

Recombinant cell lines used in the manufacturing for biopharmaceutical products, recombinant proteins, vaccines, gene therapy products among others have to be tested to confirm their identity and also to detect potential contaminations with other cell lines. Assessment of the identity and purity of the cell bank lines is a critical part of the quality evaluation as defined in International guidelines for characterization of cell substrates used for production of Biotechnological/Biological products, e.g. ICH Q5D.

With the demise of the Isoenzyme test that had for many years served as the main test for confirming identity, Virusure has taken identity testing to a new level in designing a state of the art qPCR based quantitative identity test assay capable of detecting cross-contaminations of other species down to <0.01% with a high level of specificity.

The following species are covered by the qPCR assays using specific primer sets targeting the Cytochrome C-Oxidase gene:

- **Bovine** (*Bos taurus*)
- **Chinese Hamster** (*Cricetulus griseus*)
- **Dog** (*Canis familiaris*)
- **Equine** (*Equus caballus*)
- **Feline** (*Felis catus*)
- **Goat** (*Capra hircus*)
- **Human** (*Homo sapiens*)
- Other cell lines, e.g. insect to be added soon
- **Green Monkey** (*Chlorocebus aethiops*)
- **Mouse** (*Mus musculus*)
- **Ovine** (*Ovis aries*)
- **Porcine** (*Sus scrofa*)
- **Rabbit** (*Oryctolagus cuniculus*)
- **Rat** (*Rattus norvegicus*)

As standard procedure according to the acceptance criteria defined by Virusure Quality systems for PCR assays specific controls to ensure system suitability and to exclude assay interference from the test sample matrix with both the extraction procedure and the QPCR assay are always included.

The advantages of the Virusure identity testing include

- **Fully validated** assay according to ICH principle
- **Interference controls** included as standard
- Able to **detect a cross-contamination level of 0.01%** in all species (except for Goat contamination in a Sheep cell line- 0.1%)
- Fully **GMP compliant**

