



**Diagnostic
BioSystems**

Instructions For Use KT 038-IFU

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Papanicolaou (PAP) Stain Kit

Description and Principle

The Papanicolaou (PAP) Stain Kit is designed to differentiate between a variety of cells in vaginal smears for detection of vaginal, uterine and cervical cancer. In addition, this procedure is valuable for staining a variety of other bodily secretions and cell smears. The procedure was developed in the early 1940's by George Papanicolaou.

Papanicolaou (PAP) Stain Kit utilizes a combination of stains visualize nuclear and cytoplasmic detail of cytology specimens. Nuclei are rapidly and progressively stained by a Mayer's hematoxylin solution. Orange G in an alcohol solution with phosphotungstic acid stains keratinized cells bright orange. EA-50 stain solution is a polychrome cytoplasm stain that stains cells varying shades of pink and blue/green due to differences in dye penetration rates.

Expected Results

Nuclei:	Blue
High Keratin Cells:	Orange
Superficial Cells:	Pink
Erythrocytes:	Dark Pink
Parabasal Cells:	Blue/Green
Intermediate Cells:	Blue/Green
Metaplastic Cells:	May contain both Blue/Green and Pink.

Kit Contents

1. Hematoxylin, Mayer's (Lillie's Modification)
2. OG-6 Solution
3. EA-50 Stain Solution

Storage

- 15-30°C
- 15-30°C
- 15-30°C

Suggested Controls (not provided)

Gynecological Smear, Any Superficial Cell Smear.

Uses/Limitations

For In-Vitro Diagnostic use only.

Do not use if reagents become cloudy or precipitate

Do not use past expiration date.

Use caution when handling reagents.

Non-Sterile

Intended for FFPE sections cut at 5-10µm.

This procedure has not been optimized for frozen sections.

Frozen sections may require protocol modification.

Storage

Store all components at room temperature (15-30°C).

Safety and Precautions

Please see current Safety Data Sheets (SDS) for this product and components GHS classification, pictograms, and full hazard/precautionary statements. If there is any serious incident that has occurred in relation to the device, please contact the manufacturer: Diagnostic BioSystems Technical Support at (925) 484-3350, extension 2 or techsupport@dbiosys.com. If required, please report to the Competent Authority of the Member State in which the user and/or patient is established.

Procedure:

1. Place slide in 95% alcohol for 5 minutes.

2. Place slide in 70% alcohol for 5 minutes.

3. Place slide in distilled water for 2 minutes.

4. Apply Hematoxylin, Mayer's (Lillie's Modification) for 5 minutes.



Oral squamous cells viewed at 40X stained with the Papanicolaou (PAP) Stain Kit.

5. Rinse slide 1 time in distilled water to remove excess stain.

6. Rinse slide in tap water for 2 minutes.

7. Rinse slide in 2 changes of distilled water.

8. Dip slide several times in 95% alcohol and blot excess off.

9. Apply OG-6 Stain Solution for 2 minutes.

10. Rinse slide gently using absolute alcohol.

11. Apply EA-50 Stain Solution for 3 minutes.

12. Rinse slide gently using absolute alcohol.

13. Quickly dehydrate slide in 3 changes of absolute alcohol.

14. Clear slide and mount in synthetic resin.

References

1. Papanicolaou, G.N. Atlas of Exfoliative Cytology, Harvard University Press, Cambridge, 1954.



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