

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