

DIN EN ISO 4307:2022-02 (E)

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for saliva - Isolated human DNA (ISO 43 07:2021)

Contents		Page
European foreword		3
Foreword		4
Introduction		5
1	Scope	6
2	Normative references	6
3	Terms and definitions	6
4	General considerations	9
5	Activities outside the laboratory	10
5.1	Specimen collection	10
5.1.1	Information about the specimen donor/patient	10
5.1.2	Selection of the saliva collection device by the laboratory	10
5.1.3	Saliva specimen collection from the donor/patient and stabilization procedures	11
5.1.4	Information on the specimen and storage requirements at saliva collection facility/site	12
5.2	Transport requirements	13
5.2.1	General	13
5.2.2	Using saliva collection devices with DNA stabilizers	13
5.2.3	Using saliva collection devices without DNA stabilizers	13
6	Activities inside the laboratory	14
6.1	Specimen reception	14
6.2	Storage requirements	14
6.3	Isolation of the saliva DNA	14
6.3.1	General	14
6.3.2	Using a commercial kit	15
6.3.3	Using the laboratory's own protocol	15
6.4	Quantity and quality assessment of isolated DNA	15
6.5	Storage of isolated saliva DNA	16
6.5.1	General	16
6.5.2	Saliva DNA isolated with commercially available kits	16
6.5.3	Saliva DNA isolated with the laboratory's own protocols	16
Bibliography		17