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Title: Bioline™ HCV		

Part II. Components Specification

1. Introduction
2. List of Components

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1. Introduction

Listed below is the full set of kit components required for the Bioline™ HCV rapid assay

2. List of Components

Catalogue number	02FK10	02FK11	02FK16	02FK17
Product kit size (number of tests per kit)	30 tests/kit	100 tests/kit	25 tests/kit	25 tests/kit
Test device individually packed in foil pouch with a desiccant	30 test devices	100 test devices (10 tests multi-device*10)	25 test devices	25 test devices
Assay diluent	1 x 5ml/vial	2 x 8.5ml/vial	1 x 5ml/vial	1 x 5ml/vial
Specimen transfer device Capillary pipettes (10µl)	N/A	N/A	25 ea	25 ea
Lancet Disposable, sterile	N/A	N/A	25 Sterile lancets	25 Safety lancets
Alcohol swab	N/A	N/A	25ea	25ea
Instructions for use	1 copy	1 copy	1 copy	1 copy

2.1 Bioline™ HCV Devices and Strips

2.1.1 Characteristic

Nitrocellulose-based membrane pre-coated with HCV specific recombinant antigen (core, NS3, NS4, and NS5).

2.1.2 Number of Devices


[Device, Multi-device type]

30 tests/kit – 1 devices/pouch x 30 (02FK10)

100 tests/kit – 10 multi-devices/pouch x 10 (02FK11)

25 tests/kit – 1 devices/pouch x 25 (02FK16)

25 tests/kit – 1 devices/pouch x 25 (02FK17)

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2.1.3 Composition

Gold conjugates : Protein A – gold colloid	1 ±0.2 µg
Test Line : recombinant HCV antigen (core, NS3, NS4, NS5).....	1.5 ±0.3 µg
Control Line : Goat anti-human Immunoglobulin	2 ±0.4 µg
Nitrocellulose membrane	25±5 x 4.5±0.9 mm
Conjugate pad	7±1.4 x 4.5±0.9 mm
Sample pad.....	18±3.6 x 4.5±0.9 mm
Absorbent pad	18±3.6 x 4.5±0.9 mm
Plastic cassette	

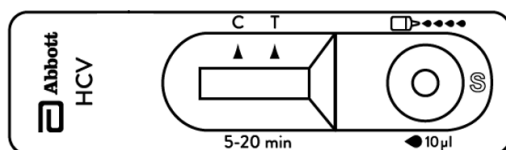
2.1.4 Biological action

The antigenic proteins on the membrane will react specifically with the HCV antibodies present in human serum, plasma or whole blood. Protein A-gold colloid will react specially with human IgG present in human serum, plasma or whole blood.


2.1.5 Appearance

[Device, Multi-device type]

The Bioline™ HCV test device has a letter of T and C as “Test Line” and “Control Line” on the surface of the case. Both the “Test Line” and “Control Line” in result window are not visible before applying any samples. The “Control Line” is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. A purple “Test Line” will be visible in the result window if there are enough antibodies against HCV in the sample. If antibodies against HCV are not present or are present at very low levels in the sample, there is no color appears in “Test Line”.



1 test device

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10 tests multi-device

2.2 Assay Diluent

2.2.1 Characteristic

Contains sodium azide as preservative.

2.2.2 Number of Bottle and Fill Volume

30 tests/kit – 5 ml / dropping bottle x 1

100 tests/kit – 8.5 ml / dropping bottle x 2

25 tests/kit – 5 ml / dropping bottle x 1

2.2.3 Composition

50 mM Tris-HCl Buffer5 ml(30 tests/kit or 25 tests)

8.5ml(100 tests/kit)


Sodium azide..... 0.02 %

2.2.4 Biological action

It is used as a diluent and developing agent.

2.2.5 Appearance

Colourless or slight yellow color, free of particulate matter.

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2.3 Other kit components and materials provided

2.3.1 Specimen transfer device



25 tests/kit (02FK16, 02FK17) – 25 pieces/pack

2.3.2 Lancet

(1) Sterile lancet



25 tests/kit (02FK16) – 25 pieces/pack

(2) Safety lancet

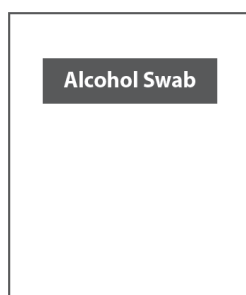


or



25 tests/kit (02FK17) – 25 pieces/pack

2.3.3 Alcohol swab



25 tests/kit (02FK16, 02FK17) – 25 pieces/pack