INTERNATIONAL STANDARD

ISO
11843-5

Capability of detection —

Part 5:
Methodology in the linear and non-linear calibration cases

AMENDMENT 1

Capacité de détection —

Partie 5: Méthodologie des étalonnages linéaire et non linéaire

AMENDEMENT 1

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This document was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 6, *Measurement methods and results*.

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Capability of detection —

Part 5:
Methodology in the linear and non-linear calibration cases

AMENDMENT 1

Page 6, 5.4 Differential method

In the first sentence, replace "Equation (10)" with "Equation (1)".

Page 7, 5.4 Differential method

In NOTE 1, replace "$\sigma_X(X) = 1/3{,}30 = 30\ \%$" with "$\rho_X(X) = 1/3{,}30 = 30\ \%$".

Page 8, 6.2 Law of propagation of uncertainty

Replace the existing Equation (11) with the following:

$$\rho_Y^2(X) = \frac{X^2}{(X+G)^2}\left(\rho_G^2 + \rho_X^2\right) + \rho_B^2 + \rho_S^2 + \left(\frac{\sigma_W}{Y}\times 100\right)^2 + \left(\frac{\sigma_N(Y)}{Y}\times 100\right)^2 \tag{11}$$

where

X is the amount of sample (net state variable);

Y is the absorbance measurement (response variable) and can be replaced by a calibration function;

G is the amount of labeled antigen (0,1 µg/l);

ρ_X is the CV of pipetted volumes of sample (0,9 %);

ρ_G is the CV of pipetted volumes of labeled antigen (0,9 %);

ρ_B is the CV of pipetted volumes of antiserum (1,9 %);

ρ_S is (2/3) × (CV of pipetted volumes of chromogen-substrate solution) where the coefficient 2/3 is used to transform the volume error of the pipette to the essential error of chromogen production which occurs on the surface of the well in a microplate (0,6 %);

σ_W is the SD of the absorbance measurements among the wells of a microplate and is constant as long as the within-plate uncertainty is concerned (0,002 absorbance);

σ_N is the SD of noise intensities appearing in a baseline (this edge effect was observed to be so small that cannot be shown and therefore $\sigma_N = 0$).

Page 12, Annex A

Replace "|dY/dX| derivative of calibration function" with "|dY/dX| absolute value of derivative of calibration function".

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