

HumaNex A1c Variant

Fast. Reliable. Certified gold-standard.

- > HPLC technology - the gold standard of HbA1c testing
- > Outstanding analytical performance - Hb-variants detection
- > NGSP and IFCC certified



HUMAN

Diagnostics Worldwide

HbA1c

Improved diagnosing and monitoring of diabetes patients

HbA1c – the most important diabetes marker

HbA1c refers to glycated hemoglobin. It develops when hemoglobin joins with glucose in the blood, becoming 'glycated'.

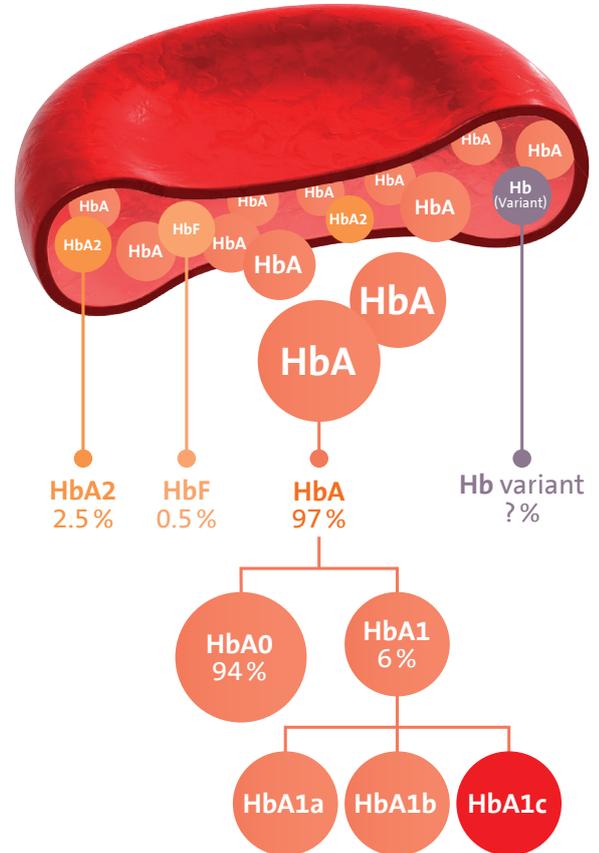
In contrast to direct glucose, the HbA1c parameter provides an average of the patient's blood sugar levels over a period of 2 - 3 months.

It is therefore not affected by daily fluctuations.

HbA1c is recommended by the American Diabetes Association (ADA) for monitoring how well the patient's diabetes treatment is working over time and to diagnose diabetes using a NGSP-certified method with a cutoff of HbA1c $\geq 6.5\%$.^{1,2}

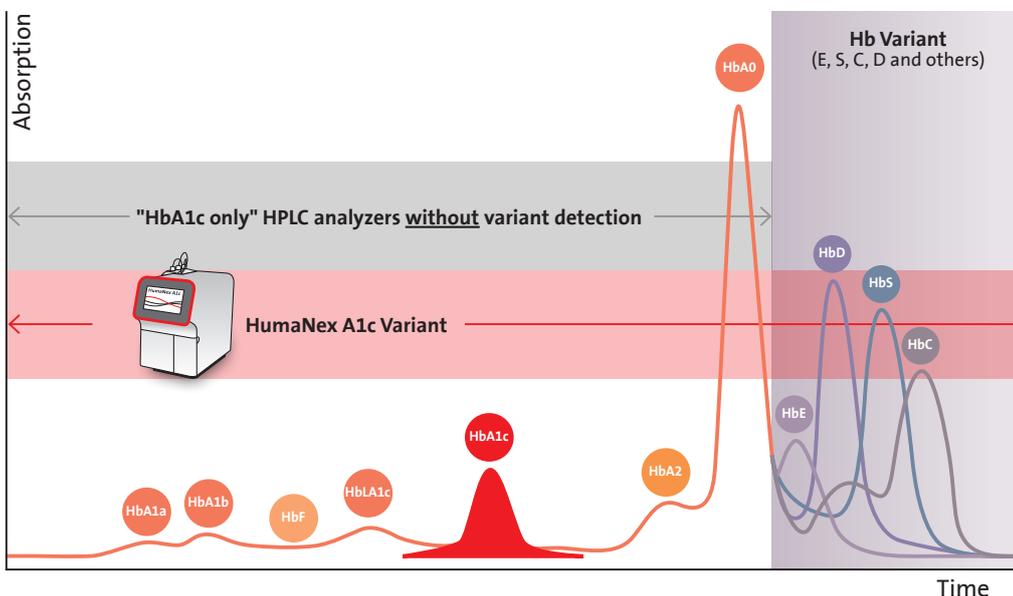
Research has also shown that people with type 2 diabetes who reduce their HbA1c level by 1% are:³

- > 19% less likely to suffer cataracts
- > 16% less likely to suffer heart failure
- > 43% less likely to suffer amputation or death due to peripheral vascular disease



Detect variants, provide more insights

In contrast to other methods, HumaNex A1c Variant will give you the details that enable you to provide the full picture to your physicians. Detected variants are visible on the chromatogram and taken into account when calculating the HbA1c result to reduce interferences. While HbE, HbD, HbS and HbC variants are the most common Hb variants, there are 1000s more rare pathological Hb variants. "HbA1c only" HPLC analyzers or immunological HbA1c tests cannot detect these variants.



This creates a blind spot for the physician, because some variants can also reduce or prolong the typical RBC lifespan and therefore require extra caution when interpreting HbA1c results. Knowing of the existence of these variants is important for many physicians.

HumaNex A1c Variant

Your dedicated HbA1c expert

Glycated hemoglobin HbA1c chemistry system

- > HbA1c result in 2.2 minutes
- > Up to 20 samples per hour with 10-sample autoloader
- > Measuring range: 3% - 18% NGSP
- > Sample volume: 5µl



Result quality – gold standard methodology

- > Certified by NGSP and IFCC
- > High quality controls and calibrators
- > Result reported in NGSP, IFCC and eAG (ADA) units

Simplicity – designed to assist you

- > Intuitive software controlled via touch
- > Primary tube sampling with cap piercing
- > Fully automated startup
- > Handheld barcode scanner

Ultra-sharp chromatographic resolution – to provide better insights

- > Detect variants
- > View the complete clinical picture
- > Integrated printer

Reliable – precision you can trust

- > Within-run CV < 1.2%
(in accordance with CLSI EP05-A3, 5x5 Model)



Easy sample identification by barcode



Intuitive and responsive user interface



Supports cap piercing and diluted samples

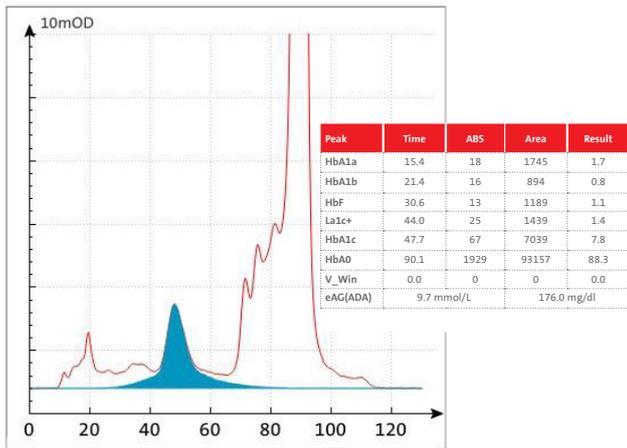
HbA1c Chromatograms

With and without Hb Variant

HumaNex A1c Variant clearly differentiates between samples with and without Hb variants.

Patient without variants

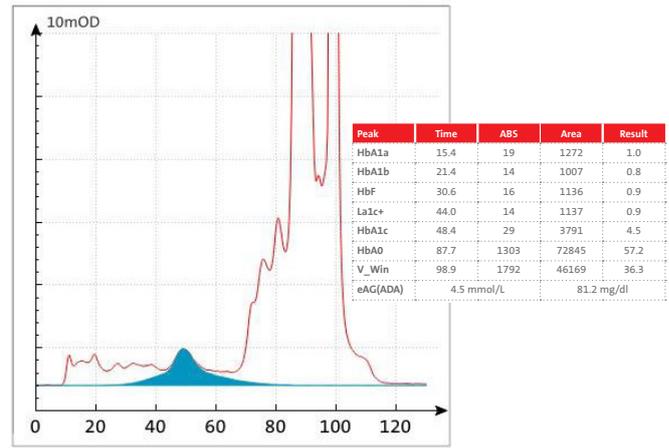
A patient with elevated HbA1c (> 6.5% NGSP).



The big HbA0 peak on the right side is clearly defined on its right flank. The V_Win is reported as 0%. No variants were detected.

Patient with HbS variant

A patient with the HbS variant.



The abnormal HbS peak is clearly visible next to the HbA0 peak and the abnormal Hb is reported as V_Win with 36%.

HumaNex A1c Variant System Reagents

Reagents

HumaNex A1c Variant Reagent Kit **REF 16195**
> 200 tests

HumaNex A1c Variant Column **16190/10**
> 1600 tests

Control

HumaNex A1c Variant Control **16199**
> 2-levels

Calibrator

HumaNex A1c Variant Calibrator **16197**
> 2-levels



Your local distributor

References

1. NGSP (National Glycohemoglobin Standardization Program), <http://www.ngsp.org/ADA.asp>, (2021-05-20)
2. ADA (American Diabetes Association), <https://www.diabetes.org/a1c>, (2021-05-20)
3. United Kingdom Prospective Diabetes Study Group: Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 352: 837-853, 1998



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