HPV Cervical Cancer Cell Line Microarray 7-Core (2 mm)

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Intended Use

For In Vitro Diagnostic Use.

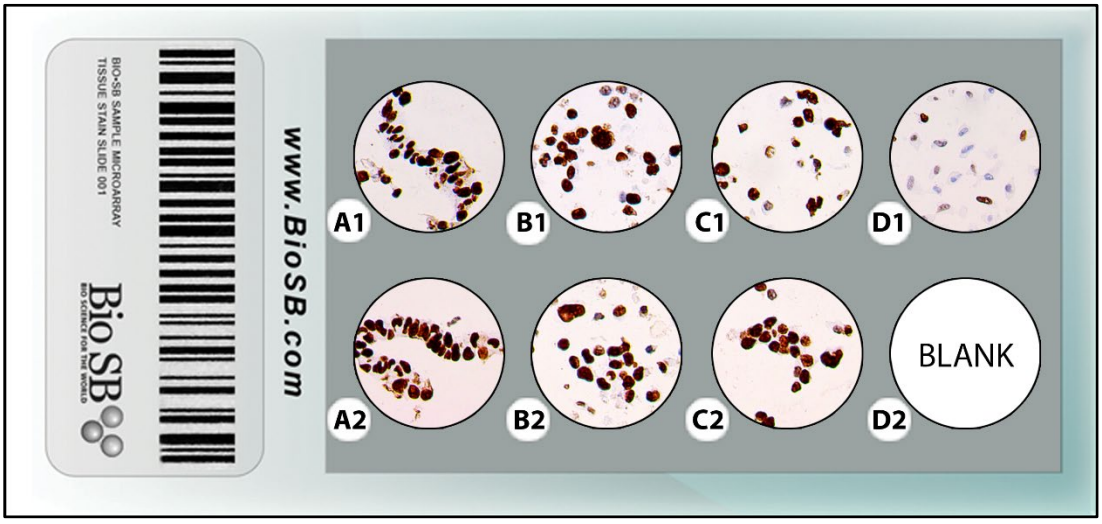
Summary and Explanation

The HPV Cervical Cancer Cell Line Microarray (CLMA) is an unstained ready-to-use microscope slide consisting of 7 - 2 mm cores of normal human formalin-fixed paraffin-embedded cell lines which were assembled in array fashion to allow multiplex molecular pathology analysis and validation of reagents, or to be used as controls for Immunohistochemistry and/or *in situ* hybridization (CISH and FISH) applications.

Presentation

Five HPV Cervical Cancer CLMA's with 7 - 2 mm cores each, mounted on Hydrophilic Plus Slides are provided in a plastic mailer.

The map below outlines the various cell lines used. Each slide comes with a "blank" core for easy orientation:



IHC of Ki67 using the PolyDetector Plus HRP/DAB in TintoStainer

A1 **HPV 16; 500 copies** Human Epidermoid Cervical Cancer Metastasis	**B1** **HPV 18; 50 copies** Human Cervical Cancer Adenocarcinoma	**C1** **HPV 16; 2 copies** Human HSIL Cervical Cancer	**D1** **HPV Negative** Normal Human Fibroblast
A2 **HPV 16; 500 copies** Human Epidermoid Cervical Cancer Metastasis	**B2** **HPV 18; 50 copies** Human Cervical Cancer Adenocarcinoma	**C2** **HPV 16; 2 copies** Human HSIL Cervical Cancer	**D2** BLANK

Catalog No.	*Number of Slides*
BSB 0294	5

Storage Store at 2-8°C

Stability

This product is stable up to the expiration date on the product label. Do not use after expiration date listed on package label.

Precautions

1. For professional users only. Results should be interpreted by a qualified medical professional.
2. Ensure proper handling procedures are used with reagent.
3. Always wear personal protective equipment such as laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused material according to local and federal regulations.
5. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
6. For additional safety information refer to Safety Data Sheet for this product.
7. For complete recommendations for handling biological specimens please refer to the CDC document, "Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories" (see References in this document).

Staining Procedure

1. Deparaffinize, dehydrate and rehydrate CLMA.
2. Subject CLMA to heat induced epitope retrieval (HIER) using a suitable retrieval solution such as ImmunoDNA Retriever with Citrate (BSB 0020-BSB 0023), or ImmunoDNA Retriever EDTA (BSB 0030-BSB 0033).
3. Any of three heating methods may be used:

a. TintoRetriever Pressure Cooker or Equivalent

Place slides in a staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA, and place on trivet in the pressure cooker. Add 1-2 inches of distilled water to the pressure cooker and turn heat to high. Incubate for 15 minutes. Open and immediately transfer slides to room temperature.

b. TintoRetriever PT Module or Water Bath Method

Place slides in a pre-warmed staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA at 95°-99° C. Incubate for 30-60 minutes.

c. Conventional Steamer Method

Place slides in a pre-warmed staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA in a steamer, cover and steam for 30-60 minutes.

4. After heat treatment, transfer slides in ImmunoDNA Retriever with Citrate or EDTA to room temperature and let stand for 15-20 minutes.
5. For manual staining, perform antibody incubation at ambient temperature. For automated staining methods, perform antibody incubation according to instrument manufacturer's instructions.
6. Wash slides with ImmunoDNA washer or DI water.
7. Continue IHC staining protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical Protocol

Step	ImmunoDetector AP/HRP	PolyDetector AP/HRP	PolyDetector Plus HRP
Peroxidase/AP Blocker	5 min.	5 min.	5 min
Primary Antibody	30-60 min.	30-60 min.	30-60 min.
1st Step Detection	10 min.	30-45 min.	15 min.
2nd Step Detection	10 min.	Not Applicable	15 min.
Substrate-Chromogen	5-10 min.	5-10 min.	5-10 min.
Counterstain / Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

Product Limitations

Due to inherent variability present in immunohistochemical procedures (including fixation time of tissues/cell lines, dilution factor of antibody, retrieval method utilized and incubation time), optimal performance should be established through the use of positive and negative controls. Results should be interpreted by a qualified medical professional.

References

1. U.S. Department of Health and Human Services: Centers for Disease Control and Prevention. Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories. Supplement / Vol. 61, January 6, 2012.

Symbol Key / Légende des symboles/Erläuterung der Symbole

EC REP EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands	Storage Temperature Limites de température Zulässiger Temperaturbereich	Manufacturer Fabricant Hersteller	REF Catalog Number Référence du catalogue Bestellnummer
IVD In Vitro Diagnostic Medical Device Dispositif médical de diagnostic in vitro In-Vitro-Diagnostikum	Read Instructions for Use Consulter les instructions d'utilisation Gebrauchsanweisung beachten	Expiration Date Utiliser jusque Verwendbar bis	LOT Lot Number Code du lot Chargenbezeichnung

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