

CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 008

Date of Recognition: 06/14/2023

SDO Name/Designation: ISO 20397-1

Year of Publication: 2022

Title: Massively parallel sequencing — Part 1: Nucleic acid and library preparation

Scope:

This document specifies the general requirements for and gives guidance on quality assessments of nucleic acid samples. It specifies general guidelines for library preparations and library quality assessments prior to sequencing and data generation.

Extent of Recognition: Complete Recognition

Rational for Recognition: This standard is relevant to regenerative medicine therapies and is recognized because it is scientifically and technically valid and does not conflict with existing regulations and policies.

Standards Development Organization: <https://www.iso.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>.