DIN EN ISO 20184-3:2021-11 (E)

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 3: Isolated DNA (ISO 20184-3:2021)

Contents

Page

European foreword ... **3**

Foreword ... **4**

Introduction ... **5**

1 Scope ... **6**

2 Normative references ... **6**

3 Terms and definitions ... **6**

4 General considerations ... **10**

5 Outside the laboratory ... **11**
5.1 Specimen collection ... 11
5.1.1 General ... 11
5.1.2 Information about the patient/specimen donor ... 11
5.1.3 Information about the specimen ... 11
5.1.4 Specimen processing ... 11
5.2 Fresh tissue transport requirements ... 12
5.2.1 General ... 12
5.2.2 Preparations for the transport ... 12
5.2.3 During transport ... 13

6 Inside the laboratory ... **13**
6.1 Information about the reception of the specimen ... 13
6.2 Evaluation of the pathology of the specimen and selection of the sample(s) ... 13
6.3 Freezing of the specimen or sample(s) ... 14
6.4 Storage requirements ... 16
6.5 DNA isolation ... 16
6.5.1 General ... 16
6.5.2 Using commercial kits ... 17
6.5.3 Using laboratory developed protocols ... 17
6.6 Quantity and quality assessment of isolated DNA ... 17
6.7 Storage of isolated DNA ... 18

Bibliography ... **19**