ULTRACARE
DIAGNOSTICS

Papanicolaou Stain EA-50

Intended Use

Detection/Measurement

UltraCare Diagnostics Cytology Stains do not detect or measure an analyte or marker. The UltraCare Diagnostics Cytology Stains are used to produce various colorations of the cytoplasm within the cellular elements of cytology specimens.

Product Function

The results obtained through use of the UltraCare Diagnostics Cytology Stains do not provide objective medical evidence. The UltraCare Diagnostics Cytology Stains are used in a cytology staining protocol to provide contrast and coloration the cytoplasm of the cellular elements. The cytology stained specimen, when interpreted by a trained professional, is utilized alongside other information such as the patient's medical history, physical condition, as well as results from other medical testing to render a medical diagnosis.

Materials Not Included

The UltraCare Diagnostics Cytology stains are commonly used with conjunction with hematoxylin and ancillary reagents as well as additional staining reagents, which are not included.

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Devices Required

UltraCare Diagnostics Cytology Stains can be used on any automated staining platform or with a manual staining method.

Storage and Stability

The product shall be stable for 24 months post-production when stored at ambient temperature. In cold weather, chilling may cause some separation. Warm to room temperature, agitate and filter before using. Store reagents at room temperature (15-25°C) in a well-ventilated place.

Infectious Material Status

The UltraCare Diagnostics Cytology Stains do not include any infectious material. However, specimens, before and after fixation, and all materials exposed to them, should be handled as if capable of transmitting infection and disposed of with proper precautions per facility guidelines.

Special Facilities

The UltraCare Diagnostics Cytology Stains should be used per facility guidelines.

Specimen Handling

Suggested fixatives include ethanol or routine cytology fixative. Ensure that the material is fixed before air drying occurs. Ensure that any polyethylene glycol has been fully removed in ethanol before rehydration.

Quality Control

A routine quality control slide(s) containing tissue fixed and processed in a similar manner to the test specimens should be performed prior to routine use to ensure Cytology Stains are performing as intended.

Readiness for Use

Once appropriate staining protocol is chosen and bathlayout is created, pour all the reagent into the reagent vessel. Place the reagent vessel back into the respective station.

Manufacturer
REF CAT NO.
LOT Number Lot number
Date of manufacture
Use by(Expiration date)

IVD For In-Vitro Diagnostic use only
Attention: See instruction for use
25°C Stored at 15-25 °C
EC REP Authorized Representative in the European Company

Ultracare For Trading, 54 Al Swesry A, Nasr City, Cairo, Egypt .

Tel. +20 1005623949 , e-mail: Info@ultracareeg.com , www.ultracareeg.com

Preparation for Use

The Cytology Stains products are available in a ready-to-use format.

1. Rehydrate as necessary using routine procedure. Immerse in Hematoxylin until desired intensity is reached.
2. Wash in tap water.
3. Differentiate as necessary when utilizing a regressive stain method. The stain should now only remain in the nuclei. This step should be controlled microscopically for optimum results. Under or over staining can be corrected at this stage by repeating the above steps as appropriate.
4. Wash well in water (the pH of the tap water should be above 7 to ensure correct color of nuclei).
5. Rinse in 95% alcohol.
6. Blue if necessary in alkaline tap water or commercial bluing agent.
7. Immerse in Orange G-6 until desired intensity is reached.
8. Rinse twice in 95% alcohol.
9. Stain in EA-50, Modified EA-50, or EA-65 for 3 minutes or until desired intensity is reached.
10. Rinse well in 95% alcohol.
11. Dehydrate, clear and mount in synthetic resin.
12. To avoid contamination, filter solutions daily and change at least weekly.

Results: The nuclei and their components should be stained in varying shades of blue/purple.

- Keratinized cells - orange.
- Cytoplasm of superficial cells - pink.
- Cytoplasm of intermediate cells - blue/green.
- Cytoplasm of parabasal cells - blue/green.

Expected Results

The nuclei and their components should be stained in varying shades of blue/purple.
Keratinized cells – orange, cytoplasm of superficial cells – pink, cytoplasm of intermediate cells - blue/green, cytoplasm of parabasal cells - blue/green.

Analytical Performance

The UltraCare Diagnostics Cytology Stains are not used to detect a specific analyte or marker. These products are used in conjunction
with other products in a Papanicolaou stain protocol to stain cytology specimens cytoplasm various colors. Analytical parameters such as analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross-reactions do not apply to the performance of this system.

Clinical Performance

The UltraCare Diagnostics Cytology Stainsare not intended for use as a means of detecting a specific disease or pathological process or state. Clinical performance indices such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative
predictive value, likelihood ratio as well as expected values in normal and affected populations do not apply to the use of the UltraCare Diagnostics Bluing Agents in a clinical setting

Reference

Data on file: UltraCare Diagnostics .

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