# Patch Ready CHO-hERG-DUO

licensed by B'SYS (Switzerland)

# Certificate of Analysis

Lot-N°: **92-180907CM01**

Date: **17.09.2018**

**BATCH SPECIFICATIONS**

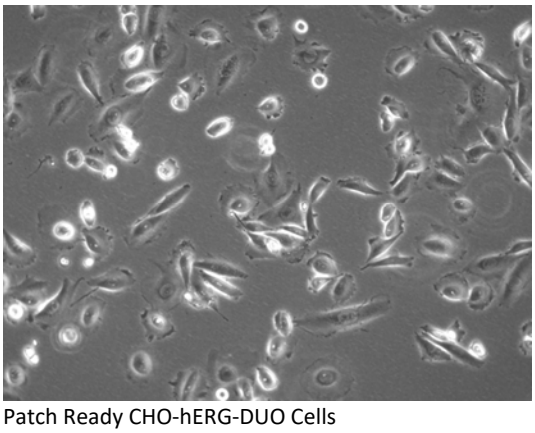
| | | | |
|---|---|---|---|
| Lot-N°: | 92-180907CM01 | Cell Designation: | CHO-hERG-DUO |
| Batch Size: | 105 Vials | Cell ID: | ID0275 |
| Cell Count (nominal): | 5 million cells / vial | Cell Origin: | B'SYS |
| Expansion: | HAM´s F12, 10% FBS, 2 mM L-Glutamine | | |
| Freezing: | HAM´s F12, 10% FBS, 2 mM L-Glutamine, 5 % DMSO | | |
| Storage: | Below -130°C (e.g. liquid nitrogen) | | |
| Approval Date: | 17.09.2018 | Approved by: | Susan Ciura (Head of Quality Control) |

**QUALITY CONTROL**

Samples Tested: 4 Vials of 105

| | Results | Specification Limits |
|---|---|---|
| Cell Count | 5,58E+06 | 90 % < > 120 % |
| Homogeneity (deviation in cell count) | 0 % | < 10 % |
| Viability (after thawing) | 97,4 % | > 90 % |
| Aggregation | 1,4 | 2,0 |
| Debris / Cell | 0,2 | < 0,5 |
| Proliferative Capacity | 96 % | > 85 % |
| Sterility (bacteria, yeast, fungi) | no contamination detected | negative after 4 days |
| Sterility (mycoplasma) | no mycoplasma detected | negative by PCR |
| Morphology | normal, no visible changes | unchanged to seed culture |
| Functional Performance | | |

**MORPHOLOGY:**



Patch Ready CHO-hERG-DUO Cells

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**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. 50 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. Equal aliquots of each cell samples were dispensed into a 96 well-plate. A cellular dye, was added to the well to obtain fluorescent signal which is proportional to the viable cell count.

Proliferative Capacity: 1,0E+04 cells from the cell samples and from a reference of a continuously passaged culture were seed in a 96-well plate (8 replica each). After 48 hours of cultivation the proliferation of the cells was determined by addition of a metabolic cell dye (Resazurin). The proliferative capacity of the cells is calculated in percent of the exponentially growing reference. (SOP-2017-03).

Sterility Testing: Cells were seeded @ 1,0E+04 cells/$cm^2$ into a T25 cell culture flask in antibiotic free cell culture medium and cultivated over a course of four days. Every day, the cultures was 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).

acCELLerate is maintaining a quality management system certified according to EN ISO 9001-2015. All equipment is subject to a guided system. Regular cleaning and maintenance intervals as well as hygienic monitoring are set and complied for the devices. Suppliers are regularly evaluated, and a risk management is established. Deviations are documented, and a CAPA-system is established. Individual certificates and verification documents can be provided upon request by the quality management department.