



Ph-IS

Ph-IS

Programme for harmonization to International Scale

www.Ph-IS.com

How was Ph-IS generated?

Step 1

We harmonized our methodology at the international level through the primary standards of the WHO

Step 2

Multiple batches of lyophilized secondary calibrators are produced by mixing two cell lines: **cal-IS**

Step 3

Quality control of each lot and assignation of the nominal value (IS%) to the different expression levels of the calibrators

Ph-IS

Our product: cal-IS

cal-IS means: "calibrator for International Scale" and constitutes a panel of 5 sealed glass vials, with the necessary cellular material for calibration.



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How is cal-IS produced?

Step 1

5 different levels of BCR-ABL1 expression are generated by mixing 2 cell lines (K562 / HL-60) in 5 different proportions

Step 2

The mixture of cell lines is fractionated in glass vials and then lyophilized by an automatic system

Step 3

Each lot of calibrators is analyzed with our RT-qPCR methodology harmonized by the primary calibrators

How is Ph-IS implemented?

Step 1

2 panels of cal-IS are shipped to the laboratory that requests them by express courier at room temperature

Step 2

The laboratory performs a certain amount of RT-qPCR reactions according to its routine methodology

Step 3

The laboratory sends us the results through an electronic spreadsheet and obtains its conversion factor and harmonization certificate



Ph-IS

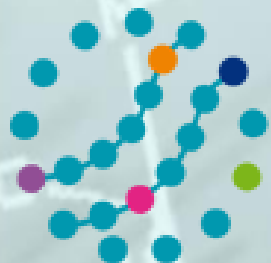
How do we certify Ph-IS?



UK NEQAS

International Quality Expertise

Our center is enrolled in the UK NEQAS quality program: *BCR-ABL1 Major Quantification Program*



NIBSC

Confidence in Biological Medicines

The nominal values of our calibrators are directly related to the WHO international standards

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Advantages of using Ph-IS

- To calculate in a simple, versatile and low-cost way the International Scale Conversion Factor.
- To harmonize any type of platform, methodology and control gene (ABL1, BCR, GUS, GAPDH etc.).
- Each laboratory can do it according to its own "in house" methodology (independent of commercial kits).
- To revalidate at any time.
- To estimate the limit of detection and validate the MR^{4.5} (thanks to the fifth calibrator included in the panel).
- Includes personalized remote assistance and certificate of calibration.

Our partners

CONICET



Consejo Nacional de Investigaciones
Científicas y Técnicas



Latin America BCR-ABL1 Standardization

Certificate



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CERTIFICATE OF STANDARDIZATION

This Acknowledges that:

Argenomics, Buenos Aires - Argentina

Has satisfactorily completed the International Scale
standardization



Dr. Michele Bianchini, PhD

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