

## A SERACARE PANEL PRODUCT

### INTENDED USE

The human papillomavirus (HPV) Genotype Qualification Panel, QSH701, 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 laboratorians 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 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.

Cat. No. QSH701-4.0 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 QSH701 should not be reused. Store vials upright to prevent leakage.

### PROCEDURE

#### Materials Provided

The 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.

This package insert (PI) in PDF form can be found at [www.seracarepanels.com](http://www.seracarepanels.com)

The printed PI may be requested by email at [info@seracare.com](mailto:info@seracare.com), or by phone at 508.244.6400

### 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 homogeneous cell suspension.
- The QSH701 qualification panel 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 QSH701 panel members.

Table 1: Member Reactivity

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

### LIMITATIONS

QSH701 is offered for research use only. Not for use in diagnostic procedures.

### PRECAUTIONS

Follow Universal precautions.<sup>1</sup>

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

1. CDC recommendations for prevention of HIV transmission in health care settings. MMWR 36 (supp.2) 1987.

**For assistance, contact SeraCare Technical Support at 508.244.6400.**

#### ASK ABOUT RELATED SERACARE PRODUCTS

- ACCURUN® independent quality controls
- SeraCon™ and other processed plasma products
- Global Patient Sample (GPS) Program – access to a vast and evolving inventory of single test patient samples

