

SOP - Criteria for Acceptable HCV Antibody Test and PCR

Test

A person claimed to be an HCV Infected Person must have either an HCV Antibody Test or a PCR Test to qualify for compensation. An HCV Antibody Test alone qualifies a person at Level 1. A PCR Test alone qualifies a person at Level 2. Either test coupled with the medical evidence called for at Levels 3-6 qualifies the person at that level.

1. HCV Antibody Test

This tests identifies the presence of antibodies to HCV in the blood of a person. It reveals whether or not the person has ever been infected with HCV. It does not reveal whether or not the person is currently infected with HCV.

1) Types of HCV Antibody Tests:

- 1) enzyme-linked immunosorbent assay ("ELISA" or "EIA")
- 2) recombinant immunoblot assay ("RIBA")

Many test forms will describe an HCV Antibody Test as "Anti-Hepatitis C Virus".

2) Generations of HCV Antibody Tests

- 1) First Generation - 1989-1990
- 2) Second Generation - 1991-1996
- 3) Third Generation - 1997 and after

3) Acceptable HCV Antibody Tests

HCV Antibody tests usually read "positive" or "reactive" when the antibodies are present in the blood. The tests usually read "negative" or "non-reactive" when there are no antibodies present. When the test is non-conclusive for the presence of antibodies, the tests usually read "discordant", "indeterminate", "inconclusive" or "weakly reactive".

- 1) First Generation ELISA or EIA confirmed or supplemented by a RIBA performed in a Canadian laboratory revealing the presence of antibodies.
- 2) Second Generation ELISA or EIA confirmed or supplemented by a RIBA performed in a Canadian laboratory revealing the presence of antibodies.
- 3) Third Generation ELISA or EIA or RIBA performed in a Canadian laboratory revealing the presence of antibodies.

4) Circumstances Requiring Further Analysis or Testing

- 1) If the Person claimed to be an HCV Infected Person is deceased and had a First Generation or Second Generation test that was not confirmed or supplemented by a RIBA, and did not have an acceptable PCR test, a microbiologist will be consulted for his or her opinion as to whether it is more likely than not that the test reveals the presence of antibodies, unless the Administrator is of the view that the medical evidence submitted other than the Antibody test demonstrates conclusively that the Person claimed to be an HCV Infected Person was infected with HCV.
- 2) If the Person claimed to be an HCV Infected Person is alive and had a First Generation or Second Generation test that was not confirmed or supplemented by a RIBA, and does not have an acceptable PCR test, the Person claimed to be an HCV Infected Person will be required to submit an acceptable test unless the Administrator is of the view that the medical evidence submitted other than the Antibody test demonstrates conclusively that the Person claimed to be an HCV Infected Person is or was infected with HCV.
- 3) If the Person claimed to be an HCV Infected Person is alive and the antibody test results are not positive or reactive but they read “indeterminate”, “inconclusive”, “weakly reactive” or “discordant”, and the person does not have an acceptable PCR test, a microbiologist should be consulted to determine if the test result can be interpreted to be more likely positive than negative, or if retesting will assist. If the microbiologist is of the opinion that retesting may assist, the Person claimed to be an HCV Infected Person will be required to submit an acceptable test unless the Administrator is of the view that the medical evidence submitted other than the Antibody test demonstrates conclusively that the Person claimed to be an HCV Infected Person is or was infected with HCV.

2. PCR Tests

A polymerase chain reaction “PCR” test reveals the presence of the virus in the blood. This demonstrates ongoing infection with HCV.

1) Types of Tests

1. The testing methodology is most commonly referred to as PCR but it may also be called RNA detection (ribonucleic acid) or NAT (nucleic acid testing).
2. The commercial assays most commonly used are Roche or Amplicor.

2) Acceptable PCR Tests

A PCR tests usually uses the words “detected” or “detectable” or “present” or “positive” to indicate that the test reveals the presence of the virus. A PCR test report usually uses the words “not

present”, “undetectable” , “undetected” , “not detected” or “negative” to indicate the test did not reveal the presence of the virus.

1. A test dated January 1, 1998 later performed at any Canadian laboratory indicating the presence of the virus.
2. A test performed by the laboratory designated to do PCR testing for the Administrator (“Designated PCR Lab”) indicating the presence of the virus.

3) Tests Requiring Further Analysis or Testing

1. If the Person claimed to be an HCV Infected Person is deceased and had a PCR test dated 1998 or earlier, and the application is made at Level 2, a microbiologist will be consulted for his or her opinion as to whether the test is sufficiently reliable to accept as more likely than not demonstrating the presence of the virus in the blood.
2. If the Person claimed to be an HCV Infected Person is deceased and had a PCR test dated 1998 or earlier, and the application is made at Level 3 or above, a microbiologist will be consulted for his or her opinion as to whether the test is sufficiently reliable to accept as more likely than not demonstrating the presence of the virus in the blood, unless the Administrator is of the view that the medical evidence submitted other than the PCR test demonstrates conclusively that the Person claimed to be an HCV Infected Person had ongoing infection with HCV.
3. If the Person claimed to be an HCV Infected Person is alive and had a PCR test dated 1998 or earlier and is applying at Level 2, the person will be required to submit an acceptable PCR Test and will be encouraged to undergo retesting through the Designated PCR Lab.
4. If the HCV Infected Person is alive and had a PCR test prior to January 1, 1998 or earlier and is applying at Level 3 or above, the person will be required to submit an acceptable PCR Test and will be encouraged to undergo retesting through the Designated PCR Lab unless the Administrator is of the view that the medical evidence submitted other than the PCR test demonstrates conclusively that the HCV Infected Person has ongoing infection with HCV.