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SUBJECT **Quantex HbA1c. NGSP factor.**

PRODUCT EVALUATION

Quantex HbA1c evaluation with NGSP method. Implementation of NGSP factor in reagent insert and control values.

Quantex HbA1c% (REF. 3000-2314) kit was evaluated in an Ilab 600 Analyser (Instrumentation Laboratory) and compared with a method standardized against NGSP.

A multiplying factor for this test was obtained after analysing all data reported by the METHOD COMPARISON STUDIES. This factor can be used with our product in order to obtain the same standardization as the reference method used in this evaluation.

We believe that this information can be really interesting for the quantex clients who would be interested in applying the NGSP standardization. That's why we are implementing this factor in our quantex HbA1c% reagent insert.

At the same time, with the aim to facilitate the work, we have modified the control values insert sheet so that it shows the expected ranges both considering and not considering this factor.

Customers who prefer to continue with our standardization will not have to do any adjustments.

As always, we will include a note in our kits (in yellow paper) explaining these implementations.

This information will be available from the quantex CD version 04.
We would like to anticipate these implementations by attaching here the new control values insert sheet of the two precedent lots together with the note.



quantex HbA_{1c}

REF 3000-2314

Note:

The **quantex HbA_{1c}** were correlated to an NGSP-certified High Performance Liquid Chromatography (HPLC) method. The correlation results were:

$$\text{NGSP}_t = 0.776\text{BK} + 0.095 \quad \text{or} \quad \text{BK} = 1.289 \text{NGSP}_t - 0.123$$

$$r = 0.990$$

Nota:

Los reactivos **quantex HbA_{1c}** han sido correlacionados con un método de cromatografía líquida de alta resolución (HPLC) certificado por el NGSP. Los resultados de la correlación fueron los siguientes:

$$\text{NGSP}_t = 0,776\text{BK} + 0,095 \quad \text{o} \quad \text{BK} = 1,289 \text{NGSP}_t - 0,123$$

$$r = 0,990$$

Hinweis:

Die **quantex-HbA_{1c}** Reagenzien wurden mit einem nach NGSP zertifizierten Hochleistungsflüssigkeitchromatographie-Verfahren (HPLC) korreliert. Die Korrelation erbrachte folgende Ergebnisse:

$$\text{NGSP}_t = 0,776\text{BK} + 0,095 \quad \text{oder} \quad \text{BK} = 1,289 \text{NGSP}_t - 0,123$$

$$r = 0,990$$

Remarque:

Les réactifs **quantex HbA_{1c}** ont été corrélés avec une méthode de chromatographie liquide haute performance (HPLC) certifiée par le NGSP. Les résultats de la corrélation ont été les suivants:

$$\text{NGSP}_t = 0,776\text{BK} + 0,095 \quad \text{ou} \quad \text{BK} = 1,289 \text{NGSP}_t - 0,123$$

$$r = 0,990$$

Nota:

I reagenti **quantex HbA_{1c}** sono stati messi in correlazione mediante un metodo di cromatografia liquida ad alta risoluzione (HPLC) validato dal NGSP. I risultati della correlazione sono stati i seguenti:

$$\text{NGSP}_t = 0,776\text{BK} + 0,095 \quad \text{o} \quad \text{BK} = 1,289 \text{NGSP}_t - 0,123$$

$$r = 0,990$$

Nota:

Os reativos **quantex HbA_{1c}** correlacionaram-se de acordo com um método de cromatografia líquida de alta resolução certificado pelo NGSP. Os resultados da correlação foram os seguintes:

$$\text{NGSP}_t = 0,776\text{BK} + 0,095 \quad \text{ou} \quad \text{BK} = 1,289 \text{NGSP}_t - 0,123$$

$$r = 0,990$$

Σημείωση:

Τα προϊόντα αντίδρασης **quantex HbA_{1c}** συγκρίθηκαν σύμφωνα με μία μέθοδο υγρής χρωματογραφίας υψηλής ευκρίνειας (HPLC) πιστοποιημένης από το NGSP. Τα αποτελέσματα της σύγκρισης ήταν τα ακόλουθα:

$$\text{NGSP}_t = 0,776\text{BK} + 0,095 \quad \eta \quad \text{BK} = 1,289 \text{NGSP}_t - 0,123$$

$$r = 0,990$$

quantex HbA_{1c} control I/II

REF 3000-2316

LOT G-4808

HbA _{1c} % iLab Instruments	Mean / Media / Mittelwert / Moyenne / Media / Média	Range / Rango / Bereich / Intervalle / Intervallo / Intervalo
I	5.78	4.68 - 6.88
II	11.20	9.06 - 13.33

HbA _{1c} % NGSP traceability	Mean / Media / Mittelwert / Moyenne / Media / Média	Range / Rango / Bereich / Intervalle / Intervallo / Intervalo
I	4.58	3.73 - 5.43
II	8.78	7.12 - 10.44

quantex HbA_{1c} control I/II

REF 3000-2316

LOT I-0108

HbA _{1c} % iLab Instruments	Mean / Media / Mittelwert / Moyenne / Media / Média	Range / Rango / Bereich / Intervalle / Intervallo / Intervalo
I	5.56	4.50 - 6.62
II	13.45	10.90 - 16.00

HbA _{1c} % NGSP traceability	Mean / Media / Mittelwert / Moyenne / Media / Média	Range / Rango / Bereich / Intervalle / Intervallo / Intervalo
I	4.41	3.59 - 5.23
II	10.53	8.55 - 12.51