

INTENDED USE

Calcofluor White Reagent and 10% Potassium Hydroxide Reagent are used as part of a rapid staining method for the detection of yeasts and pathogenic fungi in prepared slides from clinical specimens.

SUMMARY AND EXPLANATION

Calcofluor White Reagent was first described by Hageage and Harrington in 1984. Together, the stains are used for the identification of fungal elements.

PRINCIPLE OF THE TEST

Calcofluor White Reagent works as a non-specific fluorochrome that binds with cellulose and chitin contained in the cell walls of fungi and other organisms. The addition of 10% Potassium Hydroxide (KOH) Reagent works as a cleaning agent to remove any tissue cells.

MATERIALS PROVIDED

-	PL.392	Calcofluor White Reagent	10 ml
-	PL.393	10% Potassium Hydroxide Reagent	10 ml

Per 100ml solution:

- Calcofluor White Reagent contains 0.4ml of Fluorescent Brightner 28 and 0.05g of Evans Blue powder.
- Potassium Hydroxide Reagent contains 10g of Potassium Hydroxide.

MATERIALS REQUIRED BUT NOT PROVIDED

- Glass slides
- Inoculating loop
- Microscope
- Cover slip
- Immersion oil PL.396

STABILITY AND STORAGE

Calcofluor White and 10% Potassium Hydroxide Reagents should be stored at 15°C - 25°C in their original containers. Product stored under these conditions will be stable until the expiry date shown on the product label.

PRECAUTIONS

- For In Vitro Diagnostic Use only.
- For professional use only.
- Directions should be read and followed carefully.
- Do not use beyond the stated expiration dates.
- Microbial contamination may decrease the accuracy of the staining.
- Safety precautions should be taken in handling, processing and discarding all clinical specimens.
- Specimens should be processed in the correct containment level conditions.
- Dispose of all material in accordance with local regulations.

TEST PROCEDURE

1. Prepare specimen on a clean glass slide.
2. Apply 1 drop of Calcofluor White Reagent and 1 drop of 10% Potassium Hydroxide Reagent onto the slide and mix.
3. Cover with a clean cover slip.
4. Allow to stand for at least 20 minutes, before pressing down the coverslip to produce a single layer of cells.
5. Examine using a fluorescent microscope.

QUALITY CONTROL PROCEDURE

Internal quality control of the stains must be performed regularly on known reference material.

Recommended Quality Control:

Positive control – *Candida albicans* NCTC® 3179 / ATCC® 10231* (PLD42)

Negative control – *Escherichia coli* NCTC® 12241 / ATCC® 25922* (PLD02)

INTERPRETATION OF RESULTS

Positive- yeasts and fungi should fluoresce brilliant white-blue against a dark background.










Negative- no fluorescence observed.

LIMITATIONS OF THE PROCEDURE

- Only experienced personnel should carry out the interpretation of stained slides.
- Read prepared slides as soon as possible after staining. Failure to do so may affect the results.
- Non-specific reactions may occur when tissue samples are used.

REFERENCES

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	= Use by
	= Lot number
	= Catalogue number
	= Manufacturer
	= Authorized Representative in the European Community
	= Contains sufficient for <n> tests
	= In vitro diagnostic medical device
	= Temperature limitation
	= Consult instructions for use




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HAZARDS IDENTIFICATION

Please refer to Safety Data sheets for full text for all hazard and precautionary statements.

 DANGER	PL.392	H350 P201, P280, P308+P313, P501
	PL.393	H314 P280, P301+P330+P331, P303+P361+P353, P310, P305+P351+P338, P501

