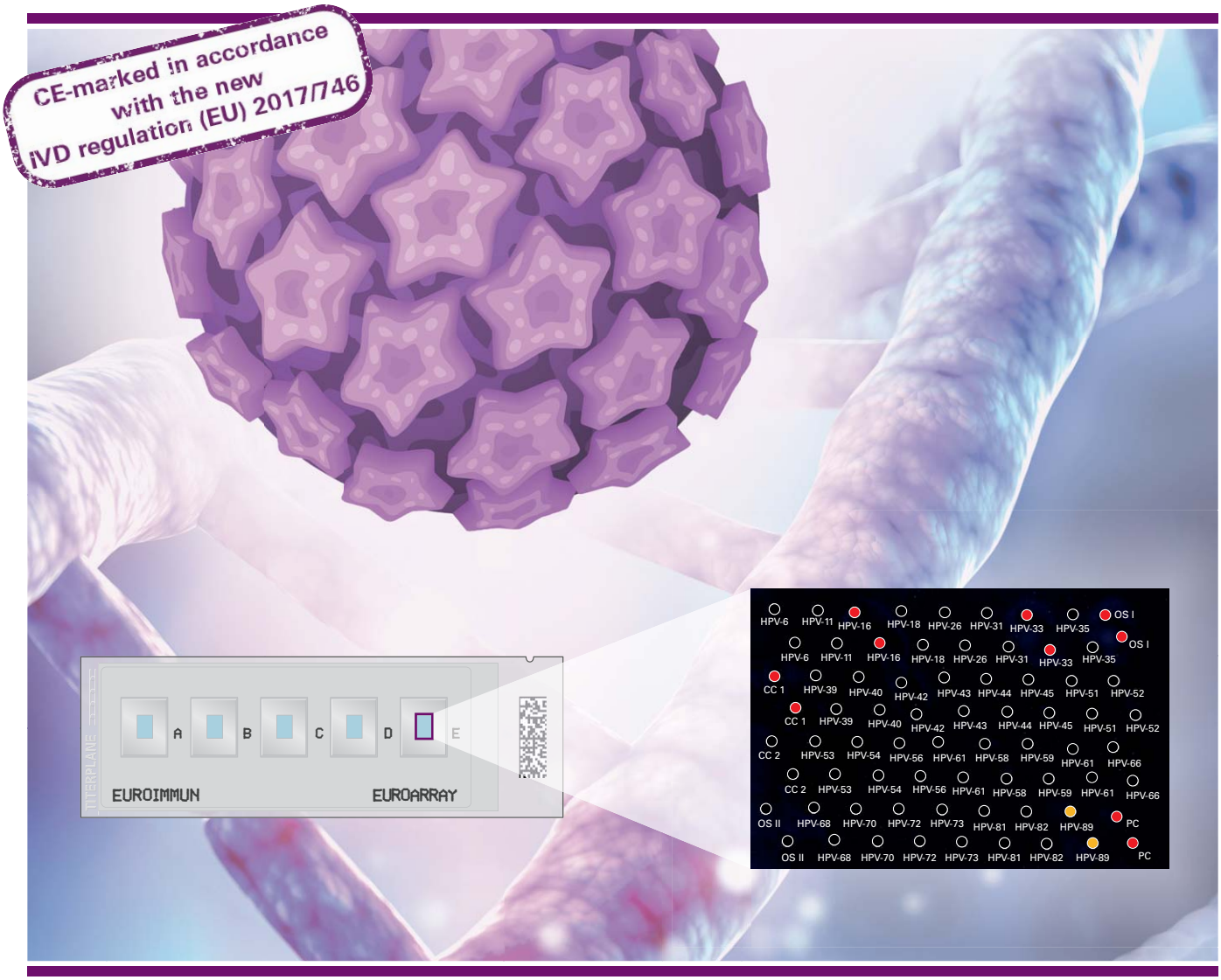
EUROIMMUN Medizinische Labordiagnostika AG

EUROArray HPV

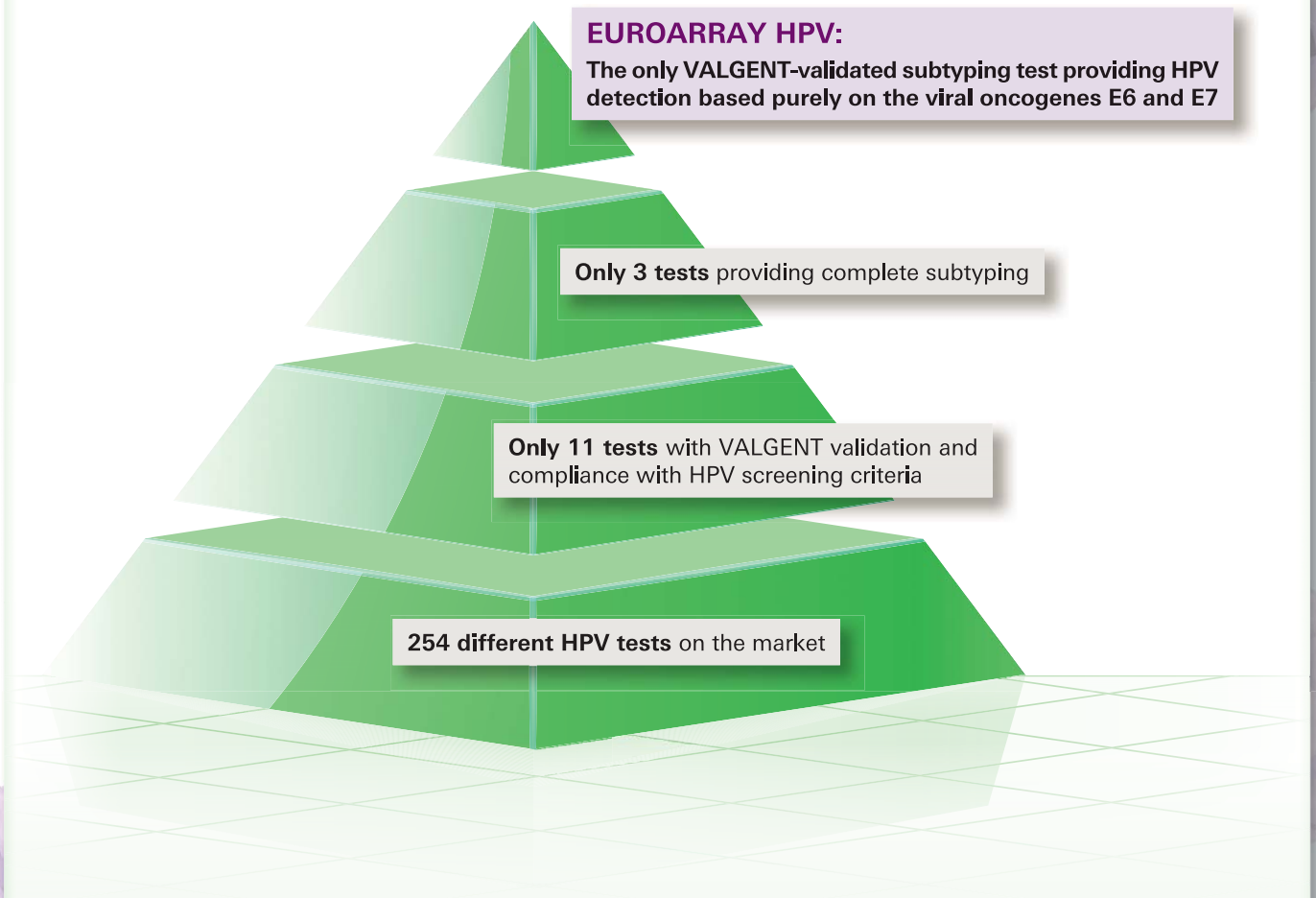
For highest quality in HPV screening



- **Compliance with international quality criteria for HPV screening tests and independent validation**
- **Complete subtyping for qualified assessment of the risk of cervical carcinoma:**
  18 high-risk HPV subtypes: HPV-16, -18, -26, -31, -33, -35, -39, -45, -51, -52, -53, -56, -58, -59, -66, -68, -73, -82
  12 low-risk HPV subtypes: HPV-6, -11, -40, -42, -43, -44, -54, -61, -70, -72, -81, -89
- **Highest sensitivity due to detection based on viral oncogenes E6 and E7**
- **Modular and efficient automation**

UNRIVALLED TOP QUALITY: THE EUROARRAY HPV

Features of HPV tests in comparison



Based on data from the study by Poljak et al. (2020) on the spectrum of worldwide available molecular HPV tests[1]

GO FOR COMPLETE SUBTYPING!

For an improved risk-based patient management owing to ...

Determination of the individual risk based on the HPV subtypes detected

HPV subtype	Risk for CIN3+
16	Very high risk (approx. 15–35 %)
18, 31, 33	Intermediate–high risk (approx. 8–20 %)
45, 52, 58	Moderate risk
35, 39, 51, 56, 59, 66, 68	Low risk

HPV subtype and risk for CIN3+ (categorisation according to Bonde et al.)[2]

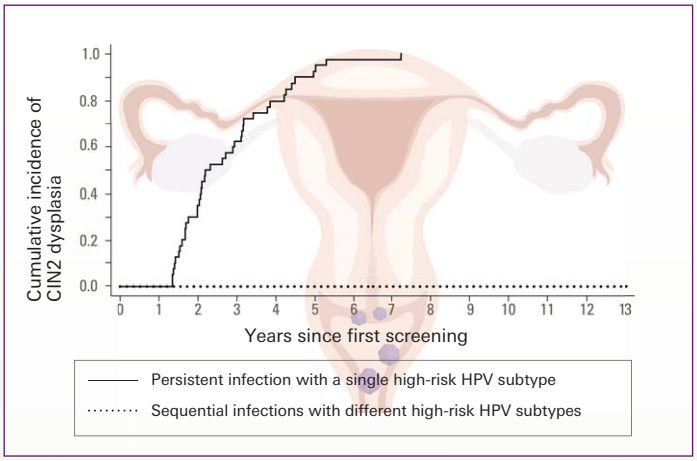
The risk of cervical carcinoma depends on the HPV subtype detected.[2, 3, 4]

Detection of persisting infections with the same HPV subtype

CIN2 dysplasia is linked to long-standing infections with the same high-risk HPV subtype.

With infections with changing subtypes, however, no increase in the incidence of CIN2 dysplasia was observed.

Correspondingly, the risk of developing cervical carcinoma is only increased in persisting infections with the same high-risk HPV subtype.[5]



Proportion of women who develop CIN2 dysplasia after a persistent infection with a single high-risk HPV subtype or after sequential infections with different high-risk HPV subtypes (modified from Elfgren et al.)[5]

Detection of multiple infections with different HPV subtypes

Infections with different HPV subtypes increase the likelihood of cytological changes of the cervical mucosa and therefore yield a higher risk of carcinoma.[6, 7]

CONCLUSION: Only complete subtyping, as provided by the **EUROArray HPV**, allows to recognise persisting infections with the same HPV subtype as well as multiple infections with different HPV subtypes and enables a corresponding risk-based patient management.

TRUST AN INDEPENDENTLY VALIDATED TEST!

With VALGENT validation

The **VALGENT** (**VAL**idation of HPV **GEN**otyping **T**ests) protocol provides a comprehensive framework for studies for clinical validation of different HPV tests and for evaluation of a test's suitability for HPV screening.[8] The **EUROArray HPV** has been VALGENT-validated since 2018.[9]

Fulfils international criteria for primary cervical cancer screening[10]

Detection of at least 13 defined high risk HPV types:*

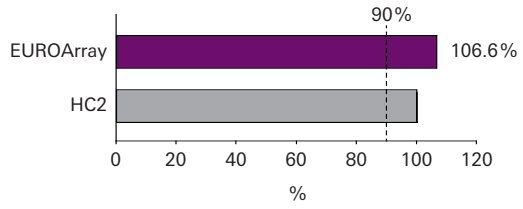
The **EUROArray HPV** enables detection and subtyping of:
18 high-risk HPV types (-16, -18, -26, -31, -33, -35, -39, -45, -51, -52, -53, -56, -58, -59, -66, -68, -73, -82) and
12 low-risk HPV types (-6, -11, -40, -42, -43, -44, -54, -61, -70, -72, -81, -89)
in only one reaction.

** HPV-16, -18, -31, -33, -35, -39, -45, -51, -52, -56, -58, -59 and -68*

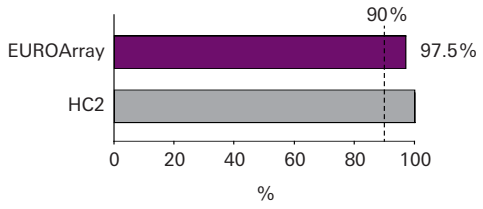
At least 90% of the sensitivity for CIN2+ of an established and validated HPV test

In two independent studies, the **EUROArray HPV** achieved **more than 95%** of the sensitivity of the reference test HC2.[9, 11]

Sensitivity**



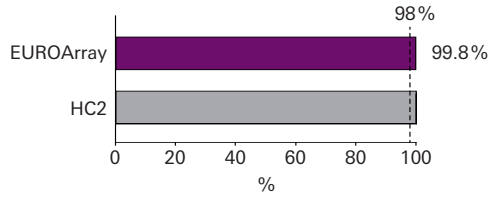
Sensitivity**



At least 98% of the specificity for CIN2+ of an established and validated HPV test

The **EUROArray HPV** achieves a specificity of **99.8%**.[9]

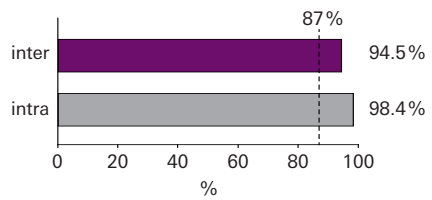
Specificity**



Inter- and intra-laboratory reproducibility of at least 87%

The **EUROArray HPV** achieves an inter- and intra-laboratory reproducibility of **94.5% and 98.4%, resp.**[9]

Inter-/intra-laboratory reproducibility



CE mark

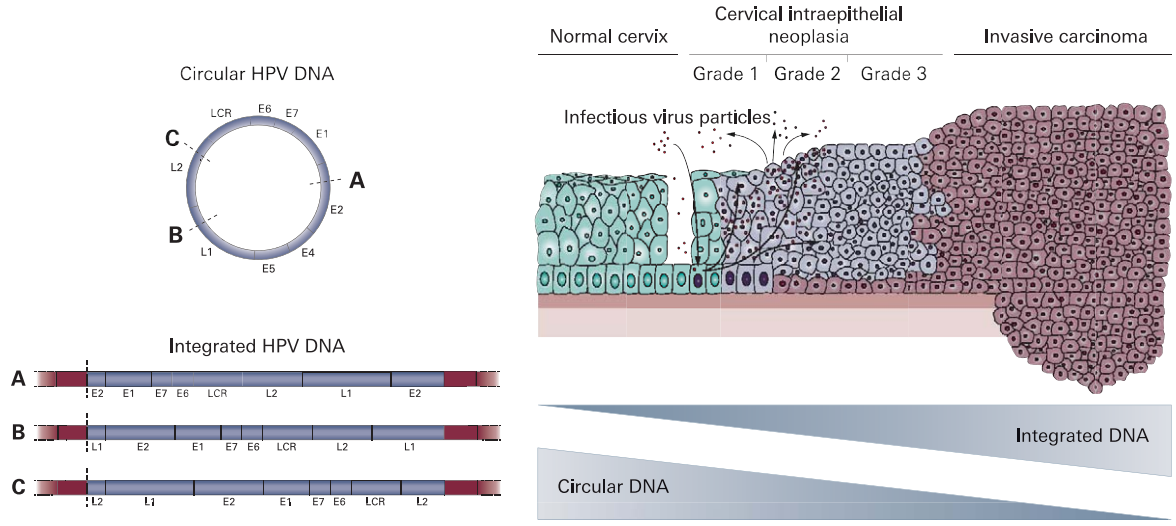
The **EUROArray HPV** is CE marked.

*** Relative values are shown. Sensitivity and specificity of the reference test HC2 were set to 100%.*

GO FOR A TEST BASED ON E6 AND E7!

For higher sensitivity even after integration of HPV DNA into the host DNA

A prerequisite for the development of carcinoma is **integration of the circular HPV genome** into the DNA of the epidermal cells of the patient. The proportion of infected cervical cells containing integrated viral DNA increases as the infection progresses (see figure).[12–16]



Course of an untreated, persistent HPV infection. The circular DNA genome of HPV is linearised and integrated into the DNA of the cervical cells of the host. Genes that are responsible for regulating the oncogenes E6 and E7 are lost during this process, leading in the long-term to invasive carcinoma.

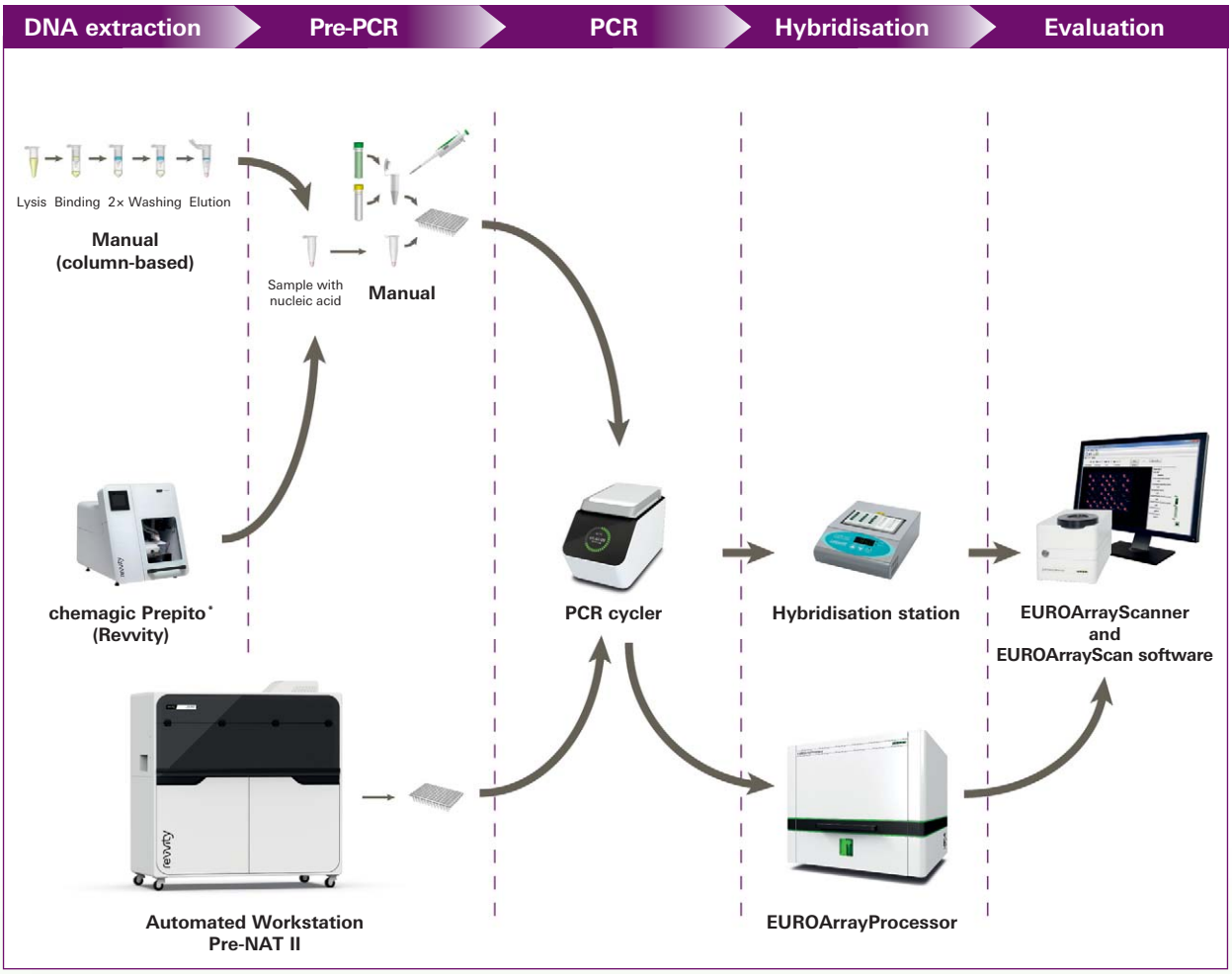
During the integration into human DNA, particular **regions of the HPV genome** (generally the E1, E2, L1 and L2 genes) are **split**, which is why tests based on the detection of these genes are unreliable: For instance, L1-based tests for the detection of HPV-16 and -18 may miss 8% to 28% of infections.[12]

The **EUROArray HPV**, however, reliably detects HPV based on the **viral oncogenes E6 and E7**, which are essential for the malign transformation of the host cell and are present intact after integration into the human DNA.[12, 17]

CONCLUSION: Only reliable detection systems based on the viral oncogenes E6 and E7, such as provided by the **EUROArray HPV**, can identify HPV infections with high sensitivity – not only before, but specifically also after the integration of the HPV DNA into the human DNA.

BENEFIT FROM A FLEXIBLE TEST SYSTEM!

Different flexible automation solutions



** For research use only*

Different sample materials possible

- Cervical and vaginal swab samples
- Swab samples from penile shaft and glans
- Samples from liquid-based cytology
- Anal swab samples
- Formalin-fixed tissues, embedded in paraffin

SCIENTIFIC STUDIES SPEAK FOR THEMSELVES!

Proof of the high quality of the EUROArray HPV

The EUROArray HPV ...

- ... **meets the international requirements for HPV screening tests** according to VALGENT (so-called Meijer criteria). [9, 11]
- ... **allows to verify the treatment success** (e.g. following conisation). [11]
- ... **delivers reliable subtyping results** compared to different other HPV subtyping tests. [18]
- ... **is suitable for HPV detection in FFPE tissue samples (also from oropharyngeal tumours*)**. [19, 20]
- ... **has an especially high sensitivity even with self-sampling*** – unlike other tests. [21]
- ... **can detect HPV subtypes even in surgery smoke* from loop electrosurgical excision procedure**. [22]

** Oropharyngeal and self-collected samples as well as surgery smoke have not been validated as sample material for the test system by the manufacturer but have been successfully used in the cited studies.*

Product	Information	Order number
EUROArray HPV	Molecular diagnostic in vitro detection and typing of 30 anogenital HPV	MN 2540-####
EUROArray HPV positive control	Verification of the correct processing of the EUROArray HPV for laboratory internal quality assurance	MC 2540-0506
Copan regular FLOQSwab (with transport and conservation medium)	Sample collection by means of swabs from different sites	ZM 0281-5001
Copan L-shape FLOQSwab (with transport and conservation medium)	Sample collection by means of swabs, especially from the cervix	ZM 0282-5002
Automated Workstation Pre-NAT II	Automated sample preparation	YG 9102-0101
Pre-NAT NA EU Kit*	Extraction kit for automated sample preparation	ZM 9102-0960
chemagic Prepito-D	Automated sample preparation (no pipetting of PCRs)	*For further information please visit: https://chemagen.com/Instruments/400-chemagic-prepito-instrument*
Prepito NA EU-Kit*	Extraction kit for automated sample preparation with the chemagic Prepito-D	ZM 9101-0168
EUROArrayProcessor	Automated processing of the EUROArray slides	YG 0671-0101-1
EUROArrayScanner with EUROArrayScan software	Automated evaluation of the EUROArray slides	YG 0602-0101

** For research use only, not for in vitro diagnostics*

References

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