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AMENDMENT 1
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Medical gloves made from natural rubber latex — Determination of water-extractable protein using the modified Lowry method

AMENDMENT 1

Gants médicaux à base de latex de caoutchouc naturel — Détermination des protéines extractibles par l'eau par la méthode modifiée de Lowry

AMENDEMENT 1

Reference number
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Foreword

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Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 12243:2003 was prepared by Technical Committee ISO/TC 45, *Rubber and rubber products*, Subcommittee SC 3, *Raw materials (including latex) for use in the rubber industry*.

Medical gloves made from natural rubber latex — Determination of water-extractable protein using the modified Lowry method

AMENDMENT 1

Page 1, Normative references

Delete Clause 2 and move the normative references to the Bibliography.

Renumber the subsequent clauses.

Renumber all cross-references to subclauses of Clauses 5, 6, 7 and 8, beginning with 7.2.1, i.e. replace “Use protein-free gloves (5.1) to handle ...” with “Use protein-free gloves (6.1) to handle ...”.

Page 3, Clause 5

Following 5.11, add the following new paragraph: “**5.12 Shaker**”.

Page 3, 6.3.2

Replace the note with the following new note.

NOTE 2 N Folin reagent is available commercially. The concentration of some commercial Folin reagents might not be 2 N.

Page 4, 6.4

Replace the first paragraph with the following: “Use ovalbumin prepared by ammonium sulfate fractionation and repeated crystallization at pH 4,5.”.

Page 4, 7.2.1

Replace the first paragraph with the following (adding a sentence to clarify why there are two extraction procedures).

The entire surface of the glove shall be exposed to the extractant at 25 °C ± 5 °C for a period of 120 min ± 5 min.

Two extraction procedures are permitted, the so-called “cut-glove” procedure and also the “glove-in-glove” procedure. In case of dispute, the “cut-glove” procedure is preferred as it is more practicable and less time consuming.

In the case of the “glove-in-glove” procedure, if pin holes exist, discard the sample and repeat the extraction with a fresh pair of gloves.

The procedure used shall be noted in the test report and all samples in a given series shall be extracted by the same procedure. The extraction shall be carried out in triplicate and single determinations run on each extract.

Page 5, 7.2.2.3

Replace the second paragraph with the following.

> Cut a rectangular piece from the back of the glove of about 0,5 dm by 0,5 dm and measure its dimensions to the nearest 0,01 dm. Calculate the area A_1.

Page 5, 7.2.2.6

Replace the paragraph with the following.

> Extract the test sample at 25 °C ± 5 °C for 120 min ± 5 min, shaking for 15 s initially and thereafter at intervals not greater than 30 min. If practicable, continuous slow shaking at approximately 200 r/min is desirable.

Page 5, 7.2.3.3

Replace the first sentence with the following: “Fix the gloves to a shaker and shake at approximately 200 r/min for 120 min ± 5 min at 25 °C ± 5 °C.”.

Page 5, 7.2.3.5

Replace the paragraph with the following (in order to harmonize the text with 7.2.2.7).

> Decant the extract from the outer glove into a centrifuge tube (5.3). If it is coloured blue, it is indicative of a pin-hole or cross-contamination. In such cases, discard the solution and repeat the extraction with a fresh pair of gloves. Clarify the extract by centrifugation at not less than 20 000 m/s^2 (2 000 × *g*) for 15 min.
>
> The extract is preferably used immediately but may be stored for up to 48 h at a temperature of not more than 7 °C or frozen for up to 15 days at below −10 °C.

Page 5, 7.2.3.6

Add the following new paragraph

> **7.2.3.7** If the result is to be reported in micrograms per unit area of the glove (e.g. µg/dm^2), follow 7.2.2.3.

Pages 8 to 9, Clause 9

Transfer the contents of Clause 9 to the following new informative Annex E.

Replace the text of the clause with: “See Annex E.”.

Annex E
(informative)

Precision

E.1 Background

An interlaboratory test programme (ITP) to evaluate the precision of the method was conducted in 2002 using the precision procedures and guidelines described in ISO/TR 9272:1986.

Both extraction procedures were evaluated: the cut-glove procedure and the glove-in-glove procedure. The ITP was conducted with four materials with increasing measurement levels. Seven laboratories participated in the ITP, and a type 1 precision was evaluated. A test result is the mean of three replicates on each of two separate test days, and precision is given in terms of test results, i.e. a mean value for each of two test days.

The precision results as determined by this ITP shall not be applied to acceptance or rejection testing for any group of materials or products without documentation that the results of this precision evaluation actually apply to the products or materials tested.

E.2 Precision results

E.2.1 General

For each of the four materials, the precision results for both procedures are given in Table E.1. These results were obtained using the outlier replacement procedures and outlier deletion procedures as described in ISO/TR 9272:1986. General statements for the use of the precision results are cited below. These are given in terms of both the absolute precision, r and R, and also for the relative precision, (r) and (R). See additional comments below.

E.2.2 Repeatability

The repeatability, or local-domain precision, for each of these procedures has been established by the values found in Table E.1, for each measurement level (for the materials) as listed in the table. Two single mean test results (obtained by the proper use of this International Standard) that differ by more than the tabulated values for r, in measurement units, and (r), in percent, shall be considered suspect, i.e. to have come from different populations. Such a decision suggests that some appropriate investigative action be taken.

E.2.3 Reproducibility

The reproducibility, or global-domain precision, for each of these procedures has been established by the values found in Table E.1, for each measurement level (for the materials) as listed in the table. Two single mean test results obtained in different laboratories (by the proper use of this International Standard) that differ by more than the tabulated values for R, in measurement units, and (R), in percent, shall be considered suspect, i.e. to have come from different populations. Such a decision suggests that some appropriate investigative action be taken.

Table E.1 — Precision data

Cut-glove procedure (procedure A)								
Material	Mean value µg/g	Within laboratory			Between laboratories			Number of laboratories
		s_r	r	(r)	s_R	R	(R)	
1	14,3	3,48	9,7	68,3	7,57	21,2	148,5	5
2	68,3	6,46	18,1	26,5	12,6	35,2	51,5	5
3	162,2	6,79	19,0	11,7	25,1	70,3	43,3	5
4	200,6	13,6	37,9	18,9	28,2	78,9	39,3	5
Glove-in-glove procedure (procedure B)								
Material	Mean value µg/g	Within laboratory			Between laboratories			Number of laboratories
		s_r	r	(r)	s_R	R	(R)	
1	13,8	1,66	4,64	33,6	4,70	13,2	95,2	6
2	53,1	4,97	13,93	26,3	16,3	45,6	86,0	6
3	140,0	5,25	14,70	10,5	21,7	60,9	43,5	6
4	164,2	11,21	31,40	19,1	32,6	91,4	55,6	6

The number of laboratories is the number after deletion of excessive-outlier laboratories.

s_r is the within-laboratory standard deviation (in measurement units);

r is the repeatability, i.e. within-laboratory precision (in measurement units);

(r) is the repeatability (in percent of mean level);

s_R is the between-laboratory standard deviation (for the total between-laboratory variation in measurement units);

R is the reproducibility, i.e. between-laboratory precision (in measurement units);

(R) is the reproducibility (in percent of mean level).

E.3 Additional comments

For the cut-glove procedure, the analysis showed that two laboratories had excessive outliers. Although an outlier replacement operation was conducted using ISO/TR 9272:1986 procedures, both repeatability and reproducibility were still quite poor. The results shown in Table E.1 for the cut-glove procedure are for the analysis with both outlying laboratories deleted from the database, i.e. for five participating laboratories. For the glove-in-glove procedure, one of the same laboratories also had excessive outliers, which again resulted in poor precision. The results given in Table E.1 for the glove-in-glove procedure are for the analysis with this one laboratory deleted from the database, i.e. for six participating laboratories.

E.4 Bias

Bias is the difference between a measured average test result and a reference or true value for the measurement in question. Reference values do not exist for these procedures and, therefore, bias cannot be evaluated.

Page 17, Bibliography

Delete the reference to ISO 9272.

Renumber the subsequent references.

Add the following footnote reference at the end of the reference to ISO/TR 9272:1986: "[2)]".

Insert the following footnote: "[2)] ISO/TR 9272:1986 has been withdrawn and replaced by ISO/TR 9272:2005.".

Replace new bibliographical reference to "ISO 11193-1:2002" with "ISO 11193-1".

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