HCV ANTIBODY AND PCR TESTS PROTOCOL

1.01 A person must have either an HCV Antibody Test or a PCR Test to qualify for compensation as an HCV Infected Class Member. An HCV Antibody Test qualifies a person at Level 1. A PCR Test qualifies a person at Level 2. Either test coupled with the medical evidence called for at Levels 3-6 qualifies the person at the appropriate level.

HCV Antibody Tests

2.01 The HCV Antibody Test identifies the presence of antibodies to HCV in the blood which reveals whether the person has ever been infected with HCV. It does not reveal whether the person is currently infected with HCV.

2.02 The types of HCV Antibody Tests are:

a. enzyme-linked immunosorbent assay ("ELISA" or "EIA"); and

b. recombinant immunoblot assay ("RIBA").

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

2.04 The generations of HCV Antibody Tests and the years they are/were in use are:

a. First Generation -1989-1990;

b. Second Generation -1991-1996; and

c. Third Generation -1997 and after.

2.05 The following HCV Antibody Test results will be accepted by the Administrator as proof that the person was infected with HCV at one time:

a. a First Generation ELISA or EIA which is confirmed or supplemented by a RIBA performed in a Canadian laboratory which reveals the presence of antibodies;

b. a Second Generation ELISA or EIA which is confirmed or supplemented by a RIBA performed in a Canadian laboratory which reveals the presence of antibodies; or

c. a Third Generation ELISA or EIA or RIBA performed in a Canadian laboratory which reveals the presence of antibodies.

Where any of these tests were performed in a laboratory outside Canada, that laboratory must be acceptable to the Administrator, in consultation with a microbiologist.

2.06 HCV Antibody Tests usually read "positive" or "reactive" when the antibodies are present in the blood. HCV Antibody Tests usually read "negative" or "non-reactive" when there are no antibodies present. When the HCV Antibody Test is non-conclusive

for the presence of antibodies, the tests usually read “discordant”, “indeterminate”, “inconclusive” or “weakly reactive”.

2.07 The Administrator may require the following additional analysis or testing in the following circumstances:

a. if the person is deceased and had a First Generation or Second Generation HCV Antibody 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/her opinion as to whether it is more likely than not that the HCV Antibody Test reveals the presence of antibodies unless the Administrator is of the view that the medical evidence submitted other than the HCV Antibody Test demonstrates conclusively that the person was infected with HCV; or

b. if the 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 will be required to submit an acceptable HCV Antibody Test unless the Administrator is of the view that the medical evidence submitted other than the HCV Antibody Test demonstrates conclusively that the person is or was infected with HCV; or

c. if the person is alive and the HCV 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 will 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 will be required to submit an acceptable HCV Antibody Test unless the Administrator is of the view that the medical evidence submitted other than the HCV Antibody Test demonstrates conclusively that the person is or was infected with HCV.

PCR Tests

3.01 The PCR Test reveals the presence of HCV in the blood which demonstrates ongoing infection.

3.02 The testing methodology is most commonly referred to as PCR testing (polymerase chain reaction) but it may also be called RNA detection (ribonucleic acid) or NAT (nucleic acid testing).

3.03 The commercial assays most commonly used are Roche or Amplicor.

3.04 The following PCR Test results will be accepted by the Administrator as proof that the person is infected with HCV:

a. a PCR Test dated January 1, 1998 or later performed at any Canadian laboratory which indicates the presence of the virus; or

b. a PCR Test which indicates the presence of the virus that has been performed by a laboratory acceptable to the Administrator, in consultation with a scientist with PCR expertise.

3.05 A PCR Test usually uses the words “detected” or “detectable” or “present” or “positive” to indicate that the test reveals the presence of the HCV 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. Where both quantitative and qualitative PCR Tests have been performed, the results of the qualitative test or tests are to be preferred to any quantitative test which does not detect the HCV virus.

3.06 The Administrator may require the following additional analysis or testing in the following circumstances:

a. if the person is deceased and had a PCR Test dated before January 1,1998 and the application is made at Level 2, a microbiologist will be consulted for his/her opinion as to whether the PCR Test is sufficiently reliable to accept as more likely than not demonstrating the presence of the virus in the blood;

b. if the person is deceased and had a PCR test dated before January 1, 1998 and the application is made at Level 3 or above, a microbiologist will be consulted for his/her opinion as to whether the PCR 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 had ongoing infection with HCV;

c. if the person is alive and had a PCR Test dated before January 1,1998 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; or

d. if the person is alive and had a PCR Test dated before January 1, 1998 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 person has ongoing infection with HCV.