

# DIN EN ISO 19238:2023-12 (E)

## Radiological protection - Performance criteria for service laboratories performing biological dosimetry by cytogenetics - Dicentric assay (ISO 19238:2023)

---

<b>Contents</b>		<b>Page</b>
<b>European foreword</b> .....		<b>4</b>
<b>Foreword</b> .....		<b>5</b>
<b>Introduction</b> .....		<b>7</b>
<b>1 Scope</b> .....		<b>8</b>
<b>2 Normative references</b> .....		<b>8</b>
<b>3 Terms and definitions</b> .....		<b>8</b>
<b>4 Abbreviated terms</b> .....		<b>10</b>
<b>5 Dicentric assay</b> .....		<b>11</b>
<b>6 Responsibility of the requestor</b> .....		<b>12</b>
<b>7 Responsibility of the service laboratory</b> .....		<b>12</b>
7.1 Setup and sustainment of the QA program.....		12
7.2 Responsibility during service.....		12
<b>8 Confidentiality of personal information</b> .....		<b>13</b>
8.1 Overview.....		13
8.2 Applications of the principle of confidentiality.....		14
8.2.1 Delegation of responsibilities within the laboratory.....		14
8.2.2 Requests for analysis.....		14
8.2.3 Transmission of confidential information.....		14
8.2.4 Anonymity of samples.....		14
8.2.5 Reporting of results.....		14
8.2.6 Storage.....		14
8.2.7 Data security plan.....		14
<b>9 Laboratory safety requirements</b> .....		<b>15</b>
9.1 Overview.....		15
9.2 Microbiological safety requirements.....		15
9.3 Chemical safety.....		15
9.4 Optical safety requirements.....		16
<b>10 Sample processing</b> .....		<b>16</b>
10.1 Culturing.....		16
10.2 Scoring.....		17
10.2.1 Coding of samples and slides.....		17
10.2.2 Scoring techniques.....		17
10.2.3 Procedure for scoring first-division metaphases.....		17
10.2.4 Laboratory scoring expertise.....		18
<b>11 Calibration curves</b> .....		<b>18</b>
11.1 Calibration source(s).....		18
11.2 Establishment of calibration curve(s).....		18
<b>12 Criteria for converting a measured aberration frequency into an estimate of absorbed dose</b> .....		<b>20</b>
12.1 General.....		20
12.2 Testing the distribution of aberrations per cell.....		20

12.3	Comparison with the background level: Characterisation of the minimum detectable dose.....	21
12.4	Confidence limits on the number of dicentrics.....	23
12.5	Calculation of absorbed dose for whole-body exposures.....	24
12.6	Calculation of uncertainty on absorbed dose.....	24
12.7	Acute and non-acute exposure cases.....	25
12.8	Partial body and prior exposure cases.....	25
12.9	Other exposure scenarios.....	26
<b>13</b>	<b>Reporting of results.....</b>	<b>27</b>
13.1	General.....	27
13.2	Content of the report (see <a href="#">Annex C</a> for a standard form).....	27
13.3	Interpretation of the results.....	27
<b>14</b>	<b>Quality assurance and quality control.....</b>	<b>28</b>
14.1	Overview.....	28
14.2	Specific requirements.....	28
14.2.1	General.....	28
14.2.2	Performance checks by laboratory inter-comparisons.....	28
14.2.3	Periodical performance check of scorer qualification.....	29
14.2.4	Performance checks of sample transport integrity.....	29
14.2.5	Performance checks of sample integrity by service laboratory.....	29
14.2.6	Performance checks for instrumentation.....	30
14.2.7	Performance checks of sample protocol.....	30
14.2.8	Performance checks of sample scoring.....	30
14.2.9	Performance checks of dose and confidence limits estimation.....	30
14.2.10	Performance checks for result report generation.....	30
	<b>Annex A (informative) Sample instructions for requestor.....</b>	<b>31</b>
	<b>Annex B (informative) Sample questionnaire.....</b>	<b>33</b>
	<b>Annex C (informative) Sample of report.....</b>	<b>35</b>
	<b>Annex D (informative) Fitting of the low-LET dose-response curve by the method of maximum likelihood and calculating the error of dose estimate.....</b>	<b>37</b>
	<b>Annex E (informative) Odds ratio method for cases of suspected exposure to a low dose.....</b>	<b>40</b>
	<b>Annex F (informative) Decision threshold and detection limit.....</b>	<b>42</b>
	<b>Annex G (informative) Sample data sheet for recording aberrations.....</b>	<b>45</b>
	<b>Bibliography.....</b>	<b>46</b>