

RIDA®QUICK Clostridium difficile Toxin A/B Control | | | |---------|---| | Control | + | |---------|---|

Art. No.: NP0804



1. Intended use

For *in vitro* diagnostic use. The RIDA®QUICK Clostridium difficile Toxin A/B Control is intended for use in the corresponding RIDA®QUICK Clostridium difficile Toxin A/B rapid test (N0803).

2. Explanation

The RIDA®QUICK Clostridium difficile Toxin A/B Control is available as a separate accessory for the RIDA®QUICK Clostridium difficile Toxin A/B rapid test. It contains partly denaturated toxin. Prior to use, the positive control as well as the respective test-specific reagents (reagents, test cassettes) must be left to stand until they reach room temperature (20 - 25 °C). The test cassettes should be removed from their packages only briefly before they are required for use. Take care to avoid direct exposure to sunlight while performing the test. The toxin concentration in the control is corresponding to a low positive sample.

3. Test principle

The RIDA®QUICK Clostridium difficile Toxin A/B Control reacts specifically with the corresponding test cassette and after the end of the reaction yield the specifically coloured reaction bands (control- and test bands) described in the instructions for use.

4. Material provided

1 x RIDA®QUICK Clostridium difficile Toxin A/B Control (1.8 ml). Up to 18 control reactions can be carried out.

5. Material required but not provided

- Corresponding RIDA®QUICK Clostridium difficile Toxin A/B Kit (N0803).
- optional: test tubes and vortex blender

6. Precautions

The RIDA®QUICK Clostridium difficile Toxin A/B Control contains denaturated toxin A. This notwithstanding, the product should be treated as potentially toxigenic material.

7. Reagents and storage conditions

The RIDA®QUICK Clostridium difficile Toxin A/B Control must be stored at 2 -8 °C and can be used up to the expiry date printed on the vial. We do not guarantee for the product or results once the stated shelf-life has expired.

8. Indications of instability or reagent deterioration

Unspecifically coloured or additional bands indicate that the reagents may have degraded.

9. Preparing the positive control

The RIDA®QUICK Clostridium difficile Toxin A/B Control is ready to use. It must be handled analogously to a prepared stool sample.

10. Test procedure

Each 0,5 ml (ca. 12-14 drops) of reagent A and reagent B from RIDA®QUICK Clostridium difficile Toxin A/B Kit (N0803) are dropped in a reagent vial. 100 µl (ca. 2-3 drops) of positive control are added and mixed thoroughly. The next procedural steps must strictly follow steps 5 up to 9 as described in the instruction of the RIDA®QUICK Clostridium difficile Toxin A/B rapid test.

11. Interpretation of results

Beside the control line C also the test line T must be visible for valid result. Other constellation of visible lines means an invalid result. (see figure 3 in the instruction of the RIDA®QUICK Clostridium difficile Toxin A/B rapid test).

If only control line C appears, the positive control is declined.

If only test line appears or none of the lines, it may indicate a mistake in the test procedure or an deterioration of any of the test reagents. In such case it is advisable to repeat the test by using a new cassette.