CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition List-Number: 007 **Date of Recognition:** 10/27/22

SDO Name/Designation: ISO 20397-2 **Year of Publication:** 2020

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

Scope: This document specifies general requirements and recommendations for quality assessments and control of massively parallel sequencing (MPS) data. It covers post raw data generation procedures, sequencing alignments, and variant calling.

This document also gives general guidelines for validation and documentation of MPS data.

Extent of Recognition: Complete Recognition

Rational for Recognition: This standard is relevant to regenerative medicine therapies and supports existing regulatory policy for products for which utilize massive parallel sequencing.

Standard 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.