

INTENDED USE

Alpha-Tec Systems, Inc. Kinyoun Carbol-fuchsin Stain is recommended for use in qualitative procedures for the microscopic detection of mycobacteria.

SUMMARY

One of the earliest methods devised for the detection of the tubercle bacillus is the microscopic staining technique. This method is valuable for the rapid initial step in the presumptive diagnosis of mycobacterial infections, and provides information about the number of acid-fast bacilli present. Species of *Nocardia* and *Rhodococcus* are also partially acid-fast. Three types of staining procedures are used for the detection of acid-fast organisms: fluorochrome, Ziehl-Neelsen (hot stain), and Kinyoun (cold stain).

The basic Kinyoun Carbol-fuchsin dye used in this stain interacts with the mycolic acids and waxes in the mycobacterial cell wall, which then fails to wash out with mild acid decolorization. Typical acid-fast bacteria, which retain the dye, appear pink to red. A counterstain of a contrasting color is used to detect non acid-fast bacteria in the smear.

FOR IN VITRO DIAGNOSTIC USE ONLY

PRECAUTIONS

Kinyoun Carbol-fuchsin Stain is poisonous and may be harmful or fatal if swallowed. May cause irritation to skin, eyes and respiratory tract. Combustible; keep away from heat and flame. Suspected cancer hazard; contains material which may cause cancer. Avoid breathing vapor and eye/skin contact.

STORAGE

This product is ready to use and no further preparation is necessary. It should be stored in its original container at 15°-30° C until use.

USER QUALITY CONTROL

This product should not be used if the color has changed, the expiration date has passed, or there are other signs of deterioration.

SPECIMEN COLLECTION AND PREPARATION

Appropriate specimens for the detection of *Mycobacterium* spp. should be collected according to prescribed standards and delivered to the laboratory in a safe and timely manner. Refer to local procedural guidelines for this information.

PROCEDURE

Materials Provided: Kinyoun Carbol-fuchsin Stain.

Materials Not Provided: Pipettes, glass slides, Bunsen burner or slide warmer, microscope, immersion oil, deionized or distilled water, AFB Stain Control Slide (#0003240), TB Decolorizer (#0003525), Methylene Blue Counterstain (#0003526) or Brilliant Green Counterstain (#0003534).

Procedure

1. Make a thin smear of the specimen over an area of 2-3 sq cm. Heat fix by warming on a slide warmer (65°-75° C) for 10 minutes, or until the smear is dry. If a Bunsen burner is used, pass the slide slowly 3 times over its cone of heat. Do not scorch.
2. Flood the smear with Kinyoun Carbol-fuchsin Stain for 5 minutes.
3. Rinse with deionized or distilled water and drain.
4. Decolorize with TB Decolorizer for 3 minutes.
5. Rinse with deionized or distilled water and drain.
6. Repeat decolorization for 1-2 minutes or until no red stain appears.
7. Rinse with deionized or distilled water and drain.
8. Flood smear with Methylene Blue Counterstain or Brilliant Green Counterstain for 3-4 minutes.
9. Rinse with deionized or distilled water and allow to air-dry.
10. Examine microscopically using low power (10x-40x), and confirm at 100x under oil immersion for the presence of acid-fast bacilli.

EXPECTED RESULTS

Positive Reaction: Acid-fast positive organisms stain pink to red. Mycobacteria appear red, small, slightly curved, possibly beaded or banded, with tapered ends.

Negative Reaction: Non acid-fast organisms stain blue with Methylene Blue Counterstain, and green with Brilliant Green Counterstain.

LIMITATIONS OF PROCEDURES

1. Overheating (burning) during fixation should be avoided.
2. Do not stain smears that have only been air-dried. Smears must also be "fixed".
3. Smears should not be too thick. After air-drying, examine under a microscope.
4. After staining, it is essential that the back surface of the slide is wiped clean.
5. If washing with distilled water is not done adequately, crystallization of the stain may appear on the slide.
6. Scan at least 100 fields before reporting as negative.
7. Some non-tuberculous species, such as *Mycobacterium avium* complex, appear pleomorphic, usually coccoid. Positive findings should be based only on typical forms but atypical cells should be noted.
8. Atypical rods may represent other partially acid-fast organisms such as species of *Nocardia* or *Rhodococcus*. A weaker acid or a shorter decolorizing period is used to detect these organisms.
9. The sensitivity of the direct acid-fast smear examination for the diagnosis of mycobacterial infection is lower than that of culture methods. Therefore, cultures should be performed on all specimens.

SPECIFIC PERFORMANCE CHARACTERISTICS

This product has been tested using the AFB Stain Control Slides, and have been found to yield acceptable stain results. Appropriate testing should be performed in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, patient results should not be reported.

BIBLIOGRAPHY


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CONTACT

Alpha-Tec Systems, Inc. offers a complete line of QC Slides, stains, reagents and digestion systems for AFB specimen processing. For Technical Assistance, email Technical@AlphaTecSystems.com and for Customer Service, email Sales@AlphaTecSystems.com or call (800) 221-6058 or (360) 260-2779 between 8 am and 4 pm Monday through Friday, Pacific Time.

WARRANTY

Alpha-Tec Systems, Inc. warrants this product to perform as described in the labeling and literature supplied. Any change or modification in the procedure may cause improper results. Unless this product is used in accordance with the labeling and literature, any and all warranties (expressed, implied or statutory) regarding the product including the implied warranty of merchantability and fitness for particular purpose are specifically denied. In no event shall Alpha-Tec Systems, Inc. be liable for any direct, indirect or consequential damages resulting from use or performance of this product.

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GLOSSARY OF SYMBOLS


LOT Lot number / Número de porción / Número de lote / Numerodi lotto / Partienummer / Numéro de sort / Het Aantal van de partij


REF Catalog number / Número de catálogo / Número de catálogo / Numero di catalogo / Katalogzahl / Numéro de catalogue / Het aantal van de catalogus


IVD For in vitro diagnostic use only / Para el diagnóstico in vitro solamente / Para in vitro o uso diagnóstico somente / Solo per uso diagnostico in vitro / Für nur in vitrodiagnosegebrauch / Pour l'usage diagnostique in vitro seulement / Voor kenmerkend slechts gebruik in vitro


EC REP Authorized European representative / Representante europeo autorizado / Representante europeu autorizado / Rappresentante europeo autorizzato / Autorisierter europäischer Repräsentant / Representant européen autorisé / Gemachtigde Europese vertegenwoordiger


 Caution, consult accompanying documents / Precaución, consulte los documentos de acompañamiento / Cuidado, consulte originais acompanhando / Attenzione. Consulti i documenti di accompagnamento / Vorsicht, beraten Begleitdokumente / Attention, consultez les documents d'accompagnement / Voorzichtigheid, raadpleeg begeleidende documenten

 Store between temperatures indicated / Almacén entre las temperaturas indicadas / Loja entre as temperaturas indicadas / Deposito fra le temperature indicate / Speicher zwischen den Temperaturen angezeigt / Magasin entre les températures indiquées / Opslag tussen vermelde temperature

 Consult instructions for use / Consulte las instrucciones para el uso / Consulte instruções para o uso / Consulti le istruzioni per uso / Beraten Sie Anwendungsvorschriften / Consultez les instructions pour l'usage / Raadpleeg instructies voor gebruik

 Use by date indicated / Uso por la fecha indicada / Uso pela data indicada / Uso entro la data indicate / Gebrauch bis zum der Dattel angezeigt / Utilisation à la date indiquée / Gebruik door vermelde datum

 Manufacturer / Fabricante / Fabricante / Fornitore / Hersteller / Fabricant / Fabrikant

 Contains sufficient for <n> tests / Contiene suficiente para <n> las pruebas / Contem suficiente para <n> testes / Contiene sufficiente per <n> le prove / Enthält genügendes für <n> tests / Contient suffisamment pour <n> des essais / Bevat voldoende voor <n> tests