



# HA1c Performance

## “Study Collaboration” between Brazil and Portugal.

Programa Nacional de Avaliação Externa da Qualidade

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### INTRODUCTION AND OBJECTIVE

The **National External Quality Assessment Program (PNAEQ)** and the **National Program of Quality Control (PNCQ)**, organizes and coordinates programs for the **External Quality Assessment Laboratory**. A comparative study was performed between Portugal and Brazil in order to detect similarities, and/or differences, of the results provided by the laboratories that participate in the “External Quality Control” HbA1c program in both countries.

The determination of glycated hemoglobin (HbA1c) is used in patients with diabetes mellitus as a key to monitoring the long term blood glucose control. More than 30 different methods used worldwide, based on ion exchange chromatography or affinity electrophoresis and immunological principles limit the comparability of HbA1c values .

There were selected to present the performance of HbA1c parameter obtained by the participants of the PNAEQ over the last 5 years and to evaluate the performance of the some sample by participants from PNAEQ and PNCQ .

### METHODS

#### PNAEQ METODOLOGY

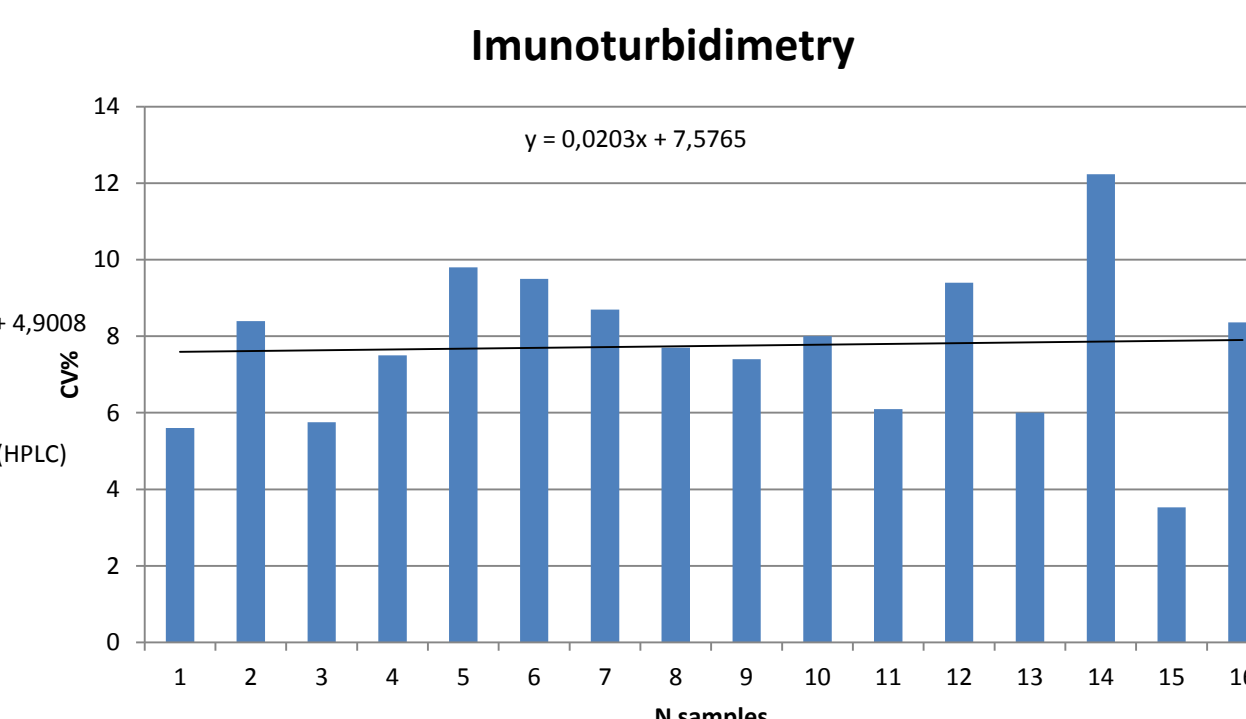
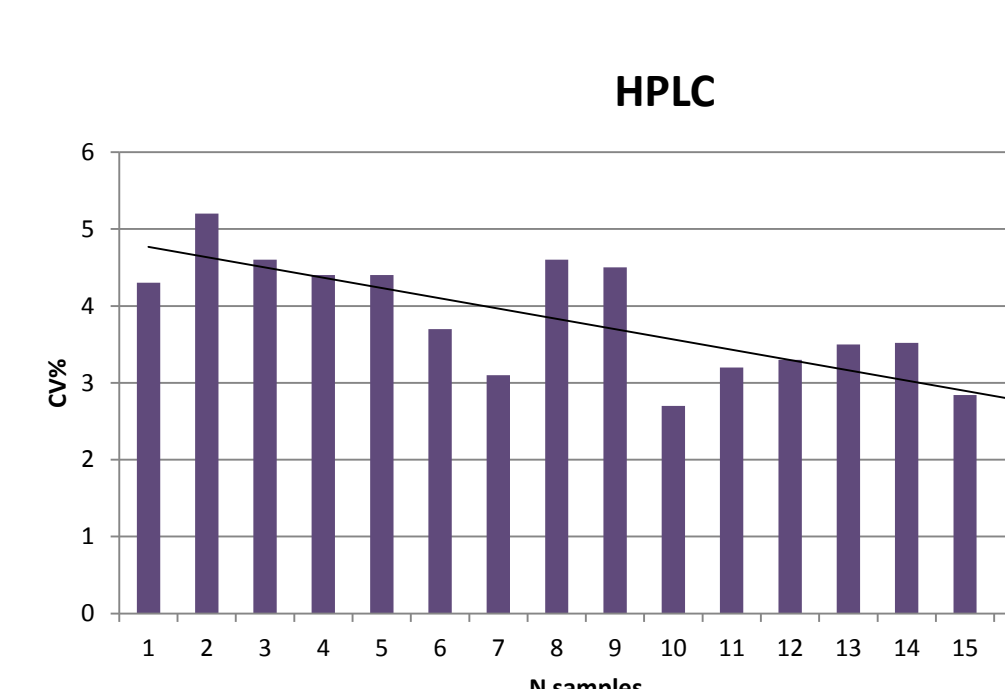
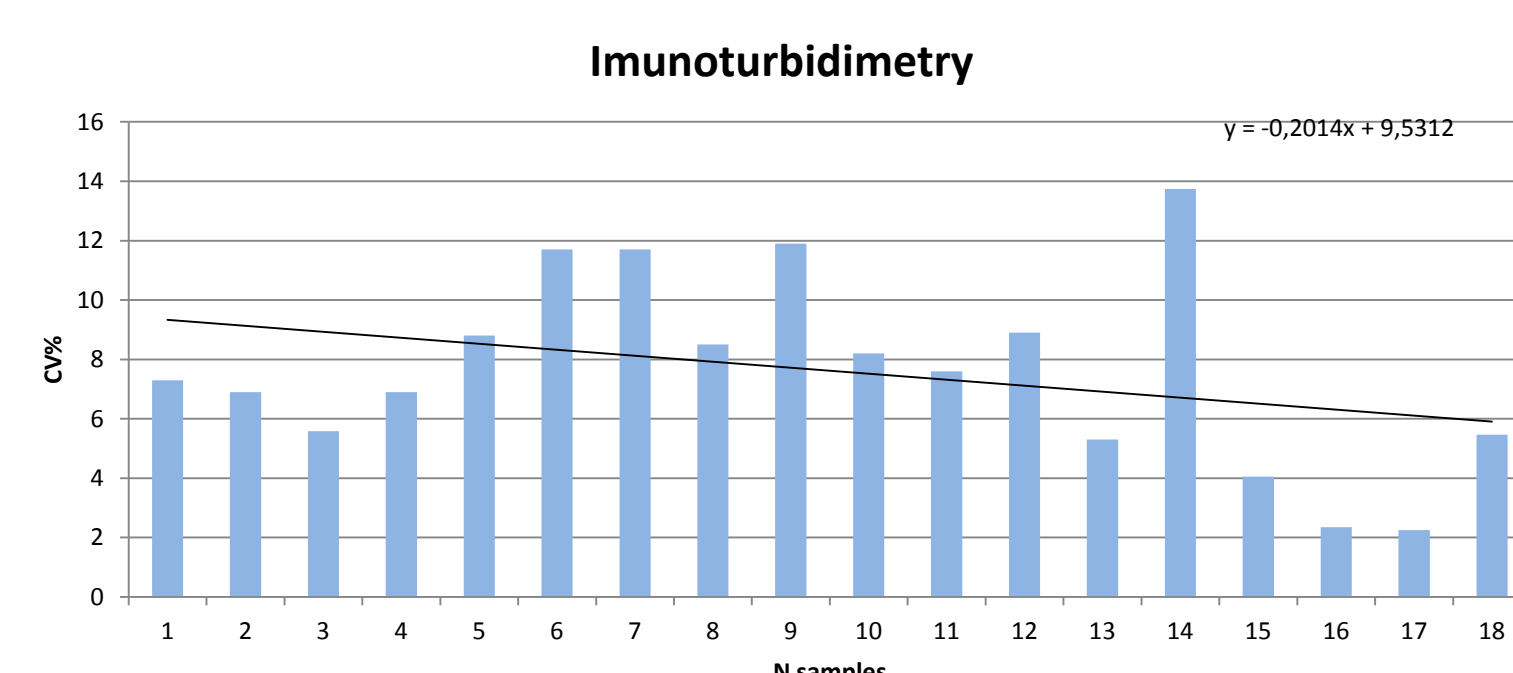
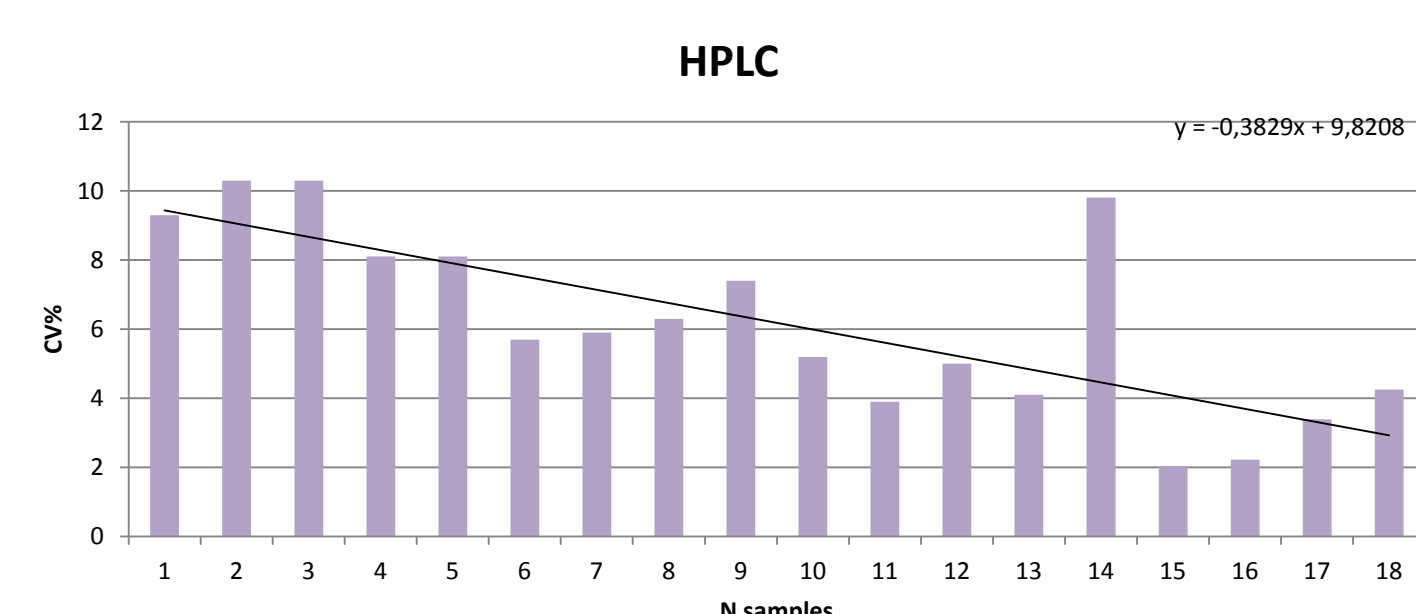
The retrospective study (2008 to 2013) control samples were distributed in each year (control samples with different concentrations were prepared from whole blood). The results of the determinations of HbA1c were statistically evaluated and analyzed according to the distribution and proper hierarchy (calibrator /method/ equipment ), finding the coefficients of variation (CV%).

#### PNCQ METODOLOGY

HbA1c samples from PNCQ are lyophilized . The samples are prepared from whole blood with stabilize additives. PNCQ has more than 170 participants for HbA1c every round, distributed by methodology, the results goal are consensus between participants with the same methodology. The results are statistically evaluated and reported by media, standard deviation e coefficient variation .


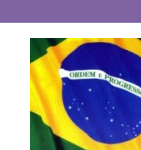

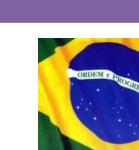
A comparison of the value targets, the CV% and the standard deviation from the external evaluation of the PNCQ/PNAEQ was realized in the sample sent in one survey of 2013.

### RESULTS



**Graphic 1, 2:** CV% variation for normal concentration samples over the years for methods HPLC and Imunoturbidimetry – PNAEQ over te last 5 years

**Graphic 3, 4:** CV% variation for pathologic concentration samples over the years for methods HPLC and Imunoturbidimetry - PNAEQ over te last 5 years

	All devices		HPLC	
				
<b>N</b>	56	83	48	27
<b>Target</b>	6,7	6,3	5,6	5,8
<b>CV%</b>	5,26	9,6	4,25	4,1

**Table 1:** Results for PNCQ and PNAEQ participants, using the same liophilized sample (Provided by PNCQ)-2013

Over the years PNAEQ HbA1c results have improved in accordance to the international guidelines in order to implement IFCC calibration and is in the way to decrease the CV %.

PNCQ analysis show that manual methodology has higher values for CV%, it is explained by the procedures used and people who work directly on it. It is important to have a continuous education to improve quality in laboratories. Automated methodologies show us low values for CV% so as closed equipment that have the lowest values.

### CONCLUSIONS

The lower coefficient of variation was observed in the pathological level, being HPLC the method with lowest values in the study period (PNAEQ). For methods of chromatography and immunoturbidimetry the calculated CV% has almost the same variation regardless of the concentration of the sample (CV% 4 – 10%).

It is found that the HPLC method is the one closer to the value of CV%(CV 3.5%) indicated on Standard 033/2011 of Portugal ‘s Health General Directorate (Prescription and determination of glycated hemoglobin A1c).

Since 2012 PNAEQ added both units (IFCC mmol/mol and NGSP/DCCT %), according to the new recommendations (National and International). No significant difference between the tests performed in the two countries was observed when the same sample was used by the participants .

PNCQ analysis show that manual methodology has higher values for CV%, it is explained by the procedures used and people who work directly on it. It is important to have a continuous education to improve quality in laboratories.

Automated methodologies show us low values for CV% so as closed equipment that have the lowest values.

It shall be assessed and valued the results of the sample with a different concentrations in both countries this year.