

RIDA® CCD-Inhibitor

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1. Intended use

For *in vitro* diagnostic use. The RIDA® CCD-Inhibitor is an accessory for RIDA® qLine Allergy tests for inhibiting anti-CCD IgE in human serum and plasma (citrate). The product does not detect disease; it is used for sample preparation. The product is intended for professional use.

2. Summary and explanation of the test

The RIDA® CCD-Inhibitor is offered as separate accessory for the RIDA® qLine Allergy.

A type I allergy is caused by the formation of specific IgE antibodies against allergens. Most allergens are proteins with a molecular weight of 50 - 500 kDa, but even small molecules like drugs (haptens) can become whole allergens when combined with a protein.

In eukaryotic organisms, most proteins are glycosylated under translational conditions and, therefore, have carbohydrate side chains.

The immune system develops IgE antibodies also against these carbohydrate side chains (cross-reactive carbohydrate determinants, CCDs), which are usually of plant origin.

The IgE antibodies targeting these CCDs also lead to cross-reactions with unrelated proteins that very probably do not have clinical relevance and, therefore, do not cause allergic symptoms. Since these antibodies produce positive results in laboratory tests, however, the positive results must be considered false-positives. In order for true-positive results to be correctly distinguished from false-positive results, the anti-CCD IgE antibodies must be inhibited so that they cannot bind with the CCDs in the laboratory test.

The occurrence of many positive reactions in the individual allergen test system is an indication of cross-reactions that could be caused by anti-CCD IgE antibodies. In these cases, the serum needs to be treated with the RIDA® CCD-Inhibitor, and the test needs to be repeated. The RIDA® CCD-Inhibitor is used for the pretreatment of samples for RIDA® qLine Allergy.

3. Test principle

The RIDA® CCD-Inhibitor binds to the variable region of the IgE antibodies, preventing the antibodies from binding to the carbohydrate side chains of the allergens in the test system.

4. Reagents provided

Table 1: Reagents provided

Kit components	Amount	Description
CCD-Inhibitor	5 x 44 µg (5 x 5 tests)	CCD inhibitor, lyophilized

5. Storage instructions

Please follow the handling guidelines in Table 2 and store the kit directly after use according to the information specified. After the expiration date has passed or the recommended storage period of the opened reagents has elapsed, the quality guarantee is no longer valid.

Table 2: Storage conditions and information

	Storage temperature	Maximum storage time	Additional notes on storage
unopened	2 - 8 °C	Can be used until the printed expiration date	-
opened	2 - 8 °C	≤ 2 weeks	Store in a refrigerator immediately after use. Microbial contamination must be prevented.

6. Reagents required but not provided

6.1 Reagents

Product	Item no.
RIDA qLine® Allergy	A6142, A6142BY, A6142EAWU, A6142EC2, A6142HVEN, A6142PSMI, A6142UY, A6142UZ, A6142VIET, A6142ZW2, A6242, A6242BY, A6242EAWU, A6242GR, A6242H, A6242PA, A6242PH, A6242UY, A6342, A6342BY, A6342EAWU, A6342KE, A6342MENA, A6342PH, A6342UY, A6442, A6442BY, A6442EAWU, A6442TZA, A6442UA1, A6442UA2, A6442UZ, AW2001, AW2002, AW2003, AW2004

6.2 Laboratory equipment

Product
Sample tubes
Vortex mixer
Micropipettes for volumes of 10 µL, 55 µL, and 400 µL

7. Warnings and precautions for the users

This test must be carried out only by qualified laboratory personnel.

The guidelines for working in medical laboratories must be followed. Always adhere strictly to the operating manual when carrying out this test. Do not pipette samples or reagents using your mouth. Avoid contact with broken skin and mucous membranes. Wear personal protective equipment (appropriate gloves, lab coat, safety glasses) when handling reagents and samples, and wash hands after completing the test. Do not smoke, eat, or drink in areas where samples are handled.

Hazardous materials are indicated according to labeling obligations.

Further details on the Safety Data Sheet (SDS) can be found under the item number at <https://clinical.r-biopharm.com/search/>.

Users are responsible for the proper disposal of all reagents and materials after use. For disposal, please adhere to national regulations.

The reagent must not be used if the bottle is damaged or has a leak.

The reagents in the kit were tested for HIV and HCV ABs and for HBsAg, and were found to be negative. Still, they should be treated as potentially infectious, as should the patient samples and all materials that come into contact with them, and they should be handled according to the respective national safety regulations.

For users in the European Union: Report all serious adverse events associated with the product to R-Biopharm AG and the appropriate national authorities.

8. Test procedure

Before use, bring the reagents to room temperature (20 - 25 °C). Remove the test tube from the refrigerator and let it sit for approximately 30 minutes until it reaches room temperature (RT).

- Pipette 55 µL H₂O into the test tube and vortex thoroughly for 30 seconds.
- Centrifuge briefly to ensure that no liquid remains in the lid.
- Pipette 10 µL of the dissolved RIDA® CCD-Inhibitor into 400 µL serum or plasma (citrate) and shake.
- Incubate for one hour at RT under shaking.

The treated serum or plasma must be tested on RIDA qLine® Allergy test immediately after incubation.

9. Quality control – Indication of instability or expiration of reagents

For CCD-positive samples, the signal of the CCD lines on the RIDA qLine® Allergy must be reduced to < 1.00 RAST. For allergens without known CCD cross-reactivity, the result should not deviate by more than 1.0 RAST after addition of the inhibitor.

If the specified values are not met, check the following items before repeating the test:

- Expiration date of the reagents used
- Functionality of the equipment being used (e.g., calibration)
- Correct test procedure
- Visual inspection of the kit components for contamination or leaks

If the conditions are still not fulfilled after repeating the test, please consult the manufacturer or your local R-Biopharm distributor.

10. Evaluation and interpretation










The RIDA® CCD-Inhibitor is intended for sample preparation. Evaluation and interpretation are done using RIDA qLine® Allergy.

11. Version history

Version number	Section and designation
2019-12-02	Previous version
2022-04-11	General revision <ol style="list-style-type: none">1. Intended use2. Summary and explanation of the test3. Test principle4. Reagents provided5. Storage instructions6. Reagents required but not provided7. Warnings and precautions for the users8. Test procedure9. Quality control – Indication of instability or expiration of reagents10. Evaluation and interpretation

12. Explanation of symbols

General symbols

	For in vitro diagnostic use
	Observe operating manual
	Batch number
	Use before
	Storage temperature
	Item number
	Number of tests
	Date of manufacture
	Manufacturer

13. References

1. Holzweber F, et al. Inhibition of IgE binding to cross-reactive carbohydrate determinants enhances diagnostic selectivity. *Allergy*. 2013; 68(10): 1269-1277. doi:10.1111/all.12229
2. Jin, Chunsheng & Hantusch, et al. Affinity of IgE and IgG against cross-reactive carbohydrate determinants on plant and insect glycoproteins. *The Journal of allergy and clinical immunology*. 2008; 121. 185-190.e2. 10.1016/j.jaci.2007.07.047