

IEQAS HbA1c Scheme

**Selected Extracts from
Report to Participants' Conference
16th October 2003**

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DCCT

Diabetes Control and Complications Trial

- The landmark nine-year US study completed in 1993 (Type 1 diabetes)
- Showed that the risk for development and progression of the chronic complications of diabetes is closely related to the degree of glycaemic control as measured by HbA1c

N Engl J Med 1993; 329: 977-986

UKPDS

UK Prospective Diabetes Study

- Major UK study on control of glycaemia in Type 2 diabetes (1977 – 1991)

Lancet 1998; 352: 837-853; 854-865

The USA's National Glycohemoglobin Standardization Program (NGSP)

Purpose:

To align reported results to clinical outcomes data (DCCT and UKPDS) and to assure optimal assay method and laboratory performance

IFCC Reference Method

- Publication of approved IFCC Reference Method for the Measurement of HbA1c in Human Blood (Jan 2002)
- Clin Chem Lab Med 2002; 40: 78-89
- The new reference method will be the basis for the uniform standardisation of HbA1c routine assays worldwide

IEQAS HbA1c Scheme

- Scheme formally established in 1997 following pilot survey of 1996
- Provides objective assessment of the analytical performance of HbA1c assays in Irish clinical laboratories and clinics
 - National, independent, confidential, self-funded, not-for-profit
- Managed by the professional bodies in Irish laboratory medicine

Methods

- Volunteer donor panel
 - Established in association with the Diabetes Federation of Ireland
 - Fresh whole blood
- 4 distributions per year
- 20 participating laboratories, clinics

Methods

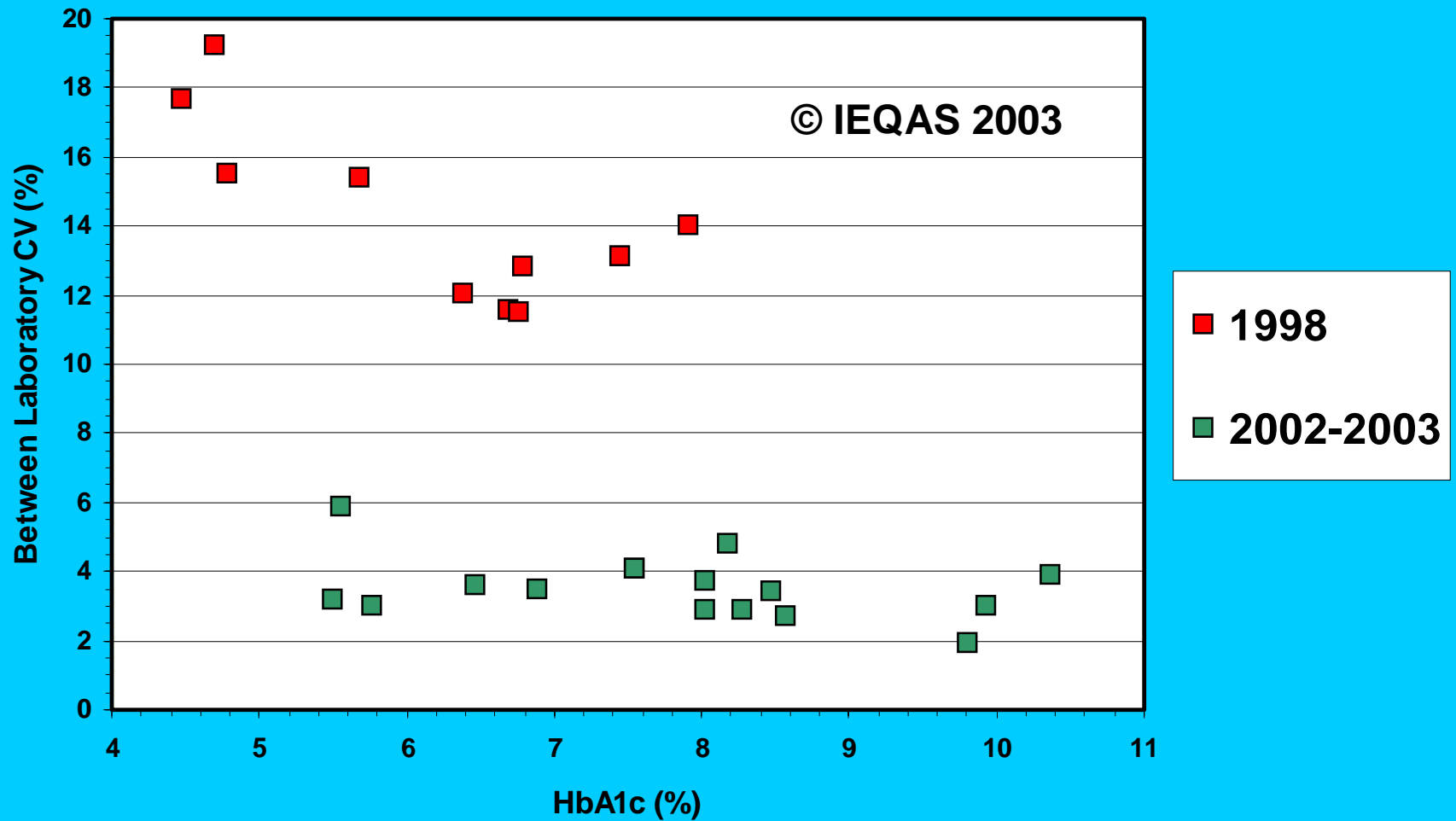
- Results analysed by IEQAS software
- DCCT values from NGSP Certified Laboratory
- IFCC values from IFCC Reference Laboratory

IEQAS HbA1c Scheme

Laboratory Testing	Menarini 8140
	BioRad Variant II
	Tosoh 2.2
	Roche Integra
	Beckman-Coulter CX5
Point of Care Testing (PoCT)	Bayer DCA
	Provalis

Impact of EQA on HbA1c in Participating Laboratories 1997 - 2003

IEQAS Between-laboratory Variation



International Standardisation of HbA1c

Purpose of the USA's National Glycohemoglobin Standardization Program (NGSP)

To align reported results to clinical outcomes data (**DCCT** and **UKPDS**) and to assure optimal assay method and laboratory performance

Problems with NGSP

- Issue of chemical entity being measured is not addressed
- DCCT method is a designated comparison method and is not standardised or calibrated in the true sense
- DCCT method is not specific for HbA1c

IFCC Initiative

Aim of IFCC HbA1c Standardisation

“Development of a reference method for the determination of HbA1c in human blood and the establishment of a European network of Reference Laboratories for this method”

IFCC Reference Method

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Clin Chem Lab Med 2002; 40: 78-89

- The new reference method will be the basis for the uniform standardisation of HbA1c routine assays worldwide

HbA_{1c}

N-terminal hexapeptide of the β -chain

HbA₀-peptide

Val-His-Leu-Thr-Pro-Glu

HbA_{1c}-peptide

Glucose-Val-His-Leu-Thr-Pro-Glu

EU IVD Directive

With effect from the 7th December 2003
(In Ireland S.I. 304 of 2001)

Manufacturers will be required to document the traceability of values assigned to calibrators and controls to available reference methods and/or reference materials of “higher order”

EU IVD Directive

Calibration of HbA1c assays within the EU will have to be traceable to the IFCC Reference Method and Standards by 7th December 2003

Relationship Between HbA1c Results From NGSP Network and IFCC Network

The Master Equation (Aug 2003)

$$\text{NGSP} = (0.915 \times \text{IFCC}) + 2.15$$

IFCC (HbA1c %)	NGSP (HbA1C %)	Difference
2.0	3.98	1.98
3.0	4.90	1.90
4.0	5.81	1.81
5.0	6.73	1.73
6.0	7.64	1.64
7.0	8.56	1.56
8.0	9.47	1.47
9.0	10.39	1.39
10.0	11.30	1.30

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- DCCT Secondary Reference Laboratory
- IFCC Reference Laboratory