

smart HbA1c Test

Test kit for quantitative determination of hemoglobin A1c in human blood on SMART Photometer.



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DIAGNOSTICA

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Order Information

Art Code ST0110
Art Code ST1100
Art Code ST1110

Description

smart HbA1c-Test Kit
smart HbA1c Control kit
smart HbA1c Calibrator kit

kit size

24 Tests/kit
2 x 0,5 ml /high and low
1 x 0,5 ml

Summary and Explanation of the Test:


Throughout the circulatory life of the red cell, Haemoglobin A1c (HbA1c) is formed continuously by adduction of glucose to the N-terminal of the haemoglobin beta chain. This process which is non enzymatic reflects the average exposure of haemoglobin to glucose over an extended period. Studies have shown that HbA1c on diabetic subjects was 2-3 fold over levels found in normal individuals.

Method-Range: Enzymatic Method: Typical Range (Lot pending!) NGSP: 4,5% - 14,0 %

Principal: endpoint measurement of the HbA1c- Concentration at 700nm.

Testkit:

ERS Cuvette pre-filled with: 800µl Enzyme Reagent
ERS CAP pre-filled with: 240µl Enzyme Reagent
Lyse buffer-pump dispenser: 9ml Lyse Buffer Natriumazid 0,5g/L

Storage and Stability: At 2-8°C stable until the expiration date stated on the labels .

Warnings and precautions:

The reagents contain sodium azide (0.95g/l) as preservative. Do not swallow! Avoid contact with skin and mucous membranes. Take the necessary precautions for the use of laboratory reagents

Precautions: this kit is for in vitro diagnostic use only.

Kit preparation: the test kit is ready to use

Sample material: Capillary blood (fresh) or venous whole blood EDTA (stable for 1 week if cooled to 2-8°C)

Referene Range:

IFCC < 4,21 % for non diabetic (< 5,3% for glycemic controlled persons with diabetes)

NGSP < 6,00 % for non diabetic (< 7,0% for glycemic controlled persons with diabetes)

Values are calculated according the master equation: IFCC = (NGSP - 2.15) / 0.915

Controls: For internal QC we recommend to use the HbA1c Control kit Art Code ST1100

Precision: Control low: Mean 5,52%; Std. Dev 0,16; %CV 2,85; Control High Mean: 11,28%; Std. Dev 0,21; %CV 1,89 N=20

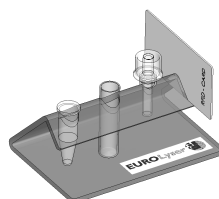
Correlation with Roche Immunoassay: $y=0,9448x + 0,2457$ $r^2=0,9552$ $x=$ Roche Immunoassay $y=$ smart HbA1c

Literature : Trivelly, LA Ranney H.M and Lai, HAT New Eng J Med284,353; Gonen B. and Rubenstein AHDiabetologia 15,1 (1978)

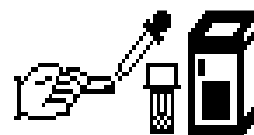
Preparation of the smart test-system



insert RFID card



place test kit in smart test kit rack



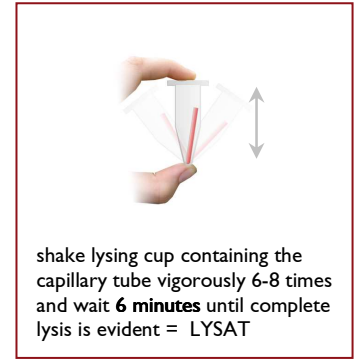
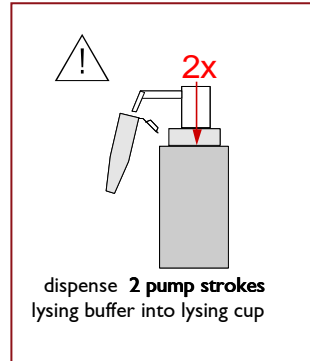
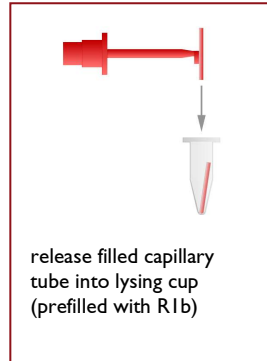
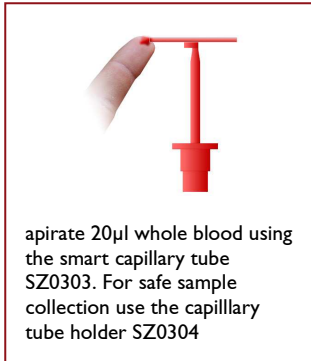
push symbol button on touch screen

Test application for smart HbA1c test

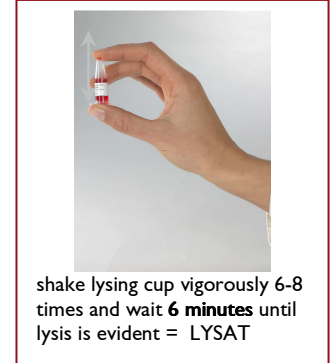
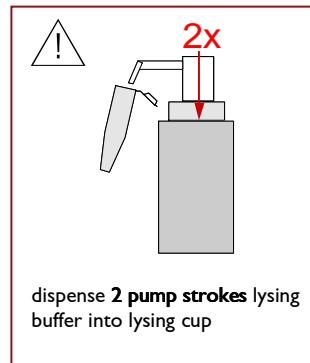
Test kit for quantitative determination of hemoglobin A1c in human blood on smart photometer.



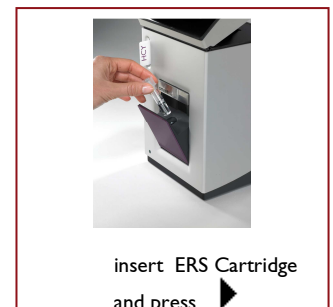
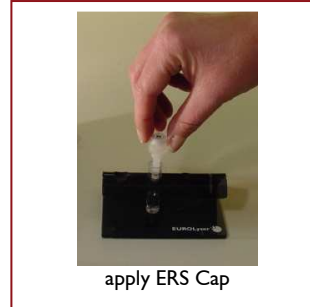
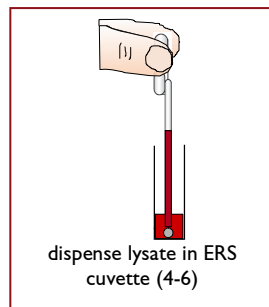
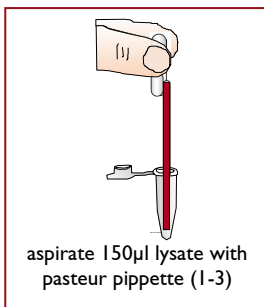
1. sample peraration (direct from finger brick using end to end capillary SZ0303)



2. sample preparation (from EDTA Tube)



3. application

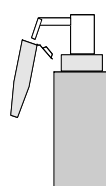


correct usage of the pasteur pipette:

1. firmly squeeze and hold upper bulb.
2. completely immerse tip into the liquid of lysing cup.
3. release bulb slowly to aspirate liquid. Overflow of liquid is not critical as it flows into the chamber!
4. put end of pipette into ERS cuvette
5. squeeze upper bulb completely
6. with the bulb squeezed, release the pipette from liquid



correct usage of pump dispenser:



1. Before very first test application prime the dispenser with 2 pump strokes to avoid air within the pump system.
2. Handling in between use if pump dispenser is not used within 14 days, prime the dispenser with 1 pump stroke before the next tests are performed.
3. Storage store pump dispenser in a upright/standing position. (2-20°C)