AccuTrak™

aTSHR Calibration Verification Panel

INTENDED USE

AccuTrak aTSHR Calibration Verification Panel solutions are intended for *in vitro* diagnostic use in the determination of calibration verification and verification of reportable range in automated instrument systems for the following analyte: Anti-Thyroid Stimulating Hormone Receptor (aTSHR).

AccuTrak Panels are non-automated and intended for laboratory professional use only.

Each panel consists of one bottle each of Levels 1 through 5. Each bottle contains 3.0 milliliters.

SUMMARY

The **AccuTrak** Calibration Verification Panel contains five levels of individually manufactured unassayed controls that will assist in the documentation of calibration verification and verification of reportable range required by many inspection agencies. The solutions will also provide assistance when troubleshooting instrument systems, reagent problems and calibration anomalies.

Please see APPROXIMATE VALUES section for more information as this product is not manufactured using CLSI EP06-A recommended equal-delta formulation.

REAGENTS

Reactive Ingredients:
Purified chemicals and constituents of human and/or animal source in human serum.

Nonreactive Ingredients:
Preservatives and stabilizers.

Precautions and Warnings:
For In Vitro Diagnostic Use
Disposal of all waste material should be in accordance with local guidelines.
Full SDS is available at www.mainestandards.com\doc-search.
Consult this SDS for detailed safety information including handling spills.

WARNING: Sodium Azide
This product contains sodium azide. Dispose in a safe manner in accordance with institutional, local, and national regulations. Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.

WARNING: Potentially Biohazardous
Human source material is considered potentially biohazardous. Use the Centers for Disease Control (CDC) recommended universal precautions for handling **AccuTrak** products.

STORAGE AND STABILITY

The **AccuTrak aTSHR** Calibration Verification Panel is stored at -10° to -25°C. ***Do NOT store in a frost-free freezer.*** Panels are stable until the expiration date printed on the storage container when handled according to instructions. Do not use the Kit past its expiration date. ***A maximum of four (4) freeze-thaw cycles is recommended.***

PREPARATION

Prior to use, remove the **AccuTrak aTSHR** Calibration Verification Panel from storage and allow to come to room temperature (18° to 25°C). Invert gently several times before dispensing.

To maximize stability, it is recommended that exposure to room temperature be minimized. Tightly cap opened bottles and return to -10° to -25°C immediately after dispensing.

Discard any solutions that appear to have gross bacterial contamination.

AccuTrak Calibration Verification Panels should be treated in the same manner as patient samples. If dilutions or pre-treatment are required as part of the testing procedure, follow the manufacturer's instructions.

ASSAY

Analyze each level in replicates.

LIMITATIONS

AccuTrak Calibration Verification Panel solutions are not intended for use as routine quality control materials or as calibration materials.

APPROXIMATE VALUES

The values listed are approximate and provided only for reference. Actual observed values will vary depending on the lot number, temperature, reagent and/or calibrator.

Level	Range	Units
1	0.8 – 3.4	IU/L
2	7 – 14	IU/L
3	16 – 23	IU/L
4	25 – 31	IU/L
5	33 – 40	IU/L

The following symbols may be used where applicable in labeling for LGC Clinical Diagnostics products:



Lot Number


Expiration Date


Manufacturer


Temperature Limit



***In Vitro* Diagnostic Medical Device**



Catalog Number


Instructions for Use


Biological Risk


Do Not Reuse


Caution

ORDERING INFORMATION

ORDER NO.: 2400-0255

AccuTrak aTSHR
Calibration Verification Panel:
5 x 3 mL

Any serious incident occurring in relation to the use of this device shall be reported to the Manufacturer as well as the Competent Authority of the member state in which the user/patient is established.

CONTACT INFORMATION:

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Issue Date	Modification
Aug 7, 2025	Corrected Units and added manufacturing verbiage