

CHO-CaV1.2

Assay Ready Cells

Certificate of Analysis

BATCH SPECIFICATIONS

Cell Designation:	CHO-CaV1.2	Source:	ID0829
Cat-N°:	RE306	Lot-N°:	92-211012NR01
Packaging Unit:	5 million cells / vial	Patch Buffer:	C, D, E
Passage:	11	Storage:	below -150°C (e.g. liN ₂)
Approval Date:	09 Nov 2021	Approved by:	
Expiry Date:	30 Oct 2023		

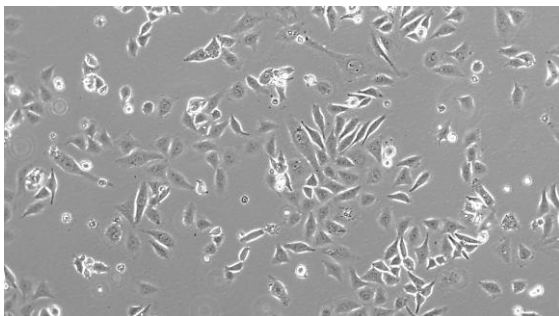


Susan Ciura (Head of Quality Control)

QUALITY CONTROL

	Batch Results	Specification Limits
Cell Count	5.50E+06	≥ 90% of nominal cell count
Homogeneity (cell count)	97%	≤ 90%
Viability (after thawing)	95%	≥ 90%
Aggregation	1.6	≤ 2.0
Debris Ratio	0.3	≤ 1.0
Proliferative Capacity	100%	≥ 70%
Sterility (bacteria, yeast, fungi)	passed	sterile after 7 days
Sterility (mycoplasma)	passed	negative by PCR
Morphology	passed	unaltered to reference

MORPHOLOGY:



Morphology of CHO-CaV1.2 assay ready cells



METHODS

Cell Viability Parameters: Viability parameters (viable cell count after thawing, grade of aggregation, percentage of debris) were determined from a pooled sample (SOP-2015-02). Briefly, assay ready cells were thawed in a water bath. 100 µl of each sample were pooled, diluted 1:1000 in CASY Ton buffer and measured (3 replica) in a CASY TT automatic cell counter. Vial to vial variation was determined in a plate-based viability assay.

Proliferative Capacity: Proliferative Capacity compares mean growth rate (T0 - T72 hours) of all sample vials with mean growth rate of exponentially growing culture. Freshly thawed cells from the assay ready cell samples were seed in a 96-well plate (3 replica each) according their specific 3 day seeding density. After 72 hours of cultivation, the proliferation of the cells was determined by addition of a metabolic cell dye (Resazurin) (SOP-2017-03).

Sterility Testing: Assay ready cells were seed in two specific bacteria growth brothes (Tryptic Soy Broth for aerob and Thioglycollate broth for anaerob conditions) and cultivated over a course of 14 days. After day 1, 4, 7 and 14 the cultures were analyzed microscopically for cell growth, cell morphology, and incidences of contamination (bacteria, yeast, or fungi). For mycoplasma testing from a three days old, sub-confluent culture 500 µl of the supernatant was taken and analyzed by PCR using a Mycoplasma detection kit (Minerva). Assay was performed according to the manufacturer protocol (SOP-2015-06).

LIMITED USE

The product is sold under the terms of a Limited Use Label License attached to the product. By breaking the seal of the product package, the user explicitly agrees to the license terms. Assay Ready Cells are for immediate assay use only. The user shall not propagate, passage, or refreeze the cells.