

# ISO/TS 20399-2:2018 (E)

## Biotechnology — Ancillary materials present during the production of cellular therapeutic products — Part 2: Best practice guidance for ancillary material suppliers

---

### Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Abbreviated terms
5	General considerations
6	AM characteristics and quality attributes
6.1	AM components, identity and purity
6.1.1	General
6.1.2	Identity and quantity of component(s)
6.1.3	Purity/impurity
6.1.4	Lot-to-lot consistency for AMs containing proprietary components
6.2	AM storage and stability
6.2.1	General
6.2.2	Storage conditions
6.2.3	Stability and expiration dating
7	AM manufacturing and biosafety
7.1	Quality management system
7.2	Manufacturing process
7.3	Container and closure systems
7.4	Animal- and human-derived materials
7.5	Safety to cells and humans
8	AM performance
8.1	General
8.2	Performance assay
8.2.1	General
8.3	Cells used for performance assays
8.4	Performance assay results
9	AM documentation
9.1	General
9.2	Certificate of analysis (CoA)
9.3	Additional certificates
9.3.1	Certificate of origin (CoO)
9.3.2	Certificate of compliance (CoC)
9.3.3	Certificate of irradiation (Col)
9.4	Other items