

# ISO 20046:2019 (E)

## Radiological protection — Performance criteria for laboratories using Fluorescence In Situ Hybridization (FISH) translocation assay for assessment of exposure to ionizing radiation

---

### Contents

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

- 11.2 Establishment of calibration curve(s)
- 12 Criteria for converting a measured aberration frequency into an estimate of absorbed dose
  - 12.1 Determination of estimated whole-body absorbed dose and confidence limits
    - 12.1.1 General
    - 12.1.2 Comparison with the background level: Characterisation of the minimum detectable dose
    - 12.1.3 Confidence limits on the number of translocations
    - 12.1.4 Adjustment for background yield
    - 12.1.5 Calculation of absorbed dose
    - 12.1.6 Calculation of uncertainty on absorbed dose
    - 12.1.7 Acute and non-acute exposure cases
    - 12.1.8 Other exposure scenarios
- 13 Reporting of results
  - 13.1 General
  - 13.2 Content of the report (see Annex C for an example of a standard form)
  - 13.3 Interpretation of the results
- 14 Quality assurance and quality control
  - 14.1 Overview
  - 14.2 Specific requirements
    - 14.2.1 General
    - 14.2.2 Performance checks by inter-laboratory comparisons
    - 14.2.3 Performance check of scorer qualification
    - 14.2.4 Performance checks of sample transport integrity
    - 14.2.5 Performance checks of sample integrity by service laboratory
    - 14.2.6 Performance checks of instrumentation
    - 14.2.7 Performance checks of sample protocol
    - 14.2.8 Performance checks of sample scoring
    - 14.2.9 Performance checks of result report generation
- Annex A (informative) Sample instructions for customer
- Annex B (informative) Sample questionnaire
- Annex C (informative) Sample of report
- Annex D (informative) Sample data sheets for recording painted aberrations
- Annex E (informative) Fitting of the dose response-curve by the method of maximum likelihood and calculating the uncertainty of the absorbed dose estimate
- Annex F (informative) Process for dose estimation
  - F.1 Decision threshold and detection limit
  - F.2 Conversion to genome equivalent
  - F.3 Confidence limits on the yield of translocations
  - F.4 Adjustment for background yield
  - F.5 Calculation of absorbed dose and uncertainty
  - F.6 R script for calculating the decision threshold