RIDA®QUICK IFX Monitoring Control Set

REF GP3041

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1. Intended use

For *in vitro* diagnostic use. The RIDA®QUICK IFX Monitoring Control Set is intended for the use with the corresponding, batch specific kit RIDA®QUICK IFX Monitoring (GN3041).

2. Summary and explanation of the test

RIDA®QUICK IFX Monitoring Control Set is used to check the test reagents and to perform the RIDA®QUICK IFX Monitoring (GN3041) test procedure. RIDA®QUICK IFX Monitoring Control Set is sold as a separate accessory for RIDA®QUICK IFX Monitoring and must be used with the lot-compliant RIDA®QUICK IFX Monitoring (GN3041).

3. Test principle

RIDA®QUICK IFX Monitoring Control Set is ready for use and can be used like a serum or plasma specimen.

4. Reagents provided

High control	1.2 ml	Lot-specific high positive control
Low control	1.2 ml	Lot-specific low positive control

The positive controls contain the therapeutic antibody infliximab. The high positive control has a concentration of approximately 6 µg/ml, and the low positive control a concentration of approximately 3 µg/ml. The exact specifications can be found in the respective certificate included with RIDA®QUICK IFX Monitoring Control Set. A result within this concentration range indicates proper function of the components and correct processing.

5. Storage instructions

RIDA®QUICK IFX Monitoring Control Set must be stored at 2 - 8 °C and may be used up to the expiration date printed on the product. After the expiration date, the quality guarantee is no longer valid. Non-specific stained or additional bands indicate possible expiration of the reagents.

6. Reagents required but not provided

Not included are RIDA®QUICK IFX Monitoring (GN3041) Kit and the required accessories.

7. Warnings and precautions for the users

Indicated for *in vitro* diagnostic use only. This test must be carried out only by trained laboratory personnel. The guidelines for working in medical laboratories must be followed. Always adhere strictly to the user instructions for carrying out this test. The reagents contain sodium azide as a preservative. This substance must not be allowed to come into contact with skin or mucous membranes.

8. Test procedure

Before using the product, bring the positive controls, the reagents contained in RIDA®QUICK IFX Monitoring (GN3041) Kit, and the test strips to room temperature (20 - 25 °C).
First dilute the high positive control High control and the low positive control Low control in sample diluent Sample diluent 1:50 (20 µl specimen + 980 µl sample diluent). In a separate reaction vial, mix 90 µl Reagent | A (blue liquid, bottle with blue lid) with 90 µl Reagent | B (yellow liquid, bottle with transparent lid). Pipette 20 µl of the diluted specimen solution into the 180 µl of the mixture of reagents A and B, which is equivalent to a further dilution of the sample of 1:10. Incubate at room temperature for 5 minutes, then apply 100 µl of each positive control diluted to 1:500 to a separate test cassette.
Incubate for 15 minutes. During that time, a band appears at the level of the test line labeled “T”. Another band appears at the level of the control line labeled “C”.

9. Quality control – indication of instability or deterioration of reagents

The test can only be evaluated, if the test cassette is unharmed and there are no color changes or lines present before applying the sample suspension. The control line (marked with C on the test cassette) has to show up in every test run. In case this band is missing, the following should be checked before repeating the test:
- Expiry date of the reagents and test cassette used
- Correct test procedure
- Contamination of reagents

If the control line is still not visible after repeating the test with a different test cassette contact the manufacturer or your local R-Biopharm distributor.

10. Evaluation and interpretation

The read out is performed on the RIDA®QUICK SCAN II (also see RIDA®QUICK SCAN II-manual).
The intensity of the test bands depends on the concentration of infliximab in the control samples used and on the incubation period. Only after the total run time of 15 minutes the final test result can be determined by using the RIDA®QUICK SCAN II.

The bands can change during the total incubation time and may also change after drying. The color of the band can vary from red to blue-violet/grey.

11. Version history

Version number	Chapter and description
2017-02-23	Release version
2018-07-11	General revision
2018-07-11	8. Test procedure

12. Explanation of symbols

General symbols

IVD	For in vitro diagnostic use
LOT	Lot number
	Expiry
	Store at
	Manufacturer

Test-specific symbols

High control	Lot-specific high positive control
Low control	Lot-specific low positive control