remel

A.L.A. DISK

REF R21115 ..... 25 Disks/Vial

1. INTENDED USE

Remel A.L.A. Disk™ is a reagent-impregnated disk recommended for use in qualitative procedures to differentiate *Haemophilus* species based on the detection of porphyrin synthesis.

2. SUMMARY AND EXPLANATION

Members of the genus *Haemophilus* are small nonmotile Gram-negative bacilli traditionally defined by a requirement for X and/or V factor.[1] X factor is derived from hemoglobin and V factor through the satellite relationship with *Staphylococcus aureus*. Biberstein et al. studied the action of *Haemophilus* on δ-aminolevulinic acid (ALA) and reported a perfect correlation between X factor-independence and the ability to convert ALA to porphyrins.[2] In 1974, Kilian described a rapid method for identification of X factor-independent *Haemophilus* spp. based on the ability to synthesize heme precursors from ALA.[3] Lund and Blazevic determined the porphyrin test is more rapid and accurate for identification of X factor-independent strains of *Haemophilus* (e.g., *H. parainfluenzae* and *H. parahaemolyticus*) than the satellite test.[4]

3. PRINCIPLE

The A.L.A. Disk is a rapid and accurate test for detection of porphyrins which are excreted by X-independent *Haemophilus* spp. After incubation, the disk is exposed to long wave ultraviolet light. A positive test is indicated by development of bright-orange fluorescence.

4. REAGENTS

Reactive Ingredient: δ-Aminolevulinic Acid

5. PRECAUTIONS

This product is for *in vitro* diagnostic use and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and media after use. Directions should be read and followed carefully.

6. STORAGE

This product is ready for use and no further preparation is necessary. Store product in its original container at 2-8°C until used. Allow product to equilibrate to room temperature (20-25°C) before use and protect from light, as the substrate is highly light sensitive.

7. PRODUCT DETERIORATION

This product should not be used if (1) the disk color has changed from white, (2) the expiration date has passed, (3) the desiccant has changed from blue to pink, or (4) there are other signs of deterioration. Protect disks from moisture by removing from the vial only those disks necessary for testing. Promptly replace the cap and return the vial to 2-8°C.

8. SPECIMEN COLLECTION, STORAGE, TRANSPORT

Specimens should be collected and handled following recommended guidelines.[5,6]

9. MATERIALS REQUIRED BUT NOT SUPPLIED

(1) Loop sterilization device, (2) Inoculating loop, swabs, collection containers, (3) Incubators, alternative environmental systems, (4) Supplemental media, (5) Quality control organisms, (6) Forceps, (7) Long wave ultraviolet lamp, (8) Filter paper, (9) Petri dish, (10) Sterile water.

10. PROCEDURE

1. Verify the test isolate resembles *Haemophilus* spp., both by Gram stain and colony morphology.
2. Place an A.L.A. Disk™ on the agar surface or in a sterile petri dish with the A side down.
3. Rehydrate the disk with 40 µl of sterile water. Do not oversaturate the disk.
4. Inoculate the disk with a heavy, visible inoculum removed from a pure, 18-24 hour culture of the test isolate.
5. Place a piece of filter paper moistened with water in the lid of the petri dish to keep the disk moist during incubation.
6. Incubate in ambient air at 35-37°C for up to 6 hours.
7. Examine the disk at 1 hour with a long wave ultraviolet light in a dark room for bright-orange fluorescence. If negative, reincubate the test and examine periodically for up to 6 hours before reporting as negative.

11. INTERPRETATION

Positive Test - Bright-orange fluorescence

Negative Test - No fluorescence

12. QUALITY CONTROL

All lot numbers of A.L.A. Disk have been tested using the following quality control organisms and found to be acceptable. Testing of control organisms should be performed in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, patient results should not be reported.

CONTROL	INCUBATION	RESULTS
Haemophilus parahaemolyticus ATCC® 10014	Ambient, 1-6 h @ 35-37°C	Positive
Aggregatibacter aphrophilus (formerly Haemophilus parainfluenzae) ATCC® 7901	Ambient, 1-6 h @ 35-37°C	Positive
Haemophilus influenzae ATCC® 10211	Ambient, 1-6 h @ 35-37°C	Negative

13. LIMITATIONS

1. Organisms that are strongly oxidase-positive or catalase-positive may result in a false-positive test with the A.L.A. Disk. Such organisms produce heme and its precursors from ALA in the process of synthesizing oxidase or catalase. The A.L.A. Disk is validated for use only with *Haemophilus* spp.
2. Observation for fluorescence must be made in a darkened room or black box.

14. BIBLIOGRAPHY

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15. PACKAGING

REF R21115, A.L.A. Disk™ ..... 25 Disks/Vial

16. SYMBOL LEGEND

REF	Catalogue Number
IVD	*In Vitro* Diagnostic Medical Device
	Consult Instructions for Use (IFU)
	Temperature Limitations (Storage temp.)
LAB	For Laboratory Use Only
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)
	Manufactured by

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