IFA SORBENT

REF S002 Σ 100

CE For *in vitro* diagnostic use

INTENDED PURPOSE

IFA SORBENT is intended to be used as an aid for IgM or IgA immunoassays using VIRCELL IFA kits (IgM or IgA), and following the indications of the kit.
Anti-human IgG (Fc specific) serum developed in goat, aimed to capture human IgG to avoid interferences in IgM or IgA assays.

MATERIALS PROVIDED

[7] VIRCELL ANTI HUMAN IgG GLOBULIN (SORBENT): 2 x 1.5 ml sorbent. Contains sodium azide as a preservative. Contains material of animal origin.

STORAGE AND HANDLING CONDITIONS

Store at 2-8°C. Do not use the kit reagents beyond the expiration date. This will be valid only if reagents are stored closed and at 2-8°C.

IN-USE STABILITY

VIRCELL ANTI HUMAN IgG GLOBULIN (SORBENT): Refer to package label for expiration date (at 2-8°C).
Discard if a cloudy appearance develops before use. Once the sorbent gets in contact with the samples, a visible immunoprecipitate is to be expected, corresponding to the removed IgG.
VIRCELL, S.L. does not accept responsibility for the mishandling of the reagents included in the kit.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only. For professional use only.
2. Clean pipette tips must be used for every assay step. Use only clean, preferably disposable material.
3. Never pipette by mouth.
4. Do not use in the event of damage to the package.
5. Do not use the kit after expiration date.
6. Handle in aseptic conditions to avoid microbial contaminations.
7. Use only the amount of product required for the test. Do not return the excess solution into the vial.
8. Only use with IFA VIRCELL kits.
9. This product includes a substance of animal origin. Although it is controlled in its origin, the product and all assay material should be handled and disposed as potentially infectious. No present method can offer complete assurance that infectious agents are absent. Observe the local regulations for clinical waste disposal.
10. Any serious incident that occurs in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

INTERNAL QUALITY CONTROL

Each batch is subjected to internal quality control (Q.C.) testing before batch release. Final Q.C. results for each particular lot are available.

VALIDATION PROTOCOL FOR USERS

Ensure that the sorbent addition to the sample produces an immunoprecipitate visible to the naked eye; otherwise, it would be convenient to perform the following validation assay:
Perform two IgG assays in parallel using at least 5 known positive sera, the first assays with non-treated sera and the second one with IFA SORBENT treated sera. At least 80% of the treated samples should turn to negative. Otherwise, the sorbent and the test results should be discarded. Contact your supplier or VIRCELL, S.L. technical service.

SYMBOLS USED IN LABELS

IVD	*In vitro* diagnostic medical device
	Use-by (expiry date)
Y°C / X°C	Store at x-y °C
Σ n	Contains sufficient for <n> test
LOT	Batch code
REF	Catalogue number
	Consult instructions for use
	Manufacturer

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