

INTENDED USE

For the detection and preliminary identification of *Corynebacterium diphtheriae* in prepared slides from clinical specimens.

SUMMARY AND EXPLANATION

Albert's stain was first described in 1920 as a differential stain used to stain the volutin granules, also known as metachromatic or food granules, found in *Corynebacterium diphtheriae*.

PRINCIPLE OF THE TEST

The Albert's stain procedure comprises two stains: Albert's Stain 1 and Albert's Stain 2. Albert's Stain 1 contains Toluidine Blue and Malachite Green, basic dyes with a high affinity for acidic tissue like cytoplasm. When stained with Albert's Stain 1 the volutin granules are stained blue and the cytoplasm is stained blue-green. Albert's Stain 2 stains the blue-stained volutin granules blue-black so they are more visible against the blue-green cytoplasm background.

MATERIALS PROVIDED

Ready to use stains:

-	PL.7129	Albert's Stain 1	500 ml
-	PL.7130	Albert's Stain 1	1000 ml
-	PL.7131	Albert's Stain 1	2000 ml
-	PL.7132	Albert's Stain 2	500 ml
-	PL.7133	Albert's Stain 2	1000 ml
-	PL.7134	Albert's Stain 2	2000 ml

Per 100ml solution:

- Albert's Stain 1 contains 0.15g Toluidine Blue powder and 0.2g Malachite Green powder.
- Albert's Stain 2 contains 0.66g of Iodine.

MATERIALS REQUIRED BUT NOT PROVIDED

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

STABILITY AND STORAGE

Albert's Stains 1 and 2 should be stored at 15-25°C in 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.
- Samples should be processed in the correct containment level conditions.
- Dispose of all material in accordance with local regulations.
- Any serious incident that occurs in relation to the device should be reported to the manufacturer and the competent authority of the member state in which the incident occurred.

TEST PROCEDURE

1. Prepare a smear on a clean glass slide and allow to air dry.
2. Flood the slide with Albert's Stain 1, and allow to stain for approximately 5 minutes.
3. Drain off the excess stain. Do not rinse the slide with water.
4. Flood the slide with Albert's Stain 2 for approximately 1 minute.
5. Wash the slide with water and air dry.
6. Examine using a microscope.

QUALITY CONTROL PROCEDURE

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

Recommended Quality Control:

Positive control – *Corynebacterium diphtheriae* NCTC® 11397/ATCC® 27010*

Negative control – A proven negative

INTERPRETATION OF RESULTS

Positive- *Corynebacterium diphtheriae* appear as green rods arranged at angles to each other (resembling letter 'L' or 'V'), along with blue-black metachromatic granules at the poles.

Negative- short nonpathogenic diphtheroids or other organisms will lack the blue-black granules.

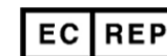
LIMITATIONS OF THE PROCEDURE

- 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.

REFERENCES

- Albert, H. Modification of stain for diphtheria bacilli. *The Journal of the American Medical Association*. 1921 76:240.
- Anderson, N.L. et al. Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory. Coordinating ed., A.S. Weissfeld. *American Society for Microbiology*, Washington, D.C.
- Arnold WM, Weaver RH. Quick microtechniques for the identification of cultures. *Journal of Laboratory and Clinical Medicine* 1948; 33:1334-7.
- Chapin, K. C., and T.-L. Lauderdale. 2003. Reagents, stains, and media: bacteriology. p. 354-383.
- Cruickshank, R., Duguid, J. P., Marmion, B. P. and Swain, R.H.A. The Practice of Medical Microbiology. 12th Edition. V2
- Jorgensen et al. Manual of Clinical Microbiology. *American Society for Microbiology*, Washington, D.C. 1974.
- Lennette. 1974. Manual of Clinical Microbiology. *American Society for Microbiology*, Washington, D.C., 1974.
- Payle, B., Serrano, L., Biele, H.C. and Reyes, B.A. Albert's solution versus potassium hydroxide solution in the diagnosis of tinea versicolor. *International Journal of Dermatology*. 1994 Mar; 33(3):182-3.
- Sutter, V.L. and Carter, W.T. (1972). *American Journal of Clinical Pathology* 58:335-338
- Tille, P. et al. Bailey and Scott's Diagnostic Microbiology, C.V. Mosby Company, St Louis, MO.

	= 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



Advena Ltd. Tower Business Centre, 2nd Floor,
Tower Street, Swatar, BKR 4013, Malta.

*NCTC® and NCPF® are trademarks of Public Health England. ATCC® strains are listed for reference only. ATCC® is a registered trademark of the American Type Culture Collection.

HAZARDS IDENTIFICATION

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

PL.7129 PL.7130 PL.7131 PL.7132 PL.7133 PL.7134	This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]. Not classified (SI 2019/758 as amended).
--	---

