

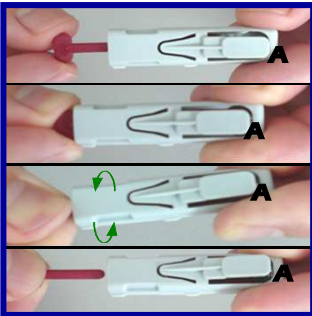
## ALFA (Allergy Lateral Flow Assay)

**Please read instruction for use carefully before starting the assay! (See also IfU in reagent box!)**

It is absolutely necessary to perform the test in the **indicated order** and **without interruption**.

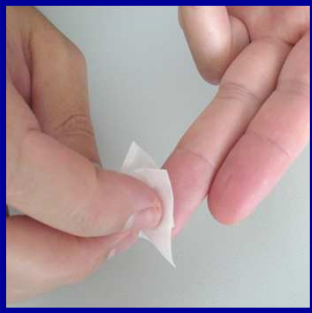
All reagents must be brought to **room temperature (18-25°C)**, at least **30 minutes** before starting the assay.

### How to use the lancet when performing ALFA with whole blood



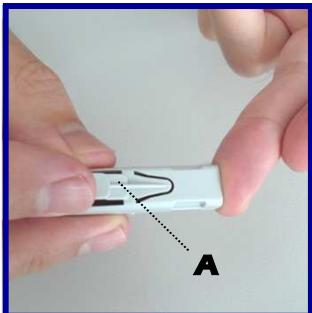
#### 1. Preparation of the lancet device

- Press the dark red pin strongly into the lancet device until it snaps into place, afterwards strongly spin around (see green arrows) until it comes undone and excerpt it off the lancet device
- The lancet device is now ready for use and is put aside



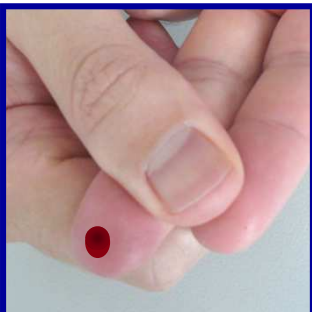
#### 2. Prepare taking blood sample

- Wipe fingertip, from which blood should be taken, carefully by an alcohol sponge
- Let fingertip dry for 1 minute
- The following steps must be performed one after another without any interruption!



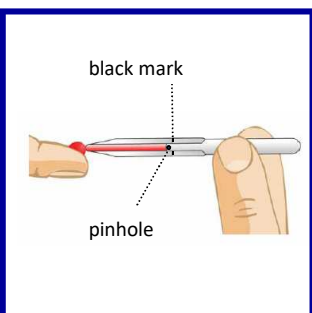
#### 3. Taking of blood sample

- Caution! Don't press the activator (A) yet
- Press the prepared lancet device with the big round opening (from which the dark red pin was excerpted) completely sideways on the disinfected fingertip
- Activate the lancet device by strongly pressing the activator (A)
- The fingertip should not be cold



#### 4. Blood withdrawal

- Agglomerate the arm, hand or finger with the other hand in the direction of the fingertip until a sufficient drop of blood (see picture) occurs
- Hold the finger horizontally so that the drop of blood doesn't get lost
- Don't press too hard because cell components will also come out



#### 5. Admission of the blood

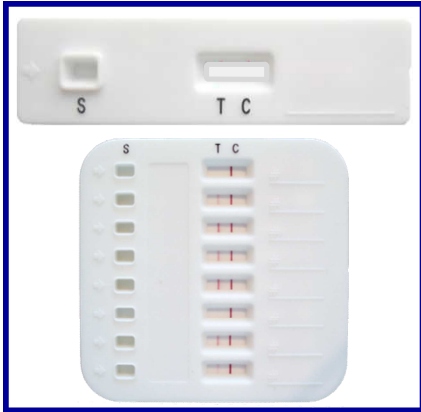
- Don't compress the upper part of the pipette!
- Only touch the drop of blood lightly with the top of the pipette; at the same time hold the pipette horizontally; don't press the pipette on the finger!
- The blood is automatically drawn up to the black mark in the pipette (see picture)
- If the pipette doesn't fill properly, replenish blood and bring the pipette once more to the finger
- If the pipette fails use a new one

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### 1. Preparation of the basis set

- After bringing the basis set (in foil pouch) to room temperature unpack the basis set and place it on the bench
- The test should be laid on a plane surface and should not be moved or lifted while performance and running the test
- Place the allergen solution, the lancet device, the alcohol sponge and the pipette on the bench
- Single-strip and eight-strip cassette can be used in the same way,
- Mark each strip with used allergen and patient for evaluation and documentation

### 2. Blood transfer into the basis set

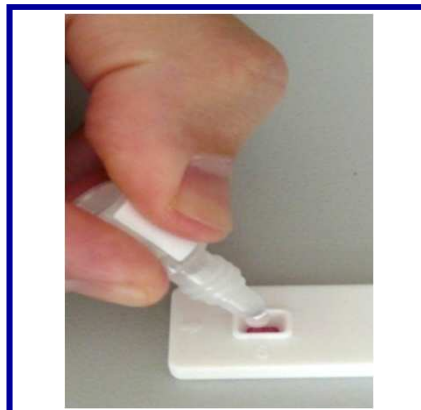
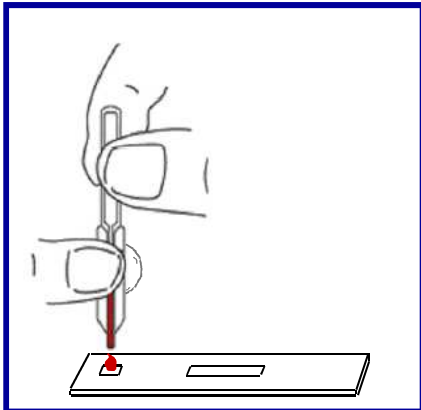
#### When using whole blood

- To bring the blood into the basis set compress the upper part of the pipette over the sample application field until the pipette is completely drained (at the same time keep the pinhole shut); pipette contains 25  $\mu$ L blood
- whole blood samples must be transferred to the test device immediately; Anticoagulant should not be used.
- don't touch the membrane and the side of the application field
- If the pipette is not completely drained, strip the blood with a finger out of the pipette

#### When using serum or plasma

- To bring the serum or plasma into the basis set hold the pipette over the sample application field and add 20  $\mu$ L
- don't touch the membrane and the side of the application field
- If the sample was frozen thaw it bring it to room temperature and mingle it carefully

The use of haemolytic or lipemic specimens must be avoided.



### 3. Addition of the allergen solution

- Immediately after transferring the blood into the basis set bring two drops of allergen solution into the sample application field (hold dropper bottle 1 cm above the sample application field, don't touch the membrane and the side of the application field)
- Don't move the basis set until the analysis after 20 minutes

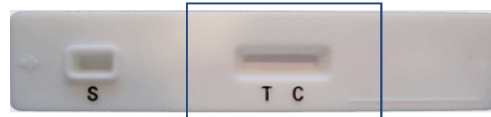
## How to read the results after 20 min



### Analysis of the results

- The test results become visible in the assay window after a short time, for reading wait 20 min.
- The test result can either be analyzed by eye or by an reader
- For using the reader please see instruction for use for LFA Reader

## after 20 min



### Positive test result:



Test line (T)      Control line (C)

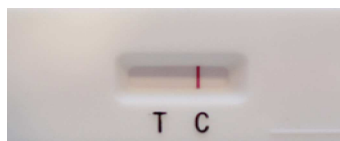
Control line (C) and Test line (T) visible.

-Caution! Control line is normally stronger colored than the test line!

-The intensity of the test line ranges from faintly pink (low titer of sIgE) to dark ruby (high titer of sIgE).

-Even a faintly colored test line is rated as positive!

### Negative test result:



Control line (C)

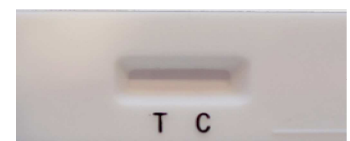
Control line (C) visible, Test line (T) not visible.

-A strong sensitization against the tested allergen is unlikely.

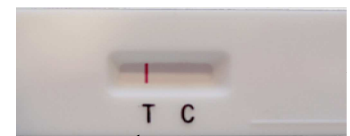
-Other allergens are not detected with this test!

### Invalid test result:

a)



b)



Test line (T)

a) Control line (C) and Test line (T) are not visible.

b) Test line (T) visible and Control line (C) not visible.

Both test results are invalid, each test must be repeated with new basis sets.

# Lateral Flow Assay Reader

Mobile measuring device for the evaluation and documentation of rapid tests

The LFA (Lateral Flow Assay) Reader is a mobile measuring device for the quantitative evaluation and documentation of ALFA (Allergy Lateral Flow Assay) and AI-LFA (Autoimmune Lateral Flow Assay), rapid tests for the determination of sIgE (ALFA) and autoimmune parameters (AI-LFA)



Figure 1 LFA Reader

LFA Reader REF 190002



Figure 2 Report printout LFA Reader for ALFA

## LFA Reader Specifications

- ▲ Quantitative Evaluation
  - Measuring results in Units for ALFA (U/mL) and AI-LFA (RU)
  - Allocation in classes analog to RAST classes for ALFA
- ▲ Documentation of the results by
  - Printout (provided printer)
  - Storage on the internal memory of the device
  - Export of results
- ▲ Simplified use by an integrated Barcode Scanner for importing allergens, antigens and patient samples
- ▲ Single- and eight-strip cassettes can be read

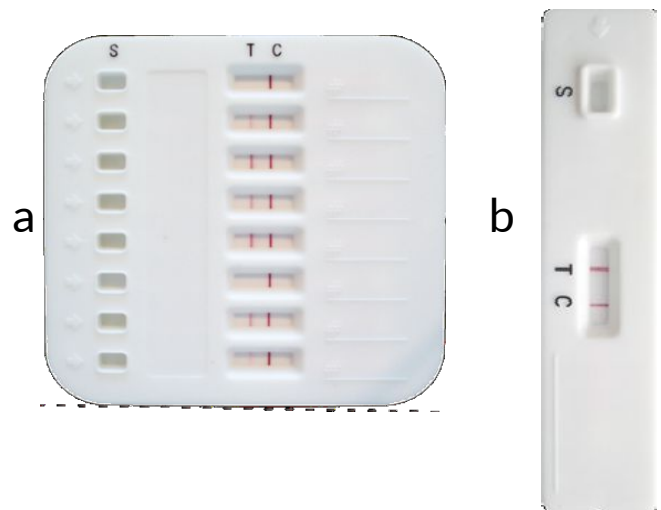


Figure 3 a) different results eight-strip cassette, b) positiv result single-strip cassette