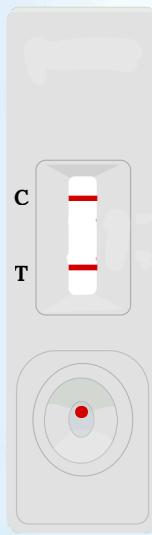


HbA1c Rapid Test Kit (Whole blood)



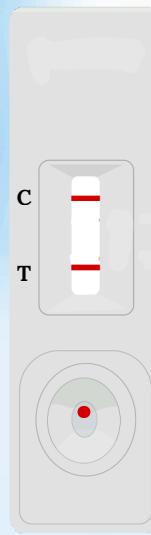
INTERPRETATION OF RESULTS

Figure 1



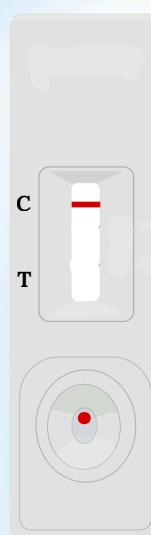
9%

Figure 2



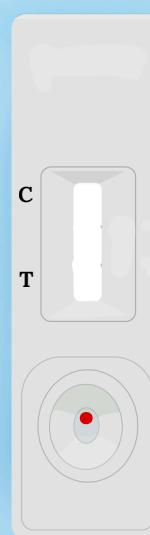
6%

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 |
|---|----------|----------|---------------|
| | Positive | Negative | |
| HbA1c Rapid Test Cassette (Whole Blood) | 69 | 1 | 70 |
| | 1 | 99 | 100 |
| | 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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Mumbai - 400059.

Factory Address:-

G/F- 12/13, Evershine-2, Survey NO.
307/3/1, Balitha, N.H No 48, Vapi, Valsad,
Gujarat, 396191.