

DIN EN ISO 20046:2021-04 (E)

Radiological protection - Performance criteria for laboratories using Fluorescence In Situ Hybridization (FISH) translocation assay for assessment of exposure to ionizing radiation (ISO 20046:2019)

| Contents | | Page |
|--|--|-------------|
| European foreword | | 4 |
| Foreword | | 5 |
| Introduction | | 6 |
| 1 Scope | | 7 |
| 2 Normative references | | 7 |
| 3 Terms and definitions | | 7 |
| 4 Translocation assay by FISH | | 11 |
| 4.1 General..... | | 11 |
| 4.2 Culturing and fixation..... | | 11 |
| 4.3 Types of staining..... | | 11 |
| 4.4 Scoring..... | | 12 |
| 4.5 General requirement of the laboratory..... | | 12 |
| 5 Responsibility of the customer | | 12 |
| 6 Responsibility of the laboratory | | 13 |
| 6.1 Setup and sustainment of the QA program..... | | 13 |
| 6.2 Responsibility during service..... | | 13 |
| 7 Confidentiality of personal information | | 14 |
| 7.1 Overview..... | | 14 |
| 7.2 Applications of the principle of confidentiality..... | | 14 |
| 7.2.1 Delegation of responsibilities within the laboratory..... | | 14 |
| 7.2.2 Requests for analysis..... | | 15 |
| 7.2.3 Transmission of confidential information..... | | 15 |
| 7.2.4 Anonymity of samples..... | | 15 |
| 7.2.5 Reporting of results..... | | 15 |
| 7.2.6 Storage of data and results..... | | 15 |
| 8 Laboratory safety requirements | | 15 |
| 8.1 Overview..... | | 15 |
| 8.2 Microbiological safety requirements..... | | 16 |
| 8.3 Chemical safety requirements..... | | 16 |
| 8.4 Optical safety requirements..... | | 17 |
| 8.5 Safety plan..... | | 17 |
| 9 Sample processing | | 17 |
| 9.1 Culturing and staining..... | | 17 |
| 9.2 Scoring..... | | 18 |
| 9.2.1 Criteria for scoring..... | | 18 |
| 9.2.2 Conversion of translocation frequencies to genome equivalence..... | | 18 |
| 10 Background levels of translocations | | 19 |
| 11 Calibration curves | | 20 |
| 11.1 Calibration source(s)..... | | 20 |
| 11.2 Establishment of calibration curve(s)..... | | 20 |

| | | |
|-----------|---|-----------|
| 12 | Criteria for converting a measured aberration frequency into an estimate of absorbed dose | 22 |
| 12.1 | Determination of estimated whole-body absorbed dose and confidence limits..... | 22 |
| 12.1.1 | General..... | 22 |
| 12.1.2 | Comparison with the background level: Characterisation of the minimum detectable dose..... | 22 |
| 12.1.3 | Confidence limits on the number of translocations..... | 25 |
| 12.1.4 | Adjustment for background yield..... | 26 |
| 12.1.5 | Calculation of absorbed dose..... | 27 |
| 12.1.6 | Calculation of uncertainty on absorbed dose..... | 28 |
| 12.1.7 | Acute and non-acute exposure cases..... | 28 |
| 12.1.8 | Other exposure scenarios..... | 29 |
| 13 | Reporting of results | 29 |
| 13.1 | General..... | 29 |
| 13.2 | Content of the report (see Annex C for an example of a standard form)..... | 29 |
| 13.3 | Interpretation of the results..... | 30 |
| 14 | Quality assurance and quality control | 30 |
| 14.1 | Overview..... | 30 |
| 14.2 | Specific requirements..... | 30 |
| 14.2.1 | General..... | 30 |
| 14.2.2 | Performance checks by inter-laboratory comparisons..... | 30 |
| 14.2.3 | Performance check of scorer qualification..... | 31 |
| 14.2.4 | Performance checks of sample transport integrity..... | 31 |
| 14.2.5 | Performance checks of sample integrity by service laboratory..... | 32 |
| 14.2.6 | Performance checks of instrumentation..... | 32 |
| 14.2.7 | Performance checks of sample protocol..... | 32 |
| 14.2.8 | Performance checks of sample scoring..... | 32 |
| 14.2.9 | Performance checks of result report generation..... | 32 |
| | Annex A (informative) Sample instructions for customer | 33 |
| | Annex B (informative) Sample questionnaire | 35 |
| | Annex C (informative) Sample of report | 37 |
| | Annex D (informative) Sample data sheets for recording painted aberrations | 38 |
| | Annex E (informative) Fitting of the dose response-curve by the method of maximum likelihood and calculating the uncertainty of the absorbed dose estimate | 40 |
| | Annex F (informative) Process for dose estimation | 41 |
| | Bibliography | 46 |