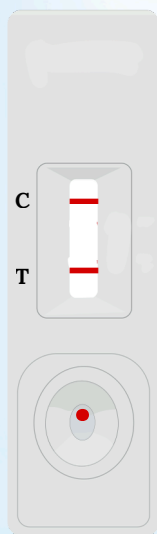


## HbA1c Rapid Test Kit (Whole blood)

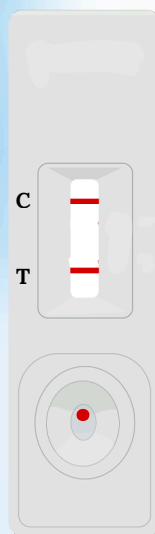
### INTERPRETATION OF RESULTS

Figure 1



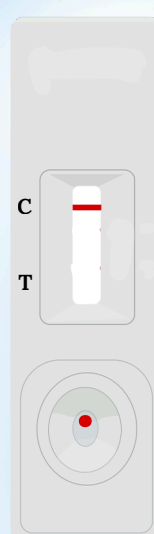
9%

Figure 2



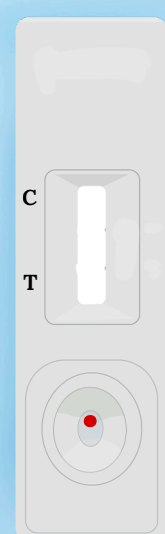
6%

Figure 3



Negative

Figure 4



Invalid

### DIRECTIONS FOR USE

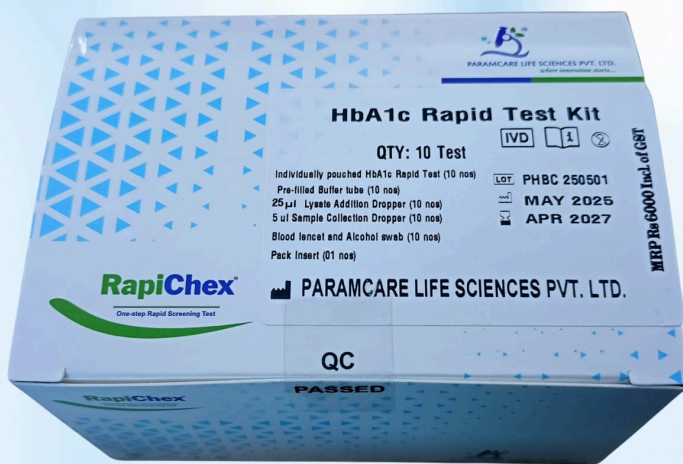
1. Bring the test device, sample buffer, and specimens to room temperature (15-30°C) before use.
2. Open the pouch and place the test device on a clean and flat surface.
3. Add 5µl whole blood sample in prefill assay buffer after that mix 10 times and incubate 2 mins.
4. Dispense 3 drops (approximately 75µL) of the diluted sample into the sample well of the test device using the sample dropper
5. Follow the testing procedure exactly as mention in the insert.

### INTERPRETATION OF RESULTS

1. Positive: Two distinct red bands appear, one in the test region (T) and the second one in the control region (C).
2. Negative: Only one red band appears in the control region (C). No band appears in the test region (T) or the test line is weaker than the reference line representing 6 % on the color chart. This indicates HbA1c to be healthy level meaning excellent control.
- 3-Invalid: If no red band appears in the control region (C), the test is invalid. Repeat the test with a new device.

## HbA1c Rapid Test Kit (Whole blood)

## HbA1c Rapid Test Kit



## Sensitivity and Specificity

Method		ECLIA		Total results
HbA1c Rapid Test Cassette (Whole Blood)	Results	Positive	Negative	
	Positive	69	1	
	Negative	1	99	
Total Results		70	100	170

Relative Sensitivity: > 98.6% (95%CI\*:96.1%-100%)

Relative Sensitivity: 98.7% (95%CI\*: 95.3%-99.8%)

Overall Accuracy: 99.1% (95%CI\*: 96.8%-99.9%)

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