

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 |