

Size : 137 x 218 mm

Seroquant TSH

Lyophilized Control set for Neonatal TSH assay

INTENDED USE

TSH Controls are intended for use as quality control materials in the routine monitoring of precision and accuracy of Neonatal TSH immunoassay.

SUMMARY

ATSH (Thyroid-Stimulating Hormone) test is a blood test that measures the level of TSH, a hormone produced by the pituitary gland to regulate the thyroid. It is used to evaluate thyroid function and diagnose conditions like an underactive thyroid (hypothyroidism) or overactive thyroid (hyperthyroidism). High TSH levels can indicate hypothyroidism, while low levels may point to hyperthyroidism or a pituitary issue.

A TSH (thyroid-stimulating hormone) test is a key part of newborn screening (NBS) to check for congenital hypothyroidism, which is a deficiency of thyroid hormone essential for brain development. The test is performed on a blood sample, usually collected from a heel prick, after 24 hours of age to minimize the effects of a temporary, normal surge in TSH.

PRODUCT DESCRIPTION

Seroquant TSH controls are prepared in a synthetic buffered matrix. Each control is a lyophilised, buffer-based material containing Thyroid Stimulating Hormone (TSH) at Low and High concentration levels. Stabilizers and preservatives are added to maintain analyte integrity during storage.

PRINCIPLE

Quality control materials are analyzed along with patient samples to verify the reliability of assay performance. Results should fall within the assigned range for the respective control level. Deviations may indicate reagent deterioration, calibration errors, or instrument malfunction.

PRESENTATION

REF	547030201
Pack Size	2x0.1 ml
Control Level-I	0.1 ml
Control Level-II	0.1 ml
PACKAGE INSERT	01 No.

REAGENTS PROVIDED

Component	Description	Quantity
TSH Control – Level 1 (Low Level)	Lyophilized, buffer-based control containing TSH at a low concentration	1 vial
TSH Control – Level 2 (High Level)	Lyophilized, buffer-based control containing TSH at a high concentration	1 vial

MATERIAL REQUIRED BUT NOT PROVIDED

- Distilled or deionized water
- Calibrated pipettes and tips
- TSH assay reagents and analyzer

PROCEDURE

1. Remove the vial from 2–8 °C and allow it to reach room temperature.
2. Add 0.1 ml of distilled or deionized water to the vial.
3. Gently swirl (do not shake) until completely dissolved.
4. Allow to stand for 5 minutes before use.
5. Mix gently before each use.
6. Run the controls in the same manner as patient samples according to the instructions of the TSH assay kit.

STORAGE AND STABILITY

Condition	Stability
Unopened (lyophilised)	Stable until expiry when stored at 2–8 °C.
After reconstitution	Stable for 2 days at 2–8 °C.

Colour	C	M	Y	K
Black	0	0	0	100
Green	100	20	100	10

Size : 137 x 218 mm

PRECAUTIONS AND WARNINGS

- For in vitro diagnostic use only.
- Avoid microbial contamination.
- Do not interchange caps or mix controls from different lots.
- Protect reconstituted material from contamination, evaporation, and repeated freeze-thaw cycles.
- Discard vials showing turbidity or precipitate after reconstitution.

LIMITATIONS

- Control values are method- and instrument-dependent and may vary between assay systems.
- Not intended for calibration or standardization purposes.
- Results outside the assigned range may indicate procedural or reagent issues that require investigation.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Juliane Leger et al. European Society for Paediatric Endocrinology Consensus Guidelines on Screening, Diagnosis and Management of Congenital Hypothyroidism. *J Clin Endocrinol Metab*. Feb 2014; 99(2):363-384.
2. The Basic Concepts of Quality Control Reference: Interval Studies, Diagnostic Efficiency, and Method Evaluation in Quality Control. Ayed Dera <http://dx.doi.org/10.5772/intechopen.76848>
3. Data on file: Zephyr Biomedicals.

SYMBOL KEYS

	Temperature limitation		Manufacturer		Batch Number/ Lot Number
	Use by		Consult Instructions for use		<i>In vitro</i> Diagnostic Medical Device
	Date of Manufacture		Catalogue Number		This way up



Manufactured by:

Zephyr Biomedicals

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