1. Device identification

Device name	Visitect CD4 Test Reader
Device type	Software-only in vitro diagnostic medical device for professional use, CE and UKCA marked
Delivered in	ClearScreen Test Reader (Powered by TestCard) app, as a module enabled by your organisation
Reads	VISITECT CD4 Advanced Disease Test Cassette (Accubio Limited)
Software version	Shown on the App Info screen in the app
UDI-DI	(01) 506069757CD4RAG(8012)XXX(11)YYYYMMDD
Manufacturer	TestCard Limited, Unit 6, Betton Business Park, Racecourse Road, East Ayton, Scarborough, North Yorkshire, YO13 9HT, United Kingdom
EU authorised representative	CS LifeSciences Europe Limited, The Black Church, St. Mary's Place, Dublin 7, Dublin, D07 P4AX, Ireland

2. Intended use

The VISITECT CD4 Test Reader is a software application accessory that is downloaded onto, and used in combination with, a smart-device with camera using an appropriate launcher and operating system (e.g. Android or iOS) within a clinical or non-clinical environment for the purpose of evaluating the presence of control and/or test bands obtained from the VISITECT CD4 Advanced Disease Test Cassette.

The VISITECT CD4 Test Reader provides, in a non-automated manner, qualitative information to the clinical professional on the detection of CD4 positive cells by the VISITECT CD4 Advanced Disease Test Cassette, to aid in the semi-quantitative enumeration of CD4 positive immune cells in blood.

For in vitro diagnostic use only

Intended user: Healthcare professionals. **Setting:** Clinical or non-clinical environments.

3. Before you start

- **Training:** your organisation must make sure you are trained and competent in using the device to perform the tests enabled for your organisation.
- **Smart device:** a device with a camera running Android 8+ or iOS 16+. Give the app permission to use the camera; it can't scan without it.
- **Internet connection:** needed to analyse the scan and return the result.

- **Test cassette:** a VISITECT CD4 Advanced Disease Test Cassette. Collect and apply the sample following the test manufacturer's instructions for use. This app does not replace them.
- **Scanning conditions:** scan in good light, with the cassette flat on a surface and the device held steady.

4. How to use

The app guides you through each step on screen. The steps below follow the order you'll see them in.

1. **Select the test.** After signing in and entering the patient or test request ID, choose "Visitect CD4" on the Select Test screen.
2. **Scan the test QR code (if your organisation uses it).** When asked, scan the QR code on the cassette to start.
3. **Read the scanning tips.** Scan in good light, hold your device steady, and follow the test manufacturer's instructions to obtain a blood sample and to apply the sample. Apply the sample to Well A and tap **Start timer**.
4. **Wait for the test to develop.** A 3-minute countdown timer runs while the test develops. Keep the app on this screen.
    a. You can tap **Skip timer** (if your organisation has enabled this function), but the app will then not time the test. You must make sure the test is exposed for 3 minutes.
5. **Apply buffer to Well A.** Add buffer to Well A as per the test manufacturer's instructions, then tap **Start timer**. A 17-minute countdown timer runs while the test develops. Keep the app on this screen.
    a. You can tap **Skip timer** (if your organisation has enabled this function), but the app will then not time the test. You must make sure the test is exposed for 17 minutes.
6. **Apply buffer to Well B.** Add buffer to Well B as per the test manufacturer's instructions, then tap **Start timer**. A 20-minute countdown timer runs while the test develops. Keep the app on this screen.
    a. You can tap **Skip timer** (if your organisation has enabled this function), but the app will then not time the test. You must make sure the test is exposed for 20 minutes and scanned within a further 5 minutes.
7. **Capture the image.** When the timer ends, place the cassette flat and line it up in the blue frame. You have 5 minutes to scan. Hold still when the app shows "Perfect! Please hold still".
8. **Review the result.** When the scan is analysed, tap **Review result**.
9. **Confirm the result.** For CD4, the app shows the indicated result. What you can do on this screen depends on how your organisation has configured the app. See Confirming results, below.
10. **Submit.** If you can change results, check the summary, which shows the CD4 Advanced Disease result, and tap **Submit results**.
11. **Finish.** The Results Recorded screen shows what you selected. Choose **Test another patient** (to stay logged in) or **Finish and logout**.

Confirming results

Your organisation sets up the app in one of two ways, and you'll see only one of them.

If you can change results: the Result Analysis screen shows the indicated result for CD4. Compare it with your visual reading of the cassette and select >200 cells per µL or ≤200 cells per µL. Tick **Invalid - Control and/or Reference line not present** if the control and/or reference line is not visible. Then go to step 10.

If you can accept or reject results: the Submit Results screen lists the analysed result for CD4. If it matches your visual reading of the cassette, tap **Submit results** and go to step 11. If it doesn't, tap **Reject and retest**, then **Confirm reject**. The result is not sent to the patient record. Tap **Cancel** to go back without rejecting.

5. Results and messages

CD4 is reported as >200 cells per µL, ≤200 cells per µL or Invalid. The result recorded is the one you confirm or submit (see Confirming results in section 4).

Message on screen	What it means	What to do
Indicated result: >200 cells per µL / ≤200 cells per µL	The reader's analysis of the CD4 test	If you can change results: confirm or change it to match your visual reading. If you can accept or reject: submit it if it matches your visual reading, or reject and retest if it doesn't
Indicated result: Invalid	The control and/or reference line was not detected	Retest with a new cassette. If you can change results, tick Invalid - Control and/or Reference line not present first
Failed scan – "there is still time for rescan"	The image could not be captured	Tap **Retry scan** or **Exit test**
Failed scan – "the test is now over-exposed"	The time limit for scanning has passed	Tap **Start a new test** and use a new cassette
Test scan pending – "You are offline"	The scan worked but couldn't be sent for analysis	Reconnect and tap **Retry sending now**. **Exit and lose test** discards the scan
Permission required for app use	Camera access was not allowed	Allow camera access, then start a new test

6. Performance characteristics

Compared with by-eye reading of the VISITECT CD4 Advanced Disease Test Cassette, the reader shows the following:

Analyte	Sensitivity	Specificity	Accuracy	Precision
CD4	95.28%	99.58%	98.25%	99.02%

How the reading works: the reader samples the intensity profile from each gel lane on the cassette and converts it into digital values. A 1-D Gaussian filter removes high-frequency noise, and a baseline

correction separates the signal from background effects such as stains or lighting gradients. Peaks in the corrected signal are checked against a calibrated set of absolute and relative tests for each control and test line supported by the cassette. The overall result is based on the combination of lines that are detected.

7. Symbols and reporting serious incidents

These symbols appear on the Test Select Screen or the App Info screen:

Symbol	Meaning
	CE Mark
	UKCA Mark
	Manufacturer
	EU authorised representative
	Batch number (used for the software version and build)
	In vitro diagnostic medical device
	Near-patient testing
	Consult instructions for use

Serious incidents: any serious incident that has occurred in relation to the device must be reported to the manufacturer and to the competent authority of the country where the user and/or patient is established. Contact TestCard at support@clearscreen.com.

8. Limitations and warnings

This medical device module has been assessed for risk, and there are no limitations or warnings associated with the VISITECT CD4 Test Reader. For any warnings or limitations associated with the VISITECT CD4 Advanced Disease Test Cassette, please refer to the Instructions for Use for the test.