Instructions for use

Diagnostic test kit

INFLAEYEZ®

REF IE100

Kit for the identification of bacterial etiology of ocular surface inflammation. The kit is intended for professional users.

DESCRIPTION: The INFLAEYEZ® diagnostic kit by 4EYEZ Solutions Sp. z o.o. consists of diagnostic strips and disposable, sterile swabs. The diagnostic strips contain a reaction field with reagents for the determination of granulocyte esterase levels in conjunctival secretions. Granulocyte esterase is mainly produced by neutrophil granulocytes in response to inflammation caused by bacteria. The diagnostic kit is intended exclusively for the professional in vitro diagnosis of conjunctival discharge.

PREPARATION FOR TESTING: To test, remove one diagnostic strip from the plastic container of diagnostic strips and place it on a flat surface with the reaction window facing up.

COLLECTING THE CONJUNCTION BAG: Conjunctival sac secretions should be collected using the disposable, sterile swab provided in the diagnostic test package. The immediate packaging of the swab should be opened from the side opposite the swab collection tip. Once the swab is removed from the immediate packaging, avoid touching any other objects, especially the end intended for collection from the conjunctival sac. After tilting the lower eyelid, collect the secretions there. When collecting material from the conjunctival sac, avoid directly touching the surface of the eye with the swab.

PROCESSING THE TEST: Swab the conjunctival sac and place it on the reaction field which is located on the diagnostic strip. After placing the conjunctival swab on the reaction field, wait approximately 30-60 seconds to read the test result.

TEST READING: Compare the degree of colour in the reaction field with the result interpretation on the label of the INFLAEYEZ® diagnostic strips container. If granulocyte esterase is present in the conjunctival sac aspirate, the reaction field is coloured purple, the intensity of which is proportional to the amount of granulocyte esterase in the aspirate. If there is a significant amount of granulocyte esterase in the specimen, the reaction box will turn purple or dark purple (degree of staining + and ++). This indicates a bacterial aetiology of ocular surface inflammation. If granulocyte esterase is absent or present in small amounts in the collected material, the reaction field will not change colour or will be pale violet (degree of colour 0 and +/-). This means that the ocular inflammation is caused by inflammatory factors other than bacteria. In the case of a small amount of material taken from the conjunctival sac, in order to read the test result correctly, the change in colour of the reaction field at the

site where the material was placed must be assessed. Topical medications or medical devices such as eye drops, gels or ointments may interfere with the test result. It is recommended to perform the test at least 30 minutes after their last administration. The test can be repeated as long as a new diagnostic strip and swab are used.

STORAGE AND HANDLING OF STRIP TESTS: Diagnostic strips should be stored at 2°C to 30°C. Protect diagnostic strips and swabs from light, moisture and heat. Use diagnostic strips after opening the immediate packaging. Discard used diagnostic strip and swab after testing.

CAUTIONS: Avoid direct contact between the diagnostic strip and the reaction area and the ocular surface. Discard diagnostic strip and swab once used. The sterile swab should be used immediately after opening the immediate packaging. Do not use after the expiry date. Expiry dates of diagnostic strips and swabs are located on the immediate packaging.

CONTENTS OF THE PACKAGE: Plastic bag with diagnostic strips 100 pcs, individually packed sterile swabs 100 pcs, instructions for use.

MANUFACTURER OF DIAGNOSTIC STRIPS
AND ASSEMBLY

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More information: www.inflaeyez.com
Patent pending.
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