

mTeSR[®]1 and TeSR[™]2: The Advancement of Culture Media for Undifferentiated Pluripotent Stem Cells Towards Greater Regulatory Compliance

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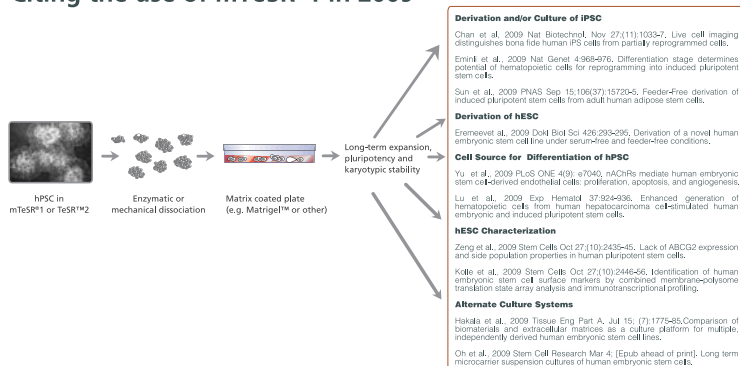
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Introduction

Defined and feeder-independent cell culture systems provide a platform for greater reproducibility and standardization in human pluripotent stem cell (hPSC) research. mTeSR[®]1 has become the most widely cited feeder-independent system for the culture of undifferentiated human ES and iPSC (Table 1). As the field develops potential therapeutic applications for hPSC-derived cells, it is increasingly important that media products are manufactured to meet applicable regulatory compliance standards. Therefore, we have developed two new products for the expansion of undifferentiated hPSCs; mTeSR[®]1 manufactured in GMP facility (mTeSR[®]1-GMP) and animal protein-free TeSR[™]2. Here we show data to support their use for maintenance of high quality undifferentiated hPSC cultures.

FIGURE 1: The TeSR[™] System and Ten Select Publications Citing the use of mTeSR[®]1 in 2009



Results

FIGURE 2: Expansion of Undifferentiated Cells in mTeSR[®]1-GMP is Comparable to Expansion in mTeSR[®]1

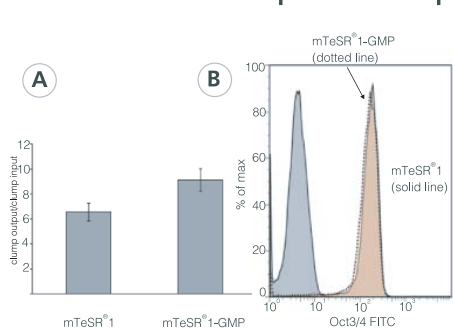


FIGURE 3: Long-Term Culture of Undifferentiated Cells in Animal Protein-Free TeSR[™]2 Provides Robust Expansion and Maintenance of Pluripotency Marker Expression

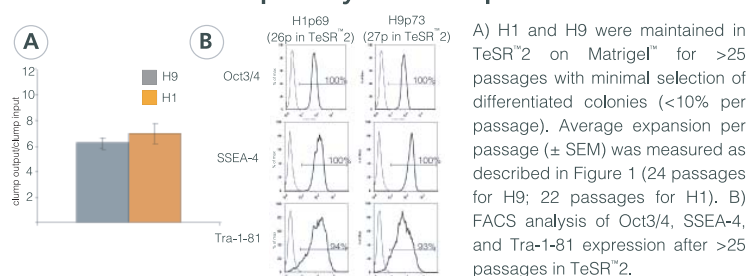
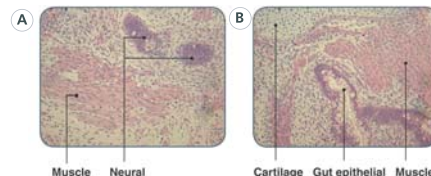
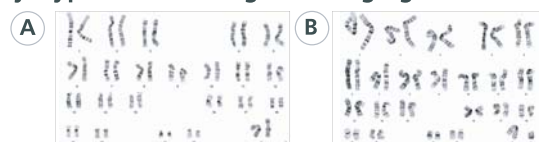


FIGURE 4: hPSC Maintained in TeSR[™]2 are Functionally Pluripotent



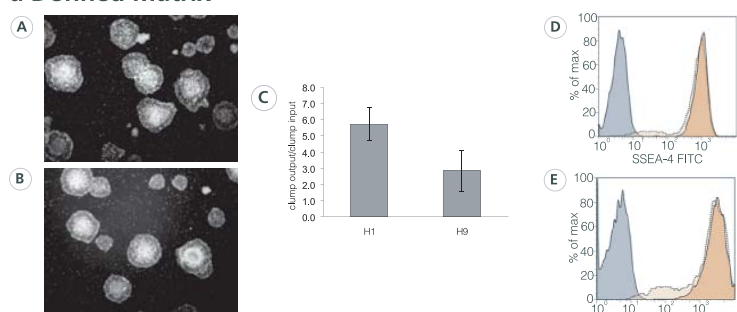
H9 cells isolated after 11 passages in TeSR[™]2 on Matrigel[™] and then injected into mice, generated teratomas over a period of 9 weeks. A,B) Histological analysis of H&E stained sections of the resulting teratomas revealed tissues representative of all three germ layers as indicated. (gut epithelia = endoderm; neural = ectoderm; cartilage, muscle = mesoderm)

FIGURE 5: hPSC Cultured in TeSR[™]2 Maintain a Normal Karyotype with Prolonged Passaging



G band karyotype analysis of A) H9 cells (normal, XX) after 22 passages in TeSR[™]2 on Matrigel[™] and B) H1 cells (normal, XY) after 19 passages in TeSR[™]2 on Matrigel[™].

FIGURE 6: Undifferentiated Growth of hPSC in TeSR[™]2 on a Defined Matrix



Conclusions

- mTeSR[®]1 manufactured in a GMP facility provides equivalent performance to mTeSR[®]1.
- TeSR[™]2 is an animal protein-free formulation that can be used with Matrigel[™] or more defined matrices to maintain pluripotent and karyotypically normal hPSC.
- These two new products represent STEMCELL's ongoing commitment to provide ongoing regulatory compliant reagents to facilitate the translation of basic research to pre-clinical studies.