# AccuTrak™

**sFlt-1 Calibration Verification Panel**

## INTENDED USE

**AccuTrak sFlt-1** 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 analytes Soluble fms-like tyrosine kinase-1 (sFlt-1).

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

Eash panel consists of one bottle each of Levels 1 through 5. Each bottle contains 4.0 milliliters.

## SUMMARY

The **AccuTrak** Calibration Verification Panel 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.

## 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: 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 sFlt-1** 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 sFlt-1** 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 | 85 – 111 | pg/mL |
| 2 | 17,828 – 20,509 | pg/mL |
| 3 | 35,441 – 41,185 | pg/mL |
| 4 | 49,810 – 65,469 | pg/mL |
| 5 | 67,985 – 84,864 | pg/mL |

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.: 2400-0257**

**AccuTrak sFlt-1**
Calibration Verification Panel:
5 x 4 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 |
|---|---|
| Feb 25, 2025 | Updated Approximate values table |