A single, intradermal dose of PPD is the standard tuberculin test. The test is performed by injecting a 0.1 mL dose of Aplisol (tuberculin PPD, diluted) into the skin of the forearm. The test is read at 48-72 hours, and the reaction is measured by the diameter of induration (in mm). A positive reaction is indicated by an induration of 5 mm or greater. The test is used to screen for active tuberculosis (TB) in individuals who are at risk for infection, and to detect past infection with TB in those who have no symptoms of active disease.

CLINICAL PHARMACOLOGY

In the United States, the prevalence of Mycobacterium tuberculosis infection and active disease varies for different groups. The prevalence of TB in the general population is estimated to be 0.01% for those over the age of 35. However, the prevalence is much higher among certain populations, such as the homeless, injection drug users, and those with HIV/AIDS.

The tuberculin PPD test is a safe and effective way to screen for TB infection. The test is not painful and does not cause fever or other symptoms. However, the test can cause a localized swelling at the injection site in some individuals. This reaction is usually mild and resolves within a few days.

PRECAUTIONS

General

The tuberculin PPD test is contraindicated in patients who have a history of tuberculosis or who have been exposed to M. tuberculosis. The test is not recommended for use in pregnant women, as it may cause fetal harm.

Aplisol (tuberculin PPD, diluted) is available in 10 mL vials and is intended for intradermal use. The product is not sterilized and should not be used in patients who have a history of hypersensitivity to tuberculin or the constituents of the diluent.

Adverse Reactions

The most common adverse reaction is a localized swelling at the injection site. Other reactions may include pain, redness, and itching. These reactions are usually mild and resolve within a few days.

Other Reactions

Rare serious reactions may occur, including anaphylaxis, anaphylactoid reactions, and other systemic reactions.

Contraindications

The tuberculin PPD test is not recommended for use in individuals who have a history of hypersensitivity to tuberculin or the constituents of the diluent.

Indications and Usage

The tuberculin PPD test is used to screen for active tuberculosis (TB) in individuals who are at risk for infection, and to detect past infection with TB in those who have no symptoms of active disease.

Dosage

The 0.1 mL dose of Aplisol (tuberculin PPD, diluted) is equivalent to the 5 tuberculin units (TU) dose of Tuberculin PPD, which is the standard strength used for intradermal Mantoux testing.

Standard Method (Aplisol Test)

The Aplisol test is performed by administering a 0.1 mL dose of Aplisol (tuberculin PPD, diluted) intradermally to the tuberculin-reactive donor. The test is read at 48-72 hours, and the reaction is measured by the diameter of induration (in mm). A positive reaction is indicated by an induration of 5 mm or greater. The test is used to determine the presence or absence of TB infection in the recipient.

Contraindications

The Aplisol test is contraindicated in patients who have a history of hypersensitivity to tuberculin or the constituents of the diluent.

ADVERSE REACTIONS

Local reactions, including pain, redness, and swelling, may occur at the injection site. These reactions are usually mild and resolve within a few days.

TUBERCULOSIS VACCINE TESTS

A tuberculosis vaccine test is used to determine the level of immune response to a vaccine. The test is performed by injecting a 0.1 mL dose of Aplisol (tuberculin PPD, diluted) intradermally to the test site. The test is read at 48-72 hours, and the reaction is measured by the diameter of induration (in mm). A positive reaction is indicated by an induration of 5 mm or greater.

CONTRAINDICATIONS

The tuberculin PPD test is contraindicated in patients who have a history of hypersensitivity to tuberculin or the constituents of the diluent.

WARNINGS

The tuberculin PPD test is not recommended for use in individuals who have a history of hypersensitivity to tuberculin or the constituents of the diluent.

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Skin test conversions

† For persons who are otherwise at low risk and are tested at the start of employment, a reaction of > 15 mm

Reaction ≥ 5 mm of induration

Reaction ≥ 10 mm of induration

Reaction ≥ 15 mm of induration

considered to minimize the likelihood of interpreting a boosted reaction as a conversion.

Effect can be seen on a second test done one week after the initial stimulating test and can persist for a year, and

significant reaction may not be detected. However, the stimulus of the test may boost or increase the size of the

Infection of an individual with tubercle bacilli or other mycobacteria or BCG vaccination results in a delayed

Booster Effect and Two-Step Testing

(symptoms compatible with tuberculosis).

but by some other mycobacterium. The negative tuberculin skin test should never be used

procedures (e.g., chest radiograph, sputum smear and/or culture examination) should be carried out before

A positive tuberculin reaction does not necessarily signify the presence of active disease. Further diagnostic

known to have been exposed to a person with tuberculosis must not be adjudged free of infection until that

is absent only after normal reactivity to non-specific irritants has been demonstrated. A primary injection of

may affect potency.

DO NOT FREEZE

Storage

This product is ready for use without further dilution.

REFERENCES


*PPO-6 World Health Organization/International PPD-Tuberculin Standard

**C.T. Tuberculin Standard

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