

# CLIAwaived™ Inc.

## Rapid TSH Control Set

A Qualitative Human Liquid Control Set for use with Assays for  
Hypothyroidism Screening in Ambulatory Adults

For Technical Assistance Call 1-888-882-7739  
Outside the USA Call 210-699-8800

**FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY**

Store at 15°C to 28°C

**PLEASE READ ALL INSTRUCTIONS BEFORE BEGINNING ASSAY**

### INTENDED USE

The CLIAwaived™ Inc. Rapid TSH Control Set 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

The Rapid TSH Control Set 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 (2) vials. Each vial contains 0.5 mL liquid fluid.

### STORAGE

The Rapid TSH Control Set 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 test kit manufacturer. Please read the *Quick Reference Instructions* included with kit, when substituting the Rapid TSH Control Set for fresh whole blood.

### PERFORMANCE CHARACTERISTICS

The Rapid TSH Control Set 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.

### TARGET VALUES

The vial labeled Negative should yield a "negative" test result. The vial labeled Positive should yield a "positive" test result.

Results	Concentration
Negative	0.001 uIU/ml
Positive	> 5.0 uIU/ml

### CAUTION

**This product has been found to be non-reactive for Hepatitis-B surface antigen. However, 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.**

Manufactured for:  
CLIAwaived™ Inc.  
San Diego, CA 92121  
Email: [info@cliawaived.com](mailto:info@cliawaived.com)  
[www.cliawaived.com](http://www.cliawaived.com)