

CHO-hERG-DUO, cl.:K32

Assay Ready Cells

Certificate of Analysis

Lot-N°: 92-190222JP02

BATCH SPECIFICATIONS

Name: CHO-hERG-DUO, cl.: K32

Batch Size: 71 Vials Cell ID: 0275

Cell Count (nominal): 5 million cells / vial Passage: 31

Freezing Medium: 85 % Ham's F12; 10 % FBS; 5 % DMSO Approval Date: 28.02.2019

Storage: Below -130°C (e.g. liquid nitrogen)

Approved by:



Susan Ciura (Head of Quality Control)

QUALITY CONTROL

Samples Tested: 4 Vials

Parameter	Specification Limits	Batch Results
Cell Count	≥ 90 % of nominal cell count	5.00E+06 cells / vial
Homogeneity (cell count)	≥ 90 %	93 %
Viability (after thawing)	≥ 90 %	98 %
Aggregation	≤ 2.0	1.4
Debris Ratio	≤ 1.0	0.2
Morphology	matches reference image	passed
Sterility Testing (bacteria, yeast, fungi)	sterile after 7 days	passed
Mycoplasma Testing	negative by PCR	passed
Identity (cross species contamination)	species-specific PCR fragment	passed (hamster)
Identity (human STR analysis)	matches reference STR profile	passed (CHO-K1)

METHODS

Cell Viability Parameters (cell count, viability, aggregation, amount of debris) are determined in a CASY TT automatic cell counter. Homogeneity is analyzed in a plate-based assay.

Sterility is tested by inoculation of aerob and anaerob growth broths (Tryptic Soy and Thioglycollate for bacteria, yeast and fungi) with samples and cultivation over a course of 7 days.

Mycoplasma are detected by PCR using a mycoplasma detection kit.

Species Identity is tested by amplification of a specific fragment of 18S rRNA coding region via multiplex PCR (dog, mouse, Chinese hamster, human, monkey, rat, pig and bovine).

