

# 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)

---

<b>Contents</b>		<b>Page</b>
European foreword .....		3
Foreword .....		4
Introduction .....		5
<b>1</b>	<b>Scope .....</b>	<b>6</b>
<b>2</b>	<b>Normative references .....</b>	<b>6</b>
<b>3</b>	<b>Terms and definitions .....</b>	<b>6</b>
<b>4</b>	<b>General considerations .....</b>	<b>9</b>
<b>5</b>	<b>Activities outside the laboratory .....</b>	<b>10</b>
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
<b>6</b>	<b>Activities inside the laboratory .....</b>	<b>14</b>
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