Quality Control Summary

EBiSC Production Facilities

All cell lines distributed by EBiSC have been banked and rigorously tested under a bespoke quality manual outlining the tests and standards adopted by EBiSC. All QC tests have under gone qualification and are performed and documented to industry standards agreed by EFPIA, and have been summarised below. Release of cell lines is dependent on full completion of Quality Control testing.

Microbial Contamination and Viability

All cell lines are have tested negative for mycoplasma and viral contamination (HIV1, HIV2, HBV and HCV; N.B. viral screening may have been performed on donors or donor tissue). Testing is also performed by a broth inoculation sterility test and cultures have shown extended recovery in antibiotic free culture with no visual evidence of bacterial or fungal contamination.

Pluripotency

Cell lines have demonstrated differentiation to a culture phenotype indicating cell populations capable of generating cells of each of the three human germ layers. In addition, directed differentiation to specific cell types or other assays demonstrating pluripotent potential may have been performed on selected cell lines; see cell line specific CoA for further details.

Cell Line Identity

Genetic profiles of each cell line have been recorded using STR profiling prior to cell line release. These data will be used to identify and resolve any cases of cell line cross-contamination. Data on chromosomal complement of EBiSC cell lines will be made available to users. Cell lines showing chromosomal abnormalities will be made available subject to bringing relevant EBiSC data to the attention of EBiSC users. Where a test for a genetic lesion has been confirmed in relevant disease related iPSC lines, details will be included in the cell line specific CoA available from EBiSC.

Disclaimer: Early released cell lines may have been banked in a number of special supplier laboratories according to EBiSC protocols and tested according to the principles adopted by the main EBiSC banking facility; this will be indicated on each cell line specific certificate of analyses. However, procedures in each laboratory will inevitably vary to some degree and users are advised to adopt best stem cell culture practice and perform careful testing and characterisation of the lines they use.

All testing methods used by EBiSC have a finite sensitivity and lifespan. Therefore, recovered cultures should be treated as if potentially infectious and screened for pluripotency, cell line identity and chromosomal stability on a regular basis. Advice on appropriate methodologies can be obtained from EBiSC.

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The EBiSC - European Bank for induced pluripotent Stem Cells project has received support from the Innovative Medicines Initiative Joint Undertaking under grant agreement n° 115582, resources of which are composed of a financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution. www.imi.europa.eu