1. Device identification

Device name	Healgen One Step Pregnancy Test Reader
Device type	Software-only in vitro diagnostic medical device for professional use, CE marked
Delivered in	ClearScreen Test Reader (Powered by TestCard) app, as a module enabled by your organisation
Reads	Healgen One Step Pregnancy Test Cassette (Healgen Scientific LLC)
Software version	Shown on the App Info screen in the app
UDI-DI	(01)506069757HGPREK(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 Healgen One Step Pregnancy 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), used by a healthcare professional within both clinical and non-clinical settings for the purpose of evaluating the presence of control and/or test bands obtained from the Healgen One Step Pregnancy Test Cassette.

The Healgen One Step Pregnancy Test Reader provides, in a non-automated manner, qualitative information to the clinical professional on the detection of hCG as an indication of pregnancy.

For in vitro diagnostic use only

Intended user: Healthcare professionals. **Setting:** Clinical and non-clinical settings (near-patient testing).

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 Healgen One Step Pregnancy 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.

- **Select the test.** After signing in and entering the patient or test request ID, choose "Healgen One Step Pregnancy" on the Select Test screen.
- **Scan the test QR code (if your organisation uses it).** When asked, scan the QR code on the cassette to start.
- **Read the scanning tips.** Scan in good light, hold your device steady, and follow the test manufacturer's instructions for sampling and applying the sample. Tap **Start timer** once the sample is applied.
- **Wait for the test to develop.** A 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 5 minutes and scanned within a further 5 minutes.
- **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".
- **Review the result.** When the scan is analysed, tap **Review result**.
- **Confirm the result.** For Pregnancy, 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.
- **Submit.** If you can change results, check the summary, which includes the patient or test request ID, and tap **Submit results**.
- **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 Pregnancy. Compare it with your visual reading of the cassette and select Negative or Positive. Tick **Invalid – No control line present** if no control line is visible. Then tap **Submit** and go to step 8.

If you can accept or reject results: the Submit Results screen shows the analysed result for Pregnancy. If it matches your visual reading of the cassette, tap **Submit results** and go to step 9. 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

The Pregnancy result is reported as Positive, Negative 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: Positive / Negative	The reader's analysis of the test band	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	No control line was detected	Retest with a new cassette. If you can change results, tick Invalid – No control line 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 [Healgen One Step Pregnancy Test Cassette], the reader shows the following:

Analyte	Sensitivity	Specificity	Accuracy	Precision
Pregnancy	99.50%	100.00%	99.67%	100.00%

How the reading works: the reader samples the intensity profile from the gel lane of the test 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 the control and test line on the cassette. The overall result is based on which lines are detected.

7. Symbols and reporting serious incidents

These symbols appear on the App Info screen:

Symbol	Meaning
	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 HGPR. For any warnings or limitations associated with the Healgen One Step Pregnancy Test Cassette, please refer to the Instructions for Use for the test.