1. Device identification

Device name	Roche Combur10 UX Strip 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	Roche Combur-10 UX test strip (Roche Diagnostics)
Software version	Shown on the App Info screen in the app
UDI-DI	(01)50606975730000(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 Roche Combur-10 UX StripReader 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 environment for the purpose of evaluating colorimetric results obtained from urine using analyte test strips.

The Roche Combur-10 UX StripReader provides, in a non-automated manner, qualitative and semi-quantitative information to the clinical professional on the analytes detected by the teststrip, to aid in the determination of a physiological state associated with the analytes of interest.

For in vitro diagnostic use only.

Intended user: Healthcare professionals. **Setting:** Clinical environment.

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 strip:** a Roche Combur-10 UX test strip. 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 test strip flat on a light (not white) 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 "Roche Combur10 Test UX" on the Select Test screen.
2. **Read the scanning tips.** Lay the test strip flat on a light (not white) surface, scan in good light if possible, 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.
3. **Wait for the test to develop.** A countdown timer runs while the test develops. Keep the app on this screen.
    - 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 1 minute and scanned within 1 minute.
4. **Capture the image.** When the timer ends, place the test strip flat on a light (not white) surface and line it up in the frame. A countdown on screen shows the time left to scan. The app tells you if you need to align your test or move the strip onto a lighter or darker surface. Hold still when the app shows "Perfect! Please hold still". If the app shows the captured image, tap **Confirm image**, or **Retake image** to scan again. You have 1 minutes to scan.
5. **Review the result.** When the scan is analysed, tap **Review result**.
6. **Confirm the result.** For each parameter on the test strip (SG, pH, LEU, NIT, PRO, GLU, KET, UBG, BIL, Hb and COMP), the app shows an image of the pad and the indicated semi-quantitative result, with units where they apply. What you can do on this screen depends on how your organisation has configured the app. See Confirming results, below.
7. **Submit.** If you can change results, check that every parameter has a value and tap **Complete selections**, then tap **Accept and send**. The results screen shows the patient ID.
8. **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 Review screen shows the image of each parameter pad and the indicated result, with the Roche semi-quantitative value colour circled in green. Compare each pad with that colour and with your visual reading of the test strip. To change a value, tap the arrow to show the Roche standard colours and tap the colour that matches. Changed values are marked "Manual". You must select a value for any parameter highlighted in red. Then go to step 7.

If you can accept or reject results: the results screen lists the analysed result for each parameter, next to the image of its pad. If they match your visual reading of the test strip, tap **Accept and send** and go to step 8. If they don't, tap **Reject and retest**.

5. Results and messages

Each parameter is reported as a semi-quantitative value or level (for example NEG, NORM, POSITIVE, 2+, or a concentration shown on screen). 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 for each parameter (value and colour)	The reader's semi-quantitative reading of that parameter pad	If you can change results: confirm it, or tap the Roche standard colour that matches the pad to change it. If you can accept or reject: accept and send it if it matches your visual reading, or reject and retest if it doesn't
Parameter highlighted in red	A value for this parameter must be selected by the user	Tap the arrow to show the Roche standard colours and tap the colour that matches the pad
"Align your test"	The test strip is not lined up in the frame	Line the test strip up in the frame and hold your device steady
Background too dark – "Move strip onto a lighter surface"	The surface under the test strip is too dark for a good image	Move the test strip onto a lighter surface
Background too light – "Move strip onto a darker surface"	The surface under the test strip is too light for a good image	Move the test strip onto a darker surface
Scan failed – "Unfortunately, we were unable to catch that"	The image could not be captured	Tap **Retry scan**
Timed out – "Unfortunately the scan has timed out"	The time limit for scanning has passed	Tap **Start new test** and use a new test strip, or tap **Add results** (if enabled by your organisation) to enter the results manually by comparing the test strip with the Roche standard colours
Scan pending – "We have detected 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

Sensitivity: Consult the Roche Combur-10 UX Instructions for Use for information about the test strip's sensitivity.

Specificity: Consult the Roche Combur-10 UX Instructions for Use for information about the test strip's specificity.

Accuracy and precision: See below

Roche Combur10 UX Strip Reader running on the Cobas Pulse		Repeatability (within-run precision)		Urisys 1100	Reproducibility (intermediate/between-run precision)		Urisys 1100
Parameter	Control	Result	Percentage Agreement	Percentage Agreement	Result	Percentage Agreement	Percentage Agreement
SG	Control A	1.025	98.94%	100.00%	1.025	97.50%	82.50%
	Control D	1.005	100.00%	93.12%	1.005	100.00%	95.00%
pH	Control A	5	100.00%	99.47%	5	99.58%	99.17%
	Control D	8	100.00%	100.00%	8	100.00%	87.08%
LEU	Control A	neg.	99.47%	100.00%	neg.	100.00%	100.00%
	Control D	500	100.00%	99.47%	500	97.50%	93.33%
NIT	Control A	neg.	100.00%	100.00%	neg.	100.00%	100.00%
	Control D	pos.	100.00%	100.00%	pos.	100.00%	100.00%
PRO	Control A	neg.	100.00%	100.00%	neg.	100.00%	93.33%
	Control D	100	100.00%	97.88%	100	97.50%	100.00%
GLU	Control A	norm.	100.00%	100.00%	norm.	100.00%	99.17%
	Control D	1000	100.00%	100.00%	1000	100.00%	100.00%
KET	Control A	neg.	100.00%	100.00%	neg.	100.00%	97.92%
	Control D	150	100.00%	100.00%	150	99.58%	100.00%
UBG	Control A	norm.	100.00%	100.00%	norm.	100.00%	100.00%
	Control D	12	100.00%	100.00%	12	100.00%	100.00%
BIL	Control A	neg.	99.47%	100.00%	neg.	100.00%	97.08%
	Control D	3+(6mg/dL)	100.00%	100.00%	3+(6mg/dL)	100.00%	100.00%
Hb	Control A	neg.	100.00%	100.00%	neg.	99.58%	99.17%
	Control D	250	99.47%	100.00%	250	100.00%	100.00%

How the reading works: The reader samples the colour of each parameter pad on the Roche Combur-10 UX test strip and converts it into digital values. It uses the colour of the COMP pad to work out a white balance correction, and applies this correction to the colour of each parameter pad. A classifier then compares each corrected colour with a set of reference (ground truth) colours and selects the semi-quantitative result for each parameter. The results are then shown on screen.

7. Symbols and reporting serious incidents

These symbols appear on the App Info screen:

Symbol	Meaning
	Manufacturer
	EU authorised representative

Symbol	Meaning
	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

Very light or dark scanning backgrounds may introduce interference to ideal image capture. The Roche Combur10 UX Strip Reader will give feedback to the user in real time if it detects that the background is too dark or too light. For any warnings or limitations associated with the Roche Combur-10 UX test strip, please refer to the Instructions for Use for the test.