06762123001V2.0

Reflotron Clean + Check

REF	Σ	SYSTEM
11142577 196	16 wipes and 15 control strips	Reflotron

English

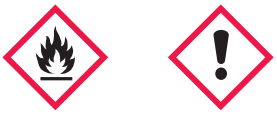
Intended use

Wipes and control strips for cleaning and checking the performance of the optical system of Reflotron instruments.

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

Avoid any contact with the application zone of a test strip (e.g., during pipetting of sample).



Danger

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.

Prevention:

P210	Keep away from heat/sparks/open flames/hot surfaces. — No smoking.
P233	Keep container tightly closed.
P240	Ground/bond container and receiving equipment.
P241	Use explosion-proof electrical/ventilating/lighting/equipment.
P242	Use only non-sparking tools.
P243	Take precautionary measures against static discharge.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash hands thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear gloves/clothing/eye/face protection.

Response:

P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P370 + P378	In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

Storage:

P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P403 + P235	Store in a well-ventilated place. Keep cool.
P405	Store locked up.

Disposal:

P501	Dispose of contents/container to an approved waste disposal plant.

Product safety labeling primarily follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

Cleaning and Quality checking

The measuring chamber and the optical system of the Reflotron instrument must be cleaned every 100 measurements or 7 days after the last cleaning. In case the instrument is visibly dirty, clean the measurement chamber regardless of the expiries indicated above.

For cleaning instructions please consult the Reflotron Manual. Instead of the moist wipes, any other soft, moistened non-linting cloth or moistened cotton buds may also be used for cleaning. In this case the instrument should be wiped dry afterwards. Use 70 % isopropanol for disinfection.

For more details on cleaning the instrument and and checking the optical system with Reflotron Check strip, follow the instructions in the Reflotron operator`s manual

- Switch off the instrument.
- Open the measuring chamber.
- Take the wipe out of its wrapper.
- Clean the upper heater, particularly the aperture.
- Clean the lower heater.
- Clean the magnetic head and the transporter.
- Check the correct position of the lower heater: springing, free-moving, parallel to the transporter surface.
- Allow to dry for at least 10 minutes.
- Close the measuring chamber.
- Check performance with Reflotron Check.

Checking the performance of the optical system

After every cleaning operation the optical system must be checked using Reflotron Check strip. Additional checks of the optical system should be performed as required by the individual laboratory. Each laboratory must set up quality assurance procedures to meet the accreditation criteria of the respective authorities.

Principle:

The Reflotron Check strip has a grey test area with a defined reflectance value. The back of the strip contains all the data necessary for the performance check in the form of a magnetic code. On insertion of the strip, the coded data are read into the instrument, and the Reflotron automatically switches into the check mode and measures the reflectance of the test area at three different wavelengths: red (642 nm), green (567 nm) and infrared (951 nm). The reflectances obtained are displayed per mille and are evaluated by means of comparison with the reference values specified on the container label.

Procedure:

Accurate results can only be obtained if Reflotron is used correctly. If necessary, consult the Reflotron manual and familiarize yourself with the operation of the instrument.

- Clean the optical system with a moist wipe or cotton bud as described.
- Switch on the Reflotron.
- Take a Reflotron Check test strip out of the container and close the container again immediately.

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- Do not touch or wipe the grey test area on the strip.
- Do not apply sample material to the grey test area.
- Insert the Reflotron Check strip into the instrument as for a normal test.
- Close the flap. - The display ”CHEK” confirms that the coded data have been read into the instrument.
- The remaining time before the result appears is displayed, e.g.: ”CHEK 73 sec”
- The result is displayed in the form of three three-digit values, e.g.: CHEK 647 648 642
- Compare each value with the reference ranges printed on the container label.
- If all three values are within the specified confidence limits, i.e. between the min. and max. values given on the label, the optical system is working properly.

The Reflotron Check control strip can be used up to 5 times, provided that the grey area is free from scratches. Used Reflotron Check strips should be stored separately from unused control strips. Scratched or soiled control strips should be discarded.

Values outside the confidence limits:

If one or more values are outside the specified confidence limits, proceed as follows:

1. Clean transporter and heater (see Reflotron Manual).
2. Let the instrument warm up for 10 minutes.
3. Repeat the measurement with a new, unused control strip. If the values displayed are still outside the confidence limits, please contact your nearest Roche Diagnostics office or authorized dealer.

Storage and stability

If stored at 2-30 °C the wipes and control strips may be used up to the expiry date printed on the pack, the control strip container or the wrappers of the wipes. After removal of a control strip, the container should be tightly closed again so that the control strips do not become unusable through exposure to outside influences.

Materials provided

- Isopropanol-moistened wipes and control strips with a grey test area of defined reflectance.

Expected values

The reference ranges (confidence limits) are printed on the label of the control strip container.

For further information, please refer to the appropriate operator’s manual for the analyzer concerned, and the Method Sheets of all necessary components.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

SYSTEM	Analyzers/Instruments on which reagents can be used
GTIN	Global Trade Item Number

Additions, deletions or changes are indicated by a change bar in the margin.

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