KEY-COAG K70006

INTENDED USE

Lyophilized rabbit plasma in 0.5 ml single use aliquots is intended for the tube coagulase test to assist in the identification of *Staphylococcus aureus.*

SUMMARY

Coagulase from *Staphylococcus aureus* binds plasma fibrinogen, causing the organisms to clot plasma. Two different forms of coagulase, free and bound, can be produced by *Staphylococcus aureus.* The tube test can detect the presence of both bound and free coagulase, therefore the isolates that do not produce the bound coagulase (clumping factor) must be tested for the ability to produce extracellular coagulase (free coagulase).

FORMULA

KEY-COAG contains lyophilized rabbit plasma in 0.5 ml single use aliquots.

STORAGE AND SHELF LIFE

Storage: Upon receipt store vials at 2-8 degrees C. The product may be shipped without refrigeration if transit time is less than one week.. Product should not be used if there are any signs of deterioration, contamination, or if the expiration date has passed. The expiration date applies to the product in its intact packaging when stored as directed.

PRECAUTIONS

For *in vitro* diagnostic use only. Observe aseptic technique and established procedures against microbiological contamination / hazards throughout performing the test. Discard in an appropriate manner in accordance with institutional guidelines and good laboratory practices. To be used by adequately trained and qualified laboratory personnel only. Sterilize biohazard waste before disposal.

PROCEDURE

Re-hydrate the KEY-COAG tube with 0.5 ml or 10 drops of sterile distilled water. Shake gently for 30 seconds to dissolve the dehydrated plasma. Inoculate with a loop full of the test organism and incubate the tube at 35° C for four hours without shaking. Observe hourly during incubation since fibrinolysin produced by some staphylococci could lyse the clot, thus giving a false negative result.

INTERPRETATION OF RESULTS

A clot formation is considered a positive coagulase test.

LIMITATIONS

The coagulase test is used for presumptive identification of *Staphylococcus aureus*.

Coagulase positive organisms should be examined by gram stain to determine morphology and gram reaction, and tested for catalase activity.

Additional tests are recommended for complete identification.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as sterile water, loops, other culture media, swabs, applicator sticks, incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

Quality control should be performed in accordance with applicable state, local, and/or federal regulations or accreditation requirements. Sterilize specimens, containers, slides, tubes, and other contaminated material by autoclaving.

Minimal quality control requires testing a coagulase negative and another coagulase positive organism at the time test is performed.

The following organisms are suggested for minimal QC:

ATCC 25923 *Staphylococcus aureus*
Results: Clot formation within 4 hours

ATCC 12228 *Staphylococcus epidermidis*
Results: No clot formation

REFERENCES

1. Baron, E.J., L.R. Peterson and S.M. Finegold, 1994, Bailey & Scott's diagnostic microbiology, 9th ed. Mosby-Year Book, Inc., St. Louis, MO.

2. Murray, P.R., E.J. Baron, M.A. Pfaller, F.C. Tenover and R.H. Yolken, 2007. Manual of clinical microbiology, 9th ed. Ameri can Society for Microbiology, Washington, D.,C.

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