

THYROCHEK®

TSH CONTROL SET

A qualitative control (Human Serum)

Product Number: 120 C

Vitro Diagnostic Use.

INTENDED USE

TSH Control is an assayed, stable, ready to use liquid, bi-level control for use with assays designed for qualitative detection of TSH. It is intended to assist in quality control assurance of TSH test devices.

SUMMARY AND PRINCIPLE

This control will assist in the evaluation of proper performance of TSH test devices.

REAGENT

TSH Control is prepared using human serum with purified human TSH added to achieve the desired concentration levels and 0.1% sodium azide as a preservative.

The set consists of two vials. Each vial contains 1.0mL. Liquid fluid.

STORAGE

TSH Control is stored at 15-28°C and is stable until the expiration date on the vial. After opening, the vials should be used at room temperature and immediately refrigerated. The stability after opening is up to 30 days, and closed, 2 years.

PROCEDURE

To be used in the same manner as samples and run according to the procedure provided by the reagent kit manufacturer.

PERFORMANCE CHARACTERISTICS

TSH Control is a ready to use liquid product manufactured according to standard quality control procedures. Stability and consistency of this product is guaranteed by the manufacturer.

CAUTION

This product has been found to be non-reactive for Hepatitis-B surface antigen (HbsAg, or other infectious material are absent, this product should be handled as potentially infectious.

This product contains sodium azide which may react with lead and copper plumbing to form potentially explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

TARGET VALUES

The vial labeled Negative (Blue) should yield a negative test result.

The vial labeled Positive (Red) should yield a positive test result.

Negative 0.001uIU/ml

Positive > 5.0uIU/ml

For more information, contact:

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