

TESTING HEPATITIS C

Understanding IVD kit

In vitro diagnostic IVD test kit consists of materials used to determine the outcome of a given test. Laboratories use a variety of methodologies to test the countless chemical substances that are of interest to healthcare professionals and patients.

Find out how an IVD kit is used to test for Hepatitis C.

When testing for Hepatitis C, a laboratory method, namely, polymerase chain reaction (PCR) is used to amplify a single copy or a few copies of a piece of DNA.

What does a Hepatitis C test kit contain?

Cassette 1 contains Magnetic Glass Particles (MGPs) used during the nucleic acid isolation and purification process.

Cassette 2 contains Lysis Reagent used to extract the nucleic acids.

UserManual is included.

Cassette 3 contains proteinase solution (pase) used to break down proteins during the isolation process.

Cassette 4 contains several items:

- A) The **Internal Control** confirms whether the test is performing properly.
- B) **PCR master mixes** provide the key ingredients necessary for performing PCR.
- C) The **Manganese Solution** necessary for running the PCR reaction.

CONTROLS

- Positive controls contain the same components as the sample.
- Negative Controls contain everything but the template DNA.



How is the test performed?

1 Denaturation at 94-96°C

The first step or cycle of PCR is to separate the strands of DNA into two single strands by increasing the temperature of the sample that contains the DNA of interest. This is called 'denaturing' the DNA.

2 Annealing at ~68°C

Once the strands separate, reverse primers are added and allowed to bind to the single DNA strands. Primers are short sequences of DNA made specifically to recognize and bind to the target to be amplified, which are the very specific sequence of bases that are part of the gene or genes of interest.

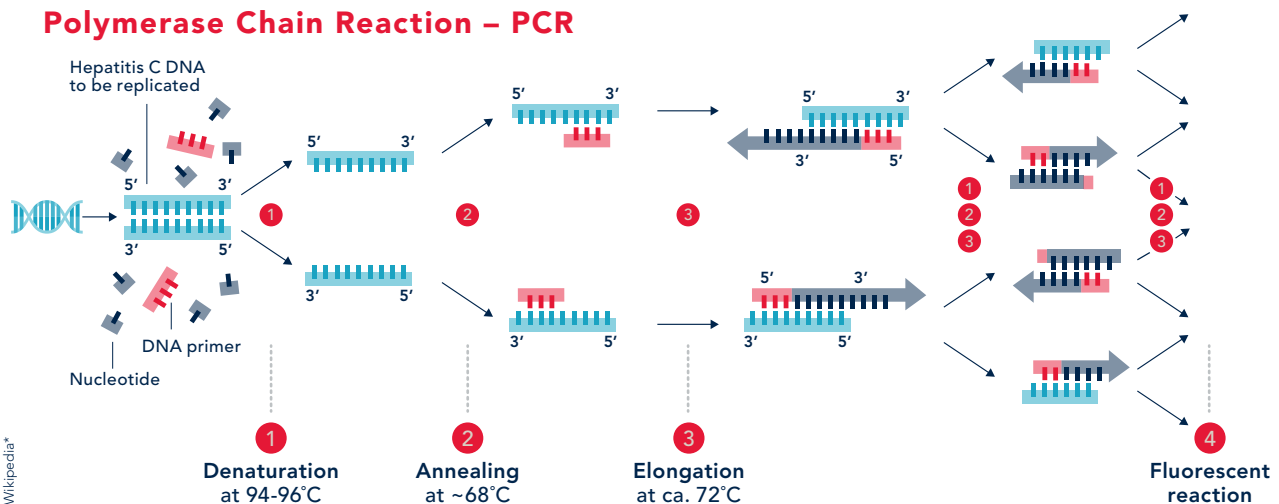
3 Elongation at ca. 72°C

Once the two primers attach to each strand of the DNA, the primers and polymerase act to make four double strand sections. The four strands becomes eight in the next cycle, eight become sixteen, and so on.

4 Fluorescent reaction

A fluorescent reaction takes place, enabling the laboratory professional to make an informed decision; in turn providing the doctor the data needed to prescribe treatment.

Polymerase Chain Reaction – PCR



— United States Centers for Disease Control and Prevention —

"The only way to know if you have Hepatitis C is to get tested. Early detection can save lives."

— About Hepatitis C —



Hepatitis C is a liver disease caused by the Hepatitis C virus: the virus can cause both acute and chronic hepatitis infection, ranging in severity from a mild illness lasting a few weeks to a serious, lifelong illness.



**130-150
MILLION PEOPLE**

130-150 million people globally have chronic Hepatitis C infection.



**30,607
PEOPLE IN EU**

In 2012, 30,607 cases of Hepatitis C were reported in 27 EU countries.

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Sources: – World Health Organization, Hepatitis C, Factsheet No 164, April 2014 www.who.int/mediacentre/factsheets/fs164/en
– *Wikipedia, polymerase chain reaction (PCR), www.en.wikipedia.org/wiki/Polymerase_chain_reaction
– Lab Tests Online, Laboratory Methods, polymerase chain reaction (PCR), www.labtestsonline.org/understanding/features/methods/start/5
– European Centre for Disease Prevention and Control, Hepatitis C: www.ecdc.europa.eu/en/healthtopics/hepatitis_C/Pages/index.aspx