

CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 023

Date of Recognition: 06/14/2023

SDO Name/Designation: ASTM F3106

Year of Publication: 2022

Title: Standard Guide for in vitro Osteoblast Differentiation Assays

Scope:

1.1 This document provides guidance on how to conduct in vitro osteoblast differentiation assays with progenitor stem cells including mesenchymal stromal cells.

1.2 This document describes the roles of various osteogenic supplements that are added to the cell culture medium of an osteoblast differentiation assay to encourage and support the differentiation of progenitor cells into matrix-producing osteoblasts.

1.3 This document provides recommendations for the concentrations of osteogenic supplements that may prevent the precipitation of artifactual mineral deposits that are not directly produced by osteoblasts, nor correlated with osteoblastic gene expression of the cells.

1.4 This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.

1.5 This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Extent of Recognition: Complete Recognition

Rational for Recognition: This standard is relevant to regenerative medicine therapies and does not conflict with regulation or FDA guidance.

Standards Development Organization: <https://www.astm.org/>

Please note that this standard may also be recognized under the Center for Devices and Radiological Health's (CDRH) Recognized Consensus Standards Database for Medical Device, found here: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.