ISO 17099:2024-06 (E)

Radiological protection - Performance criteria for laboratories using the cytokinesis-block micronucleus (CBMN) assay in peripheral blood lymphocytes for biological dosimetry

Contents

Page

Foreword ..... **v**

Introduction ..... **vii**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 CMBN assay methodology used in this document **3**
4.1 General 3
4.2 Requests for analysis and blood sampling 3

5 Responsibility of the requestor **3**

6 Responsibility of the service laboratory **4**
6.1 Setup and sustainment of the quality assurance program 4
6.2 Responsibility during service 4

7 Confidentiality of personal information **5**
7.1 Overview 5
7.2 Applications of the principle of confidentiality 5
7.2.1 Delegation of responsibilities within the laboratory 5
7.2.2 Requests for analysis 6
7.2.3 Transmission of confidential information 6
7.2.4 Anonymity of samples 6
7.2.5 Reporting of results 6
7.2.6 Storage 6
7.2.7 Data security plan 6

8 Laboratory safety requirements **6**
8.1 Overview 6
8.2 Microbiological safety requirements 7
8.3 Chemical safety requirements 7
8.4 Optical safety requirements 8
8.5 Safety plan 8

9 Sample processing **8**
9.1 Culturing 8
9.2 Staining 10
9.3 Microscopy 10
9.4 Scoring of slides 10
9.4.1 General 10
9.4.2 Criteria for scoring 10
9.4.3 Scoring data sheets 11
9.5 Automated analysis 11

10 Calibration source(s), calibration curve, and minimum detectable dose **11**
10.1 Calibration source(s) 11
10.2 Calibration curve 11
10.3 Background MN frequency 12
10.4 Comparison with the background level: Characterisation of the minimum detectable dose 13

11 Accidental exposure involving few individuals **15**

11.1 Procedure for scoring MN in BNCs 15
11.1.1 Coding of samples and slides 15
11.1.2 Scoring techniques 16
11.1.3 Laboratory scoring expertise 16
11.2 Criteria for converting a MN yield into an estimate of absorbed dose 16
11.2.1 Overview 16
11.2.2 Comparison with controls 16
11.2.3 Confidence limits on the number of MN 16
11.2.4 Calculation of absorbed dose for whole-body exposures 16
11.2.5 Calculation of uncertainty on absorbed dose 17
11.2.6 Acute and non-acute exposure cases 17
11.2.7 Testing the distribution of MN per BNC 18
11.2.8 Other exposure scenarios 18
11.3 Reporting of results 18
11.3.1 General 18
11.3.2 Content of the report (see Annex D for a standard form) 18
11.3.3 Interpretation of the results 19

12 Population triage 19
12.1 General 19
12.2 Use of a CBMN assay network for large scale exposures 19
12.3 Procedure for scoring MN in BNCs 20
12.4 Criteria for converting a MN yield into an estimate of absorbed dose 20
12.5 Reporting of results 20

13 Quality assurance and quality control 20
13.1 Overview 20
13.2 Specific requirement 20
13.2.1 General 20
13.2.2 Performance checks by laboratory inter-comparisons 20
13.2.3 Periodical performance check of scorer qualification 21
13.2.4 Performance checks of sample transport integrity 21
13.2.5 Performance checks of sample integrity by service laboratory 21
13.2.6 Performance checks for instrumentation 21
13.2.7 Performance checks of sample protocol 22
13.2.8 Performance checks of sample scoring 22
13.2.9 Performance checks of dose and confidence limits estimation 22
13.2.10 Performance checks for result report generation 22

Annex A (informative) **Sample data sheet for recording MN in BNCs 23**

Annex B (informative) **Instructions for requestor (sample) 24**

Annex C (informative) **Sample questionnaire 25**

Annex D (informative) **Sample of report for single assessment 27**

Annex E (informative) **Sample group report 29**

Annex F (informative) **Decision threshold and detection limit 31**

Bibliography 34