

Alere Technologies AS Kjelsåsveien 161 P.O. Box 6863 Rodeløkka NO-0504 Oslo Norway

# NycoCard™ CRP and NycoCard™ HbA1c

## Instructions for serial measurements of venous samples

C-reactive protein (CRP) and glycated haemoglobin (HbA1c) can be measured in series up to 6 samples at a time using the NycoCard test system.

The following instructions for serial measurements are supplementing the instructions for use provided in the package insert of the test kit.

### Procedure for serial measurements of CRP in 6 samples at a time

Reagent:

NycoCard™ CRP

Instrument:

NycoCard™ READER II

#### Venous blood

- 1. Collect venous blood (heparin, citrate or EDTA) using standard blood sampling equipment. Serum or plasma (heparin, citrate or EDTA) can also be used.
- 2. Line up 6 NycoCard CRP <u>R1/Dilution Liquid</u> tubes and mark the tubes with sample IDs. Bring the R1/Dilution Liquid tubes to room temperature before use.
- 3. Dilute sample 1 by adding 5  $\mu$ L of the sample to the R1 tube dedicated for that sample. 5  $\mu$ L capillary tubes or a 5  $\mu$ L pipette can be used for the transfer. Close the tube and mix well for 10 seconds. Repeat for samples 2-6.
- 4. Line up 6 NycoCard CRP <u>Test Devices</u> and mark the devices with the sample IDs.
- 5. Apply 50  $\mu$ L diluted sample 1 to the test device dedicated for that sample, using a 50  $\mu$ L pipette. Repeat for samples 2-6. Use a new pipette tip for each sample.
- 6. Apply one drop of NycoCard CRP <u>R2/Conjugate</u> to the Test Device dedicated for sample 1. Repeat for samples 2-6.
- 7. Apply one drop of NycoCard CRP <u>R3/Washing Solution</u> to the test device dedicated for sample 1. Repeat for samples 2-6.
- 8. White calibrate the NycoCard READER II (see instructions in the READER II User Manual)
- 9. Read the result of sample 1 using the NycoCard READER II (see instructions in the READER II User Manual). Repeat for samples 2-6.

### Capillary blood

- 1. Line up 6 NycoCard CRP <u>R1/Dilution Liquid</u> tubes and mark the tubes with sample IDs. Bring the R1/Dilution Liquid tubes to room temperature before use.
- 2. Collect capillary blood from finger stick. Dilute sample 1 by adding 5  $\mu$ L of the sample to the R1 tube dedicated for that sample. 5  $\mu$ L capillary tubes or a 5  $\mu$ L pipette can be used for the transfer. Close the tube and mix well for 10 seconds. Repeat for samples 2-6. The diluted capillary blood can be stored up to 1 hour before analysis.
- 3. Line up 6 NycoCard CRP <u>Test Devices</u> and mark the devices with the sample IDs.
- 4. Apply 50  $\mu$ L diluted sample 1 to the test device dedicated for that sample, using a 50  $\mu$ L pipette. Repeat for samples 2-6. Use a new pipette tip for each sample.
- 5. Apply one drop of NycoCard CRP <u>R2/Conjugate</u> to the Test Device dedicated for sample 1. Repeat for samples 2-6.
- 6. Apply one drop of NycoCard CRP <u>R3/Washing Solution</u> to the test device dedicated for sample 1. Repeat for samples 2-6.
- 7. White calibrate the NycoCard READER II (see instructions in the READER II User Manual)

Alere Technologies AS



8. Read the result of sample 1 using the NycoCard READER II (see instructions in the READER II User Manual). Repeat for samples 2-6.

NOTE: Allow the sample/reagent to soak into the membrane before the next reagent is applied to the test device. The applications should be done successively without further delays between the steps. If 6 samples are difficult to handle at a time, reduce the number to 3-4.

The further instructions given in the package insert should be followed.

## Procedure for serial measurements of HbA1c in 6 samples at a time

Reagent:

NycoCard™ HbA1c

Instrument: NycoCard™ READER II

- 1. Collect venous whole blood (EDTA, heparin or NaF) using standard blood sampling equipment. Capillary blood cannot be used for serial measurements.
- 2. Line up 6 NycoCard HbA1c R1/Reagent tubes and mark the tubes with sample IDs. Bring the R1/Reagent tubes to room temperature before use.
- 3. Add 5  $\mu L$  sample 1 to the R1 tube dedicated for that sample. 5  $\mu L$  capillary tubes or a 5  $\mu L$ pipette can be used for the transfer. Mix well, Repeat for samples 2-6. Use a new pipette tip for each sample. Leave the tubes for 2 minutes, maximum 3 minutes. Use a timer.
- 4. Line up 6 NycoCard HbA1c <u>Test Devices</u> and mark the devices with the sample IDs.
- 5. Remix the sample/reagent mixture to obtain a homogenous suspension. Apply 25 µL of the sample 1 mixture to the test device dedicated for that sample. Use a 25 µL pipette for the transfer. Hold the pipette tip approximately 0.5 cm above the test well and empty the pipette quickly in the middle of the test well. Avoid air bubbles. Allow the mixture to soak completely into the membrane. Wait for minimum 10 seconds. Repeat for samples 2-6. Use a new pipette tip for each sample.
- 6. Apply 25 µL NycoCard HbA1c R3/Washing Solution to the Test Device dedicated for sample 1. Avoid air bubbles. Allow the reagent to soak completely into the membrane. Wait for minimum 10 seconds. Repeat for samples 2-6.
- 7. White calibrate the NycoCard READER II (see instructions in the READER II User Manual)
- 8. Read the result of sample 1 using the NycoCard READER II (see instructions in the READER II User Manual). Repeat for samples 2-6.

NOTE: The applications should be done successively without further delays between the steps. If 6 samples are difficult to handle at a time, reduce the number to 3-4.

The further instructions given in the package insert should be followed.

Alere Technologies AS

Eldri Prestegård

Regulatory Affairs Manager

Alere Technologies AS