



**Microarray
Zelllinienkontrollen**



Microarray Zelllinienkontrollen

Qualität beginnt bei der Kontrolle



Vom Sehen
zum Erkennen.

medac

Qualität beginnt bei der Kontrolle

Eine Anforderung an die Qualitätsstandardisierung ist die angemessene Verwendung von Kontrollen. Diese müssen reproduzierbar, kostengünstig und robust genug für Immunhistochemie (IHC) und In-situ-Hybridisierung (ISH) sein. Mittlerweile hat sich die Verwendung von Zelllinienkontrollen auch in der Routinediagnostik etabliert. Im Gegensatz zu den klassischen Gewebekontrollen besitzen Zelllinien zudem den Vorteil, dass die Gen- und Proteinexpression innerhalb eines Blocks, aber auch chargenübergreifend, konstant ist und Abweichungen bei der immunhistochemischen Färbung leichter erkannt werden können.

Microarray Zelllinienkontrollen der Firma HistoCyte Laboratories Ltd.

- Microarray Zelllinienkontrollen enthalten Stanzen von Zelllinien mit einem **definierten Expressionsbereich der jeweiligen Biomarker**
- Zelllinien wurden in 10% neutral gepuffertem Formalin fixiert, in Paraffin eingebettet und **können nach Standardprotokollen prozessiert werden**
- Zelllinien besitzen eine **hohe Zelldichte mit einer gewebeähnlichen Struktur**
- Kontrollen sind geeignet für **Immunhistochemie (IHC) und In-situ-Hybridisierung (ISH)**
- **Dynamic Range^{DR}: Unterschiedliche Expressionsniveaus** zeigen die Test Performance innerhalb eines dynamischen Bereiches der Proteinexpression
- Verfügbare Parameter: **ALK, ER, Her2, HPV/p16, MLH1, MSH2, MSH6, NTRK, PD-L1, PMS2, PR, ROS1**

Verschiedene Formate passen sich Ihrem Bedarf an

Die Zelllinienkontrollen sind erhältlich als Paraffinblock und als bereits aufgezogene Schnitte. Gerade für Labore mit einem hohen Bedarf an Kontrollmaterial ist der Block eine kosteneffektive Wahl.



Paraffinblock:

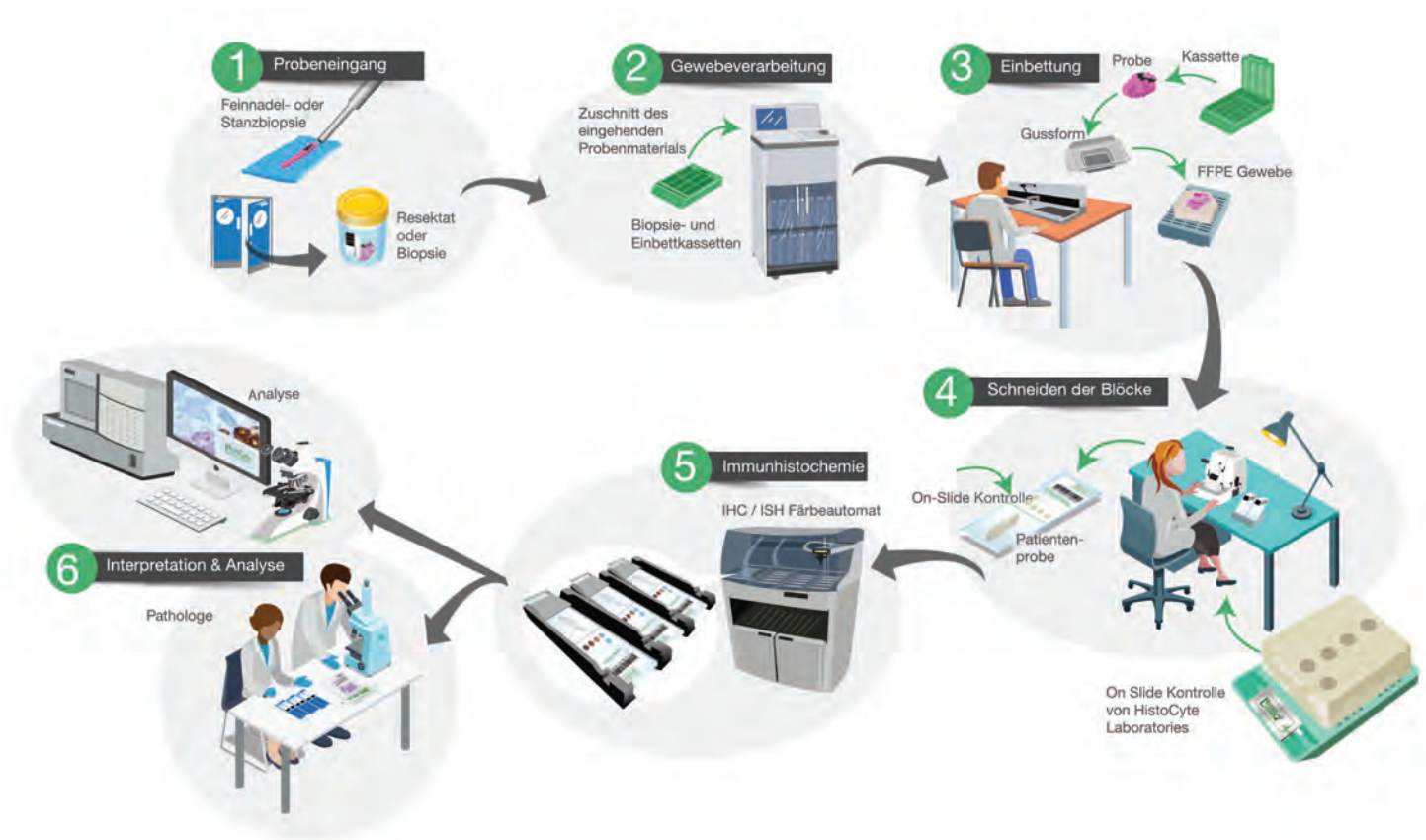
- Microarray Zelllinienkontrollen enthalten Stanzen mit einem Durchmesser von ca. 2mm und einer Höhe von ca. 3 – 3,5mm
- Block ist ausreichend für mindestens 300 Schnitte
- Haltbarkeit von bis zu 3 Jahren



Objektträger:

- Vorgeschnittene Schnitte besitzen eine Schnittdicke von 4µm
- Schnitte wurden auf positiv geladene Objektträger aufgezogen und über Nacht bei 37°C inkubiert
- Erhältlich als 2 und 5 Objektträger pro Packung

Schnell und einfach in die Arbeitsabläufe der Routinediagnostik integrierbar.



Da die Zelllinienkontrollen nach gängigen Standardprotokollen hergestellt wurden, sind diese schnell und einfach in die Arbeitsabläufe der Routinediagnostik integrierbar. Zudem können anhand der Zelllinienkontrollen auch Abweichungen bei vorangegangenen Arbeitsschritten wie Gewebeverarbeitung identifiziert werden. Nicht zuletzt ist die Verwendung von Zelllinienkontrollen zeitsparend, da die sonst erforderliche Zeit der Gewebeprozessierung und Validierung entfällt.

Ihre Vorteile auf einen Blick:

- ✓ Standardisiert, zuverlässig und kosteneffektiv
- ✓ Validiert mittels standardisierter Assays
- ✓ Ermöglicht eine konsistente Kontrolle der Assay Performance
- ✓ Dauerhafte Verfügbarkeit der Kontrollen
- ✓ **Dynamic Range^{DR}**: Unterschiedliche Expressionsniveaus zeigen die Test Performance innerhalb eines dynamischen Bereiches der Proteinexpression

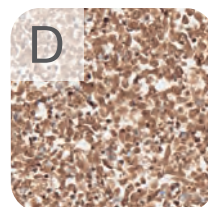
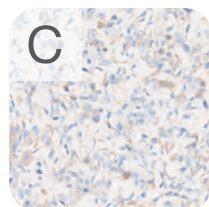
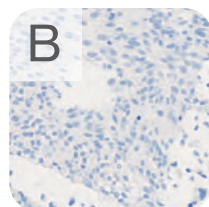
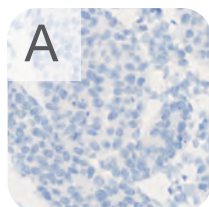
ALK Analyte Control

4 Zellstanzen
positiv bzw. negativ für WT ALK, positiv für EML4-ALK und NPM-ALK

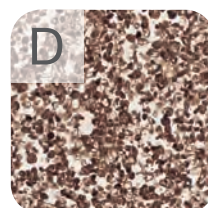
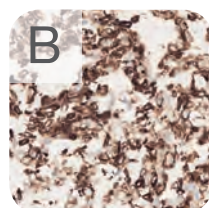
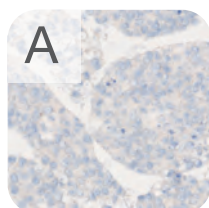


Größe	Kat.-Nr.
2 OT	HCL053
5 OT	HCL054
1 Block	HCL055

ALK
01



D5F3



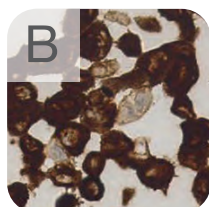
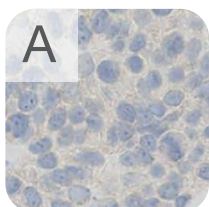
ALK (Lunge)

2 Zellstanzen
positiv bzw. negativ für EML4-ALK Gentranslokation und
Expression des Fusionsproteins

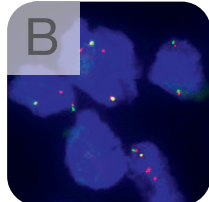
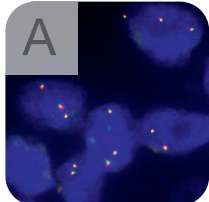


Größe	Kat.-Nr.
2 OT	HCL007
5 OT	HCL008
1 Block	HCL009

IHC



ISH



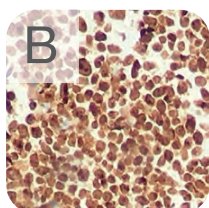
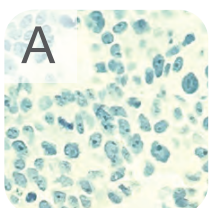
ALK (Lymphom)

2 Zellstanzen
positiv bzw. negativ für NPM-ALK Gentranslokation und
Expression des Fusionsproteins



Größe	Kat.-Nr.
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5 OT	HCL011
1 Block	HCL012

IHC



Breast Analyte Control^{DR}

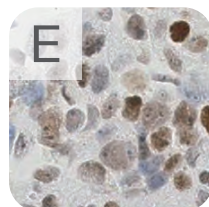
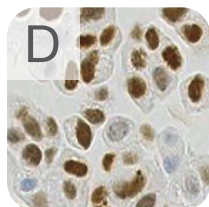
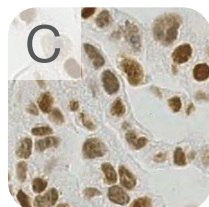
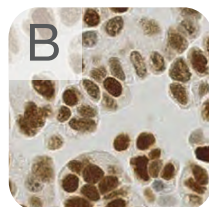
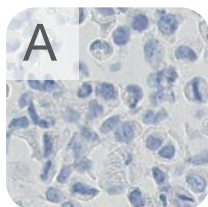
5 Zellstanzen

Dynamic Range: positiv bzw. negativ für Her2 Genamplifikation, verschiedene ER, PR und Her2 Proteinlevel

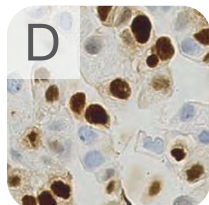
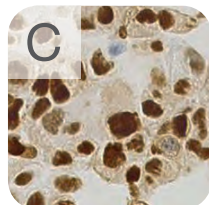
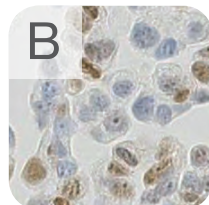
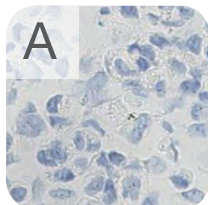


Größe	Kat.-Nr.
2 OT	HCL016
5 OT	HCL017
1 Block	HCL018

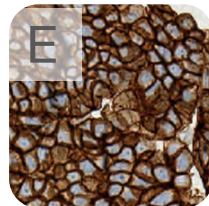
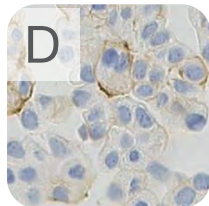
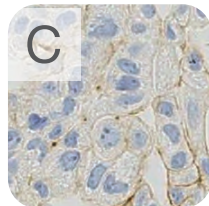
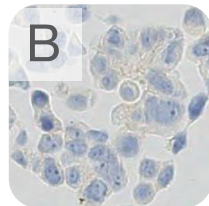
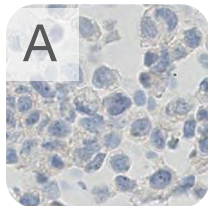
IHC
ER



IHC
PR



IHC
Her2



Breast Analyte Control

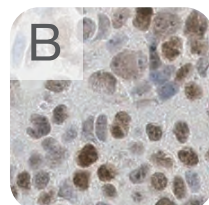
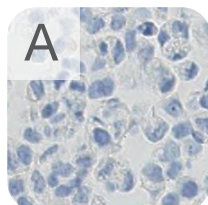
2 Zellstanzen

positiv bzw. negativ für Her2 Genamplifikation und Protein-expression von ER, PR und Her2

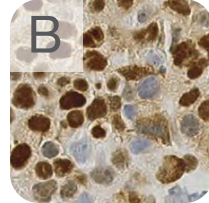
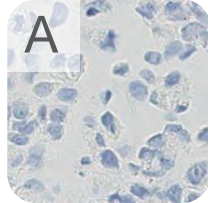


Größe	Kat.-Nr.
2 OT	HCL013
5 OT	HCL014
1 Block	HCL015

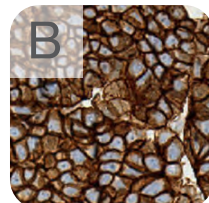
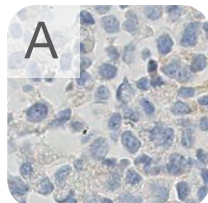
IHC
ER



IHC
PR



IHC
Her2



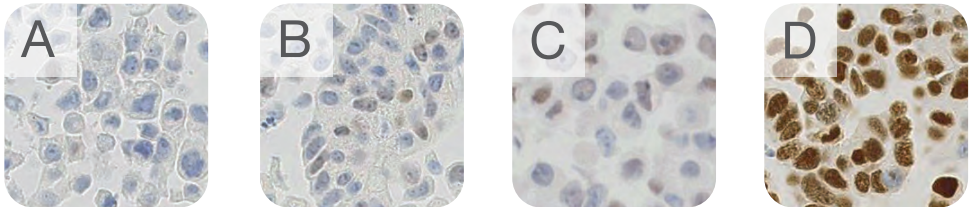
Estrogen Receptor Analyte Control^{DR}

4 Zellstanzen
Dynamic Range: negativ, schwach, mittel und stark positiv
für Expression des Östrogenrezeptors



Größe	Kat.-Nr.
2 OT	HCL029
5 OT	HCL030
1 Block	HCL031

IHC
ER



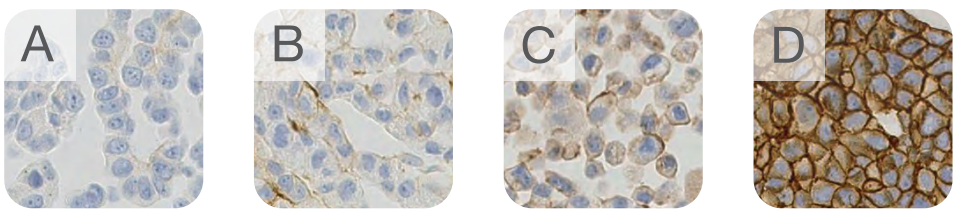
Her2 Analyte Control^{DR}

4 Zellstanzen
Dynamic Range: 0, 1+ (HER2 nicht amplifiziert),
2+ (keine eindeutige Amplifikation), 3+ (HER2 amplifiziert)

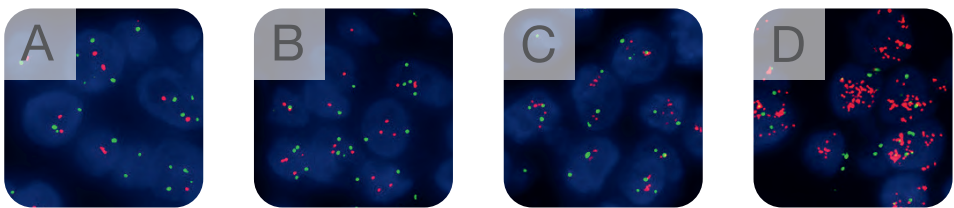


Größe	Kat.-Nr.
2 OT	HCL026
5 OT	HCL027
1 Block	HCL028

IHC
Her2



FISH

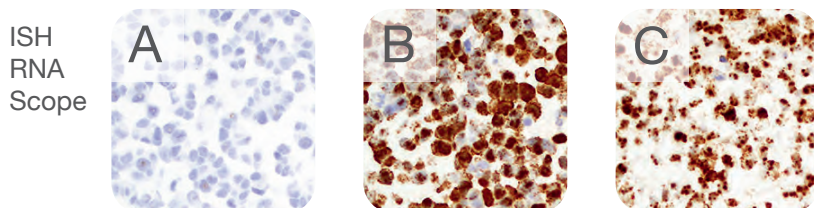
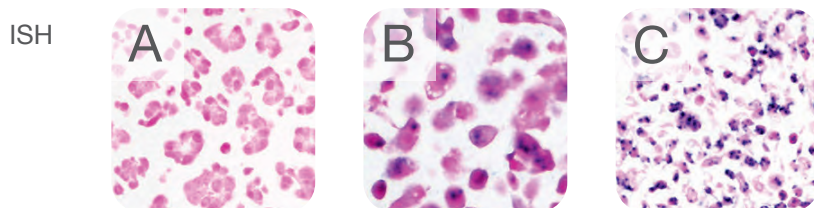
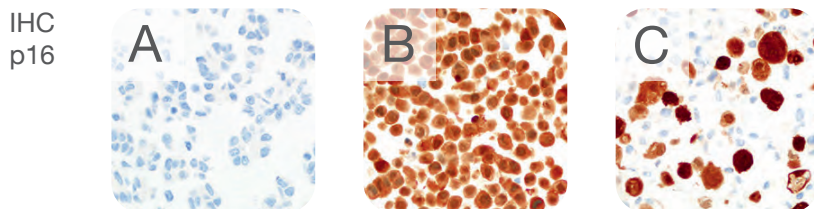


HPV/p16

3 Zellstanzen
positiv bzw. negativ für HPV-Gen, E6/E7 mRNA und p16
Proteinexpression



Größe	Kat.-Nr.
2 OT	HCL004
5 OT	HCL005
1 Block	HCL006

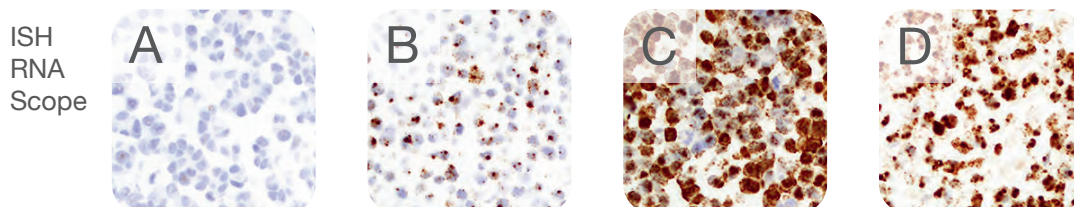
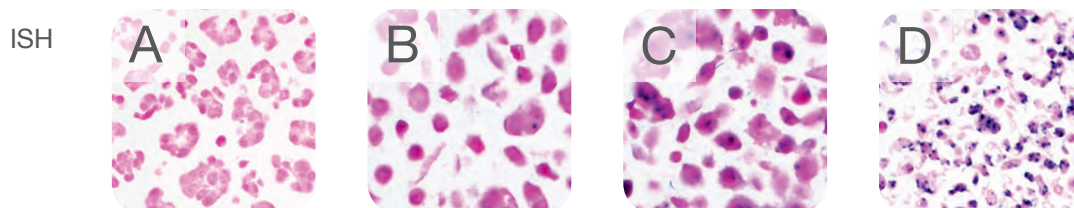
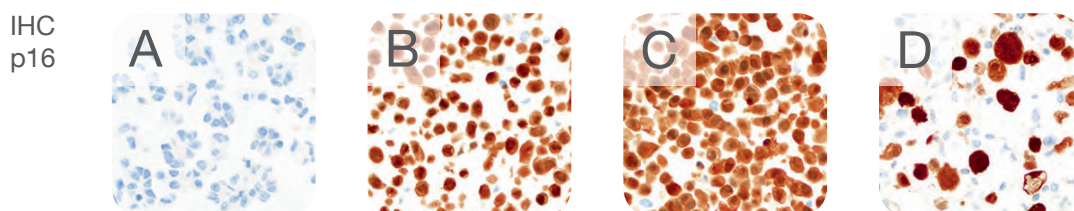


HPV/p16^{DR}

4 Zellstanzen
Dynamic Range: verschiedene HPV-Gen Kopien, E6/E7 mRNA
Level und p16 Proteinexpressionslevel



Größe	Kat.-Nr.
2 OT	HCL001
5 OT	HCL002
1 Block	HCL003



Mismatch Repair Analyte Control

4 Zellstanzen

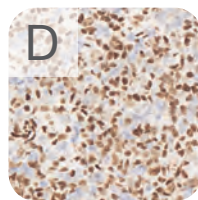
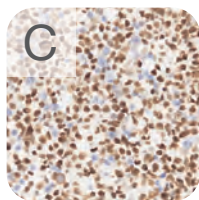
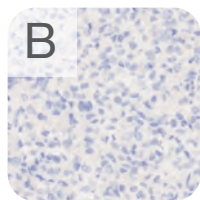
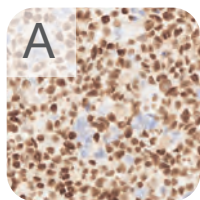
intakt bzw. loss of expr. for MLH1, MSH2, MSH6, PMS2



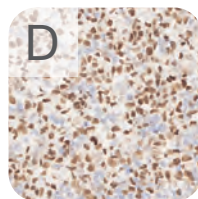
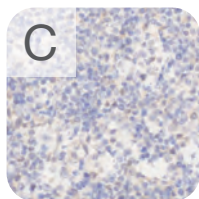
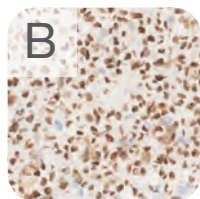
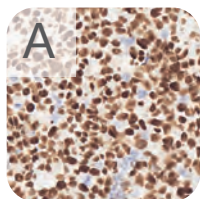
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5 OT	HCL042
1 Block	HCL043

AGILENT

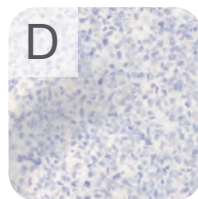
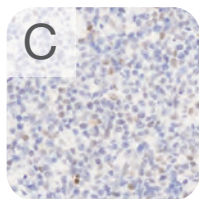
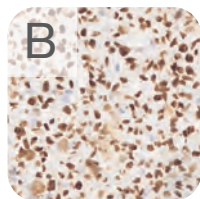
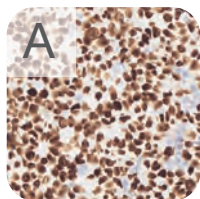
MLH1
ES05



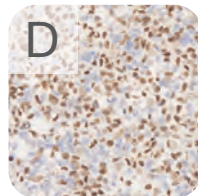
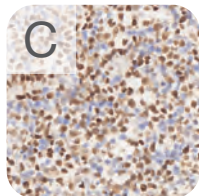
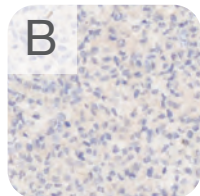
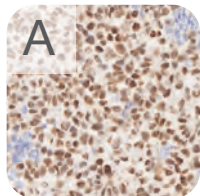
MSH2
FE11



MSH6
EP49

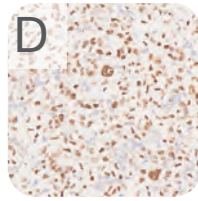
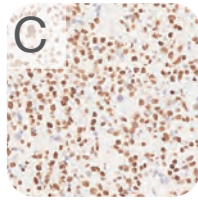
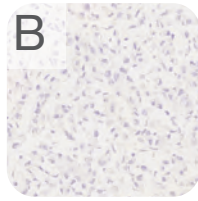
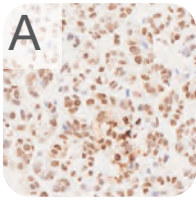


PMS2
EP51

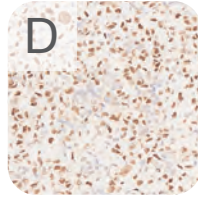
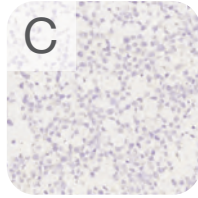
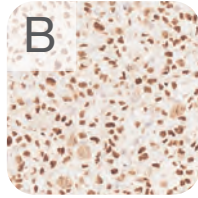
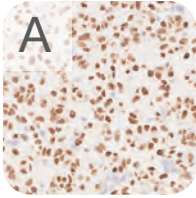


LEICA

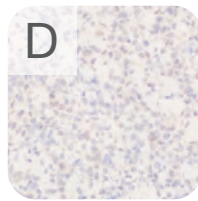
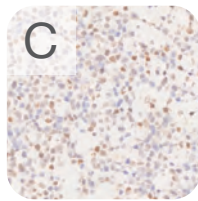
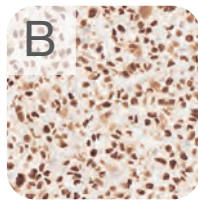
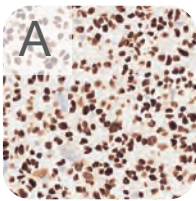
MLH1
ES05



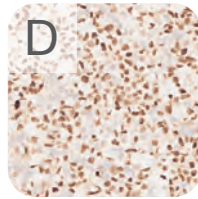
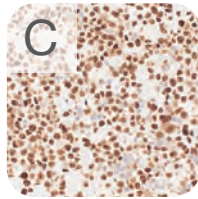
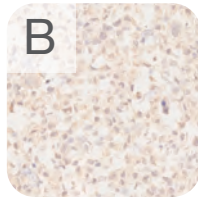
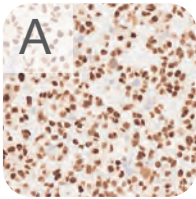
MSH2
79H11



MSH6
EP49

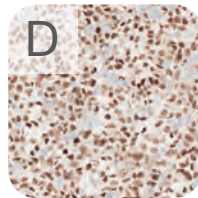
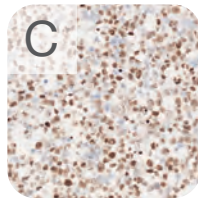
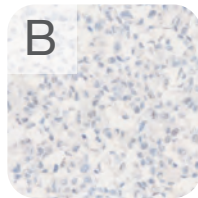
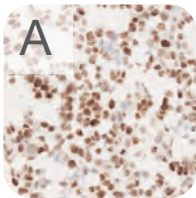


PMS2
EP51

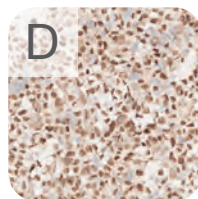
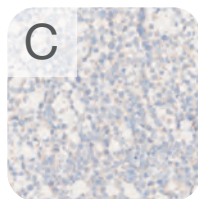
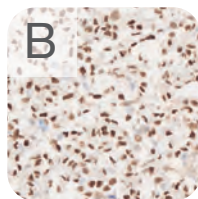
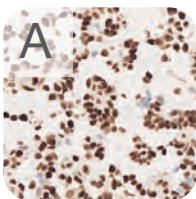


ROCHE

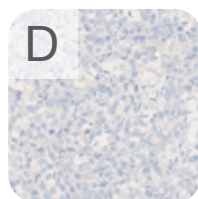
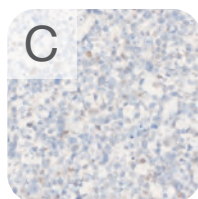
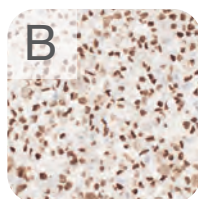
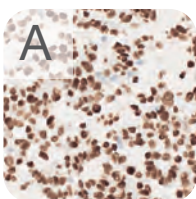
MLH1
M1



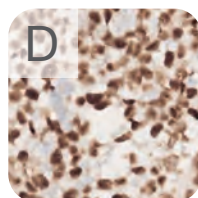
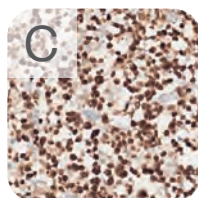
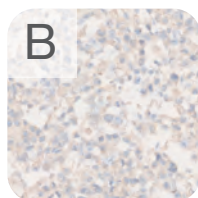
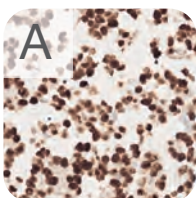
MSH2
G219-
1129



MSH6
SP63



PMS2
A16-4



MLH1/PMS2 Analyte Control

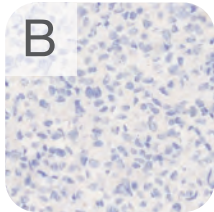
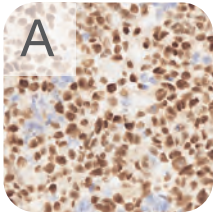
2 Zellstanzen
positiv bzw. negativ für MLH1 und PMS2



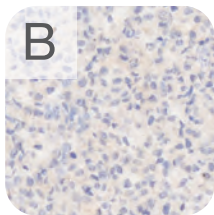
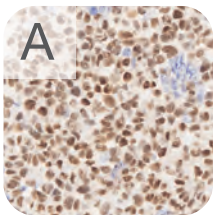
Größe	Kat.-Nr.
2 OT	HCL044
5 OT	HCL045
1 Block	HCL046

AGILENT

MLH1
ES05

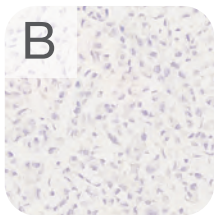
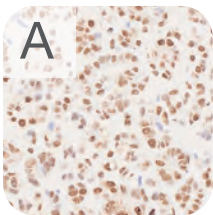


PMS2
EP51

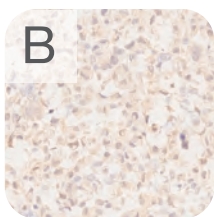
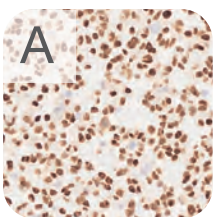


LEICA

MLH1
ES05

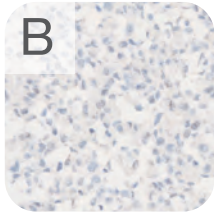
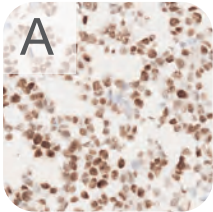


PMS2
EP51

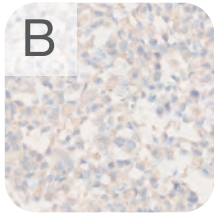
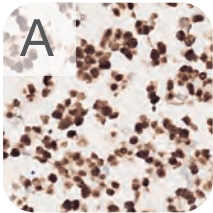


ROCHE

MLH1
M1



PMS2
A16-4



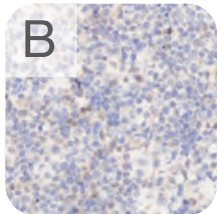
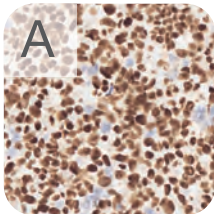
MSH2 Analyte Control

2 Zellstanzen
positiv bzw. negativ für MSH2

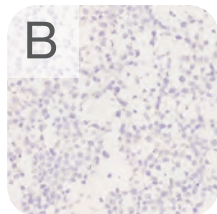
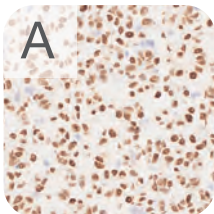


Größe	Kat.-Nr.
2 OT	HCL047
5 OT	HCL048
1 Block	HCL049

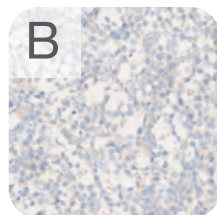
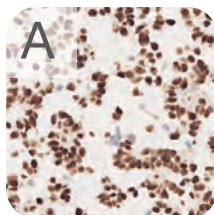
AGILENT
FE11



LEICA
79H11



ROCHE
G219-
1129



MSH6 Analyte Control

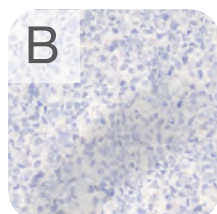
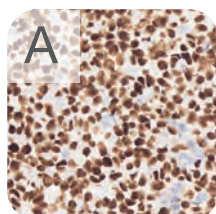
2 Zellstanzen
positiv bzw. negativ für MSH6



Größe	Kat.-Nr.
2 OT	HCL050
5 OT	HCL051
1 Block	HCL052

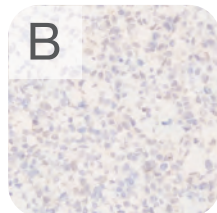
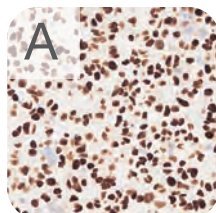
AGILENT

EP49



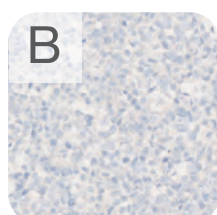
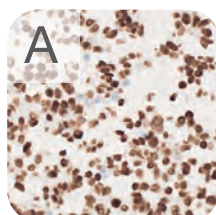
LEICA

EP49



ROCHE

SP93



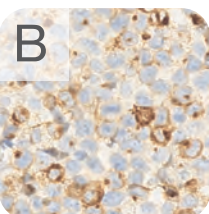
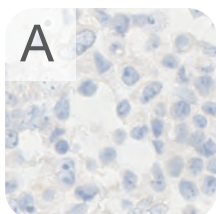
NTRK Analyte Control

2 Zellstanzen
positiv bzw. negativ für WT TrkA



Größe	Kat.-Nr.
2 OT	HCL038
5 OT	HCL039
1 Block	HCL040

EPR
17341



PD-L1 Analyte Control^{DR}

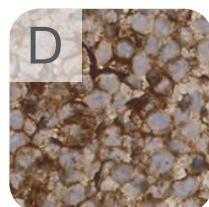
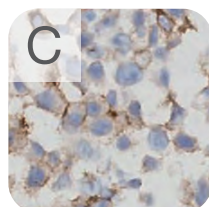
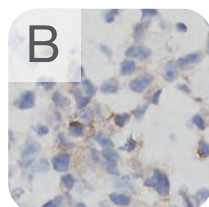
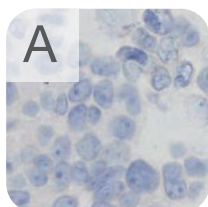
4 Zellstanzen

Dynamic Range: verschiedene PD-L1 Proteinexpressionslevel



Größe	Kat.-Nr.
2 OT	HCL019
5 OT	HCL020
1 Block	HCL021

IHC
PD-L1



Progesterone Receptor Analyte Control^{DR}

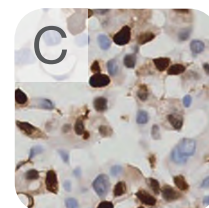
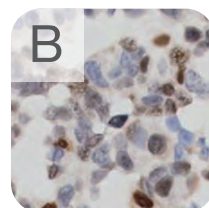
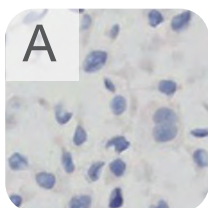
4 Zellstanzen

Dynamic Range: negativ, schwach/intermediär, intermediär/stark und stark positiv für Expression des Progesteronrezeptors



Größe	Kat.-Nr.
2 OT	HCL032
5 OT	HCL033
1 Block	HCL034

IHC
PR



ROS1 Analyte Control

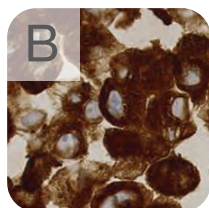
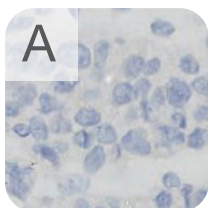
2 Zellstanzen

positiv bzw. negativ für SLC34A2-ROS1 Gentranslokation und Expression des Fusionsproteins

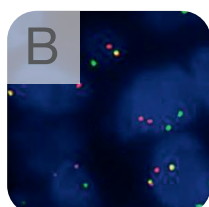
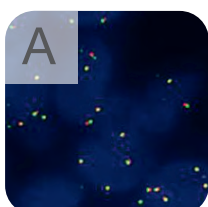


Größe	Kat.-Nr.
2 OT	HCL022
5 OT	HCL023
1 Block	HCL024

IHC



FISH





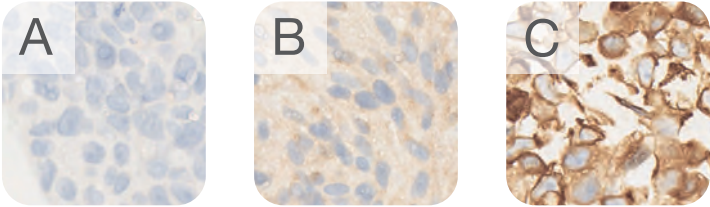
ROS1 Analyte Control^{DR}

3 Zellstanzen
negativ für FIG-ROS1, SLC34A2-ROS1

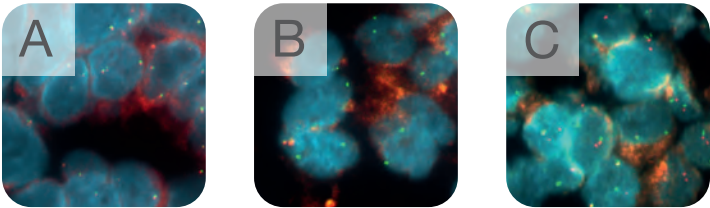


Größe	Kat.-Nr.
2 OT	HCL035
5 OT	HCL036
1 Block	HCL037

IHC



FISH





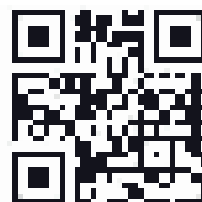
Selbstverständlich bieten wir für alle Kontrollen auch passende Primärantikörper und weitere Reagenzien an. Diese finden Sie auf unserer Homepage: www.medac-diagnostics.de.

Literatur:

1. Vyberg M. & Nielsen S. Proficiency testing in immunohistochemistry – experiences from Nordic Immunohistochemical Quality Control (NordiQC). *Virchows Arch.* 2016; 468: 19–29.
2. Torlakovic EE, et al. Standardization of negative controls in diagnostic immunohistochemistry: recommendations from the international ad hoc expert panel. *AIMM* 2014; 22: 241–252.
3. Torlakovic EE, et al. Standardization of positive controls in diagnostic immunohistochemistry: recommendations from the international ad hoc expert committee. *AIMM* 2015; 23: 1–18.
4. Torlakovic EE, et al. Getting controls under control: the time is now for immunohistochemistry. *J. Clin. Pathol.* 2015; 68: 879–882.
5. Hewitt SM, et al. Controls for immunohistochemistry: the Histochemical Society's standards of practice for validation of immunohistochemical assays. *J. Histochem. Cytochem.* 2014; 62: 693–697.
6. Elliott K, et al. Immunohistochemistry should undergo robust validation equivalent to that of molecular diagnostics. *J. Clin. Pathol.* 2015; 68: 766–770.

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Informationen aus erster Hand
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zum Erkennen.

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