RIDA®QUICK Giardia

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1. Intended use

For *in vitro* diagnostic use. The RIDA®QUICK Giardia is a quick immunochromatographic test for the qualitative determination of Giardia lamblia in stool samples.

2. Summary and explanation of the test

Giardia lamblia is an intestinal flagellate. The morphologically characteristic Trophozoites only survive for a short time outside the host organism. Transmission takes place via the highly infectious cysts. Because it is spread world-wide, Giardia lamblia has become an important cause of chronic diarrhoeas, particularly with the problems in travel medicine. The infection occurs after the ingestion of cysts in contaminated food and water. In communal facilities with inadequate hygiene, the infection usually occurs via the faecal-oral route from person to person. This mode of transmission is particularly common among children and in kindergartens, as well as among male homosexuals and inmates. The infection can also be passed on from the children to their parents. Unlike infants, older children who are infected can be free of symptoms. Nevertheless, they excrete the cysts and can infect other humans. The symptoms of Giardiasis (Lambliasis) are acute or chronic diarrhoea. The incubation time is between 3 and 42 days. The method most frequently use to diagnose Giardiasis in the past has been the detection by microscopy of cysts in the stool, which requires the services of experienced personnel. As well as this, the investigations have to be carried out over a long period of time because the excretion of cysts is subject to strong fluctuations. An important alternative method to microscopy for the detection of Giardia lamblia is the quick immunochromatographic test described in the following which, because it uses monoclonal antibodies, is equivalent to the microscopy investigation procedures in terms of sensitivity and specificity. The test is quick and simple to perform and does not require specially trained microbiologists to carry it out.

3. Test principle

The quick test is a single-step immunochromatographic lateral-flow test, where specific antibodies which are directed against Giardia lamblia attach themselves to red latex particles. Other specific antibodies against the pathogen are firmly bound to the membrane. The stool sample is first suspended in the extraction buffer and then precipitated. An aliquot portion of the clear supernatant of the sample is placed on the test strip. The sample with the coloured latex particles, to which antigen attach themselves if the test is positive, then pass through the membrane and is bonded to the specific catch band.

4. Reagents provided

There are enough reagents in the pack for 20 determinations.

Cassette	20 det.	20 individually packed test cassettes
Diluent	26 ml	Extraction buffer, ready for use; contains 0.1 % sodium azide
Pipet	25 ea..	Bag with 25 disposable pipettes

5. Storage instructions

The pack can be stored at 2 – 30 ℃ and can be used until the printed expiry date. After the expiry date, the quality guarantee is no longer valid. Likewise, the usability of the cassettes cannot be guaranteed once the external packaging of the individual cassette has been damaged.

6. Materials required but not provided

- Test tubes for stool suspension
- Vortex mixer (optional)
- Micropipette (200 µl - 1000 µl)
- Waste container containing 0.5 % sodium hypochlorite solution

7. Precautions for users

For *in vitro* diagnostic use only. This test must only be carried out by trained laboratory personnel. The guidelines for working in medical laboratories must be followed and the instructions for carrying out the test must be strictly adhered to.

The sample dilution buffer contains sodium azide as a preservative. This substance must not be allowed to come into contact with the skin or mucous membrane.

Samples or reagents must not be pipetted by mouth and contact with injured skin or mucous membranes must be prevented. When handling the samples, wear disposable gloves and when the test is finished, wash your hands. Do not smoke, eat or drink in areas where samples or test reagents are being used.

All reagents and materials which come into contact with potentially infectious samples must be treated exactly like the samples themselves with suitable disinfectants (e.g. sodium hypochlorite) or autoclaved for at least one hour at 121 ℃.

8. Specimen collection and storage

Stool samples must be collected in clean containers without any additives and stored at 2 – 8 ℃ before beginning the test. If stored for m ore than 3 days, the sample must be frozen at –20 ℃. In this case, the sample must be completely thawed out and brought to room temperature before testing begins. Multiple freezing and thawing of the sample must be avoided.

If rectal swabs have to be used, make sure that sufficient stool material (approx. 50 mg) is collected to carry out the test.

9. Test procedure

9.1. General information

Before using the samples, the extraction buffer and the test cassettes must be brought to room temperature (20 – 25 ℃). The test cassettes must o nly be removed from the external packaging shortly before they are used. Once used, the cassettes must not be used again. The test must not be carried out in direct sunlight.

Do not pour reagents back into vials as this may cause reagent contamination.

9.2. Preparing the samples

Place 1 ml Extraction Buffer Diluent in the test tubes indicated. With the **liquid** stool sample, pipette 100 µl of the sample with a disposable pipette Pipet (up to just above the second thickening) and suspend it in the buffer placed in the tube beforehand. With **solid** stool samples, suspend 50 mg in the buffer. The sample must then be well homogenised. This can be achieved either by repeated suction and ejection of the suspension using the disposable pipette Pipet or, alternatively, by mixing on a vortex mixer. Afterwards, allow the homogeneous suspension to settle for at least **3 minutes** until a clear supernatant is formed.

9.3. Testing the sample

When removed from the external packing, first lay the test cassette on a level mat. After this, pipette 200 µl of the clear supernatant of the stool suspension with a micropipette or 4 drops with a disposable pipette Pipet into the round opening of the test cassette. Makes sure that the liquid flows through the membrane unimpeded. Any particles pipetted at the same time can cause an obstruction and must be removed beforehand. The test result can be read off after **5 minutes**.

10. Quality control – indications of reagent expiry

The test must only be evaluated if the test cassette is intact **before** the sample suspension is pipetted in and no colour changes or bands are visible on the membrane. In addition to this, at least the blue control band must be visible **after** the test incubation. If this does not appear, the following must be checked before repeating the test:

- Expiry date of the test cassettes and the extraction buffer being used
- Correct test procedure
- Contamination of the extraction buffer

After this, if the control band is still not visible after repeating the test with a new test cassette, please contact the manufacturer.

11. Evaluation and interpretation

A maximum of two bands should appear, in the following order as seen from the sample-absorption site: one red test band and one blue control band. **If the blue control band is missing, the test is invalid and cannot be evaluated!**

The following interpretations are possible:

- **Giardia positive:** the **red** and **blue** bands are visible.
- **Giardia negative:** only the **blue** band is visible.
- **Not valid:** no visible band or a combination other than the one described above or other changes in band colour. Likewise, changes in band colour which only appear after 10 minutes or later are also without any diagnostic value and must not be used for evaluation.

12. Limitations of the method

The RIDA®QUICK Giardia test detects antigens of Giardia lamblia in stool samples. The test cannot be used to derive a relationship between the intensity of the specific visible bands and the occurrence or severity of clinical symptoms. **The results obtained must always be interpreted in combination with the clinical picture.**

A **positive** result does not rule out the presence of another infectious pathogen.

A **negative** result does not necessarily mean that there is no Giardia lamblia infection. This can be caused by intermittent excretion of the pathogen or by the quantity of antigens in the sample being too small. If the patient is anaemic or is suspected as being infected by the pathogen being looked for, another stool sample should be tested after four weeks.

An excess of stool sample can cause brownish bands to appear instead of the specifically coloured bands. These brownish bands do not have any diagnostic value. In such cases, it will be necessary repeat the test with a smaller stool quantity or dilute the suspension already prepared further (clear supernatant after sedimentation) in order to clarify whether the pathogen being looked for is in the sample and has been masked by too much stool matrix.

13. Performance characteristics

13.1. Clinical comparison study

In a routine laboratory, a comparative investigation was carried out between the RIDA®QUICK Giardia method and the established microscopy method on both frozen and fresh stool samples using 55 stool samples in total (and 15 Giardia lamblia positive as well as 40 negative stool samples). The results are listed in Table 1.

Table 1: Comparison of RIDA®QUICK Giardia with microscopy

		RIDA®QUICK Giardia	
		+	**-**
Microscopy	**+**	15	0
	-	2	38

Sensitivity:	**100.0 %**	**pos. prognosis value:**	**88.2 %**
Specificity:	**95.2 %**	**neg. prognosis value:**	**100.0 %**

13.2. Cross reactivity

None that led to a cross reaction in the following specified intestine parasites in the RIDA®QUICK Giardia:

Entamoeba coli
Blastocystis hominis
Jodamoeba buetschlii
Chilomastix mesnili
Endolimax nana
Eggs of Taenia spp.
Cryptosporidium parvum

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