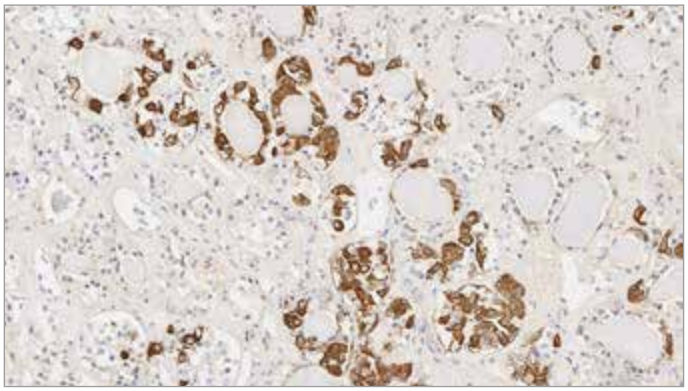
HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

Follicle stimulating hormone (FSH) is a pituitary hormone of 35 kD which is involved in the maturation of ovarian follicles and estrogen secretion in females. In males, FSH stimulates the secretion of testosterone.

Human Follicle Stimulating Hormone (beta 2) (HFSH) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Human Growth Hormone (HGH)



Human pituitary: immunohistochemical staining for HGH. Note cytoplasmic staining of somatotrophic cells. Human Growth Hormone: Polyclonal

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0704	P	IVD	IVD	IVD

PATHOLOGY MENU

HEAD, NECK AND ENDOCRINE

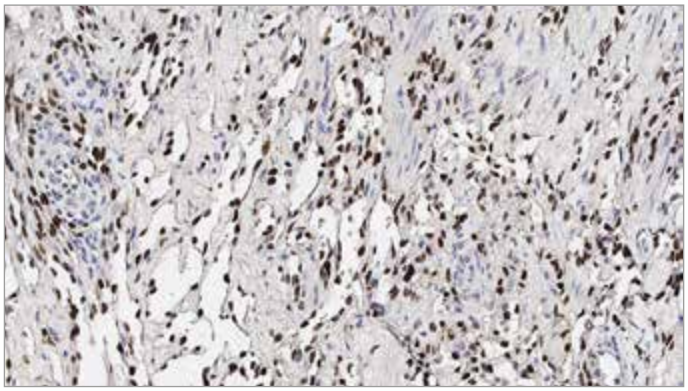
ANTIGEN BACKGROUND

Growth hormone (GH), somatotropin, is the primary hormone responsible for regulating overall body growth and is also important in organic metabolism. It is synthesized by acidophilic or somatotropic cells of the anterior pituitary gland. Human GH has a molecular weight of 22 kD.

GH stimulates growth indirectly by promoting the liver's production of somatomedins, which act directly on bone and soft tissue to cause growth. GH exerts direct metabolic effects on the liver, adipose tissue and muscle. In general, growth hormone enhances protein synthesis, conserves carbohydrates and uses up fat stores.

Human Growth Hormone (HGH) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Human Herpesvirus 8 (HHV8)



Human skin, Kaposi's sarcoma: immunohistochemical staining for HHV8.
Human Herpesvirus 8: clone 13B10

13B10

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0050	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-HHV8-LNA	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

DERMATOPATHOLOGY

ANTIGEN BACKGROUND

Human herpesvirus type 8 (HHV8), is the proposed etiological agent of Kaposi's sarcoma (KS). It is reported that HHV8 has been demonstrated in KS tissues by immunohistochemistry, in situ PCR and also in situ hybridization. HHV8 encodes a latent nuclear antigen (LNA) which is the product of the viral gene ORF73. LNA is capable of forming a complex with retinoblastoma susceptibility gene product which may be related to its oncogenic activity. HHV8 has been reported to be expressed in multicentric Castleman's disease (MCD) and in angioimmunoblastic lymphadenopathies. The localization of HHV8 in subcapsular spindle cell proliferations, which is where early intranodal KS begins, and endothelial cells in Castleman's disease may explain the link between intranodal KS and MCD. In MCD, HHV8 is reported to be expressed in mantle zone large immunoblastic B cells.

Human Herpesvirus 8 (HHV8) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Immunoglobulin A

Human appendix: immunohistochemical staining for Immunoglobulin A. Note the intense staining of plasma cells and secreted Immunoglobulin A: clone N1CLA

N1CLA

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-IgA	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

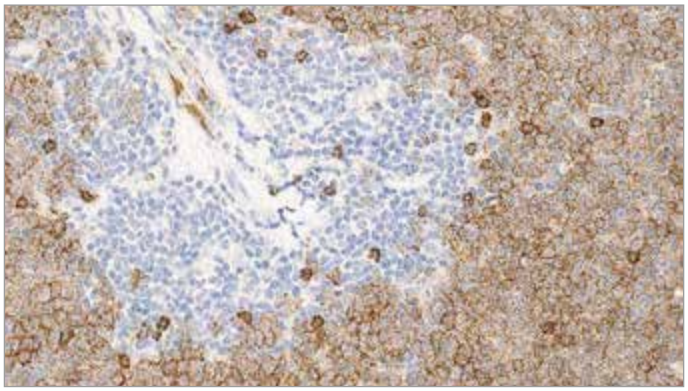
IgA is a member of the antibody class of the immunoglobulin superfamily. There are several classes and subclasses (isotypes) of antibody, the antibody isotype being defined by the immunoglobulin heavy chain present in the molecule. The basic structure of an immunoglobulin molecule consists of two identical heavy chains (gamma , mu, alpha , delta , epsilon) and two identical light chains, either kappa or lambda. IgA contains the alpha -chain and may be present in a serum or secretory form. In serum, 90% of IgA is monomeric, while in its secretory form it is the main immunoglobulin found in secretions including tears, saliva, intestinal and bronchial mucous, sweat, colostrum, and secretions from the prostate and respiratory epithelia, where it has the job of defending exposed external surfaces of the body against attack from micro organisms. Secretory IgA is synthesized locally by plasma cells and dimerized intracellularly with a cysteine-rich J-chain.

Immunoglobulin A is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone N1CLA was developed to produce reduced background staining that is associated with polyclonal antibodies on paraffin sections.

Immunoglobulin D



Mantle cell lymphoma: immunohistochemical staining for Immunoglobulin D.
Immunoglobulin D: clone DRN1C

DRN1C

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0061	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-IgD	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

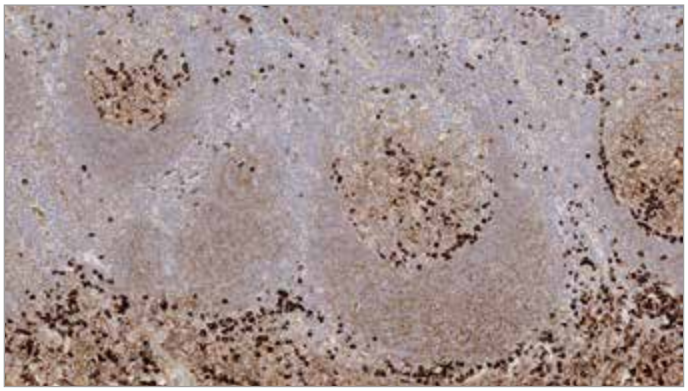
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

IgD, together with IgM, are the major immunoglobulins expressed on the surface of B cells where it seems they may operate as mutually interacting antigen receptors for the control of lymphocyte activation and suppression. The greater susceptibility of IgD to proteolysis in combination with antigen could well be implicated in such a function.

Immunoglobulin D is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Immunoglobulin G



Human tonsil: immunohistochemical staining for Immunoglobulin G. Note intense staining of plasma cells, weaker staining of follicular dendritic cell network and some B cells.
Immunoglobulin G: clone RWP49

RWP49

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0905	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-IgG	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

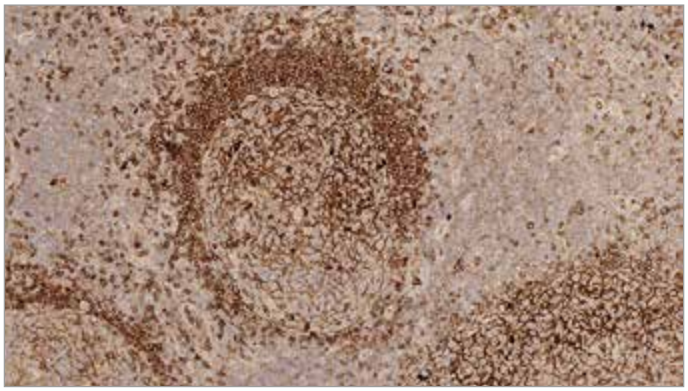
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The human immunoglobulins consist of two identical heavy chains (~50 kD) and two identical light chains, which are linked together by disulphide bonds. The light chains can be either kappa or lambda. The five immunoglobulins IgA, IgD, IgE, IgG and IgM differ in their heavy chains, and IgA and IgM differ as they can occur in polymeric forms. The heavy chain of IgG is named the gamma-chain. In humans, IgG consists of four sub classes that differ only marginally in their amino acid composition. Antibodies to IgG have been reported to be useful in the identification of plasma cells, lymphoid cells containing IgG and classifying B cell derived neoplasms. The normal B cell population is Polyclonal, expressing a range of different immunoglobulins. In contrast, the majority of B cell neoplasms are characterized by the proliferation of monoclonal cells expressing one type of light chain, whereas more than one type of heavy chain can be expressed by the same cell.

Immunoglobulin G is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Immunoglobulin M



Human tonsil: immunohistochemical staining for Immunoglobulin M. Note intense staining of plasma cells, weaker staining of follicular dendritic cell network and some B cells. Immunoglobulin M: clone 8H6

8H6

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0278	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-IgM	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

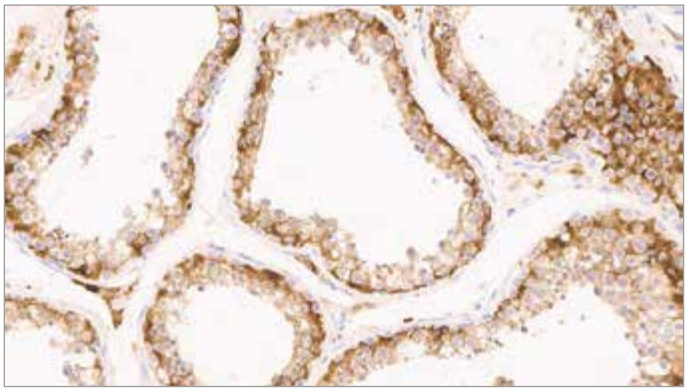
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

IgM, together with IgD, is the major immunoglobulin expressed on the surface of B cells and normally constitutes about 10 per cent of serum immunoglobulin. IgM antibody is prominent in early immune responses to most antigens and predominates in certain antibody responses such as natural blood group antibodies.

Immunoglobulin M is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Inhibin Alpha



Human testis: immunohistochemical staining for inhibin alpha showing cytoplasmic staining of Sertoli cells. Inhibin Alpha: clone R1

R1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0488	P(HIER)	IVD	IVD	IVD

AMY82

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-InhibinA	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

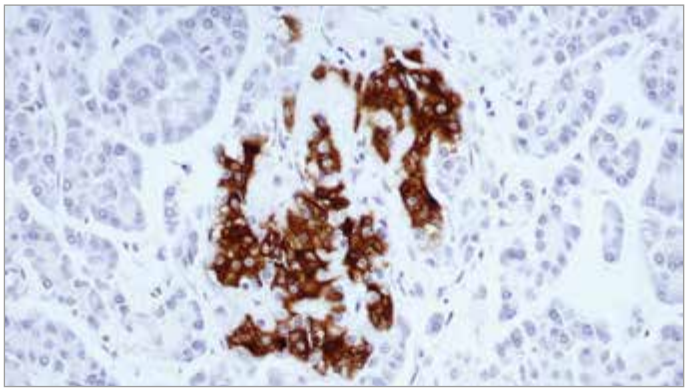
GYNEPATHOLOGY

ANTIGEN BACKGROUND

Inhibins and activins are members of the transforming growth factor beta (TGFβ) family of cytokines. Inhibins are heterodimers consisting of a common α-subunit linked to either a βA subunit (α-βA, forming inhibin A) or a βB subunit (α-βB, forming inhibin B). Activins share the β-subunit with the inhibins and may be homo or heterodimers of β-subunits forming activin A (βA-βA), activin AB (βA-βB) or activin B (βB-βB). The expression of the α-subunit, and therefore of inhibins appears to be more restricted than that of the β-subunit, and therefore of activins. Inhibins and activins play a role in the regulation of pituitary follicle stimulating hormone (FSH) secretion. The actions of inhibins and activins are thought to oppose one another, with inhibins suppressing FSH secretion and activins stimulating FSH secretion. Inhibins are secreted by granulosa cells in female follicles and Sertoli cells of the testis in the male. Inhibins are thought to have local regulatory roles in a variety of tissues, in addition to the ovary, including the brain, adrenal glands, bone marrow, fetus and placenta.

Inhibin Alpha is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Insulin



Human pancreas: immunohistochemical staining for insulin-containing cells. Note intense cytoplasmic staining. Insulin: clone 2D11-H5

2D11-H5

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0620	P	IVD	IVD	IVD
Liquid 1 mL	NCL-L-INSULIN	P	IVD	-	-

PATHOLOGY MENU

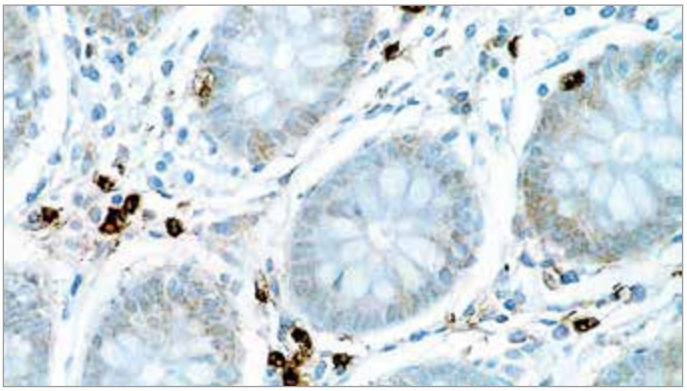
HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

Insulin is a hormone secreted by the beta cells of the islets of Langerhans in the pancreas. It promotes glycogen storage, formation of triglycerides, and synthesis of protein and nucleic acids. Reports of immunocytochemical investigation reveal the presence of insulin in the cytoplasm of certain islet tumors. However, in some instances insulin-positive granules are sparse and form a margin against the cell membrane.

Insulin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Interleukin 6



Human colon: immunohistochemical staining for Interleukin 6. Note cytoplasmic staining of a proportion of lymphoid cells. Interleukin 6: clone 10C12

10C12

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-IL6	P	RUO	RUO	RUO

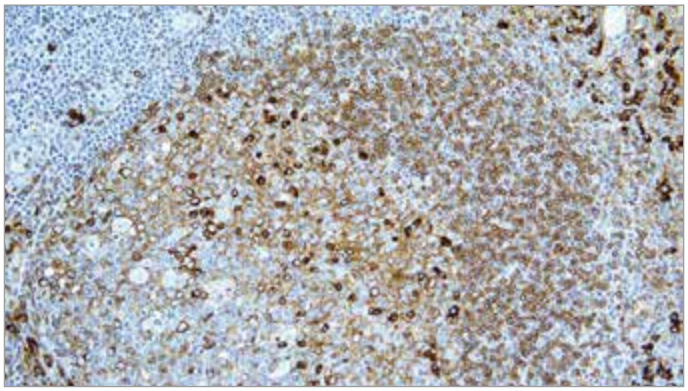
PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

IL-6 is a multifunctional cytokine that is secreted by both lymphoid and non-lymphoid cells. It plays a key role in immune responses, hematopoiesis and is an important cytokine in cell proliferation and differentiation. It may also play an important role as an autocrine growth factor in metastatic prostate cancer. IL-6 has been reported to play a role in secretion or release of pituitary hormone in pituitary hormone secreting cells and adenomas. In addition, IL-6 has been suggested to have a trophic effect in nerve cells and to have a direct pathogenic role in CNS disorders. There are an increasing number of reports that cytokines of the IL-6 family play an important regulatory role in heart physiology.

Kappa Light Chain



Human tonsil: immunohistochemical staining with Kappa Light Chain: clone CH15

CH15

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0606	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-KAP-581	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

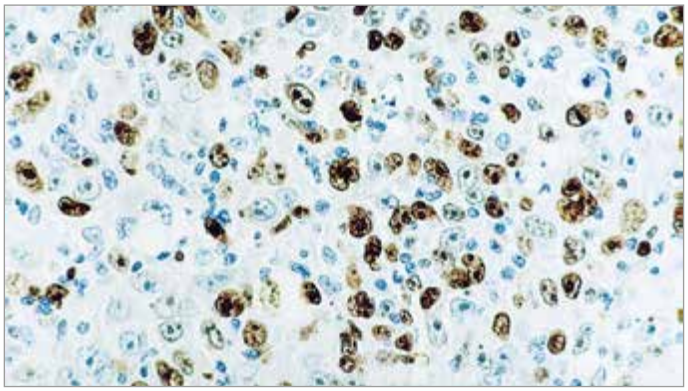
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Immunoglobulins are polypeptides and comprise five major classes; immunoglobulin G (IgG), IgA, IgM, IgD and IgE. Each immunoglobulin consists of two identical heavy (H) chains and two identical light (L) chains.These are also subdivided into sub classes, for example, IgG1. There are two classes of light chain; kappa and lambda. The ratio of kappa chains and light chains varies between Ig classes and sub classes, but is also species specific. In humans, approximately 60% of light chains are kappa; however, in any particular immunoglobulin molecule the light chain will be either kappa or lambda. B cells contain either kappa or lambda mRNA.

Kappa Light Chain is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Ki67 Antigen



Diffuse large B cell lymphoma: immunohistochemical staining for Ki67. Ki67: clone MM1

MM1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0118	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0410	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-KI67-MM1	P(HIER)	IVD	IVD	IVD/RUO

K2

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0230	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-ACK02	P(HIER)	RUO	RUO	RUO

PATHOLOGY MENU

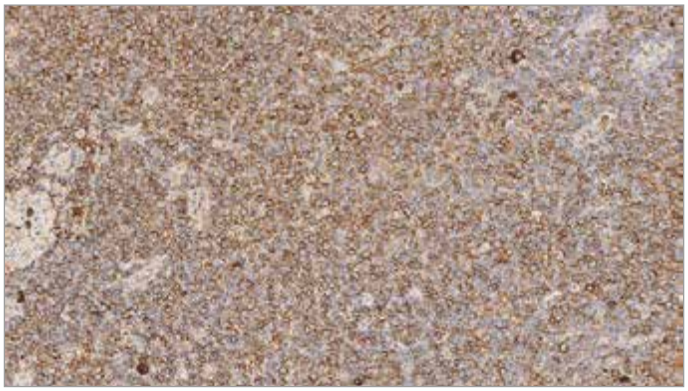
BREAST PATHOLOGY

ANTIGEN BACKGROUND

The Ki67 antigen is a nuclear protein which is expressed in all active parts of the cell cycle (G1, S, G2 and mitosis) but is absent in resting cells (G0). In contrast to many other cell cycle-associated proteins, the Ki67 antigen is consistently absent in quiescent cells and is not detectable during DNA repair processes. Thus, the presence of Ki67 antigen is strictly associated with the cell cycle and confined to the nucleus, suggesting an important role in the maintenance and/or regulation of the cell division cycle.

Ki67 Antigen is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Lambda Light Chain



B cell chronic lymphocytic leukemia: immunohistochemical staining for Lambda Light Chain. Lambda Light Chain: clone SHL53

SHL53

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0570	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-LAM-578	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

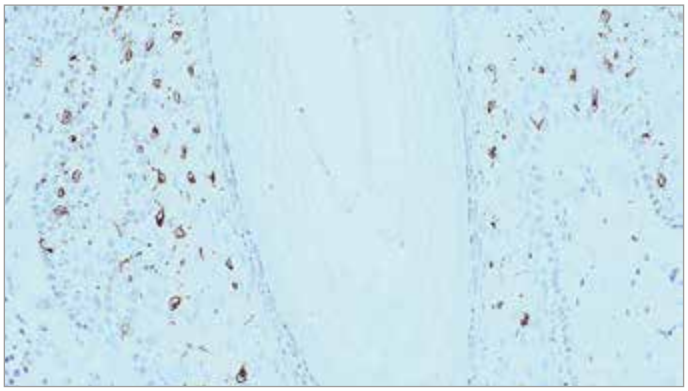
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The basic structure of an immunoglobulin molecule consists of two identical heavy chains, either gamma, alpha, delta, or epsilon and two identical light chains, either kappa or lambda. Any heavy chain can associate with either light chain but on any immunoglobulin molecule both light chains are of the same type. The ratio of kappa and lambda light chains varies between Ig classes and subclasses. In a polyclonal population the ratio of kappa to lambda bearing B cells is approximately 2:1, with individual B cells thought to express kappa or lambda light chains, never both. The majority of kappa and lambda chains are bound to heavy chain immunoglobulin, however in normal individuals low levels of free light chain are present in serum. The occurrence of a mixture of kappa and lambda chain expressing cells suggests a polyclonal population and a reactive or non-neoplastic proliferation of B cells.

Lambda Light Chain is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Langerin



Human skin: immunohistochemical staining for langerin. Langerin: clone 12D6

12D6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-LANGERIN	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

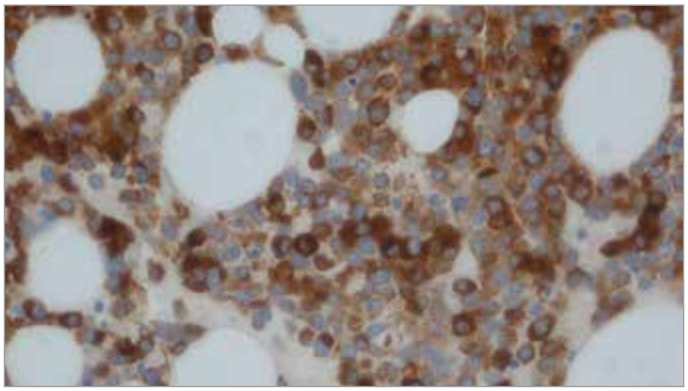
SPECIALIZED

ANTIGEN BACKGROUND

Langerin is a type II transmembrane C-type lectin which has mannose-binding specificity. It is a 40 kD protein restricted to Langerhans cells that is involved in the internalization of cell surface material in these immature dendritic cells. Dendritic cells are antigen-presenting cells that are required for initiation of a specific T cell-driven immune response. These cells are found in non-lymphoid tissue as immature cells whose primary function is to capture antigen through specialized surface membrane endocytic structures or through macropinocytosis. The dendritic cells migrate to secondary lymphoid tissue and mature into efficient antigen presenting cells. A part of the maturation process includes the loss of adhesion receptors such as E-cadherin and the disappearance of Birbeck granules. Although Langerin is reported to be located on the cell surface, it can be rapidly internalized following ligand capture into Birbeck granules. In fact, Langerin is a potent inducer of membrane superimposition and zippering leading to Birbeck granule formation. In reports it has been suggested that the induction of Birbeck granules is a consequence of the antigen-capture function of Langerin allowing passage into these organelles and providing access to a non-classical antigen processing pathway.

Langerin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Lysozyme (Muramidase)



Bone marrow: immunohistochemical staining of myeloid cells using Lysozyme: Polyclonal

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0391	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

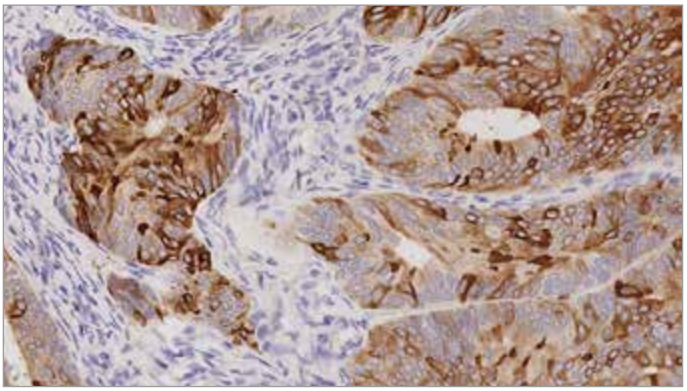
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Intracellular muramidase, also known as lysozyme, has been reported to be expressed in myeloid and monocytic cells, in leukocytes and in myelo-proliferative disorders. Muramidase is also reported to be expressed in poorly differentiated leukemic monoblasts.

Lysozyme (Muramidase) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Mammaglobin



Human ductal carcinoma of breast: immunohistochemical staining for Mammaglobin protein. Mammaglobin: clone EP249

EP249

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0378	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

BREAST PATHOLOGY

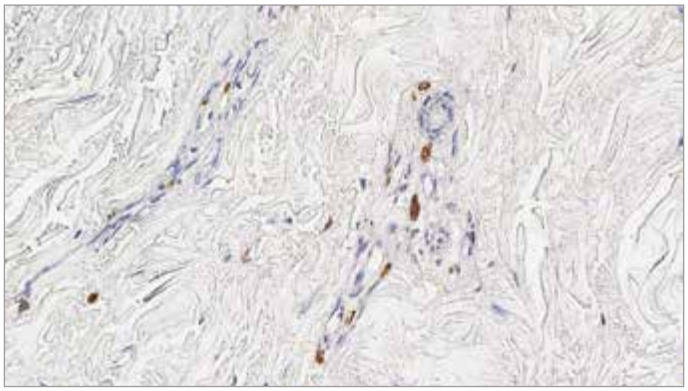
ANTIGEN BACKGROUND

Mammaglobin is a 93 kDa glycoprotein that belongs to the uteroglobin family of proteins. It was first described in 1996 and found to be overexpressed in breast cancer. Published reports suggest a role for mammaglobin in the diagnosis of metastatic breast carcinoma.

Mammaglobin has been suggested as a useful marker for carcinomas of unknown primary origin, with expression unaltered from the primary site. Additional published data suggests a role for mammaglobin in the migration and invasion of breast cancer cells.

Mammaglobin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Mast Cell Tryptase



Human skin: immunohistochemical staining for Mast Cell Tryptase. Note cytoplasmic staining of mast cells. Mast Cell Tryptase: clone 10D11

10D11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0019	P	IVD	IVD	IVD
Liquid 1 mL	NCL-L-MCTRYP-428	P	IVD	-	-

PATHOLOGY MENU

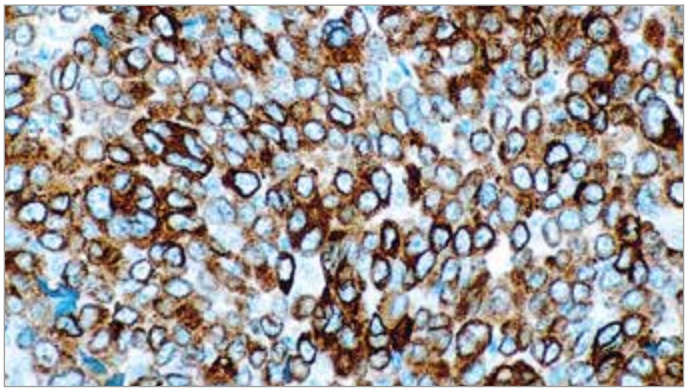
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Mast cells contain a number of preformed chemical mediators such as histamine, chymase, carboxypeptidase and proteolytic tryptase. A substantial quantity of tryptase is reported to be found in mast cells of skin and lung and suggests this enzyme plays a major role in mast cell mediated events. In vitro studies indicate tryptase can cleave C3 to form C3a anaphylatoxin, inactivate fibrinogen as a coaguable substrate for thrombin and activate latent collagenase. Models of allergenic disease in the skin, nose and lung have each indicated elevated tryptase levels. Human mast cell tryptase has been reported to be implicated as a mediator of inflammation. Mast cell degranulation in the gut causes mucus secretion, mucosal edema, increased gut permeability and may be responsible for some of the symptoms and signs of inflammatory bowel disease.

Mast Cell Tryptase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Melan A



Human skin, melanoma: immunohistochemical staining for Melan A. Melan A: clone A103

A103

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0233	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0044	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-MELANA	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

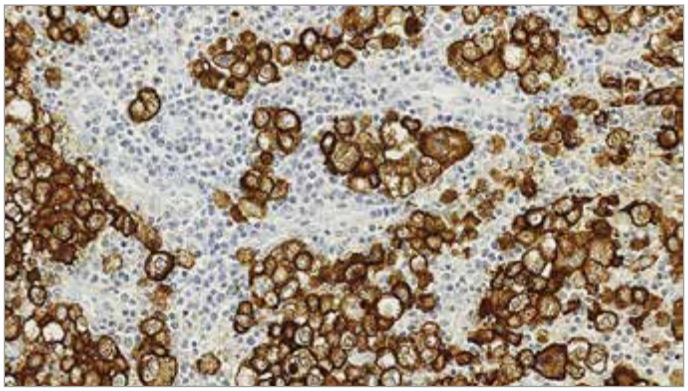
DERMATOPATHOLOGY

ANTIGEN BACKGROUND

Melan A, a product of the MART-1 gene, is a melanocyte differentiation marker recognized by autologous cytotoxic T lymphocytes. Other melanoma-associated markers recognized by autologous cytotoxic T cells are reported to include MAGE-1, MAGE-3, tyrosinase, gp100, gp75, BAGE-1 and GAGE-1. The analysis of these different molecules and their expression in individual melanomas may be of help in the study of their particular molecular roles in melanocyte differentiation and tumorigenesis.

Melan A is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Melanoma Marker (HMB45)



Human skin, melanoma: immunohistochemical staining for HMB45. Melanoma Marker (HMB45): clone HMB45

HMB45

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0027	P(ENZYME)	IVD	IVD	IVD
BOND 30 mL	PA0625	P(ENZYME)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-HMB45	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

DERMATOPATHOLOGY

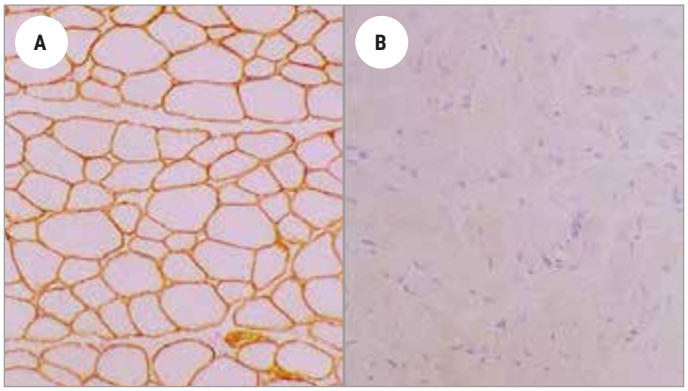
ANTIGEN BACKGROUND

The HMB45 antigen has also been identified in retinal pigment epithelium (RPE) but is reported to be reactive only with the transient prenatal and infantile RPE. No reaction is reported to be observed with intradermal nevi and normal adult melanocytes and non-melanocytic cells.

Tumor cells of epithelial, lymphoid, glial and mesenchymal origin are reported to be negative. This clone is well described in the literature. It is indicated to label an intracytoplasmic antigen in the majority of melanomas and other tumors demonstrating melanoma/melanocytic differentiation.

Melanoma Marker (HMB45) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Merosin Laminin Alpha 2 Chain



Human skeletal muscle: immunohistochemical staining for Merosin. Note membrane staining of normal muscle fibers (A) and absence of staining of muscle fibers (B). Frozen sections. Photographs supplied courtesy of Dr Louise V B Anderson. Merosin Laminin Alpha 2 Chain: clone Mer3/22B2

Mer3/22B2

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-MEROSIN	F	IVD	IVD	IVD

PATHOLOGY MENU

MUSCLE PATHOLOGY

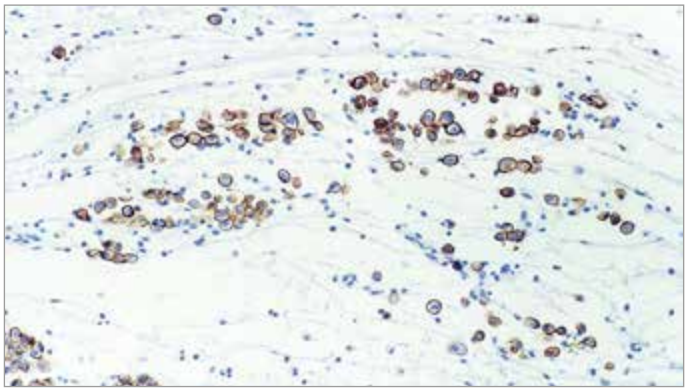
ANTIGEN BACKGROUND

The muscle-specific form of laminin, merosin, is composed of three chains: alpha 2, beta 1 and gamma 1.

Mutations in the chromosome 6 encoded gene for the laminin alpha 2 chain of merosin are responsible for a form of congenital muscular dystrophy (CMD). Merosin-negative CMD is characterized by a severe clinical phenotype and is associated with white matter changes on brain imaging.

Merosin Laminin Alpha 2 Chain is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Mesothelin



Human mesothelioma: immunohistochemical staining for Mesothelin. Mesothelin: clone 5B2

5B2

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0373	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-MESO	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

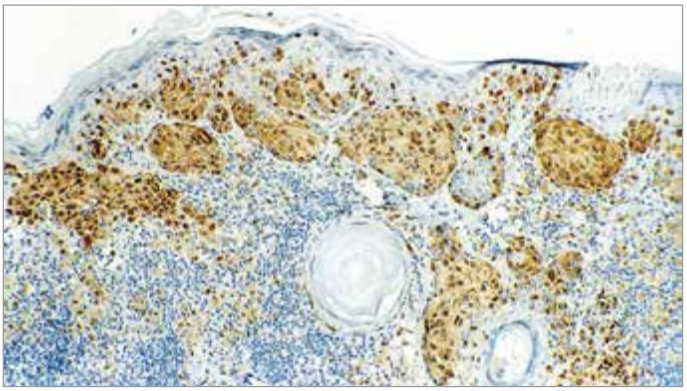
LUNG PATHOLOGY

ANTIGEN BACKGROUND

Mesothelin is a glycosyl-phosphatidylinositol-linked (GPI) glycoprotein of 40kD present on the surface of mesothelial cells, mesotheliomas, epithelial ovarian cancers and some squamous cell carcinomas. It is synthesized as a 69 kD precursor which is enzymatically processed into an N-terminal secreted form of 30 kD and the GPI-linked membrane-bound form of 40 kD. The secreted form is identical to the megakaryocyte potentiating factor, but it is the GPI-linked membrane-bound form which has generated interest. Mesothelin is abundantly expressed in the kidney and in occasional epithelial cells of the trachea, tonsil and fallopian tube. The function of mesothelin is unclear but it may have a role in cellular adhesion. Mesothelin is reported to be abundant in the normal mesothelial cells from which malignant mesotheliomas and ovarian cystadenocarcinomas are derived.

Mesothelin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Microphthalmia Transcription Factor (MITF)



Human malignant melanoma: immunohistochemical staining for Microphthalmia Transcription Factor. Microphthalmia Transcription Factor: clone 34CA5

34CA5

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-MITF	F;P(HIER)	RUO	RUO	RUO

PATHOLOGY MENU

DERMATOPATHOLOGY

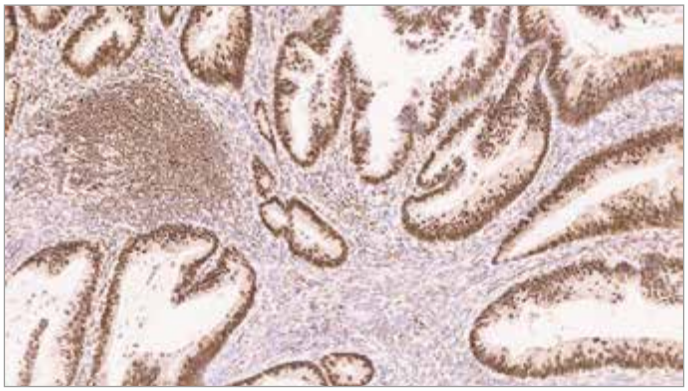
ANTIGEN BACKGROUND

Microphthalmia transcription factor (MITF) gene product, a nuclear transcription factor of the basic-helix-loop-helix type, is thought to play a role in the regulation of genes encoding the enzymes necessary for melanogenesis. These include tyrosinase, TRP-1 and TRP-2. MITF is critical for the embryonic development and postnatal viability of melanocytes. The melanocyte-specific isoform of microphthalmia transcription factor MITF-M, is reported to be expressed in normal and malignant melanocytes. The other isoforms, MITF-A, MITF-C and MITF-H, differ structurally at the N-terminus from MITF-M.

PRODUCT SPECIFIC INFORMATION

Clone 34CA5 is reported to be reactive with the MITF-M isoform.

Mismatch Repair Protein (MLH1)



Immunohistochemical staining for mismatch repair protein (MLH1). Mismatch Repair Protein (MLH1): clone ES05.

ES05

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0988	P(HIER)	IVD	IVD	-
Liquid 1 mL	NCL-L-MLH1	P(HIER)	IVD	IVD	IVD

ES05 (Previous Formulation)

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0610	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

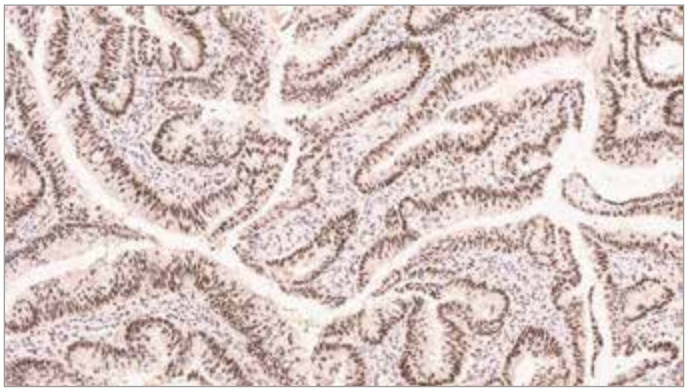
Mismatch repair gene hMLH1 is a ubiquitous gene encoding the mismatch repair protein (MMR) MutL protein homolog 1 (MLH1). MLH1 functions by repairing mutations occurring during DNA replication, in normal proliferating cells.

Mismatch Repair Protein (MLH1) is recommended for the detection of specific antigens of interest in normal and neoplastic tissue, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of the heat induced epitope retrieval (HIER) technique can enhance staining in some cases. Any changes to the recommendations should be validated by the end user.

Mismatch Repair Protein (MSH2)



Immunohistochemical staining for mismatch repair protein (MSH2). Mismatch Repair Protein (MSH2): clone 79H11.

79H11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0989	P(HIER)	IVD	IVD	-
Liquid 1 mL	NCL-L-MSH2-612	P(HIER)	IVD	IVD	IVD

25D12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0048	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

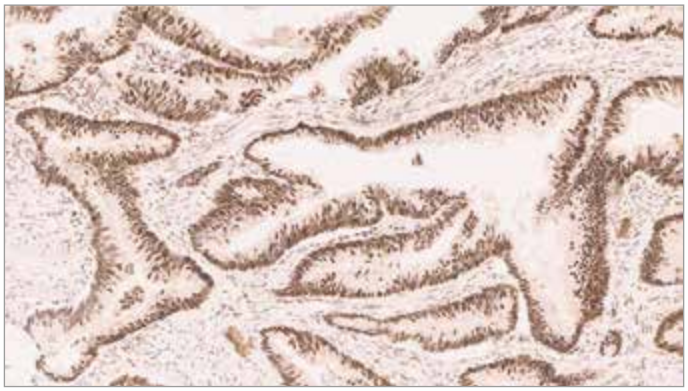
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Mismatch repair gene MutS Homolog 2 is a ubiquitous gene encoding the mismatch repair protein (MMR) MutS protein homolog 2 (MSH2). MSH2 functions by repairing mutations occurring during DNA replication, in normal proliferating cells.

Mismatch Repair Protein (MSH2) is recommended for the detection of specific antigens of interest in normal and neoplastic tissue, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Mismatch Repair Protein (MSH6)



Immunohistochemical staining for mismatch repair protein (MSH6). Mismatch Repair Protein (MSH6): clone EP49.

EP49

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0990	P(HIER)	IVD	IVD	-

PU29

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-MSH6	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

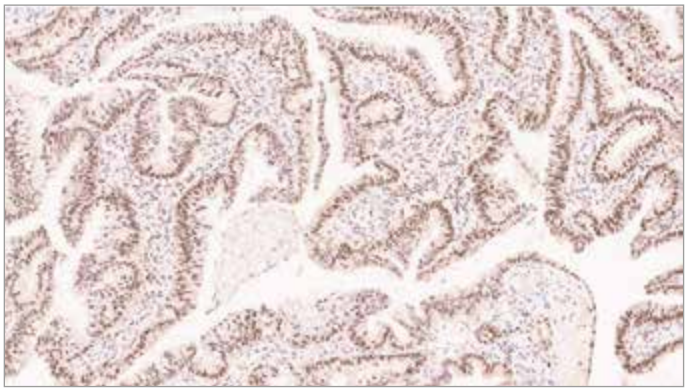
Mismatch repair gene MutS Homolog 6 is a ubiquitous gene encoding the mismatch repair protein (MMR) MutS protein homolog 6 (MSH6). MSH6 functions by repairing mutations occurring during DNA replication, in normal proliferating cells.

Mismatch Repair Protein (MSH6) is recommended for the detection of specific antigens of interest in normal and neoplastic tissue, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of PBS-based diluents may result in increased background staining.

Mismatch Repair Protein (PMS2)



Immunohistochemical staining for mismatch repair protein (PMS2). Mismatch Repair Protein (PMS2): clone EP51.

EP51

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0991	P(HIER)	IVD	IVD	-

M0R4G

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-PMS2	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

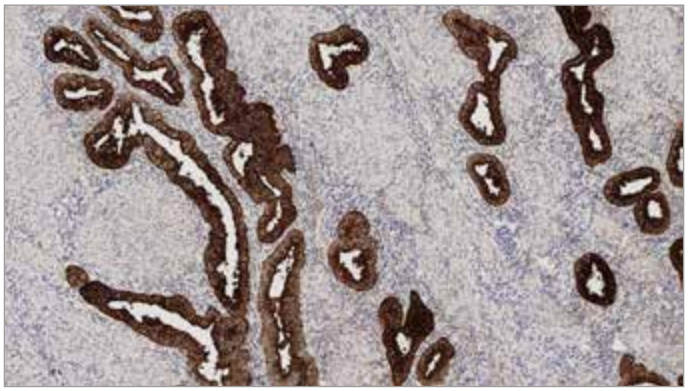
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Mismatch repair gene Postmeiotic segregation Increased 2, also known as PMS1 Homolog 2, is a ubiquitous gene encoding the mismatch repair protein (MMR) PMS1 protein homolog 2 (PMS2). PMS2 functions by repairing mutations occurring during DNA replication, in normal proliferating cells.

Mismatch Repair Protein (PMS2) is recommended for the detection of specific antigens of interest in normal and neoplastic tissue, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Muc-1 Glycoprotein



Human endometrium: immunohistochemical staining for Muc-1.
Muc-1 Glycoprotein: clone Ma695

Ma695

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0051	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

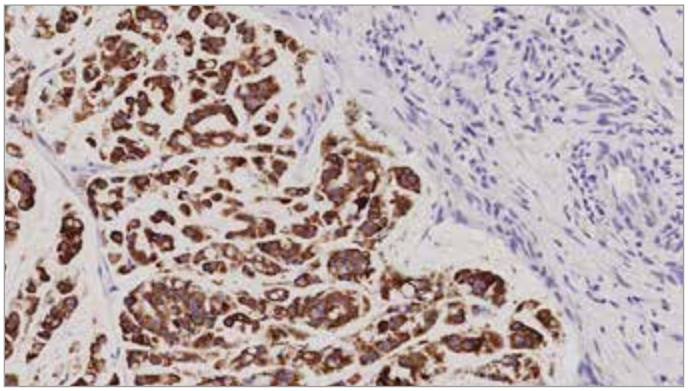
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Mucins are heavily glycosylated glycoproteins which constitute the major components of mucus that covers the surface of epithelial tissues. Nine distinct epithelial mucin genes (Muc-1, 2, 3, 4, 5AC, 5B, 6, 7 and 8) have been identified. Various immunohistochemical and in situ hybridization studies have shown that these mucins are differentially expressed in epithelia with cell-type specificity. The normal gastric mucosa shows cell-type specific expression of Muc-1, Muc-5AC and Muc-6 glycoproteins with the first two mucins found in superficial epithelium and Muc-6 glycoprotein in the deep glands. Muc-1 and Muc-5AC glycoproteins are expressed in many epithelia but Muc-6 glycoprotein is mainly expressed in gastric mucosa. In addition, Muc-2 glycoprotein is not expressed in normal gastric mucosa.

Muc-1 Glycoprotein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Muc-2 Glycoprotein



Human colon: immunohistochemical staining for Muc-2 Glycoprotein: clone Ccp58

Ccp58

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0155	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

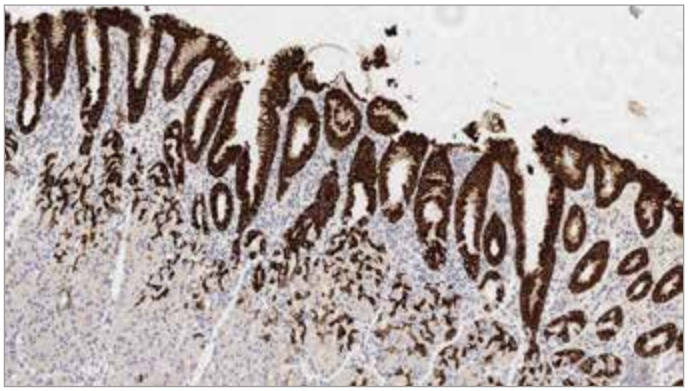
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Mucins are heavily glycosylated glycoproteins which constitute the major components of mucus that covers the surface of epithelial tissues. Nine distinct epithelial mucin genes (Muc-1, 2, 3, 4, 5AC, 5B, 6, 7 and 8) have been identified. Various immunohistochemical and in situ hybridization studies have shown that these mucins are differentially expressed in epithelia with cell-type specificity. The normal gastric mucosa shows cell-type specific expression of Muc-1, Muc-5AC and Muc-6 glycoproteins with the first two mucins found in superficial epithelium and Muc-6 glycoprotein in the deep glands. Muc-1 and Muc-5AC glycoproteins are expressed in many epithelia but Muc-6 glycoprotein is mainly expressed in gastric mucosa. In addition, Muc-2 glycoprotein is not expressed in normal gastric mucosa.

Muc-2 Glycoprotein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Muc-5AC Glycoprotein



Human stomach: immunohistochemical staining for Muc- 5AC.
Muc-5AC Glycoprotein: clone CLH2

CLH2

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0052	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

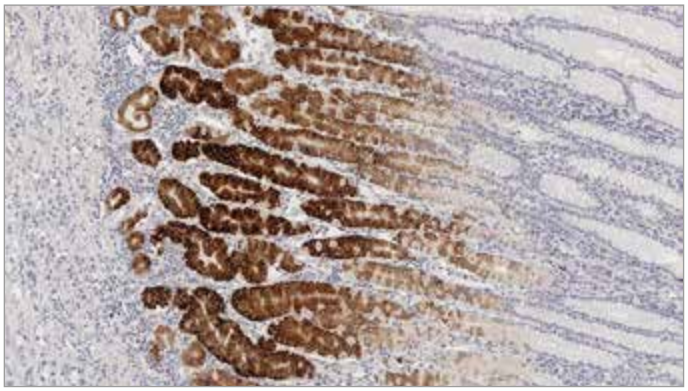
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Mucins are heavily glycosylated glycoproteins which constitute the major components of mucus that covers the surface of epithelial tissues. Nine distinct epithelial mucin genes (Muc-1, 2, 3, 4, 5AC, 5B, 6, 7 and 8) have been identified. Various immunohistochemical and in situ hybridization studies have shown that these mucins are differentially expressed in epithelia with cell-type specificity. The normal gastric mucosa shows cell-type specific expression of Muc-1, Muc-5AC and Muc-6 glycoproteins with the first two mucins found in superficial epithelium and Muc-6 glycoprotein in the deep glands. Muc-1 and Muc-5AC glycoproteins are expressed in many epithelia but Muc-6 glycoprotein is mainly expressed in gastric mucosa. In addition, Muc-2 glycoprotein is not expressed in normal gastric mucosa.

Muc-5AC Glycoprotein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Muc-6 Glycoprotein



Human stomach: immunohistochemical staining for Muc-6. Muc-6 Glycoprotein: clone CLH5

CLH5

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0053	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

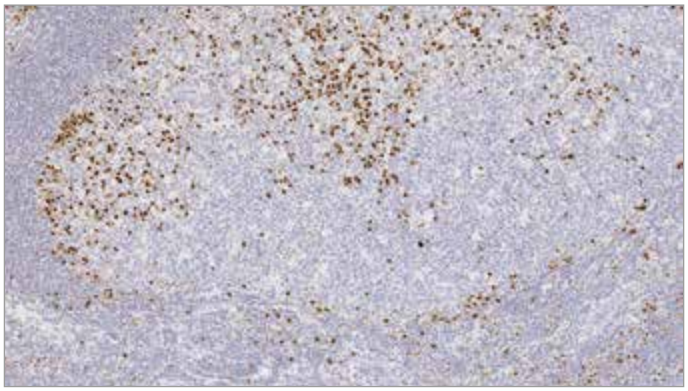
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Mucins are heavily glycosylated glycoproteins which constitute the major components of mucus that covers the surface of epithelial tissues. Nine distinct epithelial mucin genes (Muc-1, 2, 3, 4, 5AC, 5B, 6, 7 and 8) have been identified. Various immunohistochemical and in situ hybridization studies have shown that these mucins are differentially expressed in epithelia with cell-type specificity. The normal gastric mucosa shows cell-type specific expression of Muc-1, Muc-5AC and Muc-6 glycoproteins with the first two mucins found in superficial epithelium and Muc-6 glycoprotein in the deep glands. Muc-1 and Muc-5AC glycoproteins are expressed in many epithelia but Muc-6 glycoprotein is mainly expressed in gastric mucosa. In addition, Muc-2 glycoprotein is not expressed in normal gastric mucosa.

Muc-6 Glycoprotein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Multiple Myeloma Oncogene 1 (MUM-1)



Human tonsil: immunohistochemical staining for MUM-1.
Multiple Myeloma Oncogene 1: clone EAU32

EAU32

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0129	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-MUM1	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

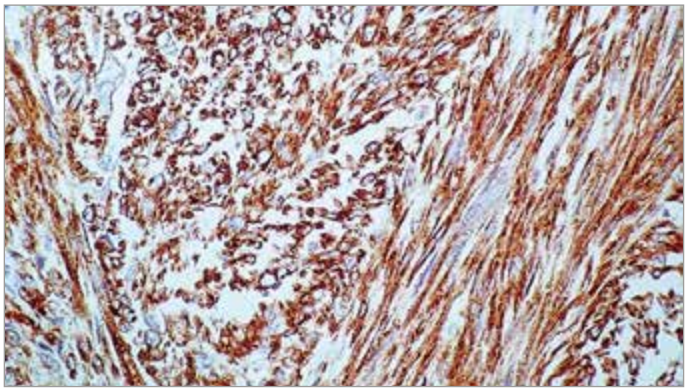
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The MUM-1 (multiple myeloma oncogene 1) gene was originally identified because of its involvement in the t(6:14) translocation observed in multiple myeloma, which causes the juxtaposition of the MUM-1 gene to the Ig heavy chain locus. MUM-1 is expressed in late plasma cell directed stages of B cell differentiation and in activated T cells, suggesting that MUM-1 may serve as a marker for lympho-hemopoietic neoplasms derived from these cells. The morphologic spectrum of MUM-1 expressing cells has been found to range from that of a centrocyte to that of a plasmablast/plasma cell. Consequently the histogenic value of MUM-1 may be to provide a marker to aid in the identification of the transition from BCL-6 positive (germinal center B cells) to CD138 positive (immunoblasts and plasma cells).

Multiple Myeloma Oncogene 1 (MUM-1) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Muscle Specific Actin



Human leiomyosarcoma: immunohistochemical staining for Muscle Specific Actin.
Muscle Specific Actin: clone HHF35

HHF35

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0258	P	IVD	IVD	IVD
Liquid 1 mL	NCL-L-MSA	P(ENZYME)	IVD	-	-

SC28

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-MSA-594	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

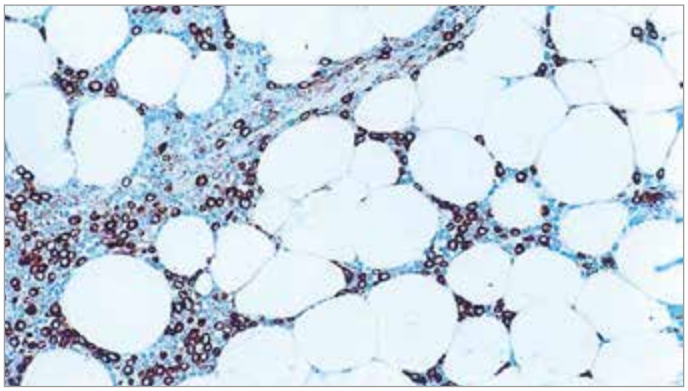
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Muscle specific actin (MSA) is a highly conserved, ubiquitous protein found in muscle and some non-muscle cells. Actins can be divided into three subsets, alpha actins found in muscle tissue cells, beta and gamma actins found in non-muscle cells and a small subset of gamma actins also found in muscle tissue cells. In normal tissues, expression is found in striated fibers of skeletal muscle, smooth muscle in arteries, veins and pericytes of smaller arteries, muscle in bowel, myometrium of the uterus, prostatic stroma, capsule cells of liver, kidney, lymph node and spleen, the myoepithelial layers of mammary ducts and glands, eccrine sweat glands and salivary glands. Expression is not found in epithelial cells, lymphoid cells, macrophages, connective tissue and neuronal cells. In neoplastic tissues, expression can be found in soft tissue tumors with muscle differentiation, for example, leiomyomas, leiomyosarcomas and rhabdomyosarcomas of varying subtypes. Non-muscle sarcomas, carcinomas, melanomas and lymphomas do not express muscle specific actin.

Muscle Specific Actin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Myeloperoxidase



Human bone marrow, granulocytic sarcoma: immunohistochemical staining for myeloperoxidase. Myeloperoxidase: clone 59A5

59A5

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0491	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-MYELO	P	IVD	-	-

PATHOLOGY MENU

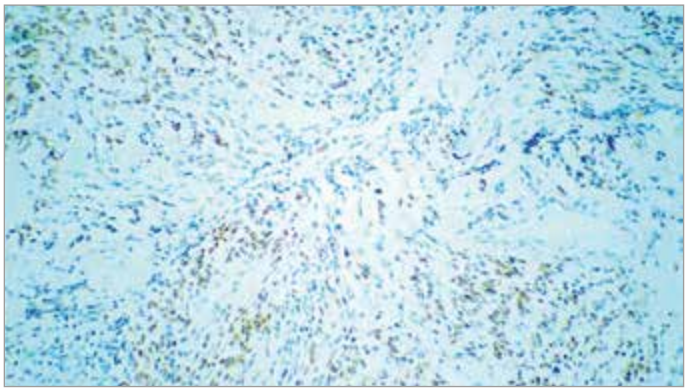
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Myeloperoxidase is a lysosomal enzyme found in cells of the myeloid series which metabolizes most of the hydrogen peroxide generated by activated phagocytes. It is a major constituent of azurophilic cytoplasmic granules that uses hydrogen peroxide to oxidize a variety of aromatic compounds and chloride ions to hypochlorous acid (HOCl), a strong oxidant. HOCl is the most bacteriocidal oxidant known to be produced by neutrophils. HOCl reacts with proteins to form cytotoxic chloramines. Myeloperoxidase is reported to be a major component in all myeloid cells, including mature granulocytes and is a superior marker to myeloperoxidase mRNA, whose level decreases with the maturation of the cell and is not detectable from the myelocyte stage onwards. Myeloperoxidase is reported to be expressed in neutrophil granulocytes and monocytes in blood, in precursors of granulocytes in the bone marrow and in Kupffer cells of the liver.

Myeloperoxidase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

MyoD1 (Rhabdomyosarcoma Marker)



Human rhabdomyosarcoma: immunohistochemical staining for MyoD1 protein. MyoD1: clone 5.8A

5.8A

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-MyoD1	P(HIER)	IVD	-	-

PATHOLOGY MENU

MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

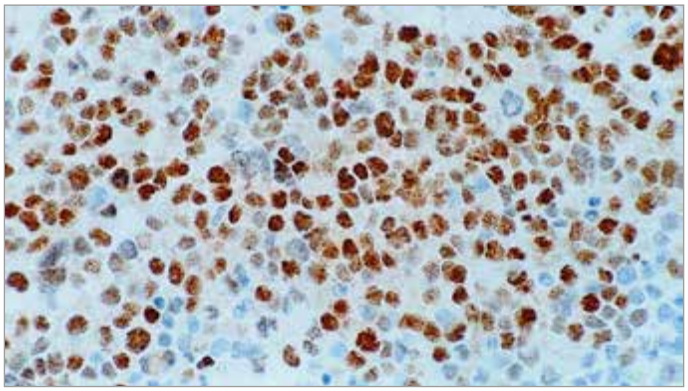
The murine MyoD1 gene encodes a phosphoprotein of 45 kD, the function of which may include the commitment, differentiation and maintenance of the myogenic lineage. MyoD1 is not expressed in normal adult tissue but is reported to be highly expressed in rhabdomyosarcomas.

MyoD1 (Rhabdomyosarcoma Marker) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

MyoD1 recognizes an epitope near the C-terminus of the MyoD1 protein (amino acids 180 to 189).

Myogenin (Myf-4)



Human rhabdomyosarcoma: immunohistochemical staining for Myf-4 protein.
Myogenin (Myf-4): clone LO26

LO26

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0226	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-Myf-4	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

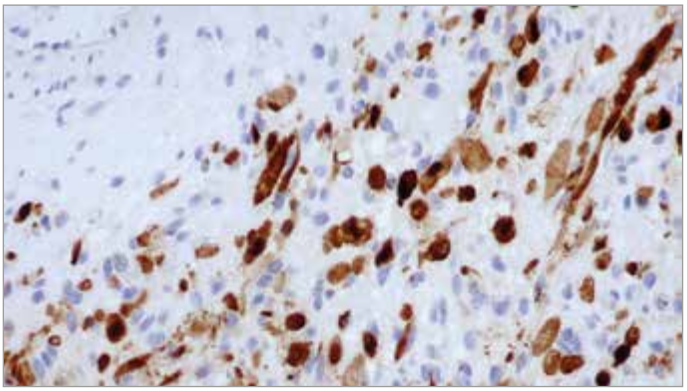
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Rhabdomyosarcomas are a class of myoblast-derived soft tissue sarcomas that usually express a number of muscle-specific genes and primarily affect children and young adults. Differentiation of myogenic cells is controlled by a set of regulatory genes including MyoD1, myogenin, Myf-5 and Myf-6. Myf-4 is the human homolog of myogenin. Its gene product, together with that of Myf-3, accumulates in the nucleus of differentiated cells.

Myogenin (Myf-4) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Myoglobin



Human rhabdomyosarcoma: immunohistochemical staining for myoglobin.
Myoglobin: clone MYO18

MYO18

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0727	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

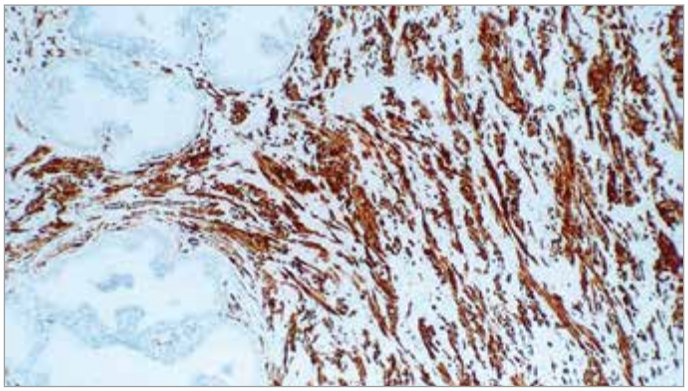
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Myoglobin is a cytoplasmic, single chain polypeptide of 153 amino acids that contains a single heme group. Myoglobin is reported to be expressed in skeletal and cardiac muscle but not in smooth muscle and functions as an oxygen transporting pigment.

Myoglobin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Myosin Heavy Chain Antibodies



Human prostate: immunohistochemical staining for myosin heavy chain. Note intense staining of muscle fibers. Myosin Heavy Chain (smooth muscle): clone S131

Smooth muscle: clone S131

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0493	P(HIER)	IVD	IVD	IVD

Developmental: clone RNMy2/9D2

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-MHCd	F	RUO	RUO	RUO

Fast: clone WB-MHCf

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-MHCf	F	RUO	RUO	RUO

Neonatal: clone WB-MHCn

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-MHCn	F	RUO	RUO	RUO

Slow: clone WB-MHCs

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-MHCs	F	RUO	RUO	RUO

PATHOLOGY MENU

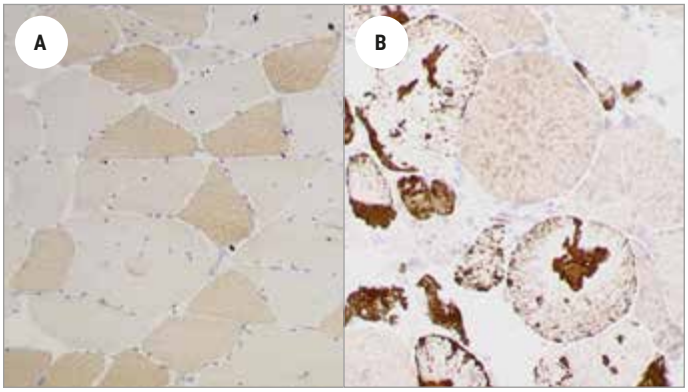
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Myosin is a contractile muscle specific protein composed of two heavy and four light chains. The myosin heavy chain has many isoforms which are specific for different muscles or fiber types, some of which are developmentally regulated. The range of myosin heavy chain antibodies may prove useful for investigating development of intrafusal and extrafusal muscle fibers and the course of muscle fiber regeneration. At the ultrastructural level, antibodies can reveal architectural details of the myofilament as well as the cytoplasmic and membrane sites of new myosin integration.

Myosin Heavy Chain Antibodies are recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Myotilin



Human skeletal muscle: immunohistochemical staining for Myotilin. Note sarcoplasmic staining of normal muscle fibers (A) and presence of protein aggregates (B).
Myotilin: clone RSO34

RSO34

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-MYOTILIN	F;P(HIER)	RUO	RUO	RUO

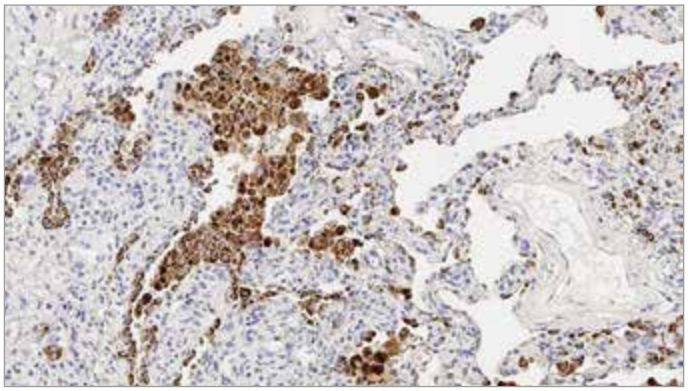
PATHOLOGY MENU

MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

The myotilin gene on chromosome 5q31 encodes a 498 amino acid polypeptide with a molecular weight of 57kD. Myotilin is a structural protein of sarcomeric Z discs and sarcolemma in human skeletal and cardiac muscle. It is homologous to palladin and titin in the two C-terminal Ig-domains and also to palladin in its unique serine-rich N-terminal region. Myotilin interacts with alpha-actinin, actin and gamma-filamin. Mutations in the myotilin gene are associated with limb-girdle muscular dystrophy 1 A (LGMD1A) and one form of Myofibrillar Myopathy. It is highly conserved between human and mouse with its expression being more widespread in the embryo than in the adult. Expression of myotilin has been reported in adult skeletal and cardiac muscle with variable expression reported in the peripheral nervous system, lung, liver and kidney. NCL-MYOTILIN will be of use in studies to determine the expression of myotilin in normal and pathological tissues.

Napsin A



Human lung: immunohistochemical staining for Napsin A. Note cytoplasmic staining of pneumocytes and alveolar macrophages. Napsin A: clone IP64

IP64

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0064	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-Napsin A	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

LUNG PATHOLOGY

ANTIGEN BACKGROUND

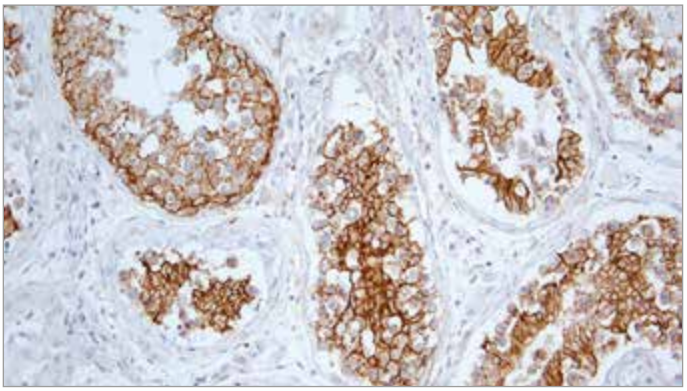
Napsin A has a specific function in normal alveolar epithelium and is proposed to play a role in the proteolytic processing of surfactant precursors.

Napsin A is reported to be predominantly expressed in lamellar bodies of type II pneumocytes, secondary lysosomes of alveolar macrophages, respiratory epithelium of terminal and respiratory bronchioles, plasma cells, within a subset of lymphocytes in normal lung, as well as in epithelial cells of renal tubules in normal kidney and is weakly expressed in normal spleen.

Studies have reported that Napsin A is expressed in 90% of primary lung adenocarcinomas.

Napsin A is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

N-Cadherin



Human testis: immunohistochemical staining for N-Cadherin. Note cytoplasmic and membrane staining of Sertoli cells. N-Cadherin: clone IAR06

IAR06

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-N-CAD	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

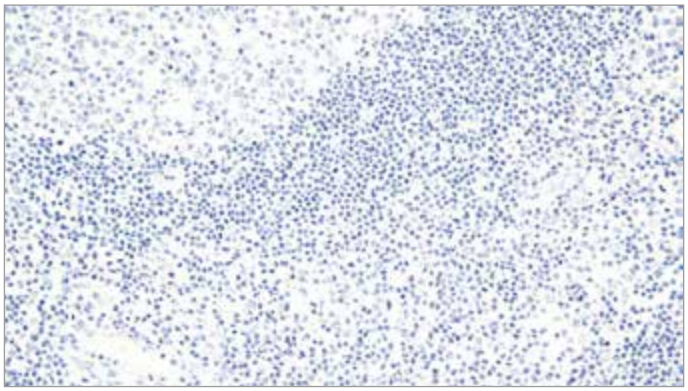
SPECIALIZED

ANTIGEN BACKGROUND

N-Cadherin is a member of the cadherin family of calcium dependent cell adhesion molecules. The classical cadherins include the E, N, R, P and VE-Cadherins which are believed to be expressed in a tissue specific manner. The classical cadherins have a characteristic structure comprising an extracellular calcium-binding domain, consisting of five repeats, a transmembrane domain and a highly conserved cytoplasmic domain, which mediates interactions with cytoskeletal components of the cell via interactions with intracellular proteins including the catenins. Cadherins play an important role in cell-cell adhesion, and are implicated in segregation and aggregation of tissues during development. N-Cadherin is reported to be expressed in various cell types including neural, myocardial and mesenchymal cells.

N-Cadherin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Negative Control (Mouse)



Human tonsil: immunohistochemical staining with BOND Ready-to-Use Negative Control (Mouse) using BOND Polymer Refine Detection. Negative Control (Mouse): clone MOPC-21

MOPC-21

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0996	P	IVD	IVD	IVD

ANTIGEN BACKGROUND

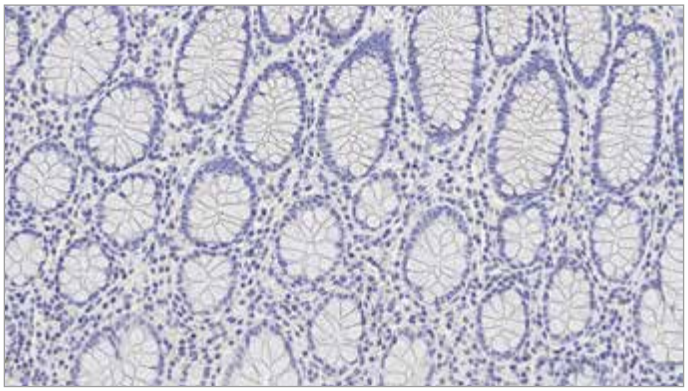
In some tissues, non-specific binding may occur, especially in neoplastic or necrotic tissue.

Negative Control (Mouse) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of Negative Control (Mouse) antibody is recommended to aid in the identification of cells, tissues or tissue components, which may non-specifically bind mouse antibodies and will help with interpretation of specific staining at the antigenic site.

Negative Control (Rabbit)



Human bowel: immunohistochemical staining with BOND Ready-to-Use Negative Control (Rabbit) using BOND Polymer Refine Detection. Negative Control

-

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0777	P	IVD	IVD	IVD

ANTIGEN BACKGROUND

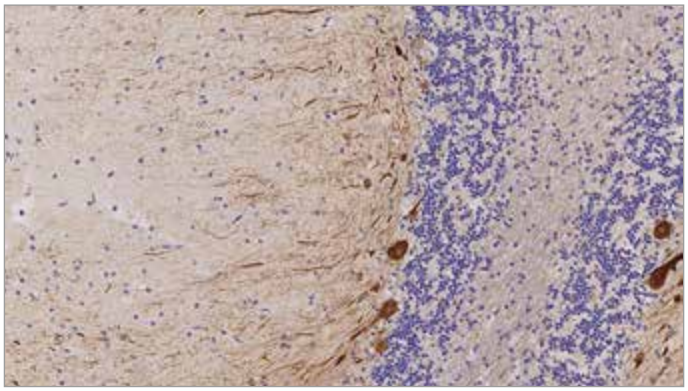
In some tissues, non-specific binding may occur, especially in neoplastic or necrotic tissue.

Negative Control (Rabbit) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of Negative Control (Rabbit) antibody is recommended to aid in the identification of cells, tissues or tissue components, which may non-specifically bind mouse antibodies and will help with interpretation of specific staining at the antigenic site.

Neurofilament 200kD



Human cerebellum: immunohistochemical staining for Neurofilament 200kD. Note cytoplasmic staining of neurons and their axons. Neurofilament 200kD: clone N52.1.7

N52.1.7

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0371	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-NF200-N52	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

NEUROPATHOLOGY

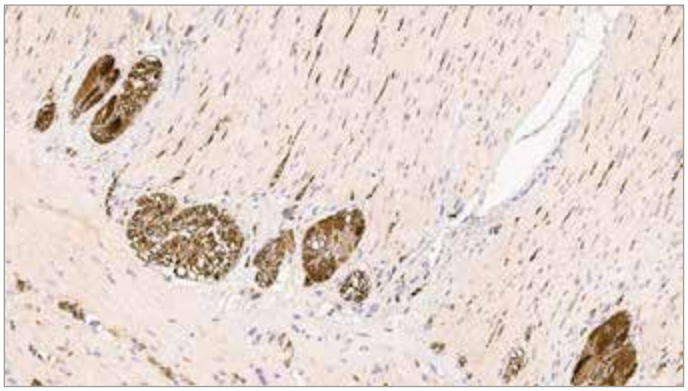
ANTIGEN BACKGROUND

Neurofilaments constitute the main structural elements of neuronal axons and dendrites. Neurofilaments are composed of three major subunits referred to as the neurofilament triplet, with molecular weights of 68 kD, 160kD and 200 kD.

Within tumors, only neoplastic cells of neural origin or those exhibiting neuronal differentiation, have been reported to express neurofilaments.

Neurofilament 200kD is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Neuron Specific Enolase



Human large bowel: immunohistochemical staining of Neuron Specific Enolase (NSE). Note the staining in the neuronal elements and the ganglia of the longitudinal and circular smooth muscle. Neuron Specific Enolase: clone 22C9

22C9

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0435	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

NEUROPATHOLOGY

ANTIGEN BACKGROUND

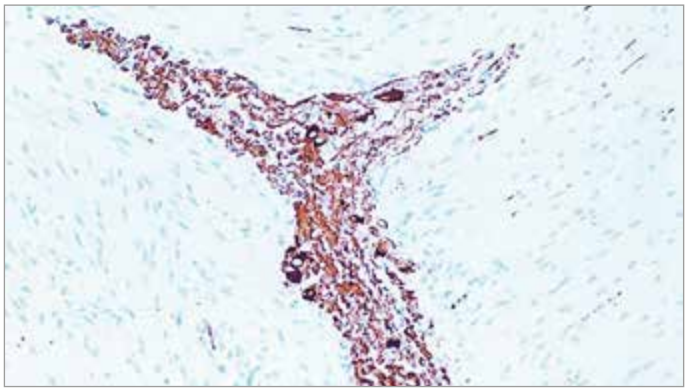
Enolase is a glycolytic enzyme catalyzing the reaction pathway between 2-phosphoglycerate and phosphoenol pyruvate. In mammals, enolase molecules are dimers composed of three distinct subunits (alpha, beta and gamma) whereas, in rats, five forms have been found. The alpha subunit and beta subunit are of approximately 47 kD and 45 kD, respectively. The gamma gamma and alpha gamma enolases are located mainly in the nervous tissue and neuroendocrine cells.

Neuron Specific Enolase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone 22C9 reacts with the gamma subunit of the enolase isoenzyme.

Nitric Oxide Synthase 1



Human small intestine: immunohistochemical staining for nitric oxide synthase 1. Note cytoplasmic staining of enteric ganglia. Nitric Oxide Synthase 1: clone NOS-125

NOS-125

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-NOS-1	P(HIER)	IVD	-	-

PATHOLOGY MENU

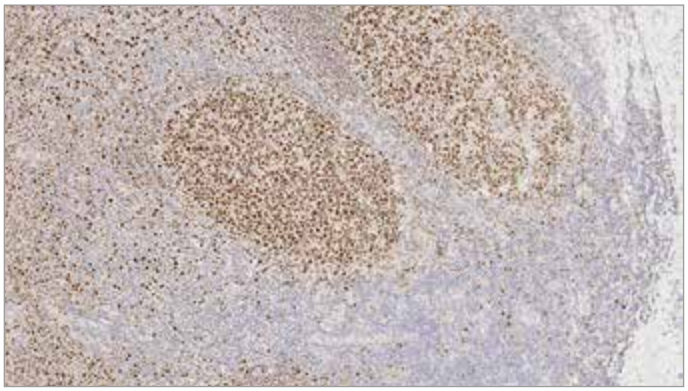
NEUROPATHOLOGY

ANTIGEN BACKGROUND

Human nitric oxide synthases are a family of enzymes responsible for the synthesis of nitric oxide (NO) from L-arginine and molecular oxygen. There are at least three nitric oxide synthases; NOS-1, also known as neuronal NOS or nNOS, NOS-2, which is referred to as inducible NOS or iNOS and NOS-3, also known as endothelial NOS or eNOS. As suggested by their nomenclature, these enzymes have different cellular distribution and are subjected to different regulatory mechanisms. NOS-3 is reported to be constitutively expressed and produces picomolar quantities of NO which play a role in signal transmission resulting in physiological effects. In the gastrointestinal tract, NO is reported to play a protective role where it has direct microbiocidal properties and acts as a first line of mucosal defence in the stomach. The function of NO in tumor development, promotion and progression is unclear. The effects may be both beneficial but also detrimental to those individuals with gastric cancer, where it is reported that NO supports tumor progression through the creation of neovasculature.

Nitric Oxide Synthase 1 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Oct-02



Human tonsil: immunohistochemical staining for Oct-2. Note strong staining of germinal centre B-cells. Oct-2: clone Oct-207

Oct-207

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0532	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

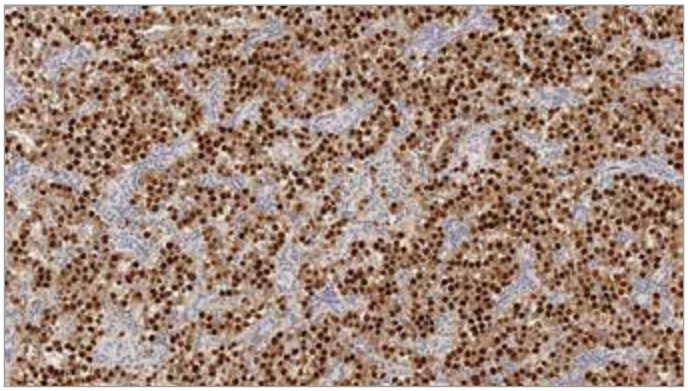
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Oct-2 is a transcription factor belonging to the POU homeo-domain family that binds to the Ig gene octamer sites regulating B cell specific genes. It is dependent on the activity of B cell restricted coactivators such as BOB.1/OBF.1. Oct-2 protein expression is not restricted to B cells, although expression levels are much higher in these cells. Reports indicate that germinal center B cells shows higher expression for Oct-2 and BOB.1/OBF.1. In addition, Oct-2 expression is reported to be significantly greater in germinal center derived lymphomas, although other B cell lymphomas also display high levels of expression. Reed Sternberg (RS) cells represent the malignant cells in classical Hodgkin's disease and are derived from germinal center B cells. In a number of these cases, cells do not express immunoglobulin due to the presence of crippling mutations within the Ig genes. As Ig gene expression in B cells also requires an interaction between octamer sites and the transactivating factors Oct-2 and BOB.1, the absence of both Oct-2 and BOB.1 expression represents a novel mechanism for immunoglobulin gene deregulation in RS cells.

Oct-2 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Oct-3/4



Human testes, seminoma: immunohistochemical staining for Oct-3/4. Oct-3/4: clone N1NK

N1NK

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0193	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-OCT3/4	P(HIER)	IVD	IVD	IVD

N1NK (Previous Formulation)

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0934	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

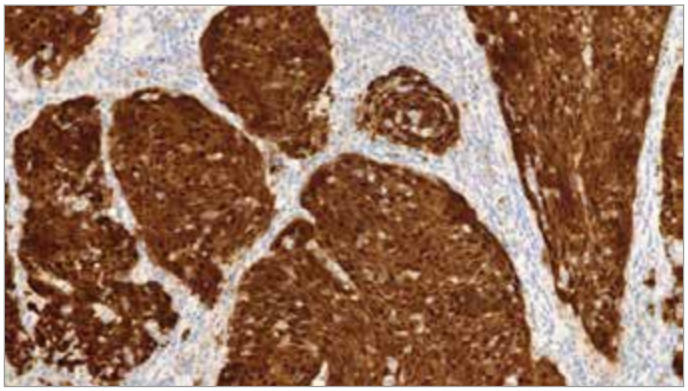
GYNEPATHOLOGY

ANTIGEN BACKGROUND

Oct-3/4 is a member of the POU homeodomain family of transcription factors, which is expressed by embryonic stem cells and germ cells. A critical amount of Oct-3/4 is required to maintain stem cell self replication. Down regulation of Oct-3/4 levels are associated with loss of pluripotency. Oct-3/4 has been proposed as a useful marker for germ cell tumors which exhibit features of pluripotentiality, including seminoma/dysgerminoma/germinoma and embryonal carcinoma, and establishing a germ cell origin for some metastatic tumors of uncertain primary origin.

Oct-3/4 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

p16



Squamous Cell Carcinoma of tonsil: immunohistochemical staining for p16. p16: clone 6H12

6H12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0016	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

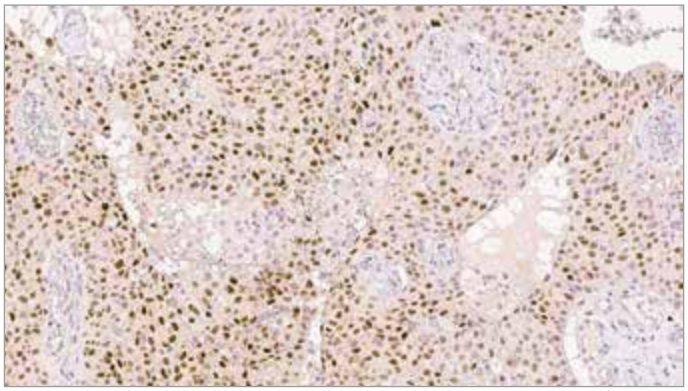
HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

p16 (INK4a) (Cyclin-dependent kinase inhibitor 2A (CDKN2A)) is a tumour suppressor protein associated with cell cycle progression, specifically in the regulation of transition from G1 phase of the cell cycle in to the S phase. Oncogenic mutations in the CDKN2A gene that encodes p16 (resulting in over or under expression of the protein) is associated with a wide range of cancers and cancer precursor lesions. Immunohistochemical identification of p16 is particularly relevant in oro-pharyngeal squamous cell carcinoma (OPSCC) and uterine cervical lesions, where expression is seen in the cytoplasm and nucleus of neoplastic cells.

p16 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

p21 (WAF1 Protein)



Squamous cell carcinoma: immunohistochemical staining of p21(WAF1): clone 4D10

4D10

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-WAF-1	P(HIER)	RUO	RUO	RUO

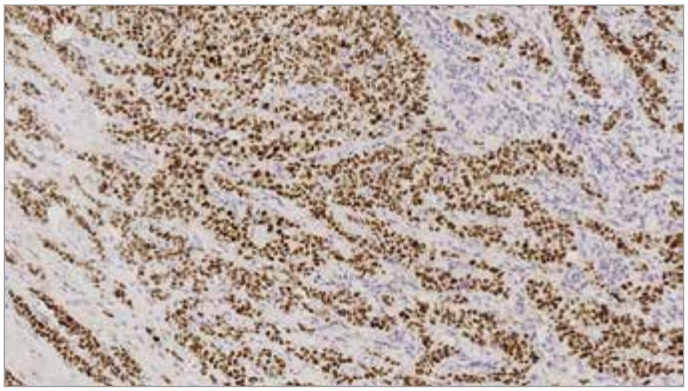
PATHOLOGY MENU

SPECIALIZED

ANTIGEN BACKGROUND

The gene encoding WAF1, also termed p21, is transcriptionally regulated by the suppressor protein, p53. Overexpression of WAF1 is growth suppressive, possibly by inhibiting the activity of cyclin/CDK complexes. One consequence of WAF1 binding to cyclin/CDK complexes is the inhibition of Rb protein phosphorylation. Induction of WAF1 expression requires wild type p53 activity in cells undergoing p53 dependent G1 arrest or apoptosis. Mutation of the p53 gene is a common event in human cancer and results in the failure to produce WAF1. The effect of this may lead to uncontrolled cell proliferation.

p53 Protein



Human ductal carcinoma of the breast: immunohistochemical staining of p53 Protein.
p53: clone DO-7

DO-7

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0057	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-p53-DO7	P	IVD	IVD	IVD/RUO

PATHOLOGY MENU

BREAST PATHOLOGY

ANTIGEN BACKGROUND

This monoclonal antibody recognizes both wild type and mutant forms of human p53 protein under denaturing and non-denaturing conditions. The epitope recognized by clone DO-7 can be destroyed by prolonged fixation in buffered formalin. The heat induced epitope retrieval technique may improve staining in some cases.

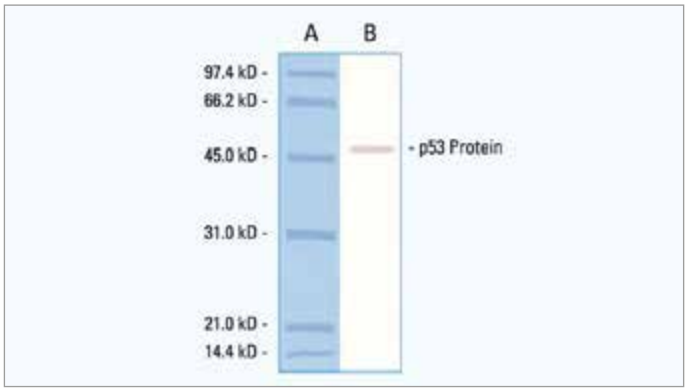
p53 Protein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

This monoclonal antibody recognizes both wild type and mutant forms of human p53 protein under denaturing and non-denaturing conditions. The epitope recognized by clone DO-7 can be destroyed by prolonged fixation in buffered formalin.

The use of the heat induced epitope retrieval (HIER) technique can enhance staining in some cases.

p53 Protein (CM5)



Western blot: detection of p53 protein (53 kD). Lane A, molecular weight markers. Lane B, T3T3 mouse cell line immunoblotted, p53 Protein (CM5): Polyclonal

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 0.5 mL	NCL-L-p53-CM5p	P(HIER)	RUO	RUO	RUO

PATHOLOGY MENU

SPECIALIZED

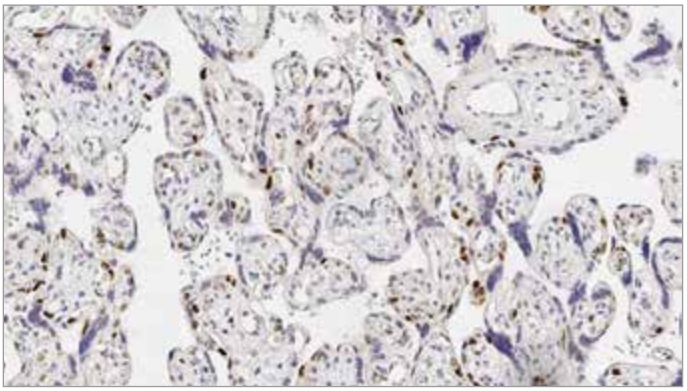
ANTIGEN BACKGROUND

The accumulation of p53 protein in response to genotoxic stress in vitro is well established and appears to induce growth arrest and apoptosis by the transcriptional regulation of other genes and possibly by other direct mechanisms.

PRODUCT SPECIFIC INFORMATION

NCL-L-p53-CM5p is specific for mouse and rat p53 protein.

p57 Protein (Kip2)



Human placenta: immunohistochemical staining for p57 protein. Note nuclear staining for cytotrophoblast and stromal cells of the villi. p57: clone 25B2

25B2

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-p57	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

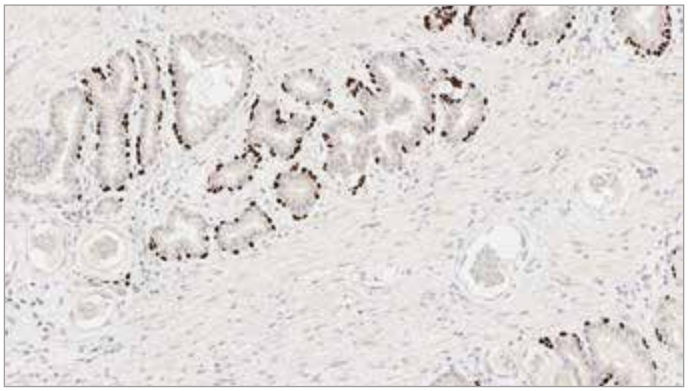
SPECIALIZED

ANTIGEN BACKGROUND

Cyclin-dependent kinases are positive regulators of cell proliferation. p57 protein acts as a tumor suppressor to counter this. It is closely related to other CDKIs such as p21 protein (CIP1) and p27 protein (Kip1) as they share a common structural N-terminal domain for binding to CDK/cyclin complexes and inhibiting their kinase activity. Human p57 protein is found on chromosome 11p15.5, a region which is reported to be a common site for loss of heterozygosity in certain sarcomas, Wilms' tumors and tumors associated with the Beckwith-Wiedemann syndrome. There is increasing interest in p57 as a marker in gestational disease. Gestational trophoblastic disease refers to a spectrum of proliferative disorders of the placental trophoblast, with a wide range of histologic appearances and clinical behaviors. Recent developments in changes in the criteria for histologic diagnosis of these lesions due to earlier clinical diagnosis have been reviewed Hui P et al., Advantages in Anatomical Pathology. 12(3): 116-125 (2005) and the ability to make more accurate diagnoses due to the introduction of newer antibodies such as p57 is discussed.

p57 Protein (Kip2) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

p63 Protein



Human prostate: immunohistochemical staining for p63. Note nuclear staining of basal cells of prostatic glands. p63: clone 7JUL

7JUL

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0103	P(HIER)	-	IVD	IVD
Liquid 1 mL	NCL-L-p63	P(HIER)	-	IVD	IVD

PATHOLOGY MENU

UROPATHOLOGY

ANTIGEN BACKGROUND

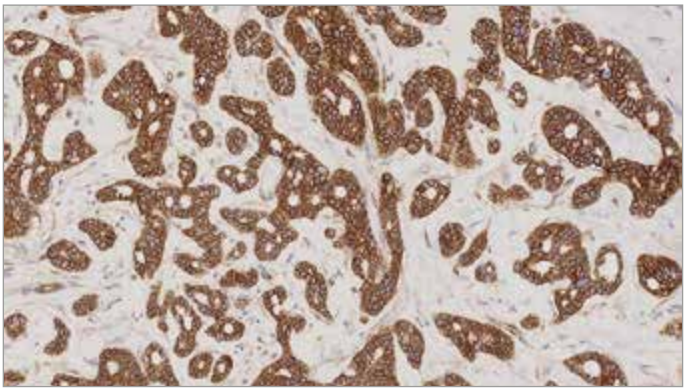
p63 is a type II integral membrane protein predominantly localized in the rough endoplasmic reticulum.

p63 is reported to be expressed in a number of normal tissues including proliferating cells of the epithelium, cervix, urothelium and prostate.

p63 is also reported to be expressed in most poorly differentiated squamous cell carcinomas.

p63 Protein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

p120 Catenin



Human breast carcinoma: immunohistochemical staining for p120 Catenin antigen. p120 Catenin: clone EP66

EP66

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0379	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

BREAST PATHOLOGY

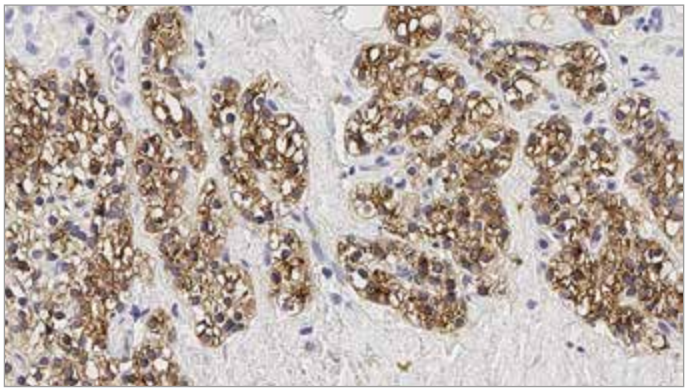
ANTIGEN BACKGROUND

p120 Catenin is a regulator of cell-cell adhesion, achieved through interaction with classical and Type II cadherins. Evidence also exists for a role in the regulation of cadherin availability on the cell surface. p120 Catenin also regulates actin dynamics, placing it as a potential master regulator of the cell motility/cell adhesion phenotypes.

Recent studies have suggested a tumor-suppression role for p120, with loss of p120 expression implicated in the development of a tumor microenvironment and induction of metastatic progression. The expression of p120 Catenin has been highlighted in early lobular breast neoplasias.

p120 Catenin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Parathyroid Hormone (PTH)



Human parathyroid adenoma: immunohistochemical staining for Parathyroid Hormone.
Parathyroid Hormone: clone 105G7

105G7

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-PTH-488	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

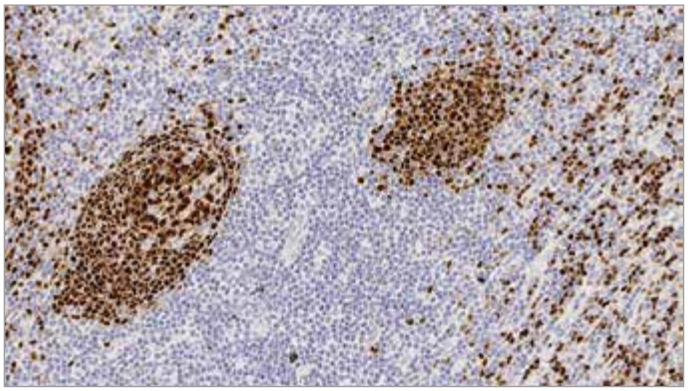
HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

The parathyroid glands are small, oval, endocrine glands closely associated with the thyroid gland. The parathyroid glands regulate serum calcium and phosphate levels via parathyroid hormone (parathormone). Parathyroid hormone raises serum calcium levels directly, by increasing the rate of osteoclastic reabsorption and promoting breakdown of the bone matrix, and indirectly, by increasing the renal tubular reabsorption of calcium ions and inhibiting the reabsorption of phosphate ions from the glomerular filtrate, and finally, by promoting the absorption of calcium from the small intestine. Parathyroid hormone is the most important regulator of blood calcium levels and is essential to life, whereas calcitonin appears only to provide a complementary mechanism for fine adjustment. Chief cells are the most abundant cells in the parathyroid gland and are responsible for the secretion of parathyroid hormone.

Parathyroid Hormone (PTH) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Pax-5



Human tonsil: immunohistochemical staining for Pax-5. Note nuclear staining of B cells.
Pax-5: clone 1EW

1EW

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0552	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-PAX-5	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

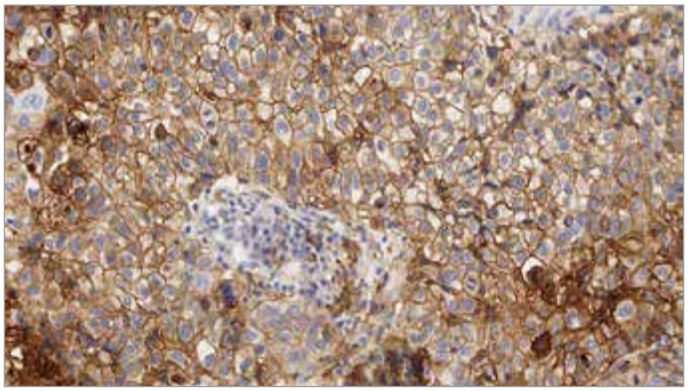
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Pax genes are a family of developmental control genes that encode nuclear transcription factors and have been implicated in the control of mammalian development. Pax-5 is a B cell specific transcription factor that is expressed in pro B cells, pre-B and mature B cells, and subsequently in all stages of B cell development until the plasma cell stage in which it is downregulated.

Pax-5 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PD-L1



Non-small cell lung cancer: immunohistochemical staining for PD-L1. PD-L1: clone 73-10

73-10

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0832	P (HIER)	IVD	IVD	IVD

PATHOLOGY MENU

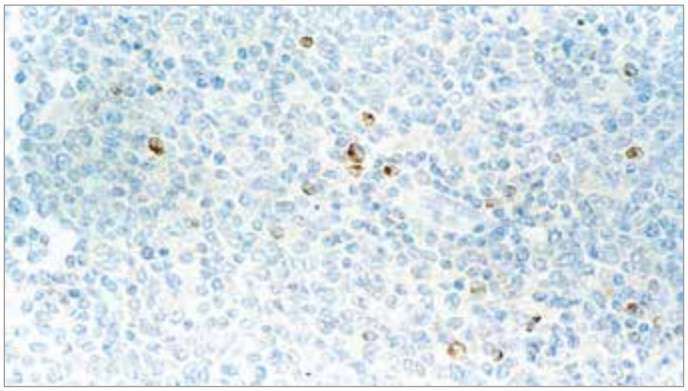
LUNG PATHOLOGY

ANTIGEN BACKGROUND

Programmed death-ligand 1 (PD-L1), CD274 or B7 Homolog 1(B7-H1) is a protein encoded by the CD274 gene. When bound to its ligands, PD-1 and B7.1, it plays an immunosuppressive role by inhibiting T-cell activity. Overexpression of PD-L1 by cancer cells may enable them to evade the host immune response, conferring a growth advantage to such tumours. PD-L1 expression levels detected by immunohistochemistry can therefore be of prognostic value in some types of cancer.

PD-L1 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Perforin



Human follicular lymphoma: immunohistochemical staining for Perforin. Perforin: clone 5B10

5B10

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-PERFORIN	P(HIER)	IVD	-	-

PATHOLOGY MENU

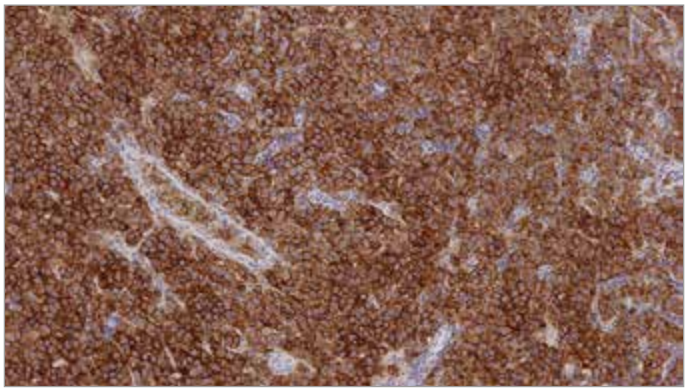
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Perforin is a pore-forming protein found in cytoplasmic granules of cytotoxic T-lymphocytes (CTLs). CTLs bind to cells which express foreign antigens and induce them to lyze. Perforin forms circular lesions on the target cell membrane similar to those induced by complement. Perforin and C9 share a high degree of homology particularly at the membrane spanning region. Perforin is reported to be constitutively expressed in human CD3 negative, CD56 positive NK cells, CD3 positive large granular lymphocytes and gamma/delta T cells. This expression is significantly induced in CD8 positive T cells but to a lesser extent in gamma/delta T cells and NK cells. The induction of perforin mRNA is partially blocked by the immunosuppressive drug cyclosporin A.

Perforin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Placental Alkaline Phosphatase



Human seminoma: immunohistochemical staining of Placental Alkaline Phosphatase.
Placental Alkaline Phosphatase (PLAP): clone 8A9

8A9

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0161	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-PLAP-8A9	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

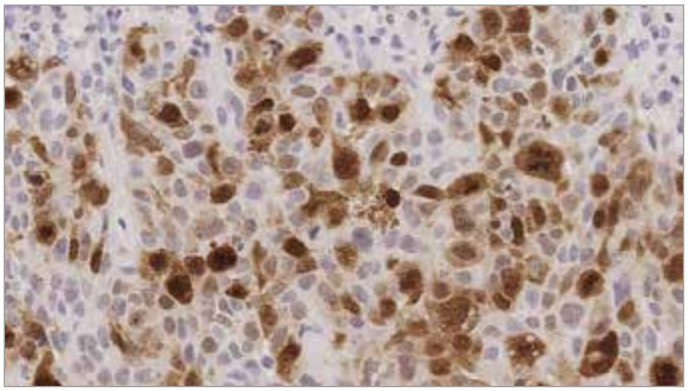
GYNEPATHOLOGY

ANTIGEN BACKGROUND

Placental alkaline phosphatase (PLAP) is a membrane-associated sialoglycoprotein enzyme normally present at high concentration in syncytiotrophoblasts within the placenta during the third trimester of gestation. The expression of PLAP was originally thought to be restricted to term placenta but a human PLAP-like variant has been described which shares more than 85% homology with PLAP itself. This high degree of homology between PLAP and PLAP-like enzyme together with cross-reacting antibodies has led to some confusion of the distribution of PLAP and PLAP-like enzyme in various tissues. PLAP is reported to be expressed only in normal term placenta, endocervix and fallopian tube and also in ovarian and proximal gastrointestinal tumors. PLAP expression is rare in malignant germ cell tumors. PLAP-like enzyme is reported to be predominantly found in normal fetal and neonatal testis, and in thymus. It is also commonly expressed in germ cell tumors and more recently described in seminomas.

Placental Alkaline Phosphatase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Polo-Like Kinase 1 (PLK-1)



Squamous cell carcinoma of oropharangeal tissue: immunohistochemical staining of PLK-1.
Polo-Like Kinase-1: clone MJS1

MJS1

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-PLK-1	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

SPECIALIZED

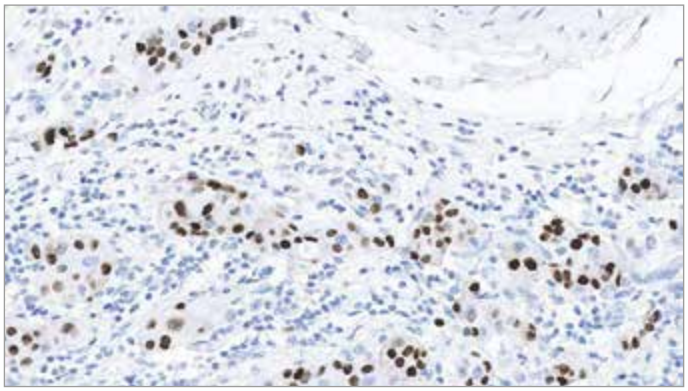
ANTIGEN BACKGROUND

Polo-Like Kinase-1 (PLK1) (also known as Serine/Threonine Protein Kinase 13) is a 66 kDa kinase. The activity of PLK-1 is crucial for mitosis and maintenance of genome stability. PLK-1 localizes to centrosomes and kinetochores where it plays a key role in late prophase and prometaphase. PLK-1 is overexpressed in many types of cancers and mediates estrogen receptor-mediated gene transcription in breast cancer cells.

Overexpression of PLK-1 is associated with tumor development, with elevated levels of expression reported in non-small cell lung cancers, head and neck, gastric, breast, ovarian, colon and several other cancer types.

Polo-Like Kinase 1 (PLK-1) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Progesterone Receptor



Breast carcinoma: immunohistochemical staining of Progesterone Receptor. Note the nuclear staining in a proportion of tumor cells. Progesterone Receptor: clone 16

16

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0312	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-PGR-312	P(HIER)	IVD	IVD	IVD
Liquid 2 mL	NCL-L-PGR-312/2	P(HIER)	-	IVD	IVD

1A6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-PGR	P(HIER)	-	IVD	IVD

PATHOLOGY MENU

BREAST PATHOLOGY

ANTIGEN BACKGROUND

The human progesterone receptor (PR) is expressed as two isoforms, PRA (94 kD) and PRB (114 kD), which function as ligand-activated transcription factors. These two isoforms are transcribed from distinct estrogen receptor (ER)-inducible promoters within a single copy PR gene.

The PRA form is a truncated version of the PRB form, lacking the first 164 N-terminal amino acids. In humans, PRA acts as a transdominant repressor of the transcriptional activity of PRB, glucocorticoid receptor, ER, androgen receptor and mineralocorticoid receptor. PRB functions mainly as a transcriptional activator. PRB is expressed strongly in endometrial glandular and stromal nuclei in the proliferative phase of the menstrual cycle and weakly during the secretory phase and early pregnancy.

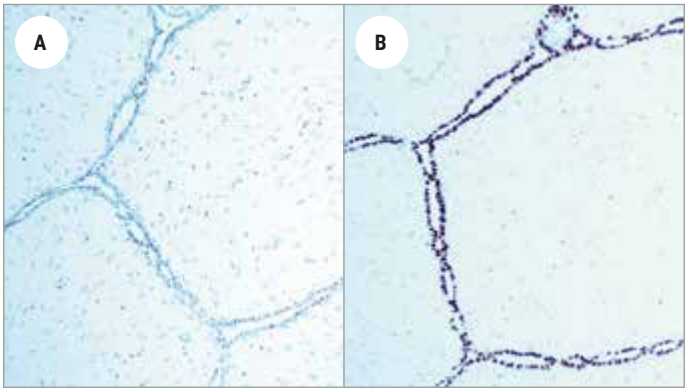
Progesterone Receptor is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone 16 is specific for a region of the N-terminus of the A form of PR. The precise epitope has not been mapped but it reacts with both A and B forms of PR by Western Blot but only with the A form by immunohistochemistry. This suggests that the epitope is inaccessible in the native folded B form of the protein.

Refer to the IFU for appropriate use instructions.

Progesterone Receptor (A/B Forms)



Human fibroadenoma (serial sections): immunohistochemical staining for Progesterone Receptor (A and B forms). Note a smaller proportion of weakly staining tumor cell nuclei in A compared to B. Progesterone Receptor (A/B Forms): clones 16/SAN27

16/SAN27

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-PGR-AB	P(HIER)	-	IVD	IVD

PATHOLOGY MENU

BREAST PATHOLOGY

ANTIGEN BACKGROUND

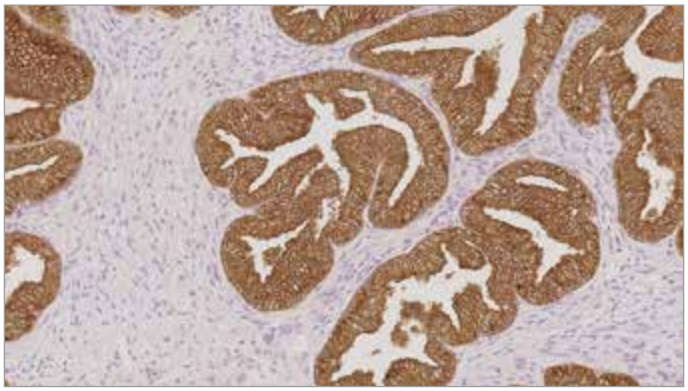
The human progesterone receptor (PR) is expressed as two isoforms, PRA (94 kD) and PRB (114 kD), which function as ligand-activated transcription factors. In vitro studies have indicated that PRA and PRB can activate different target genes and that PRA, in some circumstances, may act as a dominant inhibitor of the function of PRB and other steroid hormone receptors. PRA and PRB are both expressed in normal breast. Most endometrial carcinomas, however, are reported to express only one isoform with either PRA or PRB being expressed.

Progesterone Receptor (A/B Forms) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The cocktail has been formulated using two clones, clone 16, specific for PRA, and SAN27, specific for PRB.

Prostate Specific Antigen



Human prostatic hyperplasia: immunohistochemical staining of Prostate Specific Antigen. Prostate Specific Antigen: clone 35H9

35H9

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0431	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-PSA-431	P	IVD	IVD	IVD

PATHOLOGY MENU

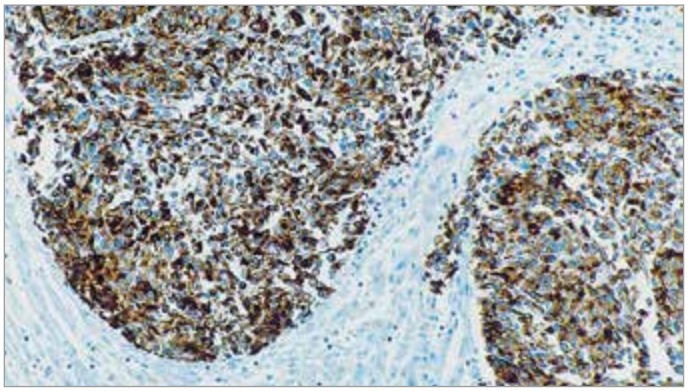
UROPATHOLOGY

ANTIGEN BACKGROUND

Prostate specific antigen (PSA) is a 34 kD protein belonging to the kallikrein family of serine proteases and was originally isolated and purified from human seminal plasma. It was found to be immunologically identical and biologically similar to a protein isolated from the prostate gland. PSA is distinct from prostatic acid phosphatase. Low levels of expression of PSA have been reported in non-prostatic tissues and tumors such as breast carcinomas.

Prostate Specific Antigen is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Prostate Specific Membrane Antigen



Human prostate: immunohistochemical staining for Prostate Specific Membrane Antigen (PSMA): clone 1D6

1D6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-PSMA	-	ASR	RUO	RUO

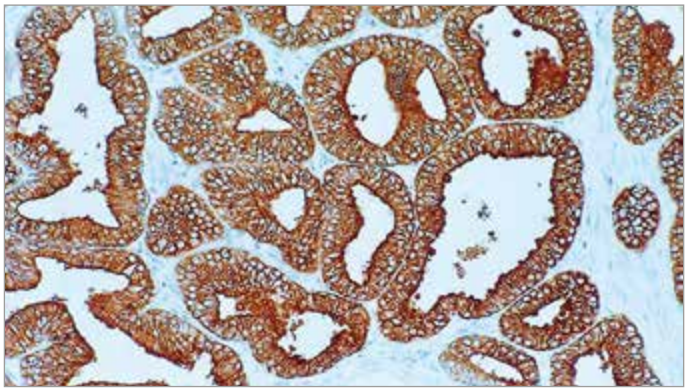
PATHOLOGY MENU

UROPATHOLOGY

ANALYTE SPECIFIC REAGENT

Analyte Specific Reagent. Analytical and performance characteristics are not established.

Prostatic Acid Phosphatase



Human prostate, adenocarcinoma: immunohistochemical staining for prostatic acid phosphatase. Prostatic Acid Phosphatase: clone PASE/4LJ

PASE/4LJ

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0006	P	IVD	IVD	IVD
Liquid 1 mL	NCL-L-PAP	F;P	RUO	RUO	RUO

PATHOLOGY MENU

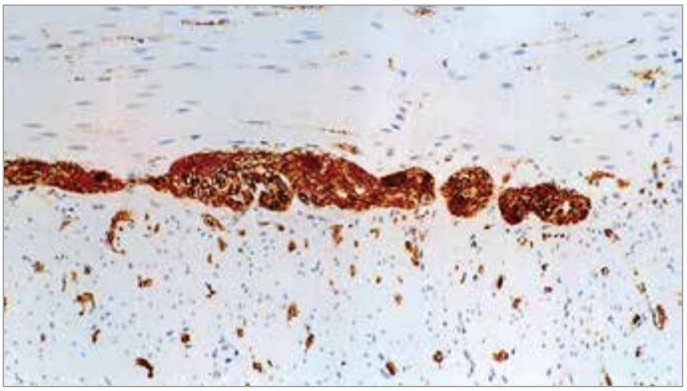
UROPATHOLOGY

ANTIGEN BACKGROUND

Prostatic acid phosphatase (PAP) is an isoenzyme of acid phosphatase found in large amounts in the prostate and seminal fluid. The precise function of PAP is unknown, but it may act as a hydrolase to split phosphoryl choline in semen and also function as a transferase. Elevated serum levels of the enzyme are reported in metastatic prostatic carcinoma.

Prostatic Acid Phosphatase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Protein Gene Product 9.5



Human colon: immunohistochemical staining of Protein Gene Product 9.5. Note the staining in the neuronal elements and the ganglia of the longitudinal and circular smooth muscle. Protein Gene Product 9.5: clone 10A1

10A1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0286	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-PGP9.5	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

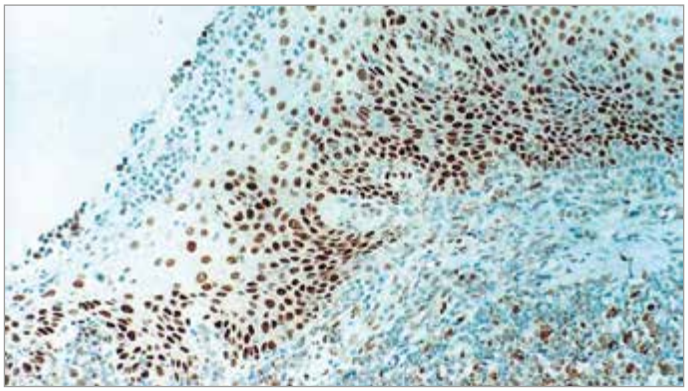
NEUROPATHOLOGY

ANTIGEN BACKGROUND

Protein gene product (PGP) 9.5 is a neuron-specific protein, structurally and immunologically distinct from neuron specific enolase. The protein which has a molecular weight of 27 kD was first identified by high resolution two dimensional PAGE. PGP9.5 expression has been reported in neurons and nerve fibers at all levels of the central and peripheral nervous system, in many neuroendocrine cells, in segments of the renal tubules, in spermatogonia and Leydig cells of the testis, in ova and in some cells of both the pregnant and non-pregnant corpus luteum. PGP9.5 is a member of the ubiquitin C-terminal hydroxylase family and is also concentrated within inclusion bodies suggesting that such structures may be metabolically active regions of the cells.

Protein Gene Product 9.5 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Retinoblastoma Gene Protein



Human tonsil: immunohistochemical staining for Retinoblastoma Gene Protein. Retinoblastoma Gene Protein: clone 13A10

13A10

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-RB-358	P(HIER);W	RUO	RUO	RUO

PATHOLOGY MENU

SPECIALIZED

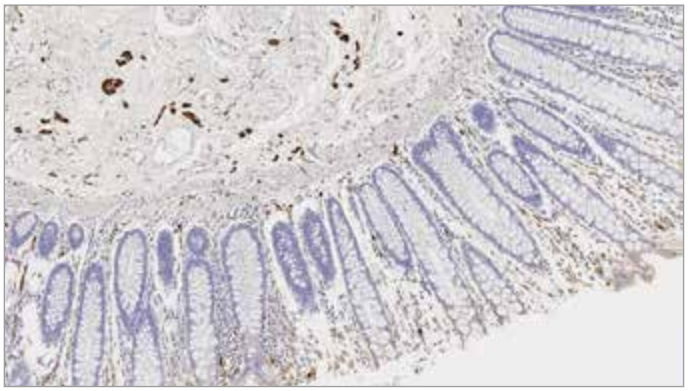
ANTIGEN BACKGROUND

Retinoblastoma (Rb) is a rare tumor of the retina associated with mutations of chromosome 13. The nuclear phosphoprotein encoded by the Rb tumor suppressor gene is present in many cells and may indirectly regulate cell growth by activating the transcription factor ATF-2. Activation of ATF-2 initiates expression of TGF-beta2, which in turn inhibits transcription of genes affecting cell growth. Bilateral mutation of the Rb gene may potentially play a role in the development of a number of malignant tumors.

PRODUCT SPECIFIC INFORMATION

NCL-L-RB-358 was raised to the N-terminal region of the Rb gene protein.

S-100



Human bowel: immunohistochemical staining for S-100. Note cytoplasmic staining of ganglia and peripheral nerve cells. S-100: Polyclonal

EP32

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0031	P(HIER)	IVD	IVD	IVD
Liquid 0.1 mL	NCL-L-S100-167	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

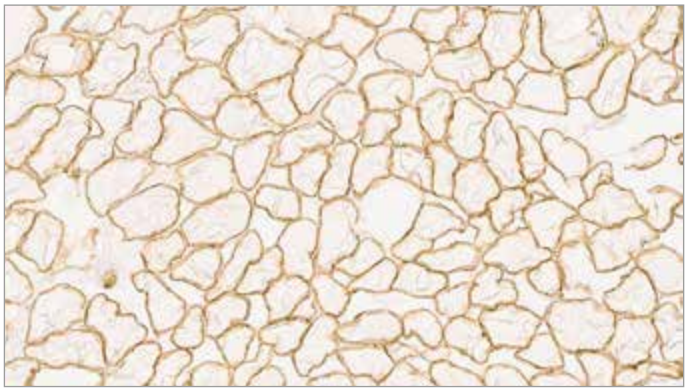
DERMATOPATHOLOGY

ANTIGEN BACKGROUND

S-100A and S-100B proteins are two members of the S-100 family of proteins. S-100A is composed of an alpha and beta chain, whereas S-100B is composed of two beta chains. S-100 protein is reported to be expressed in neuroectodermal tissue, including nerves and melanocytes. Langerhans cells in skin and interdigitating reticulum cells in the paracortex of lymph nodes are also reported to express S-100 protein. It is noteworthy that S-100 protein is highly soluble and may be eluted from frozen tissue during immunohistochemical procedures.

S-100 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Sarcoglycan Antibodies



Transverse section of skeletal muscle fibers. immunohistochemical staining for Alpha Sarcoglycan. Note the demonstration of localized Alpha Sarcoglycan to the sarcolemma of the muscle fibers. Alpha Sarcoglycan: clone Ad1/20A6

Alpha Sarcoglycan: clone Ad1/20A6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-a-SARC	F	IVD	IVD	IVD

Beta Sarcoglycan: clone βSarc1/5B1

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-b-SARC	F	IVD	IVD	IVD

Delta Sarcoglycan: clone δSarc3/12C1

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-d-SARC	F	IVD	IVD	IVD

Gamma: clone 35DAG/21B5

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-g-SARC	F	IVD	IVD	IVD

PATHOLOGY MENU

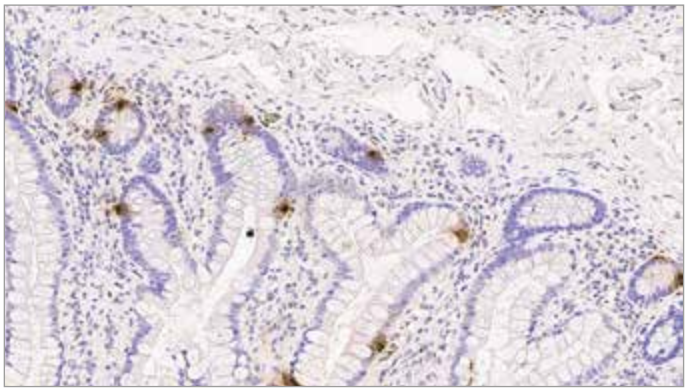
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

In normal skeletal muscle, dystrophin, the protein product of the gene which is defective in Duchenne and Becker muscular dystrophy, is attached to the muscle membrane via a complex of proteins (dystrophin-associated glycoproteins, DAGs). Dystrophin-deficient muscle shows a generalized reduction in DAG labeling. The expression of different members of the dystrophin glycoprotein complex is altered in several types of muscular dystrophy. For example, patients with LGMD2D have mutations in the gene for alpha-sarcoglycan, those with LGM2E have mutations in the beta-sarcoglycan gene, those with LGM2C have mutations in the gamma-sarcoglycan gene and those with LGM2F have mutations in the delta-sarcoglycan gene. As the sarcoglycans function together as a sub-complex, mutations in any one of the sarcoglycan genes usually results in variable expression for the whole group.

Sarcoglycan Antibodies are recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Serotonin



Human bowel: immunohistochemical staining for Serotonin-containing mucosal cells. Serotonin: Polyclonal

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0736	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

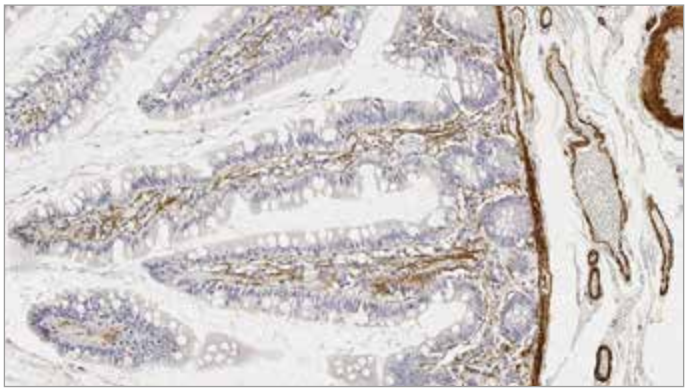
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Serotonin (5-hydroxytryptamine, 5-HT) is reported to be a widely distributed neurotransmitter and hormone in the mammalian peripheral and central nervous system (CNS). Serotonin is formed by the decarboxylation of 5-hydroxy-tryptophan, its intermediate, which in turn is formed by hydroxylation of L-tryptophan by tryptophan hydroxylase. In the CNS, the action of serotonin is terminated by reuptake into the presynaptic terminal by specific serotonin transporters. Serotonin has been implicated in several neuropsychiatric disorders such as anxiety, depression and schizophrenia. The majority of serotonergic nerve terminals in the CNS originate in neuronal cell bodies of the Raphe nuclei (dorsal, median), nucleus Raphe obscurus and nucleus Raphe pallidus in the brainstem which project to specific areas of the brain and spinal cord. Serotonin is thought to be an inhibitory neurotransmitter regulating a wide range of sensory, motor and cortical functions in the CNS. In the periphery, serotonin is reported to be present in neural and non-neural structures such as platelets, gastro-intestinal tract (myenteric plexus, enterochromaffin cells), lungs (neuroepithelial cells), thyroid gland and spleen.

Serotonin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

SMA (Alpha Smooth Muscle Actin)



Human small bowel: immunohistochemical staining for Alpha Smooth Muscle Actin. Note cytoplasmic staining of the muscularis mucosa, vascular walls and smooth muscle fibers in the lamina propria. SMA: clone αsm-1

αsm-1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0943	P	IVD	IVD	IVD
Liquid 1 mL	NCL-L-SMA	P	IVD	IVD	IVD

PATHOLOGY MENU

MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Cytoplasmic actins are part of the microfilament system of cytoskeletal proteins. Smooth muscle actin is found in vascular walls, intestinal muscularis mucosae and muscularis propria and in the stroma of various tissues.

SMA (Alpha Smooth Muscle Actin) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

An enzyme pretreatment can be used to enhance staining in some cases.

Spectrin

Human striated muscle: immunohistochemical staining for Spectrin. Note membrane staining of muscle fibers. Spectrin: clone RBC2/3D5

RBC2/3D5

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-SPEC1	F	IVD	IVD	IVD

PATHOLOGY MENU

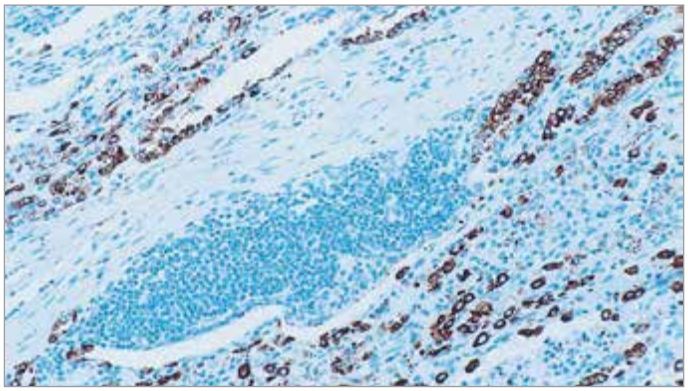
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Spectrin is a cytoskeletal protein which has some structural homology with dystrophin, the protein that is defective in Duchenne and Becker muscular dystrophy. Subtle membrane damage frequently occurs during the excision and freezing of muscle biopsies. Labeling for spectrin must be used to monitor membrane integrity. NCL-SPEC1 recognizes the beta chain of spectrin in erythrocytes and muscle. NCL-SPEC1 reacts with human beta-spectrin.

Spectrin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Surfactant Protein A



Human lung adenocarcinoma: immunohistochemical staining for Surfactant Protein A. Surfactant Protein A: clone 32E12

32E12

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-SP-A	P(HIER)	IVD	-	-

PATHOLOGY MENU

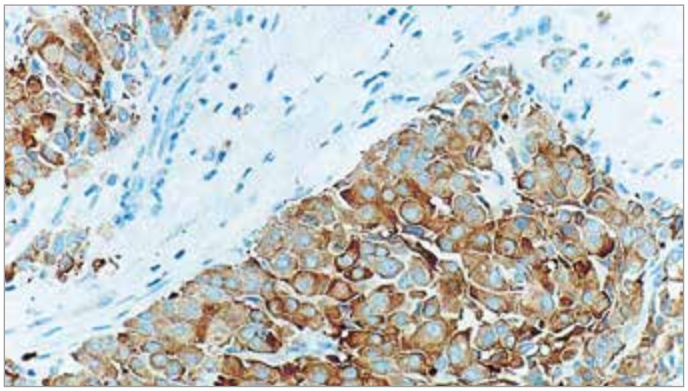
LUNG PATHOLOGY

ANTIGEN BACKGROUND

Pulmonary surfactant plays a critical role in maintaining the structural integrity of the respiratory epithelium by reducing surface tension during expiration. It is a lipoprotein complex which is synthesized and secreted into the alveoli of the lung by type II pneumocytes. Lung surfactant protein-A (SP-A) is a major phospholipid-associated glycoprotein in surfactant and is a member of the C-type lectin superfamily that also inhibits lipid secretion and enhances the uptake of phospholipid by alveolar type II cells. Levels of SP-A in amniotic fluid are reported to reflect the degree of fetal lung maturity and inadequate levels of surfactant at birth, a frequent occurrence in premature infants, results in respiratory failure.

Surfactant Protein A is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Synaptophysin



Breast carcinoma showing neuroendocrine differentiation: immunohistochemical staining for Synaptophysin. Synaptophysin: clone 27G12

27G12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0299	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-SYNAP-299	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

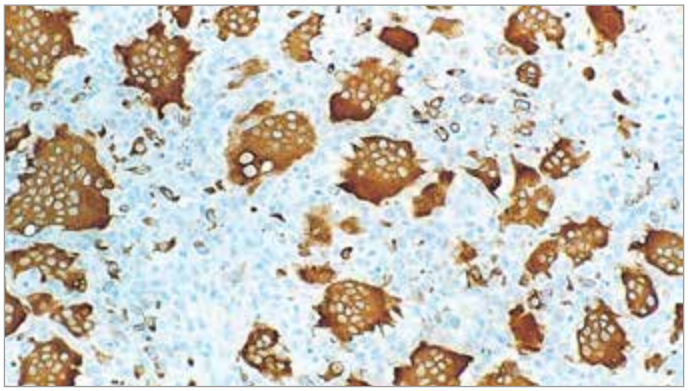
Synaptophysin is an integral membrane glycoprotein with a molecular weight of 38 kD. It is reported to occur in presynaptic vesicles of neurons in brain, spinal cord, retina, in similar vesicles of the adrenal medulla as well as in neuromuscular junctions.

Synaptophysin may be involved in synaptic vesicle formation and exocytosis. Synaptophysin is reported to be expressed in a wide spectrum of neuroendocrine tumors including neuroblastomas, ganglioneuroblastomas, phaeochromocytomas, chromaffin and non-chromaffin paragangliomas.

Synaptophysin is also reported to be expressed in neuroendocrine tumors of epithelial type including pituitary adenomas, islet cell tumors, medullary carcinomas of thyroid, parathyroid adenomas, carcinoids of the bronchopulmonary and gastrointestinal tracts, neuroendocrine carcinomas of the bronchopulmonary and gastrointestinal tract and neuronendocrine carcinomas of the skin.

Synaptophysin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Tartrate-Resistant Acid Phosphatase (TRAP)



Human osteoclastoma: immunohistochemical staining for Tartrate-Resistant Acid Phosphatase. Tartrate-Resistant Acid Phosphatase (TRAP): clone 26E5

26E5

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0093	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-TRAP	P(HIER)	IVD	-	-

PATHOLOGY MENU

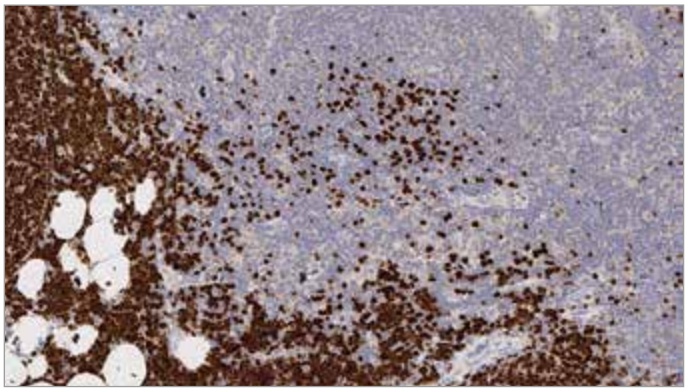
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Tartrate-resistant acid phosphatase (TRAP) is a basic, iron-binding protein with high activity towards phosphoproteins, ATP and 4-nitrophenyl phosphate. This isoenzyme has been reported through different applications to be expressed in human alveolar macrophages, osteoclasts, spleen and liver. Expression of TRAP is reported to be increased in the spleen and monocytes of individuals with Gaucher's disease, Hodgkin's disease and the sera of individuals undergoing active bone turnover. Elevated levels are also reported to be associated with various B cell and T cell leukemias and lymphomas, decidual cells, syncytiotrophoblasts and some macrophages distributed throughout maternal and embryonic tissues.

Tartrate-Resistant Acid Phosphatase (TRAP) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Terminal Deoxynucleotidyl Transferase



Human thymus: immunohistochemical staining for Terminal Deoxynucleotidyl Transferase. Note nuclear staining for cortical thymic lymphocytes. Terminal deoxynucleotidyl transferase: clone SEN28

SEN28

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0339	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-TDT-339	P(HIER)	-	IVD	IVD/RUO
Liquid 1 mL	NCL-L-TDT-339	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

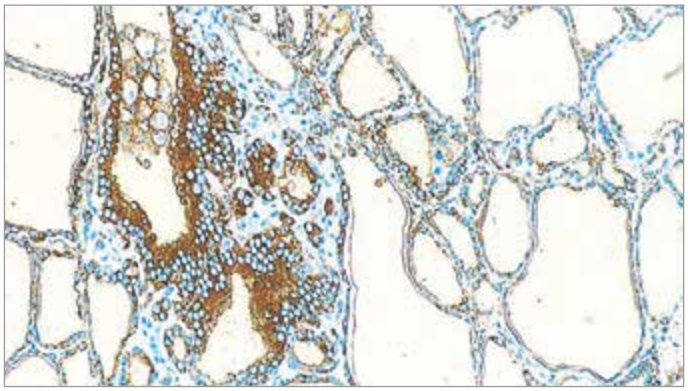
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Terminal deoxynucleotidyl transferase (TdT) is a DNA polymerase of 58 kD located in the cell nucleus which catalyzes the polymerization of deoxynucleotides at the 3' hydroxyl ends of oligo or polydeoxynucleotide initiators and functions without a template. TdT is reported to be expressed in primitive T and B lymphocytes of the normal thymus and bone marrow. The identification of TdT-positive cell populations in primary and secondary lymphoid organs during maturation of the immune system is one area of interest but it is the reported occurrence of high levels of enzyme activity in white blood cells and bone marrow in certain leukemias which is of particular interest.

Terminal Deoxynucleotidyl Transferase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Thyroglobulin



Human Thyriod: immunohistochemical staining of Thyroglobulin in the follicular epithelial cells. Thyroglobulin: clone 1D4

1D4

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-THY	F;P	RUO	RUO	RUO

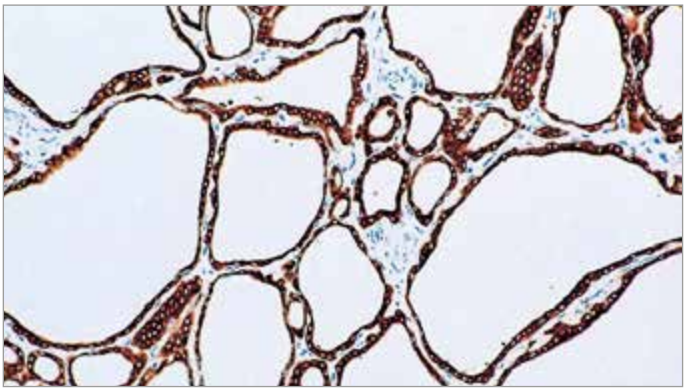
PATHOLOGY MENU

HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

Thyroglobulin is a heavily glycosylated protein of 670kD composed of two identical subunits and is synthesized by the follicular epithelial cells of the thyroid. Thyroglobulin provides iodination sites for the formation of the thyroid hormones.

Thyroid Peroxidase



Thyroid, Graves' disease: immunohistochemical staining for Thyroid Peroxidase. Thyroid Peroxidase: clone AC25

AC25

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-TPO	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

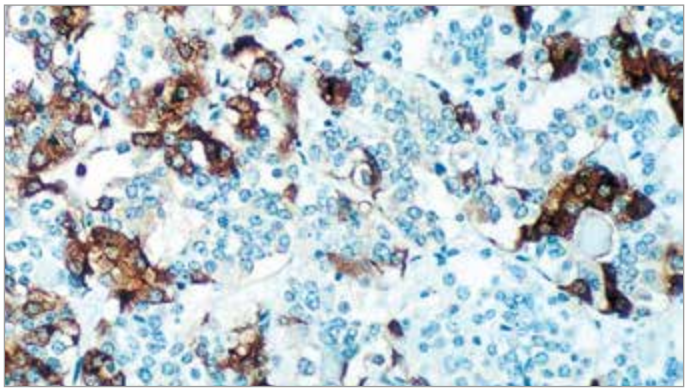
Thyroid peroxidase gene expression is under the regulation of thyroid stimulating hormone. In normal thyroid, expression of thyroid peroxidase (TPO) described immunohistochemically is reported to produce a diffuse, fine, granular cytoplasmic stain in all follicular cells. Some studies have shown qualitative, as well as quantitative differences in thyroid peroxidase expression in thyroid cancer compared to normal tissue.

Thyroid Peroxidase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

TPO stains optimally when used in TBS-based wash buffer and diluent systems.

Thyroid Stimulating Hormone



Normal human pituitary gland: immunohistochemical staining for Thyroid Stimulating Hormone. Note cytoplasmic staining of a proportion of anterior pituitary cells. Thyroid Stimulating Hormone: clone QB2/6

QB2/6

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0776	P(ENZYME)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-TSH	P(ENZYME)	IVD	-	-

PATHOLOGY MENU

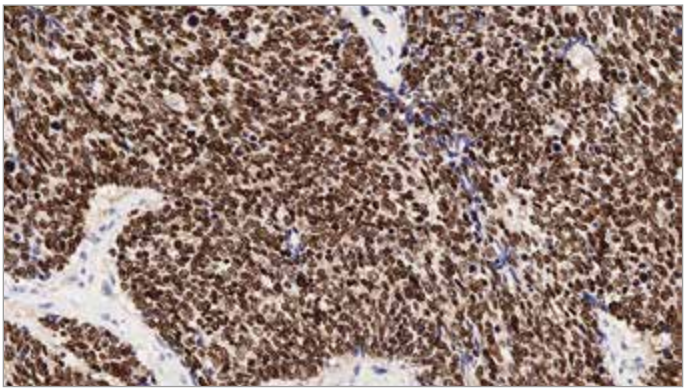
HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

Thyroid stimulating hormone (TSH) is a pituitary hormone of 28 kD which stimulates thyroid growth and production of thyroid hormones. TSH is reported to be expressed in thyrotrophic cells of the pituitary and pituitary adenomas.

Thyroid Stimulating Hormone is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Thyroid Transcription Factor-1



Human small cell lung carcinoma: immunohistochemical staining with Thyroid Transcription Factor-1. Thyroid Transcription Factor-1: clone SPT24

SPT24

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0364	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-TTF-1	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

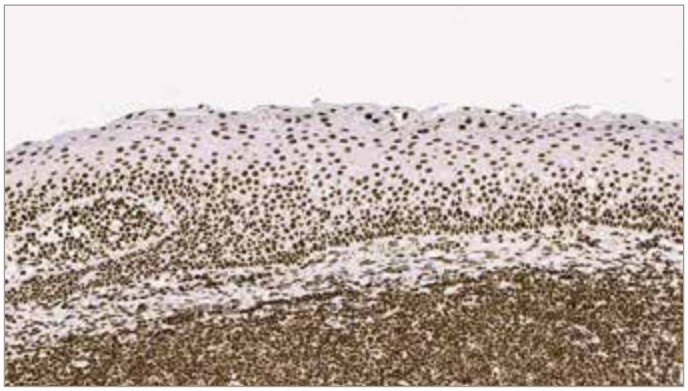
LUNG PATHOLOGY

ANTIGEN BACKGROUND

Thyroid Transcription Factor-1 (TTF-1) is a member of the homeodomain transcription factor family and plays a role in regulating genes expressed within the thyroid, lung and brain. These include thyroglobulin, thyroid peroxidase, Clara cell secretory protein and surfactant proteins. Human TTF-1 (38 kD) is a single polypeptide of 371 amino acids sharing 98% homology with the equivalent rat and mouse proteins. TTF-1 functions by binding to specific recognition sites in a manner that may be regulated by both the redox and phosphorylation status of the protein. In addition to its role as a tissue-specific transcriptional activator in adult organs, TTF-1 may also function in organogenesis. Gene targeting studies have shown TTF-1 to be essential for the proper development of the thyroid and lungs and abnormal expression may underline a number of congenital abnormalities.

Thyroid Transcription Factor-1 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Topoisomerase I



Human tonsil: immunohistochemical staining for Topoisomerase I. Topoisomerase I: clone 1D6

1D6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-TOPO I	P(HIER)	IVD	-	-

PATHOLOGY MENU

SPECIALIZED

ANTIGEN BACKGROUND

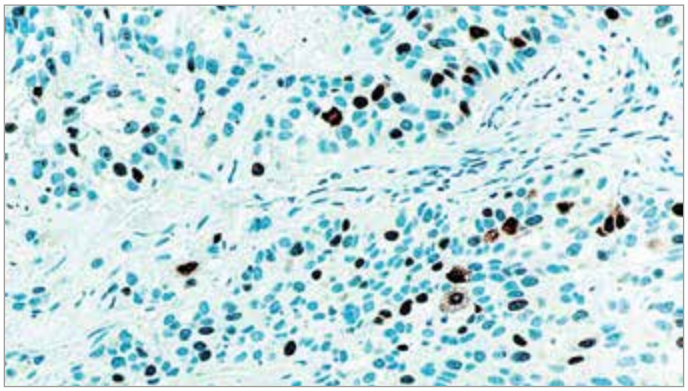
Topoisomerases are nuclear enzymes involved in a variety of cellular activities such as chromosomal condensation, DNA replication, transcription, recombination and segregation at mitosis. Human Topoisomerase I is a 100 kD protein capable of relaxing positively and negatively supercoiled DNA by performing a transient single-stranded nick which is then re-ligated at the end of the reaction. It has been shown that the enzyme is located in regions of the genome that are undergoing active RNA synthesis where it probably reduces superhelical stresses in the DNA enabling RNA polymerase to function properly. In normal eukaryotic cells, DNA topoisomerase I does not show relevant fluctuations across the cell cycle, unlike DNA topoisomerase II alpha. Both DNA topoisomerases I and II have been found to be targets of autoantibodies in the sera of individuals with certain autoimmune diseases, for example, systemic lupus erythematosus and also of some anti-tumor drugs and antibiotics. Elevated levels of DNA topoisomerase I, detected by 32P transfer assays, have been reported in colorectal tumors compared with normal colon mucosa as a result of increased transcription or mRNA stability.

Topoisomerase I is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of phosphate-containing wash buffers or diluents can have an adverse effect on staining. Tris-containing wash buffers or diluents should be used instead.

Topoisomerase II Alpha



Human bladder tumor: immunohistochemical staining for Topoisomerase II alpha. Topoisomerase II Alpha: clone 3F6

3F6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-TOPOIIA	P(HIER)	IVD	-	-

PATHOLOGY MENU

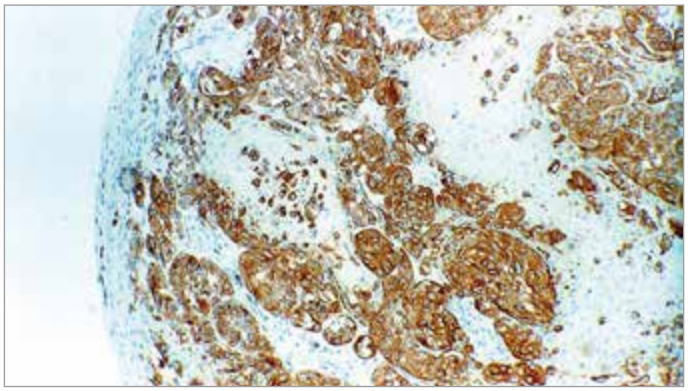
SPECIALIZED

ANTIGEN BACKGROUND

Topoisomerase II alpha is an essential nuclear enzyme involved in DNA replication and is a target for many anti-cancer drugs used for cancer therapy. Decreased expression of topoisomerase II alpha is the predominant mechanism of resistance to several chemotherapeutic agents. A significant variation in the range of expression of this protein has been reported in many different tumors. Reports of the analysis of primary breast tumors have indicated that topoisomerase II beta is more widely expressed than topoisomerase II alpha. Topoisomerase II alpha expression and activity is linked to the cell cycle and is associated with the proliferation status of cells.

Topoisomerase II Alpha is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Tyrosinase



Human malignant melanoma: immunohistochemical staining for Tyrosinase: clone T311

T311

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0322	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-TYROS	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

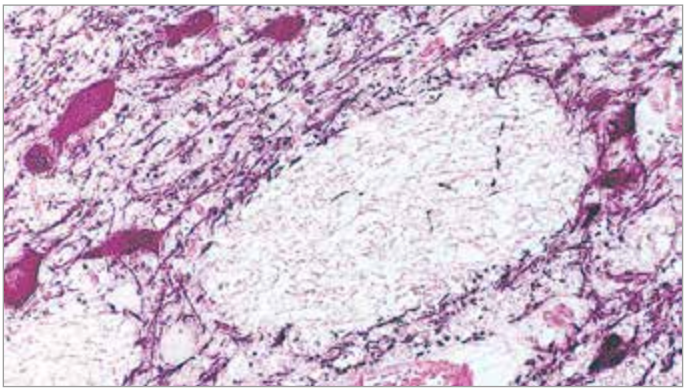
DERMATOPATHOLOGY

ANTIGEN BACKGROUND

The biosynthesis of melanin in melanocytes involves a family of enzymes, a key member of which is tyrosinase. Tyrosinase deficiency is associated with various forms of albinism and in particular oculocutaneous albinism. L-tyrosinase is the initial substrate for melanin biosynthesis and its conversion to dopaquinone is catalyzed by tyrosinase, whose expression is reported in melanocytes and melanomas.

Tyrosinase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Tyrosine Hydroxylase



Human midbrain: immunohistochemical staining of Tyrosine Hydroxylase enzyme. Note cytoplasmic staining of catecholaminergic cells and their processes. (Peroxidase substrate: nickel DAB, Counterstain: eosin). Tyrosine Hydroxylase: clone 1B5

1B5

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-TH	P(HIER)	IVD	-	-

PATHOLOGY MENU

NEUROPATHOLOGY

ANTIGEN BACKGROUND

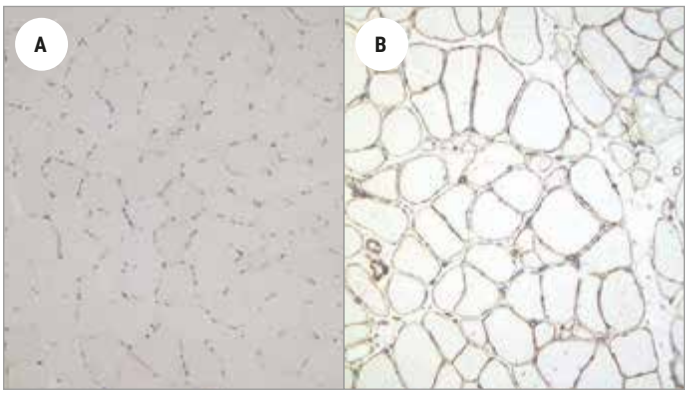
Tyrosine hydroxylase is the first enzyme in catecholamine (CA) biosynthesis and catalyzes the conversion of L-tyrosine to L-DOPA. Tyrosine hydroxylase is reported to be expressed in all CA neurons. Despite the abundant data about the distribution of catecholaminergic neurons in a wide variety of species, data on their distribution in the human brain is less comprehensive. However, one such study has reported that tyrosine hydroxylase products in the substantia nigra were restricted to neural bodies, axons and dendrites. These in turn were restricted to the third decade of life and their number increased in this location with age. This finding may be related to ageing of melanin-pigmented neurons.

Tyrosine Hydroxylase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

TH is reactive with tyrosine hydroxylase in human, mouse and rat brain tissue.

Utrophin



Human skeletal muscle: immunohistochemical staining for Utrophin. In control muscle the antibody labels blood vessels and neuromuscular junctions (A). Utrophin is expressed at the sarcolemma in individuals with mutations in the DMD gene (B). Utrophin: clone DRP3/20C5

DRP3/20C5

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 2.5 mL	NCL-DRP2	F	IVD	IVD	IVD

PATHOLOGY MENU

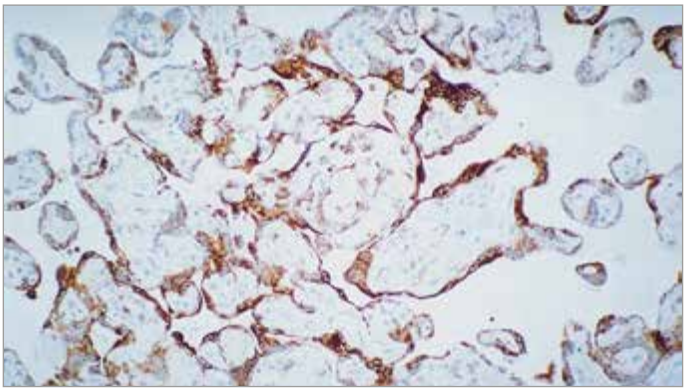
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

The utrophin gene is located on chromosome 6. The protein is a homologue of dystrophin and is known as dystrophin-related protein. In normal muscle, utrophin is restricted to neuromuscular junctions; however, in dystrophin-deficient muscle, utrophin expression may be upregulated and labeling appears around the periphery of most fibers. Immunohistochemical staining with DRP2 labels vessels and neuromuscular junctions and the upregulated form of utrophin, located around fiber membranes.

Utrophin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Vascular Endothelial Growth Factor Receptor-3



Human placenta: immunohistochemical staining for Vascular Endothelial Growth Factor Receptor-3: clone KLT9

KLT9

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-VEGFR-3	-	ASR	RUO	RUO

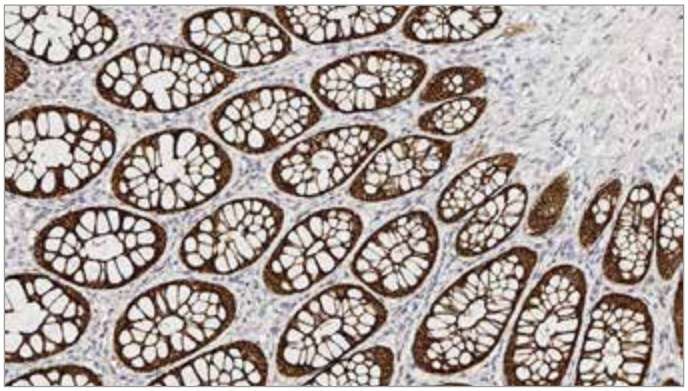
PATHOLOGY MENU

SPECIALIZED

ANALYTE SPECIFIC REAGENT

Analyte Specific Reagent. Analytical and performance characteristics are not established.

Villin



Human large bowel: immmunohistochemical staining for Villin. Note cytoplasmic staining of the epithelial cells. Villin: clone CWWB1

CWWB1

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-VILLIN	-	ASR	RUO	RUO

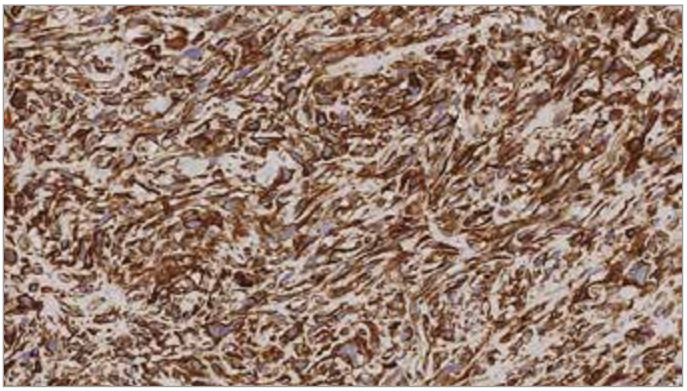
PATHOLOGY MENU

GASTROINTESTINAL PATHOLOGY

ANALYTE SPECIFIC REAGENT

Analyte Specific Reagent. Analytical and performance characteristics are not established.

Vimentin



Spindle cell carcinoma: immmunohistochemical staining for Vimentin. Vimentin: clone V9

V9

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0640	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-VIM-V9	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-VIM-V9	P(HIER)	IVD	IVD	IVD/RUO

SRL33

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-VIM-572	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

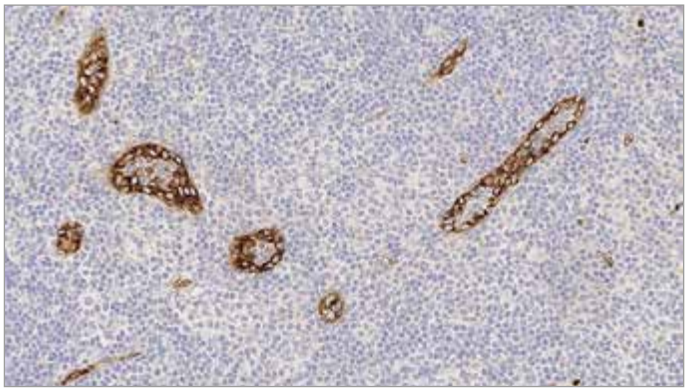
TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

Eukaryotic cells contain a number of types of cytoplasmic filamentous proteins, microtubule, microfilaments and intermediate-sized filaments (IF). Vimentin, a 57 kD protein that is an intermediate filament is reported to be expressed in most cells of mesenchymal origin, including fibroblasts, endothelial cells, smooth muscle, melanocytes as well as T and B lymphocytes.

Vimentin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

von Willebrand Factor (Factor VIII-related antigen)



Human tonsil: immunohistochemical staining for von Willebrand Factor. Note cytoplasmic staining of endothelial cells. Von Willebrand Factor: clone 36B11

36B11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0055	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-vWF	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

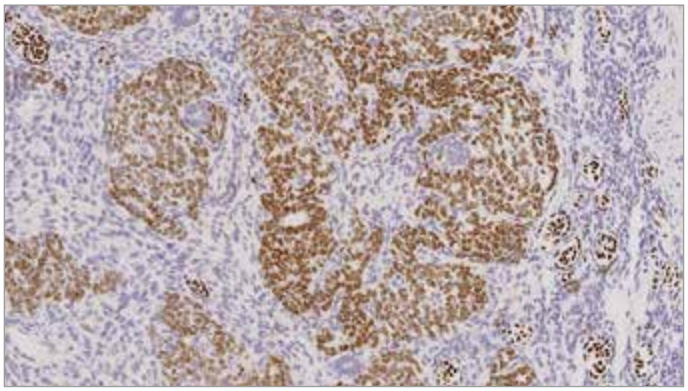
SOFT TISSUE PATHOLOGY

ANTIGEN BACKGROUND

Human von Willebrand factor (or factor VIII-related antigen) is a 270 kD multimeric plasma glycoprotein. It mediates platelet adhesion to injured vessel walls and serves as a carrier and stabilizer for coagulation factor VIII. The von Willebrand factor has functional binding domains to platelet glycoprotein Ib, glycoprotein Ib/IIIa, collagen and heparin. Von Willebrand factor is synthesized by endothelial cells and is reported to be expressed in a number of tumors of vascular origin.

von Willebrand Factor (Factor VIII-related antigen) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Wilms' Tumor



Human kidney: immunohistochemical staining for Wilms' tumor. Wilms' Tumor: clone WT49

WT49

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0562	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-WT1-562	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

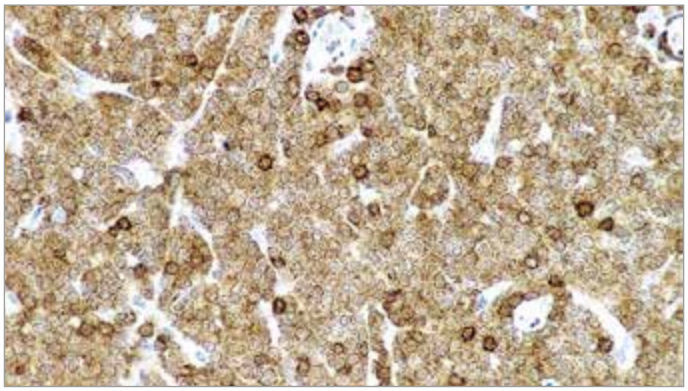
UROPATHOLOGY

ANTIGEN BACKGROUND

Wilms' tumor protein (WT1) has a role in transcriptional regulation and is expressed in the kidney and a subset of hematopoietic cells. Alteration of transcription factor function is a common mechanism in oncogenesis. The WT1 protein contains a DNA binding domain and any deletions or point mutations of the WT1 gene which destroy this activity result in the development of the childhood nephroblastoma Wilms' tumor and Denys-Drash syndrome. The description of WT1 involvement in nephroblastoma is not clear.

Wilms' Tumor is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

ZAP-70



Human B cell chronic lymphocytic leukemia: immunohistochemical staining for ZAP-70 antigen. ZAP-70: clone L453R

L453R

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0998	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-ZAP-70	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

ZAP-70 is a member of the syk family of proteins. It is expressed on T cells and NK cells and is required for the T cell receptor activation that triggers an immune response. CLL B cells that express the non-mutated immunoglobulin VH genes express levels of ZAP-70 protein that are comparable to those found in the blood T cells of healthy adults. Leukemic cells that express mutated Ig VH genes generally do not express detectable levels of ZAP-70 protein and this is correlated with the high level expression of CD38.

ZAP-70 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.