

AccuTrak™ HPV Genotype Qualification Panel

QSH701 (2400-0161)

INTENDED USE

The AccuTrak™ HPV Genotype Qualification Panel QSH701 (2400-0161) is a panel of cultured human cells containing full-length HPV episomal DNA representing high risk HPV types. This panel is provided to enable researchers, diagnostic manufacturers and laboratories to evaluate their HPV test systems using samples of high risk HPV types. Multiple tubes are provided in the kit for replicate testing. The panel may be used for assay verification and validation, method comparison, reproducibility, and lot-to-lot variability studies, and training on assays that detect and differentiate HPV types in human cervical specimens.

For research use only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

The AccuTrak HPV Genotype Qualification Panel QSH701 consists of 4 members, 3 positive and 1 negative for HPV, manufactured from cultured human cells containing full-length HPV episomal DNA. The positive members consist of transfected cells containing HPV16, HPV18, and HPV51 mixed with non-infected cells and preserved in a buffered methanol solution. The negative member consists of non-infected cells preserved in a buffered methanol solution.

Material Number: 2400-0161
4 members, 4.0 mL per vial
5 vials per positive member
10 vials per negative member

STORAGE

Panel members should be stored at 2-8 °C until use. Once opened, vials of AccuTrak HPV Genotype Qualification Panel QSH701 should not be reused. Store vials upright to prevent leakage.

PROCEDURE

Materials Provided

The AccuTrak HPV Genotype Qualification Panel QSH701 is manufactured from human cells grown in tissue culture and preserved in buffered methanol solution.

Materials Required but Not Provided

Refer to instructions supplied by the manufacturer of the test kit to be used.

Instructions for Use

- Remove needed vials from refrigerator storage and allow to equilibrate to room temperature.
- Mix by vortexing for 15 seconds to assure a homogenous cell suspension.
- The AccuTrak HPV Genotype Qualification Panel QSH701 should be included in a test run using exactly the same procedure that is used to run the unknown specimens collected in a methanol based, buffered preservative solution.

INTERPRETATION OF RESULTS

Table 1 lists the HPV reactivity of the AccuTrak HPV Genotype Qualification Panel QSH701 panel members.

Table 1: Member Reactivity

Panel Member	Reactivity
1	HPV16 Positive
2	HPV18 Positive
3	HPV51 Positive
4	Negative

LIMITATIONS

AccuTrak HPV Genotype Qualification Panel QSH701 is offered for research use only. Not for use in diagnostic procedures.

PRECAUTIONS

Follow Universal Precautions¹.

Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.

These materials should be disposed of in a manner that will inactivate pathogenic agents.

FLAMMABLE – Keep away from all sources of ignition.

REFERENCES

- Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

For assistance, contact LGC SeraCare at 508.244.6400.

The package insert for this panel can be found at www.seracare.com.

A printed copy of the package insert or data sheet may be requested by email at CDx-Info@LGCGroup.com or by phone at 508.244.6400.