

We support detection of undifferentiated human pluripotent stem cells intermingled in cell therapy products by a highly efficient culture assay

- Cell therapy products (CTPs) should be evaluated for the risk of teratoma formation due to residual undifferentiated human pluripotent stem cells (hPSCs) in intermediate and final products.
- Axcelead offers a Highly Efficient Culture (HEC) assay, a method for detecting undifferentiated hPSCs.

HEC assay

The in vitro highly efficient culture (HEC) assay using the culture system, which favors the growth of hPSCs, is able to directly detect the residual undifferentiated hPSCs in CTPs and minimize the risk of tumorigenicity of CTPs. Among currently available assays, the HEC assay is reported to be one of the most sensitive for the detection of the residual undifferentiated hPSCs. hPSCs-based colonies are identified by alkaline phosphatase staining¹⁾(Fig.1) and the number of colonies is counted manually under microscopy.

Magnetic-activated cell sorting (MACS)

Pre-treatment with MACS can concentrate cells expressing undifferentiated cell markers and consequently achieve a detection sensitivity up to 0.00002%¹⁾(Fig. 2). Although preliminary studies for assay optimization are required, we will propose ideal assay conditions based on our accumulated knowledge and experience.

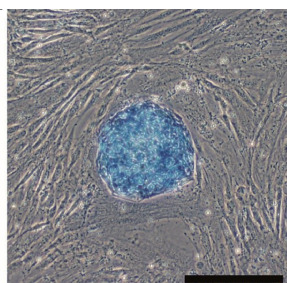


Fig. 1 hPSCs-based colonies stained by alkaline phosphatase.

1) T. Watanabe et al., Cytotherapy 23 ,2021

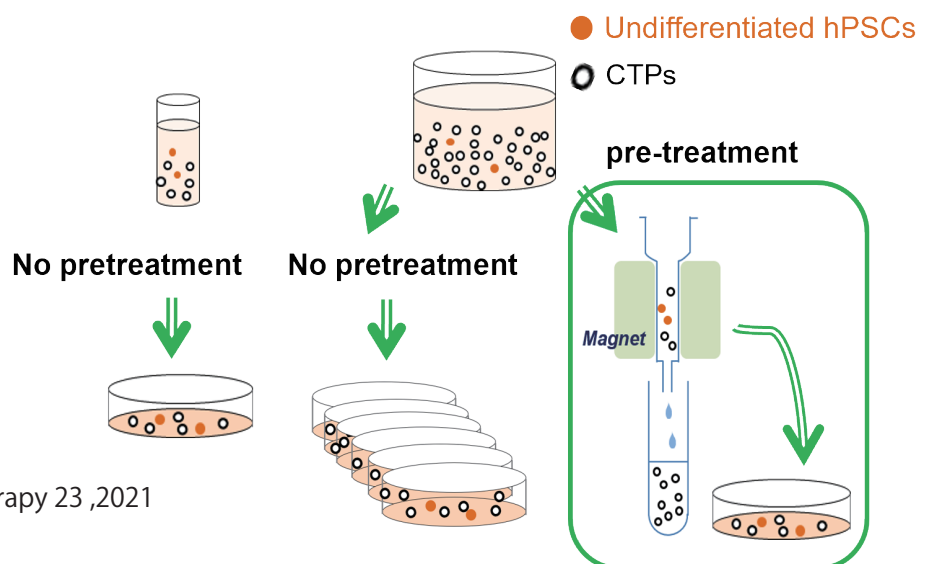


Fig. 2 Pre-treatment with MACS enables evaluation of a larger number of test cells and achieves a higher detection sensitivity of 0.00002%!