



remel

Niacin Control Disk

INTENDED USE

Remel Niacin Control Disk is a reagent-impregnated disk recommended for use in qualitative procedures as a positive control for the niacin test.

SUMMARY AND EXPLANATION

Niacin or nicotinic acid plays a vital role in the oxidation-reduction reactions that occur during metabolic synthesis in all mycobacteria.¹ While all species produce nicotinic acid, *Mycobacterium tuberculosis* accumulates the largest amount in the medium in which it is growing and can therefore be detected on the basis of this evidence. Pope and Smith, Bird, and Konno et al. have demonstrated that human tubercle bacilli produce considerably more niacin than other mycobacteria.²⁻⁴ In 1956, Konno devised the standard niacin test using chemical reagents, which was later modified by Runyon.^{5,6} Kilburn and Kubica, and Young et al. demonstrated the niacin test using a paper strip method impregnated with test reagents.^{7,8} The Niacin Control Disk contains 5 µg nicotinic acid.^{9,10}

PRINCIPLE

Niacin functions as a precursor in the biosynthesis of coenzymes. The accumulation of niacin in the culture medium of mycobacteria is due to the lack of an enzyme that converts it to another metabolite in the coenzyme pathway.¹¹ Paper strips impregnated with potassium thiocyanate and chloramine T (Niacin Reagent Strip, REF R21090) will release cyanogen chloride which reacts with *p*-aminosalicylic acid to produce a yellow color in the presence of niacin. The Niacin Control Disk serves as a positive control for the Niacin Reagent Strip to aid in the determination of a positive yellow color development.

REAGENTS

Reactive Ingredient: Nicotinic Acid

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.

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 before use.

PRODUCT DETERIORATION

This product should not be used if (1) the 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 vial only those disks necessary for testing. Promptly replace the cap and return the vial to 2-8°C.

SPECIMEN COLLECTION, STORAGE, TRANSPORT

Specimens should be collected and handled following recommended guidelines.¹²

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) Demineralized water (7) Sterile 13 x 100 mm test tubes with screw caps, (8) 1.0 ml pipettes, (9) Niacin Reagent Strip (REF R21090).

PROCEDURE

Note: Follow established safety procedures when working with acid-fast cultures and specimens. Consult appropriate references for detailed procedural information on media inoculation.¹²

Cultures grown on egg yolk medium yield the most consistent results in the niacin test.¹ When circumstances necessitate the use of cultures grown on 7H10 or 7H11 agar, use media supplemented with 0.1% potassium aspartate. Cultures should be 3-4 weeks old and have sufficient growth of 50-100 colonies.

1. A Niacin Control Disk added to 0.6 ml of demineralized water in a sterile screw cap tube serves as a positive control. The tube should be just slightly longer than a Niacin Reagent Strip (13 x 100 mm or smaller).
2. Let tube stand for 30 minutes with occasional shaking to ensure extraction of the substrate from the disk.
3. Add a Niacin Reagent Strip to the tube with the marked end up.
4. Tightly seal the tube and incubate at room temperature for 15-30 minutes with occasional shaking.
5. Observe the broth for a yellow color development.
6. A Niacin Reagent Strip added to 0.6 ml of demineralized water in a sterile screw cap tube serves as a negative control. Incubate negative control as described in steps 3-5.

INTERPRETATION

Positive Test - Yellow color development in the liquid portion of the positive control tube

Negative Test - No yellow color development in the negative control tube

MANUFACTURER QUALITY CONTROL

All lot numbers of Niacin Control Disk have been tested according to the PROCEDURE in this instruction for use (IFU) and have been found to be acceptable.

USER QUALITY CONTROL

Each new lot number of Niacin Control Disk should be tested according to the PROCEDURE in this IFU. A positive and negative control should be included with each performance of the niacin test.¹ If aberrant quality control results are noted, patient results should not be reported.

LIMITATIONS

1. The niacin test alone should not be used to identify *M. tuberculosis* because other species, including *M. simiae* and some strains of *M. chelonae*, consistently yield positive results.¹ Supportive tests such as nitrate reduction and 68°C catalase testing are recommended to confirm the identity of *M. tuberculosis*.
2. Cultures that are niacin negative at 4 weeks and have been handled aseptically, may be reincubated and retested at 6 weeks. If not handled aseptically, a fresh culture should be used.¹
3. Mycobacteria excrete niacin into the growth medium. Cultures with confluent growth may result in a false negative niacin reaction because the extracting fluid cannot contact the culture medium. When this occurs, expose the underlying medium surface by scraping away or puncturing through some of the growth.¹
4. Promptly seal tubes after inserting the Niacin Test Strip. A false negative reaction may occur due to the escape of gas evolved as chemicals mix on the strip.¹
5. Do not examine the Niacin Reagent Strip for a yellow color development; read the liquid only.
6. Do not examine the liquid for color development beyond 30 minutes of incubation because liquid color will fade.
7. This test is only part of the overall identification scheme. Further biochemical testing may be necessary for definitive identification. Consult appropriate references as necessary.^{11,12}




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PACKAGING

REF R21133, Niacin Control Disk25 Disks/Vial

Symbol Legend

REF	Catalog Number
IVD	In Vitro Diagnostic Medical Device
LAB	For Laboratory Use
	Consult Instructions for Use (IFU)
	Temperature Limitation (Storage Temp.)
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)

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