BACITRACIN 53842

PRESOMPTIVE DIAGNOSIS OF GROUP A STREPTOCOCCI

IVD

1- INTENDED USE
Presomptive identification of group A bêta-haemolytic streptococci.

2- PRINCIPE
Group A bêta-haemolytic streptococci are generally sensitive to a low concentration of bacitracine while the streptococci of other groups are generally resistant.

3- HOW SUPPLIED
- Bacitracin (cartridge of 30 disks) code **53842**

4- COMPOSITION
Bacitracine disks (BAC) : absorbent-paper disk impregnated with bacitracine at a concentration between 0,02 and 0,04 IU.

5- STORAGE
The disks stored in the cartridge and container, in a dry environment at 2 to 8°C, in the absence of contamination, are stable until the expiration date indicated on the label.
The expiration date only applies to disks contained in intact cartridges stored as per the manufacturer's instructions. The expiration date and batch number are shown on each packaging (cartridge and container).
The stability of the disks after opening (stored as per the recommendations) has been validated under routine conditions over 6 weeks.

6- PROCEDURE
Inoculate the surface of a blood agar medium with either a pure culture (dense suspension to obtain a confluent culture), or directly with the sample if the test is performed at the same time as isolation.
- Deposit a bacitracin disk on the surface of the agar (in the second quarter of depletion for agar media inoculated directly with the sample).
- Incubate at 37°C for 18 to 24 hours.

Refer to current recommendations for storage of biological specimens (4).

Reading :
Measure the zone of inhibition around the bacitracine disk.
A zone of inhibition of bêta-haemolytic colonies equal or greater than 15 mm allows presumptive identification of group A streptococci.

7- PERFORMANCE / QUALITY CONTROL OF THE TEST
- The performance of bacitracine is controlled using the following strains:

STRAINS	RESULT OF ANTIBIOTIC SENSITIVITY TESTING AFTER INCUBATION AT 37°C FOR 18-24 H Inhibition diameter (mm)
Streptococcus group A ATCC 19615	≥ 15 mm
Streptococcus group B ATCC 13813	< 14 mm

8- QUALITY CONTROL OF THE MANUFACTURER
All the products manufactured and marketed by the Bio-Rad company are prepared to our Quality System, starting from reception of raw materials to the final commercialization of the product. Each lot is submitted to quality control assessments and is only released to the market after conforming to the predefined acceptance criteria. The records relating to production and control of each single lot are kept within Bio-Rad.

9- LIMITS OF USE

- An increasing number of group A streptococci became resistant to bacitracin.
- An inhibition of the haemolysis without inhibition of the culture is not interpretable.
- Certain streptococci of groups C and G can give zones of inhibition, however generally lower than 15 mm.
- Immunological complementary tests (Pastorex® Strep, code 61721) must be performed for precise identification of the strain isolated.

10- REFERENCES

1. FACKLAM R.R. and al. Presumptive identification of group A, B and D streptococci on agar plate media. J. Clin. Microbiol., 1979, **9**, 665-672.
2. FACKLAM R.R. and al. Presumptive identification of group A, B and D streptococci on agar plate media. Appl. Microbiol., 1974, **27**, 107-113.
3. POLLOCK H.M. and DAHLGREN B.J. Distribution of streptococcal groups in clinical specimens with evaluation of bacitracin screening. Appl. Microbiol., 1974, **27**, 141-143.
4. Basic Laboratory Procedures in Clinical Bacteriology. World Health Organization. Geneva.1991. 1st edition.

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