

Division of Laboratory Medicine

Biochemistry

HbA1c

Pseudonyms: Haemoglobin A1c, Glycated Haemoglobin

For the diagnosis and monitoring of Diabetes Mellitus

HbA1c, also known as Glycated Haemoglobin, is used in the monitoring and diagnosis of diabetes mellitus. HbA1c is formed when haemoglobin joins with glucose in the blood becoming 'glycated'. The amount of HbA1c formed is directly related to the average blood glucose concentration over the previous 8 to 12 weeks and is the preferred test for long term monitoring of glycaemic control in people with diabetes. If their diabetes is not well controlled, their average blood glucose concentrations will be high, causing higher HbA1c concentrations. Evidence shows that maintaining HbA1c below recommended target concentrations can reduce the risk of developing long term vascular complications such as eye disease, kidney disease or nerve damage.

In addition HbA1c can also be used for the diagnosis of type 2 diabetes mellitus.

General information

Collection container:

Adults: 3.4 mL Whole blood K-EDTA (Sarstedt red top)

Paediatrics: 1.2 mL Whole blood K-EDTA (Sarstedt red top)

Type and volume of sample:

Whole blood, minimum 1.0 mL

Specimen transport/special precautions:

None

Laboratory information

Method principle:

Cation exchange, high performance liquid chromatography (HPLC) to separate HbA1c from other haemoglobin fractions.

Biological reference range or cut off:

Guideline for HbA1c for the monitoring of glycaemic control in diagnosed Diabetes Mellitus

Adults

Division of Laboratory Medicine

Biochemistry

HbA1c ≤ 48 is tight control and suitable for most patients with type 2 diabetes unless at risk of hypoglycaemia

HbA1c ≤ 53 is the target for those at risk of hypoglycaemia

HbA1c < 58 is good control but lower targets may be appropriate depending on the individual

HbA1c ≥ 58 in most circumstances requires improvement

Children and Adolescents (<18)

HbA1c target level of 48 mmol/mol or lower is ideal to minimise the risk of long-term complications (NICE)

Guideline for the diagnosis of type 2 diabetes mellitus

| HbA1c (mmol/mol) | Interpretation |
|------------------|---|
| < 42 | Non-diabetic |
| 42 - 47 | Impaired glucose regulation/increased risk of diabetes mellitus |
| ≥ 48 | Consistent with diabetes mellitus/impaired glucose regulation |

An HbA1c of 48 mmol/mol is recommended as the cut off point for diagnosing diabetes and can be used to diagnose diabetes in most situations (*see situations where HbA1c is not appropriate for diagnosis below*). A value < 48 mmol/mol does not exclude diabetes diagnosed using glucose tests.

HbA1c values of 42 to 47 mmol/mol suggest a high risk of future diabetes. Such individuals should be offered structured lifestyle education and support to delay/prevent development of diabetes and have an annual HbA1c test.

In symptomatic adults with relatively slow onset of symptoms a single result of ≥ 48 mmol/mol is consistent with diabetes.

In patients without symptoms of diabetes a single HbA1c result ≥ 48 mmol/mol should be repeated within 2 weeks and if this is again ≥ 48 mmol/mol confirms diabetes mellitus. If the second sample is < 48 mmol/mol treat as high risk of diabetes and repeat the test in 6 months or sooner if diabetes symptoms develop.

Situations where HbA1c is not appropriate for diagnosis of diabetes:

- ALL children and young people
- patients of any age suspected of having type 1 diabetes
- patients with symptoms of diabetes for less than 2 months
- patients at high risk who are acutely ill (e.g. those requiring hospital admission)
- patients taking medication that may cause rapid glucose rise, e.g., steroids, antipsychotics
- patients with acute pancreatic damage, including pancreatic surgery
- in pregnancy

Division of Laboratory Medicine

Biochemistry

- presence of genetic, haematologic and illness-related factors that influence HbA1c and its measurement (see annex 1 of the WHO report for a list of factors which influence HbA1c and its measurement)

Turnaround time:

3 days

Clinical information

Factors known to significantly affect the results:

HbA1c can appear falsely low in patients with variant haemoglobin (haemoglobinopathy) or in haemolytic anaemia/increased red cell fragility. It can also be falsely increased. Below is a brief summary:

- Decreased HbA1c: administration of erythropoietin, iron, vitamin B12, reticulocytosis, chronic liver disease, drugs (aspirin, vitamin C and E and antiretroviral drugs, ribavirin and dapsone)
- Increased HbA1c: Iron and vitamin B12 deficiency, erythropoiesis, alcoholism, chronic kidney disease, splenectomy.
- Altered haemoglobin: Haemoglobinopathies, HbF, methaemoglobin may increase or decrease HbA1c.

Clinical decision points:

Refer to reference range information above

References

- 1) Use of Glycated Haemoglobin (HbA1c) in the Diagnosis of Diabetes Mellitus WHO 2011
- 2) Type 1 diabetes in adults: diagnosis and management. NICE guideline [NG17] 2015 (Last updated: July 2016)
- 3) Type 2 diabetes in adults: management. NICE guideline [NG28] 2015 (Last updated: May 2017)
Diabetes (type 1 and type 2) in children and young people: diagnosis and management. NICE guideline [NG18] Published date: August 2015 (Last updated: November 2016)

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