



JILAB INC.

Biokatu 6
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VAT number : FI18058489
www.jilab.fi
email : jilab@jilab.fi

TECHNICAL FILE

Product Name: **Cytonel-PLUS Ultrarapid IHC kit**



Product ID: **CNP-100**
CNP-20
CNP-20D

JILAB INC.

Date revised **15.1.2010**
Date issued: **25.2.2009**



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1. PRODUCT NAME

Cytonel-Plus Ultrarapid IHC kit

2. PRODUCT ID

CNP-100
CNP-20
CNP-20D

3. PRODUCT MANUFACTURER

address: Jilab Oy Inc
Biokatu 6
33520 TAMPERE, FINLAND
Finn-Medi 1 building

tel. +358 3 364 2110
fax. +358 3 364 2110
mobile +358 50 300 5609
jilab@jilab.fi www.jilab.fi

VAT number: FI8058489

4. PRODUCT CLASSIFICATION

According to the European Union Directive 98/79/EC this device is classified as a class I In Vitro Diagnostic Medical Device.

5. GENERAL DESCRIPTION OF THE PRODUCT

An immunohistochemical staining kit consisting of :

-- Endogenous peroxidase blocker. Add 0.5 ml of this reagent to 100 ml of fixative (acetone containing 0.03% hydrogen peroxide). Use fixative within 4 hours.

-- Fab2 fraction of a Monoclonal Mouse Anti-Human pancytokeratin antibody coupled with multiple molecules of horseradish peroxidase. **Solvent:** PBS buffer, pH 7.4, containing preservative, blocking agent and stabilizer. The reagent is ready-to-use without further dilution.

-- Diamino benzidine (DAB) chromogen and dilution buffer.

Kit sizes for 20 and 100 tests are available.

Specificity / reactivity

The antibody reacts with an epitope which is present in cytokeratins 4, 5, 6, 8, 10,13, and 18.

Staining procedures

The staining kit is intended to be used on acetone-fixed frozen sections. See detailed instructions of use in the product leaflet. Differences in tissue processing and technical procedures in the user's laboratory may produce significant variability in results, necessitating regular performance of in-house controls.

6. AUTHORIZED DISTRIBUTORS

In Finland : ImmunoDiagnostic Inc.
Kaivokatu 16
13100 HÄMEENLINNA, FINLAND
+358 3 615 370

7. DECLARATION OF CONFORMITY

See document attached (Appendix 1).



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8. INTENDED USE OF PRODUCT

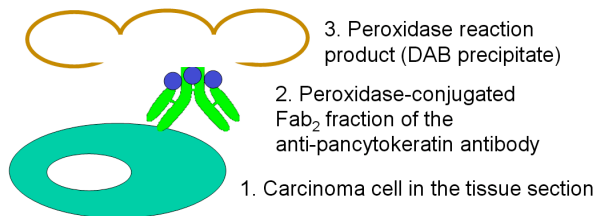
The kit provides reagents for ultrarapid pan-cytokeratin immunostaining, which is intended to assist the pathologist, who makes a rapid intraoperative histopathologic diagnosis using frozen sections. The staining should be interpreted together with a routine stain (e.g. hematoxylin&eosin and/or toluidine blue) done on an adjacent tissue section.

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

Prior to initial use of an antibody or staining system in a diagnostic procedure, the user should verify the antibody's specificity by testing it on a series of in-house tissues with known immunohistochemical performance characteristics representing known positive and negative tissues.

9. PRINCIPLE OF THE OPERATION OF THE PRODUCT

The steps of the staining procedure (1-3) as described schematically :



10. MANUFACTURING METHODS

Products are manufactured as per the quality control documents. All reagents manufactured go through testing before final approval. The results are reviewed and validated by the quality manager of the company.

11. QUALITY CONTROL PRODUCT RELEASE CRITERIA

All product lots are tested in a staining assay identical to the test procedure before delivery to customers. Quality system document: The quality assurance procedures of Jilab Inc. have been audited according to ISO13485 by an external body. For official certificate issued by the external body see Appendix 1.

12. PRODUCT SAFETY

See Materials Safety Data Sheets attached (Appendix 2).

13. COMPLIANCE WITH EUROPEAN TECHNICAL STANDARDS

Complies with ISO 13485/2003 Standard.

14. PRODUCT PERFORMANCE TROUBLESHOOTING

Contact Jilab Inc. (Jilab@jilab.fi) to report unexpected staining results.

15. STORAGE AND LIFE TIME OF THE PRODUCT

Store at 2-8 °C. Protect from light whenever possible.
Product is stable for 10 months.