



Teco Diagnostics

Intended Use

For the quantitative determination of Hemoglobin A1c (HbA1c) in human blood. The determination of HbA1c is most commonly performed for the evaluation of glycemic control in diabetes mellitus. For *in vitro* diagnostic use only.

Principle

Total hemoglobin and HbA1c have the same unspecific absorption rate to latex particles. When mouse antihuman HbA1c monoclonal antibody is added (R2), latex-HbA1c-mouse anti human HbA1c antibody complex is formed. Agglutination is formed when goat anti-mouse IgG polyclonal antibody interacts with the monoclonal antibody. The amount of agglutination is proportional to the amount of HbA1c absorbed on the surface of latex particles, which is measured as absorbance. The HbA1c value is obtained from a calibration curve.

CONTACT US:

TECO DIAGNOSTICS

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Test:

Hemoglobin A1c (HbA1c)(G560-125)

Number of Tests:

125 tests

Format:

Liquid

Method:

Turbidity

Testing Procedure:

Manual

Storage Temperature:

2-8°C

Wavelength:

670 nm

Linearity:

2.0-16.0%

Expected Values:

<6% for non-diabetic

<7% for glycemic control of a person with diabetes

Reagent Deterioration :

Alterations in the physical appearance of the reagents or values of control materials outside of the manufacturer's acceptable range may be an indication of reagent instability.

Limitations of Procedure:

This assay should not be used for the diagnosis of diabetes mellitus.

Patient specimens should always be assayed using a calibration curve.

It has been reported that results may be inconsistent in patients who have the following conditions: opiate addiction, lead-poisoning, alcoholism, ingest large doses of aspirin.

It has been reported that elevated levels of HbF may lead to underestimation of HA1c and, that uremia does not interfere with HbA1c determination by immunoassay

It has been reported that Hemoglobin variants HbS and HbA2 are not detected by immunoassay, leading to possible inaccurate determination. Also, it has been reported that labile intermediates (Schiff base) are not detected and therefore, do not interfere with HbA1c determination by immunoassay.

Other very rare variants of hemoglobin (e.g. HbE) have not been assessed